BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.
REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS

EXHIBIT LIST

Exhibit Number	Description
1	Flubendiamide; Notice of Intent to Cancel Pesticide Registrations, 81 Fed. Reg. 11,558 (Mar. 4, 2016)
2	Belt® SC Insecticide Current Label (EPA Reg. No. 264-1025) (Nov. 14, 2012)
3	Flubendiamide Technical Current Label (EPA Reg. No. 71711-26) (Mar. 23, 2011)
4	Vetica® Insecticide Current Label (EPA Reg. No. 71711-32) (Nov. 26, 2013)
5	Tourismo® Insecticide Current Label (EPA Reg. No. 71711-33) (Oct. 9, 2014)
6	EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008)
7	EPA BEAD Review of Bayer CropScience LP Flubendiamide Benefits Document (July 24, 2015)
8	EPA BEAD Public Interest Finding for Flubendiamide (Apr. 15, 2008)
9	Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362 (June 26, 1991)
10	Letter from Lois Rossi (EPA Registration Division) re Preliminary Acceptance of Flubendiamide Registrations (July 31, 2008)
11	Notices of Registration for Flubendiamide Technical (EPA Reg. No. 71711-26) and Belt® SC Insecticide (EPA Reg. No. 264-1025) (Aug. 1, 2008)
12	Letter from Richard Gebken (EPA Registration Division) re Extension of Flubendiamide Registrations to Aug. 31, 2015 (July 18, 2013)
13	Email from Carmen Rodia (EPA Registration Division) re Draft List of Required Additional Studies for Flubendiamide (Aug. 4, 2015)
14	Letter from Richard Gebken (EPA Registration Division) re Extension of Flubendiamide Registrations to Dec. 10, 2015 (Aug. 26, 2015)
15	EPA EFED Preliminary Environmental Fate and Ecological Risk Assessment for Methoxyfenozide (Excerpts) (Sept. 16, 2015)

Exhibit Number	Description
16	Letter from Richard Gebken (EPA Registration Division) re Extension of Flubendiamide Registrations to Dec. 18, 2015 (Dec. 8, 2015)
17	Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)
18	EPA EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (Excerpt) (June 23, 2008)
19	Email from Dana Sargent (Bayer CropScience LP) re Change in Flubendiamide Ecotoxicity Endpoint (Dec. 16, 2015)
20	Letter from Richard Gebken (EPA Registration Division) re Extension of Flubendiamide Registrations to Jan. 15, 2016 (Dec. 18, 2015)
21	Letter from Jack Housenger (EPA Office of Pesticide Programs) re Request for Voluntary Cancellation of Flubendiamide Registrations (Jan. 29, 2016)
22	Letter from Dana Sargent (Bayer CropScience LP) re Refusal to Request Voluntary Cancellation of Flubendiamide Registrations (Feb. 5, 2016)
23	Des-iodo Spiked Sediment Study Data Evaluation Record (July 19, 2011)
24	EPA EFED Review of Three Reports re Three-Year Flubendiamide Water Monitoring Project (Feb. 20, 2015)
25	EPA Decision Memorandum for Flubendiamide Cancellation (Jan. 29, 2016)
26	Intervenor's Response to Respondents' Motion for Voluntary Vacatur and Remand, Dkt. #122, *NRDC v. EPA*, No. 14-73353 (9th Cir.) (Dec. 7, 2015)
27	Remand Order, Dkt. #128, *NRDC v. EPA*, No. 14-73353 (9th Cir.) (Jan. 25, 2016)
28	EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Docket No. 661 (May 6, 2013)

EXHIBIT 1

Department of Energy's National Nuclear Security Administration's FSEIS #20160047, filed with EPA on 02/24/2016. TVA is a cooperating agency for the project. Therefore, recirculation of the document is not necessary under Section 1306.3(c) of the CEQ Regulations.

Amended Notices

EIS No. 20150343, Draft, NPS, AZ, Backcountry Management Plan Grand Canyon National Park, Comment Period Ends: 04/04/2016, Contact: Rachel Bennett 928–638–7326. *Revision to FR Notice Published 12/11/2015;* Extending Comment Period from 03/04/2016 to 04/04/2016.

EIS No. 20160028, Final, FHWA, WI, I–94 East-West Corridor (70th St–16th St), Review Period Ends: 04/15/2016, Contact: Michael Davies 608–829–7500. *Revision to FR Notice Published 02/12/2016;* Extending Comment Period from 03/14/2016 to 04/15/2016.

Dated: March 1, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–04833 Filed 3–3–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–0099; FRL–9943–25]

Flubendiamide; Notice of Intent To Cancel Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to section 6(e) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA hereby announces its intent to cancel the registration of four (4) pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. This document identifies the products at issue, summarizes EPA's basis for these actions, and explains how adversely affected persons may request a hearing and the consequences of requesting or failing to request such a hearing.

DATES: Under FIFRA section 6(e), affected registrants and other adversely affected persons must request a hearing within 30 days from the date that the affected registrant received EPA's Notice of Intent to Cancel. Please see Unit VII.A.2. for specific instructions.

ADDRESSES: All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Requests for hearing must be filed with the Hearing Clerk in EPA's Office of Administrative Law Judges (''OALJ''), in conformance with the requirements of 40 CFR part 164. The OALJ uses different addresses depending on the delivery method. Please see Unit VII. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

EPA is announcing its intent to cancel the registration of four (4) pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. Specifically, EPA intends to cancel each of the following pesticide products, listed in sequence by EPA registration number.

- EPA Reg. No. 264–1025—BELT SC Insecticide.
- EPA Reg. No. 71711–26—FLUBENDIAMIDE Technical.
- EPA Reg. No. 71711–32—VETICA Insecticide.
- EPA Reg. No. 71711–33—TOURISMO Insecticide.

The following is a list of the names and addresses of record for all registrants of the products listed in this unit, in sequence by EPA company number (this number corresponds to the first part of the EPA registration numbers of the products).

- EPA Co. No. 264—Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709–2014.
- EPA Co. No. 71711—Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808–2951.

In addition, this document summarizes EPA's legal authority for the proposed cancellation (see Unit II.), the registrants' failure to comply with a required condition of registration (see Unit III.), EPA's existing stocks determination (see Unit IV.), scope of the ensuing cancellation proceeding if a hearing is requested (see Unit V.), timing of cancellation of registration (see Unit VI.), and procedural matters that explain how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (see Unit VII.).

B. What is the Agency's authority for taking these actions?

The Agency's authority is contained in section 6(e) of FIFRA, 7 U.S.C. 136d(e).

C. Who is affected by this action?

This announcement will directly affect the pesticide registrants listed in Unit I.A. and others who may distribute, sell or use the products listed in Unit I.A. This announcement may also be of particular interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. EPA believes the stakeholders described above encompass those likely to be affected; however, more remote effects are possible, and the Agency has not attempted to describe all the other specific entities that may be affected by this action.

II. Legal Authority

FIFRA generally governs pesticide sale, distribution, and use in the United States and establishes a federal registration scheme that generally precludes distributing or selling any pesticide that has not been ''registered'' by EPA. 7 U.S.C. 136a(a). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used. See id. 7 U.S.C. 136a(c)(1)(A)–(F) and 136a(d)(1).

The flubendiamide products at issue in this proceeding were conditionally registered pursuant to FIFRA section 3(c)(7)(C) and EPA's regulations at 40 CFR 152.114 and 152.115. Those provisions allow that a conditional registration of an active ingredient not contained in any currently registered products be registered for a reasonably sufficient time for the registrant to generate and submit newly-required data on the condition that by the end of such time the Administrator determines the data do not meet or exceed risk criteria and subject to such other conditions as the Administrator may prescribe. The conditional registration provision was added to FIFRA to address the inequity created by the then-existing statutory scheme between existing registrants and new applicants, and to provide a ''middle ground'' in the registration process between totally denying registration and granting it. See

Woodstream Corp. v *Jackson,* 845 F. Supp. 2d. 174,181 (D.D.C. 2012). However, the utility of conditional registrations depends on affected registrants' compliance with the terms and conditions of their registrations. If registrants accept registrations subject to conditions, but then fail to honor those conditions, EPA could well become more restrictive in its use of the conditional registration authority, and society would lose some of the benefits offered by a flexible registration process.

FIFRA section 6(e) establishes procedures for cancellation of conditional registrations issued pursuant to FIFRA section 3(c)(7). Pursuant to FIFRA section 6(e), the Administrator is required to issue a notice of intent to cancel a conditional registration under FIFRA section 3(c)(7) if (1) during the period provided for the satisfaction of the condition, the Administrator determines that the registrant has failed to initiate and pursue appropriate action to satisfy any imposed condition, or (2) at the end of the period provided for satisfaction of any condition, the condition has not been satisfied. The Administrator is authorized to permit the sale and use of existing stocks of a pesticide whose conditional registration has been canceled to such extent and subject to such conditions as the Administrator may specify, if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.

If a hearing is requested by an adversely affected party, a hearing shall be conducted in accordance with FIFRA section 6(d) and 40 CFR part 164 (the regulations establishing the procedures for hearings under FIFRA). The scope of a hearing under FIFRA section 6(e) is quite narrow; FIFRA provides that the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA. A decision after completion of the hearing is final. Consistent with the narrowness of the scope of hearing, the statute also provides that a hearing under FIFRA section 6(e) shall be held and a determination made within seventy-five (75) days after receipt of a request for hearing.

III. Registrants' Failure To Comply With a Required Condition of Registration

Flubendiamide is an insecticide which targets lepidoptera pests approved for use on corn, cotton, tobacco, tree fruits, nuts, vegetables, and vine crops. EPA has determined that the flubendiamide registrations listed in Unit I.A. should be cancelled because the registrants have failed to satisfy a required condition of their registrations.

EPA issued conditional registrations for each of the flubendiamide products identified in Unit I.A., beginning with the issuance of Flubendiamide Technical and Belt SC Insecticide on August 1, 2008. The Notices of Registration (''NOR'') issued on August 1, 2008, state that the product is conditionally registered in accordance with FIFRA section 3(c)(7), incorporating by reference conditions of registration set forth in EPA's preliminary acceptance letter (''PAL''). Vetica and Tourismo flubendiamide registrations were issued March 4, 2009, and the PAL applied to those registrations as well. The NOR states that ''release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.'' The Registrants subsequently released each of these products for shipment, thereby accepting the specified conditions of registration.

EPA's PAL for flubendiamide (which, as noted previously, included conditions of registration which were specifically incorporated into the NORs) was issued on July 31, 2008, and specified the conditions under which EPA would approve registration of the flubendiamide products. The flubendiamide registrants, Bayer CropScience LP, as authorized agent for Nichino America, Inc., agreed to these terms by concurring with the Registration Division's intended terms and conditions of registration. *Application for a New Section 3 Registration of Flubendiamide with Associated Tolerance, July 31, 2008.* At the time of registration, the product was conditionally registered subject to a time limit of 5 years. EPA required flubendiamide to be conditionally registered because of concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI–001-des-iodo to invertebrates of aquatic systems; in light of these concerns, the conditional registrations required use of vegetative filter strips and submission of additional data to address the concerns. In addition, instead of the registrations automatically expiring on a date certain, a condition was added that obligated the registrants to expeditiously request voluntary cancellation of the registrations if EPA notified them that EPA determined the registrations did not meet the FIFRA standard for registration.

The Registrants understood and agreed by signing the PAL that if, after EPA review of the referenced conditional data, EPA were to make a determination that continued registration of flubendiamide products will result in unreasonable adverse effects on the environment, EPA would notify the Registrants, and within one (1) week of notification of this finding, the Registrants would submit a request for voluntary cancellation of all the flubendiamide registrations. Without that condition, the registration would likely not have been approved by EPA. Moreover, pursuant to the terms of the NORs for the four flubendiamide registrations, each Registrant accepted all conditions of their flubendiamide registrations—expressly including the conditions specified in the PAL—upon sale or distribution of pesticide products pursuant to those registrations. The Registrants were notified on January 29, 2016 that EPA had made such a finding and, under the terms of the time-limited/conditional registration, the Registrants were obligated to submit an appropriate request for voluntary cancellation to EPA by or before February 5, 2016. *Letter to Ms. Nancy Delaney, Regulatory Manager, Authorized Agent for Nichino America, Inc., c/o Bayer CropScience, from Jack E. Housenger, Director, Office of Pesticide Programs, January 29, 2016.* On February 5, 2016, Bayer submitted a letter to EPA on its behalf and as regulatory agent for Nichino, informing EPA that neither registrant would comply with the condition to submit voluntary cancellation requests for the flubendiamide registrations. *Response to Request to Submit Voluntary Cancellation Requests for Flubendiamide Technical Registration and Associated End Use Products, February 5, 2016.* Consistent with the position stated in the February 5, 2016 letter, neither Bayer nor Nichino has submitted a voluntary cancellation request in response to EPA's letter of January 29, 2016. Once EPA exercised

the registration condition set forth in the NOR, the registrants' failure to comply with that condition of registration by submitting requests for voluntary cancellation makes the flubendiamide products identified in Unit I.A. subject to cancellation under FIFRA section 6(e).

IV. EPA's Existing Stocks Determination

Existing stocks of cancelled pesticides are those products that were ''released for shipment'' before the effective date of cancellation. FIFRA sections 6(a)(1) and 6(e) allow the Agency to permit the continued sale and use of existing stocks of pesticides that have been cancelled, to the extent that the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). FIFRA section 6(a)(1) authorizes the Administrator to ''permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled . . . under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act.''

EPA's policy in regard to the disposition of existing stocks of cancelled pesticides appears in a policy statement issued in 1991 and amended in 1996. (56 FR 29362, June 26, 1991 (FRL–3846–4) and 61 FR 16632, April 16, 1996 (FRL–5363–8)). The existing stocks policy indicates that although registrants who fail to satisfy a general condition (*i.e.,* one which requires a registrant to submit required data when all other registrants of the similar product are required to do so) would typically be allowed to distribute and sell existing stocks of the cancelled pesticide for one year,

> On the other hand, if a registrant of a conditional registration fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any sale and use of existing stocks if the registration is cancelled. Accordingly, the Agency does not anticipate allowing a registrant to sell or distribute existing stocks of cancelled products that were conditionally registered if the registrant fails to demonstrate compliance with any specific requirements set forth in the conditional registration. 56 FR at 29366–67.

The registration condition in the instant case is specific and was identified at the time the registration was issued, so the Agency does not intend to allow any sale or distribution of existing stocks.

Neither FIFRA nor any other law gives the registrant or anyone else a right to continue to distribute or sell existing stocks of a cancelled pesticide. Per FIFRA section 6(a)(1), the disposition of existing stocks of cancelled pesticides is at the discretion of the Administrator. Inasmuch as the disposition of existing stocks of a cancelled pesticide is at EPA's discretion, EPA considers it inappropriate to reward registrants who disregard the terms and conditions of registration, like the condition at issue here, by allowing any distribution or sale of existing stocks. This is not a case where the registrants have made a diligent effort to comply with the condition of registration, only to fail through circumstances beyond their control. Rather, they simply refuse to comply with a condition they earlier chose to accept in order to obtain the registration initially. Their refusal to comply with the condition will likely delay the cancellation for a number of months, during which time they may not only continue to sell and distribute the previously-produced product that should by the terms and conditions of registration now be cancelled, but also to continue to produce, sell and distribute additional quantities until cancellation through the FIFRA section 6(e) proceeding. For these reasons, and consistent with EPA's existing stocks policy, EPA has determined that it would not be appropriate to allow any further sale or distribution, by any person, of existing stocks of the products identified in Unit I.A. after those registrations are cancelled, except to the extent that distribution is for purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export.

EPA has determined that use of existing stocks of the technical flubendiamide registration (EPA Reg. No. 71711–26) should be prohibited upon the cancellation of that registration. Technical products are used solely for the purpose of manufacturing other pesticide products. For the same reason discussed above with respect to sale and distribution of cancelled products, EPA believes it would be inappropriate to allow use of existing stocks of EPA Reg. No. 71711–26 to produce additional flubendiamide pesticide products unless those products are clearly designated solely for lawful export.

EPA believes it would be appropriate to allow continued use of existing stocks of the cancelled end-use flubendiamide products EPA Reg. Nos. 264–1025, 71711–32, and 71711–33, currently held by end users, provided that such use is consistent with the previously approved-labeling accompanying the product. The quantity of existing stocks of these products currently in the hands of end users is expected to be sufficiently low that the costs and risks associated with collecting them for disposal would be high compared to those associated with the use of the cancelled product in accordance with its labeling. When containers of flubendiamide have already been opened, transporting them can create a greater risk of spillage. Open containers also create additional burden when sent for disposal because proper disposal may require that the content be verified, adding additional expense. Because of the probable wide dispersal of product in user's hands, notification and subsequent supervision of users imposes significant costs on state and/or federal authorities. EPA may amend its position regarding use of existing stocks of end-use flubendiamide products at hearing if the quantity of those products in the hands of end users increases prior to cancellation. For these reasons, EPA intends to allow existing stocks of the end-use flubendiamide products EPA Reg. Nos. 264–1025, 71711–32, and 71711–33, in the hands of end users to be used until exhausted.

V. Scope of Proceeding

The scope of a hearing under FIFRA section 6(e) is quite narrow; FIFRA provides that the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA. The Statute also provides that a hearing under FIFRA section 6(e) shall be held and a determination made within seventy-five days after receipt of a request for hearing.

A FIFRA section 6(e) proceeding is intended only to address whether conditions of registration have been met, not to assess the merits of conditions or whether the registrants disagree with the conditions of their approved registration. Similarly, the FIFRA section 6(e) proceeding is limited to whether the Agency's existing stocks determination ''is consistent'' with FIFRA, not whether the existing stock provisions of the NOIC strike an optimal balance between the risks and benefits associated with the distribution, sale and use of existing stocks of a cancelled pesticide. FIFRA section 6(e)(2)

provides that where a FIFRA section 6(e) cancellation hearing is requested, the scope of the hearing and the standard of review in regard to the Administrator's determination with respect to the disposition of existing stocks is limited to whether that determination is consistent with FIFRA.

Congress mandated a final decision within seventy-five (75) days, and a broader or more complex hearing could not reasonably be completed in such a limited timeframe. Accordingly, the only matters for resolution in any hearing requested regarding this matter shall be whether the registrants satisfied the condition of registration requiring them to submit timely requests for voluntary cancellation when notified by EPA of its determination that the registrations caused unreasonable adverse effects on the environment, and whether the proposed existing stocks provision is consistent with FIFRA.

VI. Timing of Cancellation of Registration

The cancellation of registration of each of the specific products identified in Unit I.A. will be final and effective thirty (30) days after the date of receipt by the registrant, unless a valid hearing request is received regarding that specific flubendiamide product.

In the event a hearing is held concerning a particular product, the cancellation of the registration for that product will not become effective except pursuant to a final order issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator, or an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b). Pursuant to FIFRA section 6(e)(2), such order shall issue within seventy-five (75) days after receipt of a request for hearing.

VII. Procedural Matters

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Requesting a Hearing

1. Who can request a hearing? A registrant or any other person who is adversely affected by a cancellation as described in this document may request a hearing.

2. When must a hearing be requested? A request for a hearing by a registrant or other adversely affected person must be submitted in writing within thirty (30) days after the date of the registrant's receipt of the Notice of Intent to Cancel. Under FIFRA section 6(e), the time period for requesting a hearing is calculated from the date the affected registrant receives the Notice of Intent to Cancel, without regard to the date of issuance or publication in the **Federal Register**. EPA issued this Notice of Intent to Cancel and promptly sent it to each registrant by certified mail on February 29, 2016. Registrants will be able to calculate the deadline for their request based on their receipt of the Notice of Intent to Cancel. In order to assure that any requests for hearing from persons other than the registrants are received in a timely manner, persons other than the registrants who wish to submit a request for hearing are urged to assume that the registrants received the Notice of Intent to Cancel on March 1, 2016, and make sure that a request for hearing is received by EPA's Office of Administrative Law Judges on or before March 31, 2016.

3. How must a hearing be requested? All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings under FIFRA, 40 CFR part 164. Among other requirements, these rules include the following requirements:

a. Each hearing request must specifically identify by registration or accession number each individual pesticide product concerning which a hearing is requested, 40 CFR 164.22(a);

b. Each hearing request must be accompanied by a document setting forth specific objections which respond to the Agency's reasons for proposing cancellation as set forth in this document and state the factual basis for each such objection, 40 CFR 164.22(a); and

c. Each hearing request must be received by the OALJ within the applicable 30-day period (40 CFR 164.5(a)).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation of registration for the product in question by operation of law.

4. *Where does a person submit a hearing request?* Requests for hearing must be submitted to the OALJ. The OALJ uses different addresses depending on the delivery method. Please note that mail deliveries to federal agencies are screened off-site, and this security procedure can delay delivery. Documents that a party sends using the U.S. Postal Service must be addressed to the following OALJ mailing address: U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

Documents that a party hand delivers or sends using a courier or commercial delivery service (such as Federal Express or UPS) must be addressed to the following OALJ hand delivery address: U.S. Environmental Protection Agency, Office of Administrative Law Judges, Ronald Reagan Building, Rm. M1200, 1300 Pennsylvania Ave. NW., Washington, DC 20460.

B. The Hearing

If a hearing concerning any product affected by this document is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings under FIFRA, 40 CFR part 164, and the procedures set forth in Unit VII. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

Documents and transcripts will be available in the Administrative Law Judges' Electronic Docket Database available at *http://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf.* The physical public docket for the hearing is located at the U.S. Environmental Protection Agency, Office of Administrative Law Judges, Ronald Reagan Building, Rm. M1200, 1300 Pennsylvania Ave. NW., Washington, DC 20460 and documents can be viewed from 8:30 a.m. to 4:30 p.m., Monday through Friday, except federal holidays.

List of Subjects

Environmental protection, Pesticides and pests, Cancellation.

Dated: February 29, 2016.

Louise P. Wise,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–04905 Filed 3–3–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9943–37-Region 1]

Proposed Cercla Administrative Cost Recovery Settlement: Former Athol Rod and Gun Club Superfund Site, Athol, Massachusetts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comments.

SUMMARY: Notice is hereby given of a proposed administrative cost settlement for recovery of response costs concerning the Former Athol Rod and Gun Club Superfund Site, located in Athol, Worcester County, Massachusetts with the Settling Party the Town of

EXHIBIT 2

264-1025 11/14/2012 1/32

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 14, 2012

Mr. George J. Sabbagh, Ph.D.
Registration Product Manager, Herbicides
Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Acceptance of Amended Labeling; Addition of Strawberry, Low-Growing Berry Subgroup (except cranberry) & Globe Artichoke, and Increased Rate on *Brassica* Leafy Vegetables**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
Your Submission Dated November 9, 2011 & E-Submission Dated November 13, 2012

Dear Mr. Sabbagh:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comment listed below.

"The attached supplemental label is valid for a period of 36 months from the date of this letter."

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted" and the HED memo completed as part of this action are enclosed for your records. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

For Carmen J. Rodia Jr.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted," dated November 14, 2012*
HED Memorandum, dated June 26, 2012

000264-01025 D457738

ACCEPTED
November 14, 2012
Under the Federal Insecticide, F...gicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 264-1025

GROUP	28	INSECTICIDE

BELT® SC Insecticide

ACTIVE INGREDIENT:

Flubendiamide (N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide)..... **39%**

OTHER INGREDIENTS: **61%**

BELT SC Insecticide contains 4 pounds of flubendiamide per US gallon (480 grams per liter). **TOTAL:**..... **100%**

EPA Reg. No. 264-1025 **EPA Est. No.**

STOP - Read the label before use
KEEP OUT OF REACH OF CHILDREN
CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. **For medical emergencies, health concerns, or pesticide incidents, you may call the Bayer CropScience Emergency Response toll free number 24 hours a day at 1-800-334-7577.**	
NOTE TO PHYSICIAN: No specific antidote is known. Treat symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves (such as Natural Rubber). If you want more options, follow the instructions for Category A on the EPA chemical-resistance category selection chart.
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

ENGINEERING CONTROLS STATEMENT

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands thoroughly before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Ground Water Advisory

Flubendiamide and its degradate NNI-0001-des-iodo have properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.

Surface Water Advisory

Flubendiamide and its degradate NNI-0001-des-iodo may also impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. These chemicals are classified as having a medium potential for reaching both surface water and aquatic sediment via runoff several months or more after application. A well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs, as required under the Directions for Use, will reduce the potential for loading of flubendiamide and its degradate NNI-0001-des-iodo from run-off and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

USE RESTRICTIONS

- Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the treated area during application.
- For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.
- The following use restrictions are required to permit use of BELT™ SC Insecticide in the State of New York:
  - Not for sale, use, and distribution in Nassau and Suffolk Counties of New York State.
  - Aerial application of this product is prohibited in New York State.
  - This product cannot be applied within 100 ft of a water body (i.e., lake, pond, river, stream, wetland, or drainage ditch).

BUFFER ZONES

Vegetative Buffer Strip

Construct and maintain a minimum 15-foot wide vegetative filter strip of grass or other permanent vegetation between field edge and down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).

Only apply products containing flubendiamide onto fields where a maintained vegetative buffer strip of at least 15 feet exists between the field edge and down gradient aquatic habitat.

For guidance, refer to the following publication for information on constructing and maintaining effective buffers: *Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services.* USDA, 2000. Fort Worth, Texas. 21 pp. http://www.in.nrcs.usda.gov/technical/agronomy/newconbuf.pdf.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours following application.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil or water, is: coveralls, chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or viton, and shoes plus socks.

GENERAL INFORMATION

BELT® SC Insecticide is a Suspension Concentrate formulation. The active ingredient contained in BELT SC Insecticide is active by insect larval ingestion leading to a rapid cessation of feeding followed by death of the insect. Application should be timed to coincide with early threshold level in a developing larval population. Thorough coverage of all plant parts is required for optimum performance.

Use in enclosed structures, such as greenhouses or planthouses, is not permitted unless specified otherwise by state-specific supplemental labeling.

INSECT RESISTANCE STATEMENT

BELT SC Insecticide contains an active ingredient with a mode of action classified as a Group 28 insecticide – ryanodine receptor modulators. Studies to determine cross-resistance of Group 28 insecticides with other chemical classes have demonstrated no cross-resistance. However, repeated use of any crop protection product may increase the development of resistant strains of insects. Rotation to another product with a different mode of action is recommended. Contact your local extension specialist, certified crop advisor and/or Bayer CropScience representative for additional resistance management or IPM recommendations. Also, for more information on Insect Resistance Management (IRM), visit the Insecticide Resistance Action Committee (IRAC) on the web at http://www.irac-online.org.

APPLICATION GUIDELINES

For all insects, timing of application should be based on careful scouting and local thresholds.

Foliar Spray Applications

Ground applications: A minimum of 10.0 gallons of diluted product/A.

Aerial applications: A minimum of 2.0 gallons of diluted product/A. Aerial applications made to dense canopies may not provide sufficient coverage of lower leaves to provide acceptable pest control. Under these conditions, the higher rate of BELT SC Insecticide specified in the crop/pest specific tables within the Directions for Use section of this label may be necessary for optimum pest control.

Chemigation applications (see use in Chemigation Systems directions below) should be made as concentrated as possible. For best results apply at 100% input/travel speed, for center pivots or 0.10 inch (2,716 gallons) up to 0.15 inch (4,073 gallons) of water/A, for other systems. Higher labeled rates of BELT SC Insecticide may be necessary for chemigation applications.

CHEMIGATION SYSTEMS

BELT SC Insecticide may be applied through irrigation systems only on those crops listed under Recommended Applications where application through irrigation systems is recommended.

Types of Irrigation Systems: Apply BELT SC Insecticide only through sprinkler, including center pivot, lateral move, side roll, or overhead solid set irrigation systems. Do not apply BELT SC Insecticide through any other type of irrigation system.

GENERAL DIRECTIONS FOR ALL RECOMMENDED TYPES OF IRRIGATION SYSTEMS

Uniform Water Distribution and System Calibration: The irrigation system must provide uniform distribution of treated water. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water. The system must be calibrated to uniformly apply the rates specified. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Chemigation Monitoring: A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Drift: Do not apply when wind speed favors drift beyond the area intended for treatment.

Required System Safety Devices: The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump; such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Using Water from Public Water Systems: Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), back flow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection. The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Cleaning the Chemical Injection System: In order to accurately apply pesticides, the chemical injection system must be kept clean; free of chemical or fertilizer residues and sediments. Refer to your owner's manual or ask your equipment supplier for the cleaning procedure for your injection system.

Flushing the Irrigation System: At the end of the application period, allow time for all lines to flush the pesticide through all nozzles before turning off irrigation water. To ensure the lines are flushed and free of pesticides, a dye indicator may be injected into the lines to mark the end of the application period.

Equipment Area Contamination Prevention: It is recommended that nozzles in the immediate area of control panels, chemical supply tanks, pumps and system safety devices be plugged to prevent chemical contamination of these areas.

Center-Pivot and Automatic-Move Linear Systems: Inject the specified dosage per acre continuously for one complete revolution (center pivot) or move of the system. The system should be run at maximum speed. It is recommended that nozzles in the immediate area of control panels, chemical supply tanks, pumps and system safety devices be plugged to prevent chemical contamination of these areas. The use of END GUNS is NOT RECOMMENDED. End guns that provide uneven distribution of treated water can result in lack of effectiveness or illegal pesticide residues in or on the crop.

Solid Set and Manually Controlled Linear Systems: Injection should be during the last 30 to 60 minutes of regular irrigation period or as a separate 30 to 60 minute application not associated with a regular irrigation. Adjust end guns to keep treated water on the treated area in a uniform manner.

SPRAY DRIFT REDUCTION MANAGEMENT

Do not apply when wind speed favors drift beyond the area intended for treatment. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator.

Importance of Droplet Size:

An important factor influencing drift is droplet size. Small droplets (<150 - 200 microns) drift to a greater extent than large droplets. Within typical equipment specifications, applications should be made to deliver the largest droplet spectrum that provides sufficient control and coverage. Use only Medium or coarser spray nozzles (for ground and non-ULV aerial application) according to ASAE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.

Ground Applications:

Wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application. For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two (2) rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.

Aerial Applications:

The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75% of the wing span or 80% rotor diameter. Flight speed and nozzle orientation must be considered in determining droplet size. Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Making applications at the lowest height that is safe reduces the exposure of the droplets to evaporation and wind.

Wind Speed Restrictions:

Drift potential increases at wind velocities of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size, canopy and equipment specifications determine drift potential at any given wind speed. Only apply this product if the wind direction favors on-target deposition. Do not apply when wind velocity exceeds 15 mph and avoid gusty and windless conditions. Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

Restrictions During Temperature Inversions:

Do not make ground applications during temperature inversions. Drift potential is high during temperature inversions. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by stable air and increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by mist or ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source. Smoke that layers and moves laterally near the ground surface in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical mixing.

MIXING INSTRUCTIONS

COMPATIBILITY

BELT SC Insecticide is physically and biologically compatible with many registered pesticides and fertilizers or micronutrients. When considering mixing BELT SC Insecticide with other pesticides, or other additives, first contact your supplier for advice. For further information, contact your local Bayer Representative. If you have no experience with the combination you are considering, you should conduct a test to determine physical compatibility. To determine physical compatibility, add the recommended proportions of each chemical with the same proportion of water, as will be present in the chemical supply tank, into a suitable container, mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be readily re-mixed, the mixture is considered physically compatible.

ORDER-OF-MIXING

BELT SC Insecticide may be used with other recommended pesticides, fertilizers and micronutrients. The proper mixing procedure for BELT SC Insecticide alone or in tank mix combinations with other pesticides is:

1) Fill the spray tank 1/4 to 1/3 full with clean water;
2) While recirculating and with the agitator running, add any products in PVA bags **(See Note)**. Allow time for thorough mixing;
3) Continue to fill spray tank with water until 1/2 full;
4) Add any other wettable powder (WP) or water dispersible granule (WG) products;
5) Add the required amount of BELT SC Insecticide, and any other "flowable" (FL or SC) type products;
6) Allow enough time for thorough mixing of each product added to tank;
7) If applicable, add any remaining tank mix components: emulsifiable concentrates (EC), fertilizers and micronutrients.
8) Fill spray tank to desired level and maintain constant agitation to ensure uniformity of spray mixture.

NOTE: Do not use PVA packets in a tank mix with products that contain boron or release free chlorine. The resultant reaction of PVA and boron or free chlorine is a plastic that is not soluble in water or solvents.

ROTATIONAL CROP STATEMENT

Treated areas may be replanted with any crop specified on this label as soon as practical following the last application.

ROTATIONAL PLANT-BACK INTERVALS[1]

Immediate plant-back: Alfalfa, Brassica (Cole) Leafy Vegetables, Corn (Field, Pop, and Sweet), Cotton, Cucurbit Vegetables, Fruiting Vegetables, Globe Artichoke, Leafy Vegetables (except Brassica), Legume Vegetables, Okra, Peanut, Safflower, Soybeans, Strawberries, Sorghum, Sunflower, Sugarcane, Tobacco, Turnip Greens.

30-Day plant-back: Barley, Buckwheat, Clover, Grasses, Millet (pearl), Millet (proso), Oats, Rice, Root Crops (Root, Tuber, and Bulb Vegetables), Rye, Teosinte, Triticale, Wheat

9-Month plant-back: All other crops

[1] Cover Crops for soil building or erosion control may be planted at any time, but do not graze or harvest for food or feed.

USES

Recommended Applications: Apply specified dosage of BELT SC Insecticide as needed for control. For best results, treatment should be made when insect populations begin to build and before a damaging population becomes established. Rate selected for use should depend on stage of pest development at application, pest infestation level, plant size and density of plant foliage. Thorough coverage of plant foliage is recommended for optimum product performance. BELT SC Insecticide may be applied by air, ground equipment or through overhead irrigation systems as designated in the CHEMIGATION SYSTEMS statement in the *Application Guidelines* section of this label. Please contact your local Bayer CropScience representative or Pest Control Advisor for specific recommendations by crop.

ALFALFA

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Alfalfa caterpillar Armyworm Army cutworm Alfalfa looper Alfalfa webworm Beet armyworm Corn earworm Cutworms Fall armyworm Green cloverworm Loopers Velvetbean caterpillar Yellowstriped armyworm	2.0 – 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): Forage and hay – **0 days**.

Retreatment Interval - **21 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per cutting**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per year.**

Minimum application volume: 10 0 GPA – ground; 2 0 GPA – aerial application

See CHEMIGATION statement in *Application Guidelines* section of this label.

BRASSICA (COLE) LEAFY VEGETABLES and TURNIP GREENS **Crops of Crop Group 5 and Turnip Greens including**: Broccoli, Broccoli raab (rapini), Brussels sprouts, Cabbage, Cauliflower, Cavalo broccolo, Chinese broccoli (gai lon), Chinese cabbage (bok choy), Chinese cabbage (napa), Chinese mustard cabbage (gai choy),Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens, Turnip greens.	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid oz/Acre**
Alfalfa looper Alfalfa caterpillar Armyworms Beet armyworm Cabbage looper Cabbage webworm Corn earworm Cross-striped cabbageworm Cutworm species Diamondback moth Fall armyworm Garden webworm Imported cabbage worm Saltmarsh caterpillar Southern armyworm Southern cabbageworm Tobacco budworm True armyworm Yellowstriped armyworm	1.5 – 2.4
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **8 day**. Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 5-day interval.** Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season.** Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application. See CHEMIGATION statement in *Application Guidelines* section of the label.	

CHRISTMAS TREE	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Bagworm Fall webworm Gypsy moth Hemlock looper Jackpine budworm Pine tip moth Redhumped caterpillar Spruce budworm Tent caterpillar Tussock moths	3.0 – 5.0
Notes and Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Do not apply more than **5.0 fl oz per acre (0.156 lb ai/A) per 7 day interval**. Do not apply more than **10.0 fl oz per acre (0.312 lb ai/A) per crop season**. Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit. Minimum application volume: 20.0 GPA – ground; 5.0 GPA – aerial application	

CORN (FIELD CORN, POP CORN, SWEET CORN, and CORN GROWN FOR SEED)	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Armyworm Army cutworm Beet armyworm Black cutworm Common stalk borer Corn earworm European corn borer Fall armyworm Green cloverworm Southern armyworm Southwestern corn borer Western bean cutworm Yellowstriped armyworm	1.0 - 3.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): Green forage and silage - **1 day**; Sweet corn – **1 day**; Grain or stover – **28 days**. Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 3-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Do not apply more than 4 times per crop season. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial applications. See CHEMIGATION statement in *Application Guidelines* section of this label.	

COTTON	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Beet armyworm Cabbage looper Cotton bollworm Cotton leafworm Cotton leaf perforator Cutworm species European corn borer Fall armyworm Omnivorous leafroller Saltmarsh caterpillar Soybean looper Tobacco budworm Yellowstriped armyworm	1.0 - 3.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **28 days.** Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 5-day interval**. Do not apply more than **9.0 fl oz per acre (0.282 lb ai/A) per crop season**. Do not apply more than 3 times per crop season. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial applications. See CHEMIGATION statement in *Application Guidelines* section of this label.	

CUCURBIT VEGETABLES

Crops of Crop Group 9 including: Chayote (fruit), Chinese waxgourd (Chinese preserving melon), Citron melon, Cucumber, Gherkin, Edible gourd (includes hyotan, cucuzza, hechima, Chinese okra), Momordica spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon [hybrids and/or cultivars of *Cucumis melon* (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon)], Pumpkin, Squash [summer squash (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); winter squash (includes acorn squash, butternut squash, calabaza, hubbard squash, spagetti squash)], Watermelon (includes hybrids and/or varieties of *Citrullus lanatus*).

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Armyworms Beet armyworm Cabbage looper Corn earworm Cutworm species Fall armyworm Melonworm Pickleworm Rindworm species Squash vine borer Tobacco budworm True armyworm Yellowstriped armyworm	1.0 - 1.5

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **1 day**.

Do not apply more than **1.5 fl oz per acre (0.047 lb ai/A) per 7-day interval**.

Do not apply more than **4.5 fl oz per acre (0.141 lb ai/A) per crop season.**

Minimum application volume: 10 0 GPA – ground, 2.0 GPA – aerial application.

See CHEMIGATION statement in *Application Guidelines* section of the label.

FRUITING VEGETABLES (Except Cucurbits) and OKRA

Crops of Crop Group 8 plus Okra including: Eggplant, Groundcherry, Okra, Pepino, Pepper (includes: bell pepper, chili pepper, cooking pepper, pimento, sweet pepper), Tomatillo, Tomato.

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Armyworms	1.0 - 1.5
Beet armyworm	
Cabbage looper	
Celery leaftier	
Cutworm species	
Diamondback moth	
European corn borer	
Fall armyworm	
Garden webworm	
Melonworm	
Pickleworm	
Rindworm species	
Saltmarsh caterpillar	
Southern armyworm	
Southwestern corn borer	
Tobacco budworm	
Tobacco hornworm	
Tomato fruitworm	
Tomato hornworm	
Tomato pinworm	
True armyworm	
Western yellowstriped armyworm	
Yellowstriped armyworm	

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **1 day**.

Do not apply more than **1.5 fl oz per acre (0.047 lb ai/A) per 3-day interval**.

Do not apply more than **4.5 fl oz per acre (0.141 lb ai/A) per crop season**.

Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application.

See CHEMIGATION statement in *Application Guidelines* section of the label.

GLOBE ARTICHOKE	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Artichoke plume moth Cutworms Painted lady butterfly Saltmarsh caterpillar	1.5 – 2.4
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **8 day**. Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 3-day interval**. Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application. See CHEMIGATION statement in *Application Guidelines* section of this label.	

GRAPE and SMALL FRUIT VINE CLIMBING SUBGROUP (Except Fuzzy Kiwifruit) **Crops of Crop Subgroup 13-07F including:** Armur river grape, Gooseberry, Grape, Kiwifruit (hardy), Maypop, Schisandra berry	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Cutworm European grapevine moth Grape berry moth Grape leaf folder Grape leaf skeletonizer Obliquebanded leafroller Omnivorous leafroller Orange tortrix Raisin moth Redbanded leafroller	2.0 - 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **7 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 5-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit. Aerial application is prohibited.	

LEAFY VEGETABLES (Except BRASSICA VEGETABLES) (See Soybean section for uses in Soybeans)

Crops of Crop Group 4 including: Amaranth (leafy amaranth, Chinese spinach, tampala), Arugula (roquette), Cardoon, Celery, Celtuce, Chervil, Chinese celery, Chrysanthemum (edible-leaved and garland), Corn salad, Cress (garden), Cress (upland, yellow rocket, winter cress) , Dandelion, Dock (sorrel), Endive (escarole), Florence fennel (finocchio), Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio (red chicory), Rhubarb, Spinach [including New Zealand and vine (Malabar spinach, Indian spinach)], Swiss chard.

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Alfalfa looper Armyworms Beet armyworm Corn earworm Cutworm species Diamondback moth European corn borer Fall armyworm Green cloverworm Imported cabbage worm Saltmarsh caterpillar Tobacco budworm Tomato hormworm True armyworm Yellowstriped armyworm	1.0 - 1.5

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **1 day**.

Do not apply more than **1.5 fl oz per acre (0.047 lb ai/A) per 3-day interval**.

Do not apply more than **4.5 fl oz per acre (0.141 lb ai/A) per crop season**.

Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application.

See CHEMIGATION statement in *Application Guidelines* section of the label.

LEGUME VEGETABLES Except SOYBEAN

Crops of Crop Groups 6 and 7 including Edible-podded and Succulent Shelled Pea and Bean, Dried Shelled Pea and Bean and Foliage of Legume Vegetables:

Bean (*Lupinus* spp., includes grain lupin, sweet lupin, white lupin, white sweet lupin)
Bean (*Phaseolus* spp., includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean)
Bean (*Vigna* spp., includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, Crowder pea, moth bean, mung bean, rice bean, Southern pea, Urd bean, yardlong bean)
Pea (Pisum spp., includes dwarf pea, edible-pod pea, English pea, field pea, garden pea, green pea, snow pea, sugar snap pea)
Other Peas and Beans: Broad bean (fava bean), chickpea (garbanzo bean), guar, jackbean, lablab bean (hyacinth bean), lentil, pigeon pea, sword bean

PESTS CONTROLLED		RATE PER APPLICATION fluid oz/Acre
Alfalfa caterpillar	Lesser cornstalk borer	1.0 - 3.0
Alfalfa looper	Painted lady (thistle) caterpillar	
Armyworm	Saltmarsh caterpillar	
Beet armyworm	Silverspotted skipper	
Cabbage looper	Southern armyworm	
Celery looper	Southwestern corn borer	
Corn earworm	Soybean looper	
Cutworm species	Tobacco budworm	
European corn borer	Velvetbean caterpillar	
Fall armyworm	Webworm species	
Green cloverworm	Western bean cutworm	
Imported cabbageworm	Wollybear caterpillar	
Leaf sketetonizer species	Yellowstriped armyworm	
Leaftier species	Western yellowstriped armyworm	

Notes and Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **Edible podded and succulent shelled peas and beans - 1 day; Dry peas and beans – 14 days; Forage, hay and vines – 3 days**.

Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 5 day interval**.

Do not apply more than **6.0 fl oz per acre (0.188 lb ai/A) per crop season**.

Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit.

Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application

See CHEMIGATION statement in *Application Guidelines* section of this label.

PEANUT	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid oz/Acre**
Armyworm Beet armyworm Corn earworm Cutworms Green cloverworm Fall armyworm Loopers Rednecked peanutworm Southern armywormVelvetbean caterpillar Tobacco budworm	2.0 – 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **3 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval** Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

POME FRUIT **Crops of Crop Groups 11 including:** Apple, Crabapple, Loquat, Mayhaw, Oriental pear, Pear, Quince	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid oz/Acre**
Codling moth (West of the Rockies) *For use against low to moderate infestations in conjunction with alternate control measures such as in established mating disruption blocks.*	5.0
Codling moth (East of the Rockies) Eyespotted bud moth Fall webworm Fruittree leafroller Green fruitworm Lacanobia fruitworm Lesser appleworm Obliquebanded leafroller Oriental fruit moth Pandemis leafroller Redbanded leafroller Spotted tentiform leafminer Tufted apple bud moth Variegated leafroller Western tentiform leafminer	3.0 - 5.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days**. Do not apply more than **5.0 fl oz per acre (0.156 lb ai/A) per 7-day interval**. Do not apply more than **15.0 fl oz per acre (0.468 lb ai/A) per crop season**. Do not apply more than 3 times per crop season. Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit. Aerial application is prohibited.	

SOYBEAN (See Brassica Section for Use Directions on Brassica)	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Alfalfa caterpillar Armyworm Beet armyworm Cabbage looper Corn earworm Cutworm species European corn borer Fall armyworm Green cloverworm Imported cabbageworm Leaf sketetonizer species Lesser cornstalk borer Painted lady (thistle) caterpillar Saltmarsh caterpillar Silverspotted skipper Southern armyworm Soybean looper Tobacco budworm Tobacco hornworm Tomato hornworm Velvetbean caterpillar Webworm species Wollybear caterpillar Yellowstriped armyworm	1.0 - 3.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): Immature seed – **1 day**; Dry seed - **14 days**; Forage and hay – **3 days**. Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 5-day interval**. Do not apply more than **6.0 fl oz per acre (0.188 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

SORGHUM

Crops including: sorghum grain, sudangrass (seed crop), and hybrids of these grown for its seed; sorghum forage; sorghum stover; sudangrass, and hybrids of these grown for forage and/or stover; milo

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Armyworm Beet armyworm Cutworms European corn borer Fall armyworm Mexican rice borer Sorghum headworm Sorghum webworm Southern armyworm Southwestern corn borer Stalk borer Sugarcane borer Webworms Yellowstriped armyworm	2.0 – 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): Forage – **3 days**; grain and stover – **14 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application

See CHEMIGATION statement in *Application Guidelines* section of this label.

STRAWBERRY and LOW GROWING BERRY SUBGROUP (except cranberry)

Crops of Crop Subgroup 13-07G (except cranberry) including: Bearberry, Bilberry, Blueberry (lowbush), Cloudberry, Lingonberry, Muntries, Partridgeberry, Strawberry, plus cultivars, varieties and/or hybrids of these

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Armyworm Corn earworm Cutworm Lesser cornstalk borer Omnivorous leaftier Strawberry leafroller	1.5 – 2.4

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **8 day**.

Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 3-day interval**.

Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season**.

Minimum application volume: 1 0.0 GPA – ground. 2.0 GPA – aerial application.

See CHEMIGATION statement in *Application Guidelines* section of this label.

STONE FRUIT

Crops of Crop Group 12 including: Apricot, Cherry [sweet and tart], Nectarine, Peach, Plum [includes Chickasaw plum, Damson plum, and Japanese plum], Plumcot, Prune (fresh)

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Codling moth Cherry fruitworm Eyespotted bud moth Fruittree leafroller Green fruitworm Lesser appleworm Obliquebanded leafroller Omnivorous leafroller Oriental fruit moth Pandemis leafroller Peach twig borer Redbanded leafroller Redhumped caterpillar Spotted tentiform leafminer Threelined leafroller Tufted apple bud moth Variegated leafroller	2.0 - 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **7 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Do not apply more than 3 times per crop season.

Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit.

Aerial application is prohibited.

SUGARCANE	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Sugarcane borer Mexican rice borer	2.0 – 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

SUNFLOWER and SAFFLOWER	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Banded sunflower moth Cutworms Sunflower bud moth Sunflower moth Thistle caterpillar	2.0 – 4.0
Notes and Use Restrictions Do not allow grazing or feed forage to livestock. Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days** Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application	

TOBACCO	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Armyworm Beet armyworm Cabbage looper Corn earworm Cutworm species Fall armyworm Saltmarsh caterpillar Southern armyworm Tobacco budworm Tobacco hornworm Tobacco splitworm Tomato hornworm Webworm species Yellowstriped armyworm	1.0 - 3.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days**. Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 5-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Do not apply more than 4 times per crop season. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

TREE NUT CROPS

Crops of Crop Group 14 and Pistachio including: Almond, Beech Nut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filbert (hazelnut), Hickory Nut, Macadamia Nut, Pecan, Pistachio , Walnut (black and English)

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Codling moth Fall webworm Filbertworm Fruittree leafroller Hickory shuckworm Naval orangeworm Obliquebanded leafroller Omnivorous leafroller Peach twig borer Pecan nut casebearer Redhumped caterpillar Walnut caterpillar	2.0 - 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **14 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit.

Aerial application is prohibited.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

Do not store for more than 30 consecutive days at an average daily temperature exceeding 100° F. If allowed to freeze, shake well to ensure the product is homogenous before use. Store in original container and out of the reach of children, preferable in a locked storage area. Avoid cross contamination with other pesticides.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT

NET CONTENTS:

BELT is a trademark of Bayer

PRODUCED FOR

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

BELT SC Insecticide (Pending) 10/13/2011, 10/23/12, 11/13/12

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

BELT™ SC Insecticide

EPA Reg. No. 264-1025

For Use on Alfalfa, Peanut, Safflower, Sorghum, Sunflower, Tree nuts and Pistachio and small fruit vine climbing subgroup (except fuzzy kiwifruit), Brassica (Cole) Leafy Vegetables And Turnip Greens, Globe Artichoke, Strawberry And Low Growing Berry Subgroup (except cranberry)

Label Expires: 11-13-2015

Supplemental Label

BELT™ SC Insecticide

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read this label and the product package label before using this product. This Supplemental Label must be in possession of the user at the time of pesticide application. Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the registered product label for BELT™ SC Insecticide.

USE DIRECTIONS FOR SPECIFIC CROPS

ALFALFA

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Alfalfa caterpillar Armyworm Army cutworm Alfalfa looper Alfalfa webworm Beet armyworm Corn earworm Cutworms Fall armyworm Green cloverworm Loopers Velvetbean caterpillar Yellowstriped armyworm	2.0 – 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): Forage and hay – **0 days**.

Retreatment Interval - **21 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per cutting**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per year.**

Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application

See CHEMIGATION statement in *Application Guidelines* section of this label.

PEANUT	
PESTS CONTROLLED	**RATE PER APPLICATION fluid ounces/Acre**
Armyworm Beet armyworm Corn earworm Cutworms Green cloverworm Fall armyworm Loopers Rednecked peanutworm Southern armyworm Velvetbean caterpillar Tobacco budworm	2.0 – 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **3 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

SORGHUM **Crops including: sorghum grain, sudangrass (seed crop), and hybrids of these grown for its seed; sorghum forage; sorghum stover; sudangrass, and hybrids of these grown for forage and/or stover; milo**	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid ounces/Acre**
Armyworm Beet armyworm Cutworms European corn borer Fall armyworm Mexican rice borer Sorghum headworm Sorghum webworm Southern armyworm Southwestern corn borer Stalk borer Sugarcane borer Webworms Yellowstriped armyworm	2.0 – 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): Forage – **3 days;** grain and stover – **14 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

SUGARCANE	
PESTS CONTROLLED	**RATE PER APPLICATION fluid ounces/Acre**
Sugarcane borer Mexican rice borer	3.0 – 4.0
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

SUNFLOWER and SAFFLOWER	
PESTS CONTROLLED	**RATE PER APPLICATION fluid ounces/Acre**
Banded sunflower moth Cutworms Sunflower bud moth Sunflower moth Thistle caterpillar	2.0 – 4.0
Notes and Use Restrictions Do not allow grazing or feed forage to livestock. Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **14 days**. Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**. Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground; 2.0 GPA – aerial application See CHEMIGATION statement in *Application Guidelines* section of this label.	

TREE NUT CROPS **Crops of Crop Group 14 and Pistachio including:** Almond, Beech Nut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filbert (hazelnut), Hickory Nut, Macadamia Nut, Pecan, Pistachio , Walnut (black and English)	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid oz/Acre**
Codling moth Fall webworm Filbertworm Fruittree leafroller Hickory shuckworm Naval orangeworm Obliquebanded leafroller Omnivorous leafroller Peach twig borer Pecan nut casebearer Redhumped caterpillar Walnut caterpillar	3.0 - 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **14 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit.

Aerial application is prohibited.

GRAPE and SMALL FRUIT VINE CLIMBING SUBGROUP (Except Fuzzy Kiwifruit)

Crops of Crop Subgroup 13-07F including: Armur river grape, Gooseberry, Grape, Kiwifruit (hardy), Maypop, Schisandra berry

PESTS CONTROLLED	RATE PER APPLICATION fluid oz/Acre
Cutworm Grape berry moth Grape leaf folder Grape leaf skeletonizer Obliquebanded leafroller Omnivorous leafroller Orange tortrix Redbanded leafroller	3.0 - 4.0

Notes and Use Restrictions

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **7 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 5-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Apply BELT SC Insecticide in sufficient water volume that provides thorough coverage of plant foliage and fruit.

Aerial application is prohibited.

BRASSICA (COLE) LEAFY VEGETABLES and TURNIP GREENS **Crops of Crop Group 5 and Turnip Greens including:** Broccoli, Broccoli raab (rapini), Brussels sprouts, Cabbage, Cauliflower, Cavalo broccolo, Chinese broccoli (gai lon), Chinese cabbage (bok choy), Chinese cabbage (napa), Chinese mustard cabbage (gai choy),Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens, Turnip greens.	
PESTS CONTROLLED	**RATE PER APPLICATION** **fluid oz/Acre**
Alfalfa looper Alfalfa caterpillar Armyworms Beet armyworm Cabbage looper Cabbage webworm Corn earworm Cross-striped cabbageworm Cutworm species Diamondback moth Fall armyworm Garden webworm Imported cabbage worm Saltmarsh caterpillar Southern armyworm Southern cabbageworm Tobacco budworm True armyworm Yellowstriped armyworm	1.5 – 2.4
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI):**8day**. Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 5-day interval.** Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season.** Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application. See CHEMIGATION statement in *Application Guidelines* section of the label.	

GLOBE ARTICHOKE	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Artichoke plume moth Cutworms Painted lady butterfly Saltmarsh caterpillar	1.5 – 2.4
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **8 day** Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 3-day interval**. Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season**. Minimum application volume: 10.0 GPA – ground, 2.0 GPA – aerial application. See CHEMIGATION statement in *Application Guidelines* section of this label.	

STRAWBERRY and LOW GROWING BERRY SUBGROUP (except cranberry) Crops of Crop Subgroup 13-07G (except cranberry) including: Bearberry, Bilberry, Blueberry (lowbush), Cloudberry, Lingonberry, Muntries, Partridgeberry, Strawberry, plus cultivars, varieties and/or hybrids of these	
PESTS CONTROLLED	**RATE PER APPLICATION fluid oz/Acre**
Armyworm Corn earworm Cutworm Lesser cornstalk borer Omnivorous leaftier Strawberry leafroller	1.5 – 2.4
Notes and Use Restrictions Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours. Pre-harvest Interval (PHI): **8 day**. Do not apply more than **2.4 fl oz per acre (0.075 lb ai/A) per 3-day interval**. Do not apply more than **7.2 fl oz per acre (0.225 lb ai/A) per crop season**. Minimum application volume: 1 0.0 GPA – ground, 2.0 GPA – aerial application. See CHEMIGATION statement in *Application Guidelines* section of this label.	

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

As with any crop-protection product, always read and follow label directions.
For additional information call toll-free 1-866-99BAYER (1-866-992-2937).

EXHIBIT 3

71711-26 03-23-2011 1/3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 23, 2011

Ms. Sherry Movassaghi,
Product Registration Manager
Bayer CropScience LP
c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.)
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Amended Labeling; Section 3 Expansion (PP #0F7685)**
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
Your Submission Dated January 22, 2010 & E-Mail Resubmissions Dated February 2, 2011 and February 16, 2011

Dear Ms. Movassaghi:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

A copy of your label stamped "Accepted" is enclosed for your records. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

FOR

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label stamped "Accepted"*
Flubendiamide; Pesticide Tolerances, as published in the Federal Register on March 23, 2011
Human Health Risk Assessment for Flubendiamide, dated November 30, 2010
Acute and Chronic Aggregate Dietary (Food and Drinking Water) Risk Assessment, dated November 15, 2010
Summary of Analytical Chemistry and Residue Data, dated November 5, 2010
Ecological Risk Assessment for Flubendiamide, dated December 16, 2010
Drinking Water Assessment, dated October 12, 2010

071711-00026 D426757

2
3

FLUBENDIAMIDE Technical

For Use in the Manufacture of Insecticides

ACTIVE INGREDIENT:

Flubendiamide* (N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide).....**97.76%**

OTHER INGREDIENTS:.....**2.24%**

Total:.....**100.00%**

*CAS Number: 272451-65-7

EPA Reg. No. 71711-26 **EPA Est. No.**

KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF INHALED	• Move the person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, health concerns, or pesticide incidents, you may call the Bayer CropScience Emergency Response toll free number 24 hours a day at 1-800-334-7577.	

ACCEPTED
March 23, 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No: 71711-26

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if inhaled, swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes and chemical-resistant gloves. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may be used only for formulation into an insecticide for:

1. the following uses:
   Terrestrial Food and Feed Crops: Alfalfa, Brassica (Cole) Leafy Vegetables, Corn (Field Corn, Pop Corn, Sweet Corn, Silage, and Corn Grown for Seed), Cotton, Cucurbit Vegetables, Fruiting Vegetables (Except Cucurbits), Globe Artichoke, Grapes, Leafy Vegetables (Except Brassica Vegetables), Legume Vegetables (Except Soybean), Low Growing Berry Subgroup (crop sub-group 13-07G) except Cranberry, Okra, Peanut, Pistachio, Pome Fruit, Small Fruit Vine Climbing Subgroup except Fuzzy Kiwifruit (crop sub-group 13-07F), Safflower, Sorghum, Soybean, Strawberry, Stone Fruit, Sugarcane, Sunflower, Tobacco, Tree Nuts and Turnip Greens.

   Terrestrial Nonfood Crop: Christmas Trees.
2. uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and
3. uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

Do not store for more than 30 consecutive days at an average daily temperature exceeding 100° F. Keep container tightly closed when not in use. Avoid cross contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into the processing equipment. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Nichino America, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NICHINO AMERICA, INC. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Nichino America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NICHINO AMERICA, INC. DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT NICHINO AMERICA, INC.'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

Nichino America, Inc.
4550 New Linden Hill Road
Suite 501
Wilmington, DE 19808

EXHIBIT 4

71711-32

11/26/2013

1/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 26, 2013

Ms. Julie Kozlowski
Regulatory Affairs Assistant
Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808-2951

Subject: **Amended Labeling; Adjusted Rate Ranges & Supplemental Labels**
VETICA® Insecticide, EPA Reg. No. 71711-32
Your Submission Dated May 30, 2013

Dear Ms. Kozlowski:

The labeling/supplemental labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision:

General Statement:

1. The subject supplemental labels (Brassica (Cole) Leafy Vegetables, Turnips & Turnip Greens and Succulent Bean) are valid for a period of 36 months from the date of this letter; therefore, you must add the following statement to the subject supplemental labels to read: "**This supplemental label expires on November 26, 2016, and must not be used or distributed after this date.**"

Copies of your label/supplemental labels stamped "Accepted with Comments" are enclosed for your records. Please submit two (2) copies of the final printed labeling/supplemental labeling, incorporating the above change, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

For Carmen J. Rodia, Jr.

Richard J. Gebken,
Product Manager (10)
Insecticide Branch,
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated November 26, 2013*
Supplemental Label (Brassica (Cole) Leafy Vegetables, Turnips & Turnip Greens) Stamped "Accepted with Comments," dated November 26, 2013
Supplemental Label (Succulent Bean) Stamped "Accepted with Comments," dated November 26, 2013

071711-00032 D479261

2/14

GROUP	28	16	INSECTICIDES

NICHINO AMERICA

ACCEPTED
With COMMENTS
In EPA Letter Dated:
November 26, 2013
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
71711-32

VETICA® Insecticide

Marketing Brand: VETICA® insecticide

ACTIVE INGREDIENTS:

Flubendiamide: N^2 –(1,1-dimethyl-2-methylsulfonylethyl)-3-iodo-N^1-{2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoro-methyl)ethyl]phenyl}phthalamide	3.8%
Buprofezin: 2-*tert*-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one	26.4%
OTHER INGREDIENTS:	69.8%
TOTAL	**100.0%**

Contains 0.33 lbs. flubendiamide and 2.33 lbs. buprofezin as active ingredient per U.S. gallon

EPA Reg. No. 71711-32
EPA Est. No. 67545-AZ-1

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-348-5832 for emergency medical treatment information. In case of fire or spills, information may be obtained by calling 1-800-424-9300.	

NET CONTENTS: _____

Formulated and Packaged in USA

NICHINO AMERICA, INC.
4550 New Linden Hill Rd., Suite 501
Wilmington, DE 19808
888-470-7700

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear (safety glasses, goggles, or face shield). Wash hands thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

User Safety Recommendations
Users should:
- Wash hands thoroughly before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENGINEERING CONTROLS STATEMENT
When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4–6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

ENVIRONMENTAL HAZARDS
This pesticide is toxic to aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate.

Ground Water Advisory
Flubendiamide and its degradate NNI-0001-des-iodo have properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

Surface Water Advisory
Flubendiamide and its degradate NNI-0001-des-iodo may also impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow groundwater. These chemicals are classified as having a medium potential for reaching both surface water and aquatic sediment via runoff several months or more after application. A well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs, as required under the Directions for Use, will reduce the potential for loading of flubendiamide and its degradate NNI-0001-des-iodo from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

4/14

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the treated area during application.

For any use requirement specific to your State or Tribe, consult the agency in your State responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours following application.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls worn over short-sleeved shirt and short pants
- Socks
- Chemical-resistant footwear
- Protective eyewear (such as safety glasses, goggles, or face shield)
- Chemical-resistant gloves (such as nitrile or butyl)

USE INFORMATION

VETICA® insecticide is formulated as a suspension concentrate containing two active ingredients, flubendiamide (0.33 lbs) and buprofezin (2.33 lbs) with a total of 2.66 lbs per gallon. This product is used for the control of Lepidopteran and Hemipteran insect pests. VETICA insecticide is active on lepidoptera by larval ingestion leading to a rapid cessation of feeding followed by death of the insect. Vetica is also effective by contact action against the nymphal stages of listed hemipteran pests (whiteflies, scales, mealybugs, planthoppers, and leafhoppers) by inhibiting chitin biosynthesis, suppressing oviposition of adults, and reducing viability of eggs. VETICA insecticide should be used in a program with other products to provide season long protection.

VETICA insecticide works primarily through contact action and ingestion, so good spray coverage is necessary for maximum results. Mix with sufficient water and apply as a foliar spray to obtain uniform coverage. Dense foliage or excessive growth will often prevent adequate coverage; adjust spray volumes accordingly. Treat plants when pests are immature or at a susceptible stage and populations are building, before crop damage occurs.

APPLICATION DIRECTIONS

Applications should be made immediately after the spray solution is prepared. Thorough spray coverage is essential for effective control. Applications may be made with high or low volume spray equipment that provides thorough coverage of the plant. Apply with properly calibrated spray equipment. For best results, apply when pest populations are beginning to build, before reaching economic thresholds. Consult your local agricultural advisor or state cooperative extension service for recommendations.

BUFFER ZONES

Vegetative Buffer Strip

Construct and maintain a minimum 15-foot wide vegetative filter strip of grass or other permanent vegetation between field edge and down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm

ponds). Only apply products containing flubendiamide onto fields where a maintained vegetative buffer strip of at least 15 feet exists between the field edge and down gradient aquatic habitat. For guidance, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. USDA, http://www.in.nrcs.usda.gov/technical/agronomy/newconbuf.pdf

USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- **This product is not for sale, sale into, distribution, and/or use in Nassau and Suffolk counties of New York State.**
- Aerial application is prohibited in New York State.
- This product cannot be applied within 100 feet of a water body (lake, pond, river, stream, wetland, or drainage ditch) in New York State.
- Do not apply this product through any type of irrigation system.
- Do not apply by chemigation.
- Use in enclosed structures, such as greenhouses or planthouses, is not permitted unless specified otherwise by state-specific supplemental labeling.

CROP ROTATIONAL RESTRICTIONS:

CROP/CROP GROUP	PLANTBACK TIMING
All crops listed on this label	0 days following application
Cereal grains	30 days following application
Alfalfa; Peanuts; Safflower; Soybean; Sugarcane; Sunflower; Tobacco; Vegetables - Legume (except Snap Beans); Root, Tuber and Bulb	60 days following application
All other crops	9 months following application

RESISTANCE MANAGEMENT

VETICA insecticide contains two active ingredients with different modes of action. Flubendiamide is classified by IRAC in Group 28-ryanodine receptor modulators. Buprofezin is classified by IRAC in Group 16- chitin biosynthesis inhibitors. Cross-resistance between these classes of chemistry and other modes of action has not been documented. However, repeated use of the same crop protection product may increase development of resistant strains of insects. Rotate the use of VETICA insecticide with alternate mode of action insecticides. Consult your local horticultural advisor for the most appropriate alternative products.

Unless directed otherwise in the specific crop/insect sections of the label, the following practices are recommended to prevent or delay the development of insecticide resistance to VETICA insecticide:

- Do not apply VETICA insecticide or other Group 28 insecticides to successive generations of the same insect pest. Multiple successive applications of VETICA insecticide are acceptable if they are used to treat a single insect generation.
- Avoid using less than labeled rates when applied alone or in tank mixtures.
- Target most susceptible insect life stages, whenever possible.
- Incorporate IPM techniques into the overall pest management program.

For additional information on insect resistance, modes of action, and monitoring, visit the Insecticide Resistance Action Committee (IRAC) on the web at http://www.irac-online.org

MIXING DIRECTIONS

Shake well before using. Read and follow all label directions for each tank mix product prior to any tank mixing with VETICA insecticide. This product can be mixed with other registered pesticides for use on labeled crops or sites, in accordance with the most restrictive use directions and precautions. No labeled dose rate should be exceeded. VETICA insecticide cannot be mixed with any product containing a label prohibition against such mixing.

VETICA INSECTICIDE ALONE: Begin with clean equipment. Fill spray tank with ¾ of the amount of water needed for the intended application and then turn on agitation. Pour recommended amount of product on the surface of water in the spray tank. Add the balance of the water to the spray tank with agitation running. Keep agitation running during filling and spraying operations. If spraying must be stopped before emptying the sprayer, resume agitation before spraying the remainder of the load.

VETICA INSECTICIDE TANK MIXTURES: Follow all use directions as listed above under **VETICA INSECTICIDE ALONE** with the following exception: after the VETICA insecticide is thoroughly mixed and the tank is ¾ full, add the recommended amount of wettable powder, soluble powder, flowable, emulsifiable concentrate, or soluble liquid product, **while maintaining agitation**. Then continue adding water to the tank to achieve the desired level, while maintaining agitation.

VETICA INSECTICIDE TANK MIXTURES WITH PRODUCTS IN WATER-SOLUBLE PACKAGING: Follow all use directions as listed above under **VETICA INSECTICIDE ALONE** with the following exception: add the desired number of water-soluble bags to the tank (if allowed by their label instructions) at the same time the VETICA insecticide is added. **Note:** If using products in water soluble packaging, do not tank mix with products that contain boron, chromium, or other micronutrients.

VETICA insecticide is physically and biologically compatible with many registered pesticides, fertilizers or micronutrients. If you have no experience with the combination you are considering, you should conduct a test to determine physical compatibility. To determine physical compatibility, add the recommended proportions of each chemical with the same proportion of water, as will be present in the chemical supply tank, into a suitable container, mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be readily re-mixed, the mixture is considered physically compatible.

SPRAY DRIFT REDUCTION MANAGEMENT

Do not apply when wind speed favors drift beyond the area intended for treatment. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator.

Importance of Droplet Size:

An important factor influencing drift is droplet size. Small droplets (<150 - 200 microns) drift to a greater extent than large droplets. Within typical equipment specifications, applications should be made to deliver the largest droplet spectrum that provides sufficient control and coverage. Use only Medium or coarser spray nozzles (for ground and non-ULV aerial application) according to ASAE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.

Ground Applications:

Wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application. For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two (2) rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.

Aerial Applications:

The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75% of the wing span or 80% rotor diameter. Flight speed and nozzle orientation must be considered in determining droplet size. Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Making applications at the lowest height that is safe reduces the exposure of the droplets to evaporation and wind.

Wind Speed Restrictions:
Drift potential increases at wind velocities of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size, canopy and equipment specifications determine drift potential at any given wind speed. Only apply this product if the wind direction favors on-target deposition. Do not apply when wind velocity exceeds 15 mph and avoid gusty and windless conditions. Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

Restrictions During Temperature Inversions:
Do not make ground applications during temperature inversions. Drift potential is high during temperature inversions. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by stable air and increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by mist or ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source. Smoke that layers and moves laterally near the ground surface in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical mixing.

APPLICATION RATE CHART FOR VETICA INSECTICIDE

CUCURBIT VEGETABLES (CROP GROUP 9)

Chayote (fruit); Chinese waxgourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Edible gourd (includes, hyotan, cucuzza, hechima, Chinese okra); *Momordica* spp. (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); Muskmelon (hybrids and/or cultivars of *Cucumis melo* includes true cantaloupe, cantaloupe, casaba, Crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon); Pumpkin; Squash (includes summer squash types such as crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini and winter squash types such as acorn squash, butternut squash, calabaza, hubbard squash, spaghetti squash); Watermelon (includes hybrids and/or varieties of *Citrullus lanatus)*

Pest	Rate/Acre	Notes and Use Restrictions
Armyworms Cabbage looper Corn earworm Cutworm species Melonworm Pickleworm Rindworm species Squash vine borer Tobacco budworm	12.0 to 17.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 3 applications per crop cycle. • Allow at least 7 days between applications. • Do not apply more than 38.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 1 day
Leafhoppers Whiteflies	14.0 to 17.0 fl oz	
Leafhoppers (suppression) Whiteflies (suppression)	12.0 to 13.0 fl oz	

LEAFY VEGETABLES (CROP GROUP 4) - EXCEPT BRASSICA VEGETABLES

Amaranth (leafy amaranth, Chinese spinach, tampala); Arugula (Roquette); Cardoon; Celery; Celtuce; Chervil Chinese celery; Chrysanthemum (edible-leaved and garland); Corn salad; Cress (garden); Cress (upland, yellow rocket, winter cress); Dandelion; Dock (sorrel); Endive (escarole); Florence fennel (sweet anise, sweet fennel, Finocchio); Lettuce (head and leaf); Orach; Parsley; Purslane (garden and winter); Radicchio (red chicory); Rhubarb; Spinach [including New Zealand and vine (Malabar spinach, Indian spinach)]; Swiss chard

Pest	Rate/Acre	Notes and Use Restrictions
Alfalfa looper Armyworms Cabbage looper Corn earworm Cutworm species Diamondback moth European corn borer Green cloverworm Imported cabbageworm Saltmarsh caterpillar Tobacco budworm Tomato hornworm	12.0 to 17.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 3 applications per crop cycle. • Allow at least 7 days between applications. • Do not apply more than 38.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 7 days
Leafhoppers Whiteflies	14.0 to 17.0 fl oz	
Leafhoppers (suppression) Whiteflies (suppression)	12.0 to 13.0 fl oz	

9/14

BRASSICA (COLE) LEAFY VEGETABLES (CROP GROUP 5)
Broccoli; broccoli, Chinese (gai lon); broccoli raab (rapini); Brussels sprouts; cabbage; cabbage, Chinese (bok choy); cabbage, Chinese (napa); cabbage, Chinese mustard (gai choy); cauliflower; cavalo broccolo; collards; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens

TURNIP TOPS or TURNIP GREENS
Broccoli raab (raab, raab salad), hanover salad, turnip tops (turnip greens)

Pest	Rate/Acre	Notes and Use Restrictions
Alfalfa looper Alfalfa caterpillar Armyworms Cabbage looper Cabbage webworm Corn earworm Cross-striped cabbageworm Cutworm species Diamondback moth Garden webworm Green cloverworm Imported cabbageworm Leafhoppers (suppression) Planthoppers (suppression) Saltmarsh caterpillar Southern cabbageworm Tobacco budworm Tomato hornworm	10.0 to 20.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 2 applications per crop cycle. • Allow at least 7 days between applications. • Do not apply more than 40.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 1 day
Whiteflies	14.0 to 20.0 fl oz	

FRUITING VEGETABLES (CROP GROUP 8)
Eggplant, groundcherry (Physalis spp.); pepino; pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); okra; tomatillo; tomato

Pest	Rate/Acre	Notes and Use Restrictions
Armyworms Cabbage looper Celery leaftier Cutworm species Diamondback moth European corn borer Garden webworm Melonworm Pickleworm Rindworm species Saltmarsh caterpillar Southwestern corn borer Tobacco budworm Tobacco hornworm Tomato fruitworm Tomato hornworm Tomato pinworm	12.0 to 17.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 3 applications per crop cycle. • Allow at least 5 days between applications. • Do not apply more than 38.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 1 day
Leafhoppers Planthoppers Whiteflies	14.0 to 17.0 fl oz	
Leafhoppers (suppression) Planthoppers (suppression) Whiteflies (suppression)	12.0 to 13.0 fl oz	

BEAN, SUCCULENT (CROP GROUP 6)
Succulent forms of the following beans: *Cicer arietinum* (chickpea, garbanzo bean); *Lupinus* spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine). *Phaseolus* spp. (including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, and waxbean; *Vicia faba* (broad bean, fava bean); *Vigna* spp. (including asparagus bean, blackeyed pea and cowpea)

Pest	Rate/Acre	Notes and Use Restrictions
Armyworms Bean leafroller Bean leafskeletonizer Cabbage looper Corn earworm Cutworm species European corn borer Garden webworm Gray hairstreak caterpillar Green cloverworm Lesser cornstalk borer Saltmarsh caterpillar Soybean looper Yellow woollybear caterpillar	12.0 to 17.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 3 applications per crop cycle. • Allow at least 14 days between applications. • Do not apply more than 38.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 14 days
Leafhoppers Planthoppers Whiteflies	14.0 to 17.0 fl oz	

LOW-GROWING BERRY (CROP SUBGROUP 13-07G) – EXCEPT CRANBERRY Strawberry, Bearberry, Bilberry, Blueberry (lowbush), Cloudberry, Lingonberry, Muntries, Partridgeberry		
Pest	**Rate/Acre**	**Notes and Use Restrictions**
Armyworms Apple pandemis Bollworms Budworms Corn earworm Cutworm species Garden tortrix Leafrollers Leaftiers Lesser cornstalk borer Light brown apple moth Loopers Orange tortrix Saltmarsh caterpillar Tobacco budworm Tomato fruitworm Whiteflies	12.0 to 18.5 fl oz	• For ground application, use a minimum of 100 gallons of water per acre. • For aerial application, use a minimum of 10 gallons of water per acre. • Do not make more than 2 applications per crop cycle. • Allow at least 10 days between applications. • Do not apply more than 37 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 3 days

COTTON		
Pest	**Rate/Acre**	**Notes and Use Restrictions**
Armyworms Cabbage looper Cotton bollworm Cotton leafworm Cotton leafperforator Cutworm species European corn borer Omnivorous leafroller Saltmarsh caterpillar Soybean looper Tobacco budworm	24.0 to 36.0 fl oz	• For ground application, use a minimum of 10 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • For early season use, when cotton is less than 10 inches in height, apply in a directed spray using ground spray equipment. • Do not make more than 3 applications per growing season. • Allow at least 28 days between applications. • Do not apply more than 36.0 fl oz per acre per growing season. • Pre-Harvest Interval (PHI): 28 days
Whiteflies	14.0 to 17.0 fl oz	

12/14

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container, unopened in a cool, dry place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Triple rinse, or equivalent, promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State or local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be accurate and must be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. To the extent consistent with applicable law, all such risks are assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

13/14

SUPPLEMENTAL LABEL

GROUP 28 16 INSECTICIDE

Vetica® Insecticide

EPA Reg. No. 71711-32

For Use on Brassica (Cole) Leafy Vegetables, Turnip Tops and Turnip Greens

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling and the EPA approved container label must be in the possession of the user at the time of application.

New use directions appear on this supplemental labeling that supersede the Section 3 container label.

NOTICE: Before using this product, read the First Aid, Precautionary Statements, Conditions of Sale and Warranty, and complete Directions for Use found on the container labeling. All applicable directions, restrictions, and precautions on the EPA registered label are to be followed.

APPLICATION RATE CHART

BRASSICA (COLE) LEAFY VEGETABLES (CROP GROUP 5)
Broccoli; broccoli, Chinese (gai lon); broccoli raab (rapini); Brussels sprouts; cabbage; cabbage, Chinese (bok choy); cabbage, Chinese (napa); cabbage, Chinese mustard (gai choy); cauliflower; cavalo broccolo; collards; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens

TURNIP TOPS or TURNIP GREENS
Broccoli raab (raab, raab salad), hanover salad, turnip tops (turnip greens)

Pest	Rate/Acre	Notes and Use Restrictions
Alfalfa looper Alfalfa caterpillar Armyworms Cabbage looper Cabbage webworm Corn earworm Cross-striped cabbageworm Cutworm species Diamondback moth Garden webworm Green cloverworm Imported cabbageworm Leafhoppers (suppression) Planthoppers (suppression) Saltmarsh caterpillar Southern cabbageworm Tobacco budworm Tomato hornworm	10.0 to 20.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 2 applications per crop cycle. • Allow at least 7 days between applications. • Do not apply more than 40.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 1 day
Whiteflies	14.0 to 20.0 fl oz	

ACCEPTED
With COMMENTS
In EPA Letter Dated:
November 26, 2013
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
71711-32

NICHINO AMERICA
4550 New Linden Hill Road
Wilmington, DE 19808
888-740-7700

D-168 053013 Expiration Date: XX/XX/XXXX

SUPPLEMENTAL LABEL

GROUP 28 16 INSECTICIDE

Vetica® Insecticide

EPA Reg. No. 71711-32

For Use on Succulent Bean

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling and the EPA approved container label must be in the possession of the user at the time of application.

New use directions appear on this supplemental labeling that supersede the Section 3 container label.

NOTICE: Before using this product, read the First Aid, Precautionary Statements, Conditions of Sale and Warranty, and complete Directions for Use found on the container labeling. All applicable directions, restrictions, and precautions on the EPA registered label are to be followed.

APPLICATION RATE CHART

BEAN, SUCCULENT (CROP GROUP 6)
Succulent forms of the following beans: *Cicer arietinum* (chickpea, garbanzo bean); *Lupinus* spp. (including sweet lupine, white sweet lupine, white lupine, and grain lupine). *Phaseolus* spp. (including kidney bean, lima bean, mung bean, navy bean, pinto bean, snap bean, and waxbean; *Vicia faba* (broad bean, fava bean); *Vigna* spp. (including asparagus bean, blackeyed pea and cowpea)

Pest	Rate/Acre	Notes and Use Restrictions
Armyworms Bean leafroller Bean leafskeletonizer Cabbage looper Corn earworm Cutworm species European corn borer Garden webworm Gray hairstreak caterpillar Green cloverworm Lesser cornstalk borer Saltmarsh caterpillar Soybean looper Yellow woollybear caterpillar	12.0 to 17.0 fl oz	• For ground application, use a minimum of 20 gallons of water per acre. • For aerial application, use a minimum of 5 gallons of water per acre. • Do not make more than 3 applications per crop cycle. • Allow at least 14 days between applications. • Do not apply more than 38.0 fl oz per acre per crop cycle. • Pre-Harvest Interval (PHI): 14 days
Leafhoppers Planthoppers Whiteflies	14.0 to 17.0 fl oz	

ACCEPTED
With COMMENTS
In EPA Letter Dated:
November 26, 2013
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
71711-32

NICHINO AMERICA
4550 New Linden Hill Road
Wilmington, DE 19808
888-740-7700

D-169 053013

Expiration Date: XX/XX/XXXX

EXHIBIT 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 9, 2014

Ms. Julie Kozlowski
Regulatory Affairs Specialist
Nichino America, Inc.
4550 New Linden Hill Road, Suite 501
Wilmington, DE 19808-2951

Subject: **Label Amendment – Minor Formatting Changes & Updated Tree Nut DFU**
Product Name: TOURISMO Insecticide
EPA Registration Number: 71711-33
Application Date: October 9, 2014
Decision Number: 496190

Dear Ms. Kozlowski:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via e-mail at Rodia.Carmen@epa.gov.

Sincerely,

Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: October 9, 2014

Enclosure: *Amended Master Label/Supplemental Label Stamped "Accepted," dated October 9, 2014*
071711-00033 D496190

NICHINO AMERICA®

GROUP	28	16	INSECTICIDES

ACCEPTED
10/09/2014
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 71711-33

TOURISMO® Insecticide

Marketing Brand: TOURISMO insecticide

ACTIVE INGREDIENTS:

Flubendiamide: Benzenedicarboxamide, N2-[1,1-dimethyl-2-(methylsulfonyl) ethyl]-3-iodo-N1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl] phenyl] 12.5%

Buprofezin: 4H-1,3,5-Thiadiazin-4-one, 2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl- 25.0%

OTHER INGREDIENTS: 62.5%

TOTAL **100.0%**

Contains 1.17 lbs flubendiamide and 2.33 lbs buprofezin as active ingredient per U.S. gallon

EPA Reg. No. 71711-33
EPA Est. No.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-348-5832 for emergency medical treatment information. In case of fire or spills, information may be obtained by calling 1-800-424-9300.	

NET CONTENTS: _____

Formulated and Packaged in U.S.A. for
NICHINO AMERICA, INC.
4550 New Linden Hill Rd., Suite 501
Wilmington, DE 19808
888-470-7700

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear (safety glasses, goggles, or face shield). Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

User Safety Recommendations
Users should:
- Wash hands thoroughly before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENGINEERING CONTROLS STATEMENT
When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4–6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

ENVIRONMENTAL HAZARDS
This pesticide is toxic to aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate.

Ground Water Advisory
Flubendiamide and its degradate NNI-0001-des-iodo have properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

Surface Water Advisory
Flubendiamide and its degradate NNI-0001-des-iodo may also impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow groundwater. These chemicals are classified as having a medium potential for reaching both surface water and aquatic sediment via runoff several months or more after application. A well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs, as required under the Directions for Use, will reduce the potential for loading of flubendiamide and its degradate NNI-0001-des-iodo from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the treated area during application.

For any use requirements specific to your State or Tribe, consult the agency in your State responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours following application.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls worn over short-sleeved shirt and short pants
- Socks
- Chemical-resistant footwear
- Protective eyewear (such as safety glasses, goggles, or face shield)
- Chemical-resistant gloves (such as nitrile or butyl)

USE INFORMATION

TOURISMO® insecticide is formulated as a suspension concentrate containing two active ingredients, flubendiamide (1.17 lbs) and buprofezin (2.33 lbs) with a total of 3.5 lbs per gallon. This product is used for the control of Lepidopteran and suppression of Hemipteran insect pests. TOURISMO insecticide is active on lepidoptera by larval ingestion leading to a rapid cessation of feeding followed by death of the insect. TOURISMO is also suppressive by contact action against the nymphal stages of listed hemipteran pests (whiteflies, scales, mealybugs, planthoppers, and leafhoppers) by inhibiting chitin biosynthesis, suppressing oviposition of adults, and reducing viability of eggs. TOURISMO insecticide should be used in a program with other products to provide season-long protection.

Good spray coverage is necessary for maximum results. Mix with sufficient water and apply as a foliar spray to obtain uniform coverage. Dense foliage or excessive growth will often prevent adequate coverage; adjust spray volumes accordingly. Treat plants when pests are immature or at a susceptible stage and populations are building, before crop damage occurs.

APPLICATION DIRECTIONS

Applications should be made immediately after the spray solution is prepared. Thorough spray coverage is essential for effective control. Applications may be made with high or low volume spray equipment that provides thorough coverage of the plant. Apply with properly calibrated spray equipment. For best results, apply when pest populations are beginning to build, before reaching economic thresholds. Consult your local agricultural advisor or state cooperative extension service for recommendations.

BUFFER ZONES

Vegetative Buffer Strip
Construct and maintain a minimum 15-foot wide vegetative filter strip of grass or other permanent vegetation between field edge and down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds). Only apply products containing flubendiamide onto fields where a maintained vegetative buffer strip of at least 15 feet exists between the field edge and down gradient aquatic habitat. For guidance, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. USDA, Website link: http://www.in.nrcs.usda.gov/technical/agronomy/newconbuf.pdf

USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate food or feedstuffs.
- **This product is not for sale, sale into, distribution, and/or use in Nassau or Suffolk counties of New York State.**
- Aerial application is prohibited in New York State.
- This product cannot be applied within 100 feet of a water body (lake, pond, river, stream, wetland, or drainage ditch) in New York State.
- Do not apply this product through any type of irrigation system.
- Do not apply by chemigation.
- Use in enclosed structures, such as greenhouses or planthouses, is not permitted unless specified otherwise by state-specific supplemental labeling.

CROP ROTATIONAL RESTRICTIONS:

CROP/CROP GROUP	PLANTBACK TIMING
All crops listed on this label	0 days following application
Cereal grains	30 days following application
Alfalfa; Peanuts; Safflower; Soybean; Sugarcane; Sunflower; Tobacco; Vegetables - Legume (except Snap Beans); Root, Tuber and Bulb	60 days following application
All other crops	9 months following application

RESISTANCE MANAGEMENT

TOURISMO insecticide contains two active ingredients with different modes of action. Flubendiamide is classified by IRAC in Group 28-ryanodine receptor modulators. Buprofezin is classified by IRAC in Group 16- chitin biosynthesis inhibitors. Cross-resistance between these classes of chemistry and other modes of action has not been documented. However, repeated use of the same crop protection product may increase development of resistant strains of insects. Rotate the use of TOURISMO insecticide with alternate mode of action insecticides. Consult your local horticultural advisor for the most appropriate alternative products. For best results, and for resistance management practices, do not use alternate row middle sprays.
Unless directed otherwise in the specific crop/insect sections of the label, the following practices are recommended to prevent or delay the development of insecticide resistance to TOURISMO insecticide:

- Do not apply TOURISMO insecticide or other Group 28 insecticides to successive generations of the same insect pest. Multiple successive applications of TOURISMO insecticide are acceptable if they are used to treat a single insect generation.
- Avoid using less than labeled rates when applied alone or in tank mixtures.
- Target most susceptible insect life stages, whenever possible.
- Incorporate IPM techniques into the overall pest management program.

For additional information on insect resistance, modes of action, and monitoring, visit the Insecticide Resistance Action Committee (IRAC) on the web at http://www.irac-online.org

MIXING DIRECTIONS
Shake well before using. Read and follow all label directions for each tank mix product prior to any tank mixing with TOURISMO insecticide. This product can be mixed with other registered pesticides for use on labeled crops or sites, in accordance with the most restrictive use directions and precautions. No labeled dose rate should be exceeded. TOURISMO insecticide cannot be mixed with any product containing a label prohibition against such mixing.

TOURISMO insecticide alone: Begin with clean equipment. Fill spray tank with ¾ of the amount of water needed for the intended application and then turn on agitation. Pour recommended amount of product on the surface of water in the spray tank. Add the balance of the water to the spray tank with agitation running. Keep agitation running during filling and spraying operations. If spraying must be stopped before emptying the sprayer, resume agitation before spraying the remainder of the load.

TOURISMO insecticide tank mixtures: Follow all use directions as listed above under **TOURISMO insecticide alone** with the following exception: after the TOURISMO insecticide is thoroughly mixed and the tank is ¾ full, add the recommended amount of wettable powder, soluble powder, flowable, emulsifiable concentrate, or soluble liquid product, **while maintaining agitation**. Then continue adding water to the tank to achieve the desired level, while maintaining agitation.

TOURISMO insecticide is physically and biologically compatible with many registered pesticides, fertilizers or micronutrients. If you have no experience with the combination you are considering, you should conduct a test to determine physical compatibility. To determine physical compatibility, add the recommended proportions of each chemical with the same proportion of water, as will be present in the chemical supply tank, into a suitable container, mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be readily remixed, the mixture is considered physically compatible.

SPRAY DRIFT REDUCTION MANAGEMENT
Do not apply when wind speed favors drift beyond the area intended for treatment. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator.

Importance of Droplet Size:
An important factor influencing drift is droplet size. Small droplets (<150 - 200 microns) drift to a greater extent than large droplets. Within typical equipment specifications, applications should be made to deliver the largest droplet spectrum that provides sufficient control and coverage. Use only Medium or coarser spray nozzles (for ground and non-ULV aerial application) according to ASAE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.

Ground Applications:
Wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application. For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two (2) rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.

Aerial Applications:
The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75% of the wing span or 80% rotor diameter. Flight speed and nozzle orientation must be considered in determining droplet size. Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Making applications at the lowest height that is safe reduces the exposure of the droplets to evaporation and wind.

Wind Speed Restrictions:
Drift potential increases at wind velocities of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size, canopy and equipment specifications determine drift potential at any given wind speed. Only apply this product if the wind direction favors on-target deposition. Do not apply when wind velocity exceeds 15 mph and avoid gusty and windless conditions. Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

Restrictions During Temperature Inversions:
Do not make ground applications during temperature inversions. Drift potential is high during temperature inversions. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by stable air and increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by mist or ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source. Smoke that layers and moves laterally near the ground surface in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical mixing.

APPLICATION RATE CHART FOR TOURISMO INSECTICIDE

Cotton		
Pest	**Rate/Acre**	**Notes and Use Restrictions**
Armyworms Cabbage looper Cotton bollworm Cotton leafworm Cotton leafperforator Cutworm species European corn borer Omnivorous leafroller Saltmarsh caterpillar Soybean looper Tobacco budworm	7.0 to 12.0 fl oz/acre	• Apply in a minimum of 10 gallons of water per acre using ground spray equipment to ensure uniform, adequate coverage. • For aerial application, apply in a minimum of 5 gallons of water per acre. • For early season use, when cotton is less than 10 inches in height, apply in a directed spray using ground spray equipment. • Do not make more than 3 applications per growing season. • Allow at least 28 days between applications. • Do not apply more than 27.0 fl oz per acre per growing season. • Preharvest Interval (PHI): 28 days
Whiteflies*	12.0 fl oz/acre	
*suppression		

Grapes		
Pest	**Rate/Acre**	**Notes and Use Restrictions**
Cutworms European grapevine moth Grape berry moth Grape leaffolder Grapeleaf skeletonizer Leafhoppers* Leafrollers Orange tortrix Raisin moth	10.0 to 14.0 fl oz/acre	• Apply in a minimum of 50 gallons of water per acre using ground sprayer or airblast (air assist) spray equipment. Use higher spray volume in mature vineyards with dense foliage to ensure adequate coverage. • Do not make more than 3 applications per growing season. • Allow at least 14 days between applications. • Do not apply more than 37.0 fl oz per acre per growing season. • Preharvest Interval (PHI): 7 days
*suppression		

Pome Fruits (Crop Group 11)
apple, crabapple, loquat, mayhaw, pear; pear, Asian; quince

Pest	Rate/Acre	Notes and Use Restrictions
Eyespotted bud moth Green fruitworm Lacanobia fruitworm Leafrollers Lesser appleworm Mealybugs* Spotted tentiform leafminer Tufted apple budmoth Western tentiform leafminer White apple leafhopper*	12.0 to 17.0 fl oz/acre	• Apply in a minimum of 100 gallons of water per acre using ground sprayer or airblast (air assist) spray equipment. Use higher spray volume to provide adequate coverage in larger trees with dense foliage. • Do not apply by using Alternate Row Middle spray application method. • Do not make more than 3 applications per growing season. • Allow at least 7 days between applications. • Do not apply more than 46.0 fl oz per acre per growing season. • Preharvest Interval (PHI): 14 days RECOMMENDATIONS • **Codling moth and Oriental fruit moth**: Use in a complete program with other registered products and nonchemical measures such as mating disruption. Follow local university recommendations regarding pest life cycle development. This product is effective only against larval stages, so use in conjunction with ovicides and/or adulticides will provide best control.
Codling moth Oriental fruit moth	15.0 to 17.0 fl oz/acre	

*suppression

Stone Fruits (Crop Group 12)
apricot; cherry (sweet and tart); nectarine; peach; plum (includes Chickasaw plum, Damson plum, and Japanese plum); plumcot; prune (fresh and dried)

Pest	Rate/Acre	Notes and Use Restrictions
Cherry fruitworm Eyespotted bud moth Green fruitworm Leafrollers Lesser appleworm Peach twig borer Redhumped caterpillar Spotted tentiform leafminer Tufted apple budmoth	10.0 to 14.0 fl oz/acre	• Apply in a minimum of 50 gallons of water per acre using ground sprayer or airblast (air assist) spray equipment. Use higher spray volume to provide adequate coverage in larger trees with dense foliage. • Do not apply by using Alternate Row Middle spray application method. • Do not make more than 3 applications per growing season. • Allow at least 14 days between applications. • Do not apply more than 37.0 fl oz per acre per growing season. • Preharvest Interval (PHI): 14 days RECOMMENDATIONS • **Codling moth and Oriental fruit moth:** Use in a complete program with other registered products and nonchemical measures such as mating disruption. Follow local university recommendations regarding pest life cycle development. This product is effective only against larval stages, so use in conjunction with ovicides and/or adulticides will provide best control.
Codling moth Oriental fruit moth	14.0 fl oz/acre	

Tree Nuts (Crop Group 14) including pistachio almond; beechnut; Brazil nut; butternut; cashew; chestnut; chinquapin; filbert; hickory nut; macadamia nut; pecan; pistachio; walnut (black and English)		
Pest	**Rate/Acre**	**Notes and Use Restrictions**
Fall webworm Filbertworm Leafrollers Peach twig borer Redhumped caterpillar	10.0 to 14.0 fl oz/acre	• Apply in a minimum of 100 gallons of water per acre using ground sprayer or airblast (air assist) spray equipment. Use higher spray volume to provide adequate coverage in larger trees with dense foliage. • Do not apply when bees are actively foraging. • Do not apply more than 37.0 fl oz per acre per growing season. • Do not make more than 3 applications per growing season. • Allow at least 7 days between applications. • Do not apply by using Alternate Row Middle spray application method. • Preharvest Interval (PHI): 60 days.
Navel orangeworm	14.0 fl oz/acre	

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container, and keep tightly closed when not in use. Store in a cool, dry place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

Nonrefillable plastic container (Less than 5 gallons)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip . Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Nonrefillable plastic container (Greater than 5 gallons)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration , or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Nonrefillable metal container (Greater than 5 gallons)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable paper and plastic bag
Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration.

Nonrefillable fiber drum with liner
Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment then offer for recycling if available or dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Refillable plastic container
Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to point of sale or offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration or by other procedures approved by state and local authorities.

Refillable metal container
Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to point of sale or offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

IMPORTANT: READ BEFORE USE

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be accurate and must be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. To the extent consistent with applicable law, all such risks are assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.

Protected by US patent # 6603044

SUPPLEMENTAL LABEL

GROUP	28	16	INSECTICIDES

Tourismo® Insecticide
EPA Reg. No. 71711-33

ACCEPTED
10/09/2014
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 71711-33

For Use on Tree Nuts

This supplemental label expires April 9, 2016 and must not be used or distributed after this date.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling and the EPA approved container label must be in the possession of the user at the time of application.

Read the label affixed to the container for Tourismo Insecticide before applying. Use of Tourismo Insecticide according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for Tourismo Insecticide.

New use directions appear on this supplemental label that may be different from those that appear on the container label.

APPLICATION RATE CHART

Tree Nuts (Crop Group 14) including pistachio
almond; beechnut; Brazil nut; butternut; cashew; chestnut; chinquapin; filbert; hickory nut; macadamia nut; pecan; pistachio; walnut (black and English)

Pest	Rate/Acre	Notes and Use Restrictions
Fall webworm Filbertworm Leafrollers Peach twig borer Redhumped caterpillar	10.0 to 14.0 fl oz/acre	• Apply in a minimum of 100 gallons of water per acre using ground sprayer or airblast (air assist) spray equipment. Use higher spray volume to provide adequate coverage in larger trees with dense foliage. • Do not apply when bees are actively foraging. • Do not apply more than 37.0 fl oz per acre per growing season. • Do not make more than 3 applications per growing season. • Allow at least 7 days between applications. • Do not apply by using Alternate Row Middle spray application method. • Preharvest Interval (PHI): 60 days
Navel orangeworm	14.0 fl oz/acre	

NICHINO AMERICA®
4550 New Linden Hill Road
Wilmington, DE 19808
888-740-7700

EXHIBIT 6

United States
Environmental Protection Agency

Office of Prevention, Pesticides and Toxic
Substances (7505P)

Pesticide Fact Sheet

Name of Chemical: Flubendiamide
Reason for Issuance: Conditional Registration
Date Issued: August 1, 2008

DESCRIPTION OF CHEMICAL

Generic Name:	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
Common Name:	Flubendiamide
EPA Chemical Code:	027602
Chemical Abstracts Service (CAS) Number:	272451-65-7
Pesticide Type:	Insecticide
Chemical Type:	Phthalic Acid Diamide
U.S. Producer:	Bayer CropScience LP 2 T.W. Alexander Drive Research Triangle Park, NC 27709-2014

USE PATTERNS AND FORMULATIONS

Application Sites: Flubendiamide is registered for use on corn, cotton, tobacco, pome and stone fruit, tree nut crops, grapes and vegetable crops (including cucurbit vegetables, fruiting vegetables and okra, leafy vegetables [except *Brassica*] and *Brassica* [cole] leafy vegetables).

Types of Formulations:
NNI-0001 Technical (manufacturing concentrate)
NNI-0001 24 WG Insecticide (water dispersible granule)
NNI-0001 480 SC Insecticide (soluble concentrate)

Application Methods and Rates: Flubendiamide acts against various lepidopterous insect pests such as armyworms, bollworms, corn borers, cutworms, diamondback moths, fruitworms and loopers. Foliar spray applications can be made by aerial, ground or chemigation application on all crops as needed for insect control. Single application rates range from 0.03 to 0.16 lb. a.i./A and can be applied 3-5 times per season. Seasonal application rates range from 0.09 to 0.47 lb. a.i./A. Pre-harvest intervals (PHIs) range from 1 to 28 days. The proposed reentry interval (REI) is 12 hours on both labels. NNI-0001 24 WG Insecticide is a 24% a.i. water dispersible granule. NNI-0001 480 SC Insecticide is a 39% a.i. soluble concentrate.

HUMAN HEALTH RISK ASSESSMENT

Hazard and risk assessments were conducted in relation to this registration application and tolerance petition for the use of flubendiamide on corn, cotton, tobacco, tree fruit, tree nuts, vine crops and vegetable crops and suggest that its use, consistent with the proposed labeling measures, will be protective of the public health and the environment.

Acute Toxicity: Flubendiamide has a low order of acute toxicity via the oral, dermal and inhalation routes (Category III). Though it is a slight irritant to the eye, flubendiamide is not a skin irritant and it is not a skin sensitizer. The acute toxicity findings for flubendiamide are summarized below:

Acute Oral Toxicity: III
Acute Dermal Toxicity: III
Acute Inhalation: III
Primary Eye Irritation: IV
Primary Dermal Irritation: IV
Dermal Sensitization: Negative

Other Toxicity: In the longer-term studies in the flubendiamide mammalian toxicology database, the primary target organs identified were the liver, thyroid, kidney and eyes. Liver effects reported in rats, mice and/or dogs include organ

weight increase, periportal fatty change, hypertrophy, and minimal foci of cellular alteration. Thyroid effects include organ weight increase, follicular cell hypertrophy and slight perturbations of triiodothyronine (T3) and thyroid stimulating hormone (TSH) in the rat and mouse. Kidney effects include increases in absolute and/or relative to body kidney weights and chronic nephropathy in the rat. Eye effects include eye enlargement, opacity, and exophthalmus with hemorrhage and appear only in rat pups. Other changes include mild microcytic anemia, decreased serum triglycerides and cholesterol in female rat, increased gamma glutamyl peptidase, alkaline phosphatase and shortened activated prothrombin time in dogs and adrenal weight increase and increase in adrenal cortical cell hypertrophy in dogs.

The hazard assessment indicated potential toxicity resulting from exposure to flubendiamide via different routes over different durations. The observed eye effects were selected as a critical effect for the acute dietary exposure scenario; whereas liver and thyroid effects were determined critical for the chronic dietary exposure scenario. Short- and intermediate-term dermal risks were also based on liver and thyroid effects, as well as blood effects. Short- and intermediate-term inhalation risks are based on liver toxicity, as well as adrenal weight increase and an increase in adrenal cortical cell hypertrophy.

Metabolism: Rat metabolism studies at low and high doses report fairly rapid absorption, with peak blood and plasma levels reached at approximately 6 to 12 hours post-dosing followed by a continuous decline. The NNI-0001 was fairly well distributed among blood and most of the organs and tissues, with some preference to the liver, adrenal glands, and fat. Generally, the liver and kidneys contained the greatest percentage of the administered dose. Excretion of NNI-0001 residues was rapid (majority of radioactivity recovered at the first 24-hour collection point), with feces being the predominant route of excretion. Renal excretion accounted for only 2% and <1% of the dose in male and female rats, respectively. Parent NNI-0001, NNI-0001-benzylalcohol (A-16) and NNI-0001-benzoic acid (A-18) were the major residues identified in the feces. Additionally, metabolite A-14 was identified in the fat of female rats at 1% of the administered dose.

In vitro metabolism and toxicokinetic studies in multiple mammalian species appear to confirm the findings reported in the *in vivo* rat metabolism study, that female rats appear to metabolize the parent compound differently from male rats and other species. Female rats do not show an ability to convert the parent compound to the metabolite A-16 due to the lack of β-NADPH that is required for metabolism, indicating there was no abiotic degradation of the test compound in the test systems. The lack of abiotic degradation and the longer terminal elimination half-life of the parent compound in the female rats, differentiate them from other test animals.

Endpoints

Acute: The 2-generation reproduction, 1-generation reproduction and DNT studies, as 3 co-critical studies, were selected for the acute reference dose (aRfD) of 0.995

mg/kg/day using 99.5 mg/kg/day from the DNT study (the highest NOAEL) and a LOAEL from the 1-generation reproduction study of 127 mg/kg/day (the lowest LOAEL) based on buphthalmia (enlargement of eyes), ocular opacity, retinal degeneration, hemorrhage, cataract and atrophy of the optic nerve. The NOAEL/LOAEL chosen result in a more refined yet health protective acute dietary risk assessment.

The weight of evidence from various studies suggest that the finding of enlarged eyeballs in rat offspring is a rat-specific phenomenon, resulting from exposure to higher steady-state concentrations of flubendiamide which may be due to the uniquely diminished capacity of the female rat to oxidize the parent compound. While human microsomes have been shown to be capable of approximately 4 times higher hydroxylation rates than female mouse microsomes and may be able to efficiently metabolize/excrete flubendiamide, preventing accumulation of the parent compound, it remains unclear whether this ability is the only requirement to avoid ocular toxicity. Due to the potential concern for increased susceptibility of human neonates vs. adults, this perinatal ocular effect is considered in the HED risk assessment.

Chronic: The 1-year chronic rat study, 1-year chronic dog study and the 24-month rat carcinogenicity study were selected as 3 co-critical studies for the chronic reference dose (cRfD) of 0.024 mg/kg/day with a NOAEL/LOAEL of 2.4/33.9 mg/kg/day (highest NOAEL of 2.4 mg/kg/day from 1-year chronic rat study and lowest LOAEL of 33.9 mg/kg/day from 24-month rat study. Although the 1-year dog study had NOAELs of 2.21/2.51 mg/kg/day, the lowest NOAELs from each study were considered when comparing NOAELs among the 3 studies, respectively, based on the consistent liver toxicity reported across multiple studies, different durations and multiple species. The NOAEL/LOAEL chosen are protective of effects seen in other long-term studies.

Carcinogenicity: Flubendiamide is considered to be "Not Likely to be Carcinogenic to Humans." There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24- and 18-months, respectively. Flubendiamide was determined to be non-mutagenic in bacteria, negative in an *in vivo* mammalian cytogenetics assay and did not cause unscheduled DNA synthesis (repair of DNA damage) in mammalian cells *in vitro*. Overall, there was no clear evidence that flubendiamide was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. Quantification of cancer risk is; therefore, not needed for flubendiamide.

FQPA Safety Factor: EPA evaluated the quality of the toxicity/exposure data and has determined that the safety of infants and children would be adequately protected if the FQPA safety factor (SF) were reduced to 1x based on the following findings: (1) The toxicology database for flubendiamide is complete for purposes of risk assessment and the characterization of potential pre- and/or post-natal risks to infants and children. Although susceptibility was identified in the toxicological database (eye effects), the selected regulatory PODs (which are based on clear NOAELs) are protective of these effects; therefore, the human health risk assessment is protective;

(2) There are no treatment-related neurotoxic findings in the acute neurotoxicity and DNT studies in rats. Although eye effects were observed in the DNT study, the PODs employed in the HED risk assessment are protective of this effect; and (3) There are no residual uncertainties identified in the exposure databases and the exposure assessment is protective.

Dietary Exposure

Acute Risk: The acute dietary analysis assumed that 100% of crops with requested uses of flubendiamide are treated and that all treated crops contain residues at tolerance-level. In addition, tolerance-level residues for livestock commodities were included in these analyses to account for the potential transfer of plant residues to livestock tissues. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 12.93 ppb was used to assess the contribution to drinking water. These assumptions result in conservative, health-protective estimates of exposure which are well below the Agency's LOC (100% of the aPAD). **The maximum exposure estimate is less than 8% of the aPAD for the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no acute dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Chronic Risk: The chronic dietary analysis assumed that 100% of requested crops are treated and that all treated crops contain residues at the average residue levels found in the crop field trials and experimentally-determined processing factors where available. In addition, average-level residues for livestock commodities were also included in these analyses to account for the potential transfer of plant residues to livestock tissues. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 11.95 ppb was used to assess the contribution to drinking water. These assumptions result in conservative, health-protective estimates of exposure which are well below the Agency's LOC (100% of the cPAD). **The maximum exposure estimate is less than 15% of the cPAD the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Aggregate Risk: The aggregate risk assessment considers dietary exposures from food and drinking water to flubendiamide consumed over the acute and chronic durations. **Acute and chronic dietary exposure is well below the Agency's LOC and there are no acute or chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Residue Chemistry: The nature of the residue in plants, rotational crops and ruminants is adequately understood. For the purposes of tolerance establishment and

dietary/drinking water risk assessment, the residue of concern in plants, animals and rotational crops is the parent flubendiamide *per se*.

Tolerances have been established in 40 CFR §180.639 in or on the following food commodities: almond, hulls (9.0 ppm); apple, wet pomace (2.0 ppm); *brassica*, head and stem, subgroup 5A (0.60 ppm); *brassica*, leafy greens, subgroup 5B (5.0 ppm); cattle, fat (0.30 ppm); cattle, kidney (0.30 ppm); cattle, liver (0.30 ppm); cattle, muscle (0.05 ppm); corn, field, forage (8.0 ppm); corn, field, grain (0.02 ppm); corn, field, stover (15 ppm); corn, pop, grain (0.02 ppm); corn, pop, stover (15 ppm); corn, sweet, forage (9.0 ppm); corn, sweet, kernel plus cob with husks removed (0.01 ppm); corn, sweet, stover (25 ppm); cotton gin byproducts (60 ppm); cotton, undelinted seed (0.90 ppm); egg (0.01 ppm); fruit, pome, group 11 (0.70 ppm); fruit, stone, group 12 (1.6 ppm); goat, fat (0.30 ppm); goat, kidney (0.30 ppm); goat, liver (0.30 ppm); goat, muscle (0.05 ppm); grain, aspirated fractions (5.0 ppm); grape (1.4 ppm); horse, fat (0.30 ppm); horse, kidney (0.30 ppm); horse, liver (0.30 ppm); horse, muscle (0.05 ppm); milk (0.04 ppm); milk, fat (0.30 ppm); nut, tree, group 14 (0.06 ppm); okra (0.30 ppm); poultry, fat (0.02 ppm); poultry, liver (0.01 ppm); poultry, muscle (0.01 ppm); sheep, fat (0.30 ppm); sheep, kidney (0.30 ppm); sheep, liver (0.30 ppm); sheep, muscle (0.05 ppm); vegetable, cucurbit, group 9 (0.20 ppm); vegetable, fruiting, group 8 (0.60 ppm) and vegetable, leafy, except *brassica,* group 4 (11 ppm); and in or on the following raw agricultural commodities: alfalfa, forage (0.15 ppm); alfalfa, hay (0.04 ppm); barley, hay (0.04 ppm); barley, straw (0.07 ppm); buckwheat (0.07 ppm); clover, forage (0.15 ppm); clover, hay (0.04 ppm); grass, forage (0.15 ppm); grass, hay (0.04 ppm); millet, pearl, forage (0.15 ppm); millet, pearl, hay (0.04 ppm); millet, proso, forage (0.15 ppm); millet, proso, hay (0.04 ppm); millet, proso, straw (0.07 ppm); oats, forage (0.15 ppm); oats, hay (0.04 ppm); oats, straw (0.07 ppm); rye, forage (0.15 ppm); rye, straw (0.07 ppm); sorghum, grain, forage (0.03 ppm); sorghum, grain, stover (0.06 ppm); soybean, forage (0.02 ppm); soybean, hay (0.04 ppm); teosinte, forage (0.15 ppm); teosinte, hay (0.04 ppm); teosinte, straw (0.07 ppm); triticale, forage (0.15 ppm); triticale, hay (0.04 ppm); triticale, straw (0.07 ppm); wheat, forage (0.15 ppm); wheat, hay (0.03 ppm) and wheat, straw (0.03 ppm).

At this time, there are currently no established CODEX, Canadian or Mexican MRLs established for residues of flubendiamide *per se* in crop or livestock commodities.

Occupational: No chemical-specific data for assessing human exposures during pesticide handling activities were submitted in support of the registration of flubendiamide. EPA used surrogate data from the PHED Version 1.1 (PHED Surrogate Exposure Guide, August 1998) to assess exposures. The level of concern is a Margin of Exposure (MOE) of less than 100. **All occupational handler MOEs for flubendiamide are estimated to be greater than 100 at some level of risk mitigation for the proposed uses.** Combined dermal plus inhalation risks are not a concern, provided that: (1) Baseline attire (long-sleeved shirt and long pants and shoes plus socks) is worn by all occupational handlers; (2) Handlers mixing and loading liquid concentrates to support aerial and chemigation applications wear

chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber or viton; and (3) Pilots use enclosed cockpits.

There is the possibility for agricultural workers to have post-application exposure to flubendiamide following its proposed agricultural crop uses. Therefore, occupational post-application exposures and risks were assessed using data from flubendiamide-specific DFR studies and using EPA's default assumptions that 20% of the initial application is available for transfer on day 0 (*i.e.*, 12 hours after application) and that the residue dissipates at a rate of 10% per day following treatment.

For flubendiamide, the exposure durations for non-cancer post-application risk assessment were short- (1 to 30 days) and intermediate-term (>30 days and up to several months). However, since the dermal toxicological endpoint of concern is the same for short- and intermediate-term exposures, the short- and intermediate-term post-application risks are numerically identical. **Inhalation exposures are thought to be negligible in outdoor post-application scenarios, since flubendiamide has a relatively low vapor pressure (7.5×10^{-7} mm Hg).**

It should be noted that the grape and corn flubendiamide-specific DFR data indicate that flubendiamide does not dissipate characteristically in a steady state. Rather, there is evident fluctuation up and then down, though the ultimate trend is downwards. In fact, the highest residue value detected in the entire study was detected on corn on the 2nd day after the last treatment. That observation (0.390 $\mu g/cm^2$) is higher than the residue value calculated for corn using EPA default assumptions (0.21 $\mu g/cm^2$) by a factor of 1.86 (0.390/0.21 = 1.86). To ensure that the post-application assessments, using default DFRs are protective, EPA conducted a highly conservative assessment assuming that all the default DFRs would be 1.86x higher if flubendiamide-specific data were generated on each of those crops (an assumption that is not likely, since in the case of grapes, the DFR residues were less than the default assumptions). **Therefore, even when assuming an extraordinarily worse-case scenario, post-application exposure to flubendiamide does not pose a risk to occupational workers.**

Flubendiamide is classified in acute toxicity category III for acute dermal toxicity and category IV for primary eye irritation and primary skin irritation. It is not a dermal sensitizer. **A restricted entry interval (REI) of 12 hours is appropriate and meets the requirements of the Worker Protection Standard for Agricultural Pesticides (WPS).**

ENVIRONMENTAL RISK ASSESSMENT

Ecological Effects

The Agency has determined, based on the proposed uses, that there is no potential risk to freshwater and marine fish, marine crustaceans, marine mollusks and aquatic plants at the limit of solubility for parent flubendiamide. In addition, there is no

potential acute risk or reproductive effects to birds and mammals, earthworms, beneficial insects including honey bees and natural Lepidoptera predators, and terrestrial plants for all of the proposed uses.

There is a potential risk to freshwater benthic invertebrates exposed to flubendiamide and its degradate des-iodo. EPA has compared the body of toxicological data for the parent compound and des-iodo. With the possible exception of chronic testing with chironomid midges, there is no apparent difference in toxicity evident from the available data. In the case of the chironomid data, conversion of effect endpoints to pore water units results in an estimated NOAEC for the parent compound of approximately 1 µg/L. The corresponding NOAEC for des-iodo is 0.28 µg/L. Because of the estimated nature of the parent compound NOAEC (the value is estimated from the relationship between nominal and pore water measurements at other dose levels because actual measurements of pore water concentrations were not made at the NOAEC level) and because NOAEC comparisons are usually confounded by the dose selections at study design onset, EPA concluded that there was insufficient data to demonstrate a significant difference in toxicity between the parent and degradate. However, for the purposes of risk assessment and in consideration of the use of data as prescribed in the Agency's Risk Assessment Overview Document, risk calculations are based on the chronic endpoints established for each chemical, specifically.

Using these NOAEC values, RQs for parent flubendiamide would range from 0.94 to 21.3. Considering only the accumulation within the first 30 years of use for all of the crop scenarios, RQs for the des-iodo degradate would range from 0.03 to 6.9 in the 1st year, 2.9 to 64 in the 10th year, 4.9 to 127 in the 20th year and 12 to 190 in the 30th year. Uncertainties in the model results make longer term estimates of accumulation and risk unreliable. However, due to the persistence of both the parent and degradate, there is a concern for potential accumulation in aquatic sediments over time.

Testing of the formulated products 480 SC and 24 WG resulted in RQs ranging up to 0.1 for freshwater invertebrates. Results of a mesocosm study conducted with the formulated products also did not identify any serious risk concerns for water column invertebrates.

Adult ladybird beetles are potentially at risk due to ingestion of food items (aphids and pollen) containing flubendiamide residues. In addition, there is a potential direct risk to non-target lepidopterous species, including endangered species. Lepidoptera may occur in areas adjacent to treated fields, where they may be exposed to spray drift, and will likely move through treated fields. Further, the larvae of some lepidopterous species are aquatic and; therefore, may be exposed to both the parent formulation and the des-iodo degradate.

The Agency is concerned about the possible accumulation of flubendiamide and des-iodo in aquatic sediments and the effects that this would have on freshwater benthic organisms. However, given the benefits described below, the Agency is granting

registration for this chemical at this time. The risk mitigation required and conditions of registration for this chemical, as described below, are designed to address these concerns and to provide adequate information that will allow the Agency to determine: (1) if the required risk mitigation is adequate or, if this is still uncertain; and (2) through a monitoring program, determine the rate and extent of accumulation of the parent and degradate in the most vulnerable areas of use during the time period of the 5-year conditional registration.

Environmental Fate and Transport

Hydrolysis/Photolysis: Flubendiamide is stable to hydrolysis under laboratory conditions, but direct aqueous photolysis appears to be a main route of degradation. Flubendiamide degrades to NNI-0001-des-iodo (des-iodo), with a half-life estimated as 11.56 days. Flubendiamide degrades to des-iodo under laboratory soil photolysis with a half-life estimated as 35.3 days. Volatilization from soil and water surfaces is not expected to be an important dissipation route since flubendiamide has a relatively low vapor pressure (7.5×10^{-7} mm Hg) and Henry's Law constant (8.9×10^{-11} atm·m^3/mol).

Mobility/Transport: Flubendiamide is expected to be slightly to hardly mobile (K_{FOC} = 1,076 to 3,318 L/Kg). Des-iodo is expected to be moderately mobile (K_{FOC} = 234 to 581 L/kg). The main transformation product, des-iodo, is more mobile than the parent; however, des-iodo was only detected in a small quantity (<3.4% of the applied) at the 0 to 15 cm soil depth at 3 sites in the terrestrial field studies. Flubendiamide and des-iodo have the potential to contaminate surface water through run-off due to their persistence in soil and also have the potential for groundwater contamination in vulnerable soils with low organic carbon content, after heavy rainfall and/or in areas with high water tables (because there is less depth to travel before reaching groundwater).

Soil/Water Degradation: Flubendiamide is stable under aerobic and anaerobic soil metabolism and aerobic aquatic metabolism laboratory conditions. In aerobic and anaerobic aqueous environments, flubendiamide is expected to dissipate somewhat faster than in aerobic soil, likely as a result of metabolism. Laboratory experiments using anaerobic and aerobic aquatic systems resulted in flubendiamide half-lives (water plus soil/sediment) of 127 to 364 days and 32.8 to 533.2 days, respectively. Anaerobic aquatic metabolism is another main route of degradation for flubendiamide. Flubendiamide degrades to des-iodo under anaerobic aquatic conditions with a half-life estimated as 365 days. Flubendiamide and des-iodo's overall stability/persistence suggests that they will accumulate in soils, water column and sediments with each successive application.

Terrestrial Field Dissipation: Flubendiamide also degrades in the field condition very slowly. In terrestrial field experiments, flubendiamide half-lives in 3 soils ranging from loamy sand to silt loam were 210 to 770.2 days (leaching to a depth of 30 to 60 cm) and in a sandy loam soil under outdoor conditions, the half-life was 322 days. In an aerobic soil environment, flubendiamide is expected to dissipate slowly. In the

laboratory using 4 soils ranging from loamy sand to silt, flubendiamide was stable with <5% of the applied chemical dissipating at 371 days post-treatment.

REGULATORY DECISION

Conditional Registration: A 5-year conditional registration has been granted for flubendiamide use as an insecticidal control of various lepidopterous insect pests on corn, cotton, tobacco, tree fruit, tree nuts, vine crops and vegetable crops.

Flubendiamide may be a viable alternative to comparably registered and existing pesticides that tend to pose greater risk concerns and may also be an important tool as a rotational insecticide to limit or prevent the development of resistance to other insecticide chemistries. Flubendiamide has also been identified as an OP alternative for the control for the control of leafroller and fruitworm pests in tree fruit production, where the dominant pesticides used have been azinphos-methyl, chlorpyrifos and phosmet.

The EFED risk assessment; however, suggests that both flubendiamide and des-iodo will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates. As a result, EPA is requiring certain measures which the Agency believes may be effective in mitigating the apparent risk, including the requirement 15-foot vegetative buffer zones which are expected to reduce run-off of both parent and degradate to the aquatic environment, reduced application rates and other labeling statements which reduce the allowable total loading in one year and environmental hazards, ground water and surface water advisories.

To confirm the utility of the 15-foot vegetative buffers, the Agency is requiring a small-scale run-off/vegetative buffer strip study. If the utility of the 15-foot buffers cannot be demonstrated to achieve reductions in off-site transport and aquatic organism risk that would alleviate the risk concern, the Agency is requiring a monitoring program, the results of which allow the Agency to determine, at the end of the 5-year conditional registration, the rate and extent of accumulation in the most vulnerable use areas. If there are risk concerns at that time that result in the Agency being unable to determine that there are no reasonable adverse effects to the environment, the registrants have agreed that the pesticide will be voluntarily cancelled.

Conditional Data: The registrant has committed to submit the following data:

1. Flubendiamide
   - (Non-guideline) **Small-Scale Runoff/Vegetative Buffer Strip Study** – The quantitative efficacy of vegetative buffers for flubendiamide use is uncertain. To determine the magnitude of the parent, flubendiamide, retained in buffer strips, the small-scale run-off/vegetative buffer strip study and monitoring program will allow the Agency to quantitatively consider the impact of such buffers on the risk picture. The protocols for the studies will be mindful of the

need to both consider the variety of proposed use sites as well as a variety of buffer conditions.

If the employment of label enforceable buffers is empirically demonstrated to alleviate the risk concern, then no further work need be conducted. However, if buffers cannot be demonstrated to achieve these meaningful risk reductions, the other areas of critical uncertainty in the modeling assumptions must be considered. In this case, there is considerable uncertainty in the application of the EXAMS pond scenario for chemicals with suspected aquatic system accumulation. Additional information on the actual potential for the pesticide to build up in receiving waters would address the uncertainty associated with current model limitations. Therefore, a monitoring study of receiving waters within watersheds where flubendiamide will be used will be required.

2. Des-iodo Degradate
   - (161-1) **Hydrolysis** – A hydrolysis study to establish the significance of chemical hydrolysis as a route of degradation for des-iodo and to identify, if possible, the hydrolytic products formed to provide initial information on whether they may exhibit structures that may potentially adversely affect non-target organisms.

   - (162-4) **Aerobic Aquatic Metabolism** – An aerobic aquatic metabolism study to determine the effects of des-iodo on aerobic conditions in water and sediments during the period of dispersal of des-iodo throughout the aquatic environment and to compare rates and formation of metabolites. The data from this study would provide the aerobic aquatic input parameter for PRZM/EXAMS; therefore, potentially reducing modeling uncertainty.

3. For the submitted GLN 860.1850 Confined Rotational Crop studies (MRIDs 46817133 and 46817134), the registrant will submit extraction and analysis dates of samples in order to confirm that samples were extracted and analyzed within the stated intervals (or within 6 months of harvest). Otherwise, additional storage stability data may be required by EPA.

BENEFIT DETERMINATIONS: Since flubendiamide is a novel chemistry, the Agency believes that it may be a viable alternative to comparably registered and existing pesticides that tend to pose greater risk concerns. Also, it may be an important tool as a rotational insecticide to limit or prevent the development of resistance to other insecticide chemistries. BEAD's preliminary analysis of the material submitted by the registrant concludes that flubendiamide provides Lepidoptera control equivalent or superior to the insecticides currently being used for pest control in the evaluated crops. Materials submitted also suggest low toxicity to terrestrial insect predators and honey bees which should make flubendiamide an important component in IPM programs.

When assessing recent pesticide usage data for currently registered insecticide products aimed at controlling lepidopterous pests in corn, several market leaders are of concern to

the Agency. Flubendiamide's toxicity to terrestrial organisms is low, especially in comparison to the current active ingredients most commonly used against the labeled target pests.

For pesticides used to control cotton pests such as the beet armyworm and bollworm, the usage information for products used in 2007 was more broadly distributed among chemical pesticides than that indicated for corn usage, with a number of synthetic pyrethroids, namely lambda cyhalothrin, and other chemistries such as acephate and chlorpyrifos leading the usage profile.

In addition, flubendiamide has been identified as an organophosphorus pesticide alternative for the control of leafroller and fruitworm pests in tree fruit production, where the dominant pesticides used have been azinphos-methyl, chlorpyrifos and phosmet. Therefore, flubendiamide is a chemical that broadens the diversity of pest control measures available to growers for the reasons stated above.

REQUIRED LABEL STATEMENTS

The end-use product labels containing flubendiamide as an active ingredient will be amended as follows:

1. Requirement of 15-foot vegetative buffer zones and the addition updated spray drift language for aerial/ground applications for similar products with similar use patterns on both end-use labels.

2. On the proposed label for 24 WG, the registrant will reduce application rates, revise the maximum amount of product applied per acre "per year" to a "per crop season" basis and remove the number of applications per crop season for the *Brassica*, Cucurbits, Leafy Vegetables and Fruiting Vegetables crop groupings in order to reduce the per year loading allowed.

3. Addition of revised environmental hazards, ground water and surface water advisories to both end-use labels.

4. On the proposed label for 480 SC, the registrant will be required to clearly articulate what application method(s) are proposed for each listed crop.

5. The proposed rotational crop restriction for root crops (root, tuber and bulb vegetables), which specifies that "*treated areas may be replanted immediately following harvest, or as soon as practical following the last application*" will be revised to a 30-day plant-back interval on both end-use labels.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Registering flubendiamide will meet the objectives of GPRA title 3.1.1 by assuring new pesticides that enter the market are safe for humans and the environment.

CONTACT PERSON AT EPA

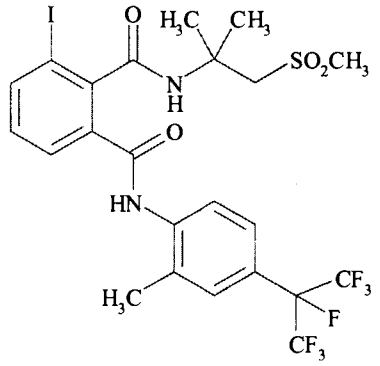
Mailing Address:

Mr. Richard J. Gebken,
Product Manager (10)
Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Insecticide Branch
1200 Pennsylvania Avenue, NW.
Washington, D.C. 20460-0001

Office Location and Telephone Number:

Room S-7319, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501
703-308-9354

Appendix 1 -- Structure and Nomenclature

Flubendiamide Nomenclature.	
Chemical structure	
Empirical Formula	$C_{23}H_{22}F_7IN_2O_4S$
Common name	Flubendiamide (proposed ISO name)
Company experimental name	NNI-0001
IUPAC name	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-{2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl}phthalamide
CAS name	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
CAS registry number	272451-65-7
End-use products (EPs)	NNI-0001 480 SC (EPA File Symbol 264-XXX) NNI-0001 24 WG (EPA File Symbol 264-XXX)
Chemical Class	Phthalic acid diamide insecticide
Known Impurities of Concern	None

Appendix 2 -- Physical and Chemical Properties

Physicochemical Properties of Flubendiamide.			
Parameter	Value		Reference
Molecular weight	682.39 g/mol		Product Chemistry Review of Flubendiamide Technical.
Melting point/range	217.5-220.7 °C		
pH	6.05 (20 °C)		
Density	1.659 g/mL (20 °C)		
Water solubility	29.90 µg/mL (20 °C)		
Solvent solubility	Solvent	Solubility (g/L)	
	p-xylene	0.488	
	n-heptane	0.000835	
	methanol	26.0	
	1,2-dichloroethane	8.12	
	acetone	102	
	ethyl acetate	29.4	
Vapor pressure	10^{-4} Pa (25°C)		
Dissociation constant, pK_a	Does not dissociate		
Octanol/water partition coefficient, $Log(K_{OW})$	4.2 (pH 5.9, 25°C)		
UV/visible absorption spectrum	204.4 nm (neutral methanol)		

Appendix 3 – Toxicity Profiles

Acute Toxicity Profile – Flubendiamide				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral – rat	46817144	LD50 = >2000 mg/kg	III
870.1200	Acute dermal- rat	46817147	LD50 = >2000 mg/kg	III
870.1300	Acute inhalation – rat	46817150	LC50 = >0.0685 mg/L	III
870.2400	Acute eye irritation –rabbit	46817203	Irritating (slight)	IV
870.2500	Acute dermal irritation – rabbit	46817206	Non-irritating	IV
870.2600	Skin sensitization – guinea pig	46817209	Negative	N/A

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3050	28-Day Oral (rat) **Not Submitted***	ppm: 0 – 20 – 50 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 1.53 – 3.88 – 15.1 – 52 – 1575 F: 0 – 1.63 – 4.17 – 16.1 – 156 – 1605	NOAEL (M/F) = 15.1 / 4.17 mg/kg/day LOAEL (M/F) = 152 / 16.1 mg/kg/day based on: liver: ↑(m/f)– periportal fatty change, ↑wt [abs/rel (m/f)] ↓(f)– ALP ↑(f)– GPT
870.3050	28-Day Oral (mice) **Not Submitted***	ppm: 0 – 20 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 2.73 – 26.9 – 265 – 2678 F: 0 – 2.88 – 30.0 – 299 – 3024	NOAEL (M/F) = 26.9 / 30.0 mg/kg/day LOAEL (M/F) = 265 / 299 mg/kg/day based on: liver: ↑(m/f)– hypertrophy (centrilobular hepatocytes);↑(m)–[dark-colored + fatty change (centrilobular hepatocytes)]
870.3050	28-Day oral toxicity (dog) **Not Submitted***	ppm: 0 – 40 – 400 – 4,000 – 40,000 mg/kg/day: M: 0 – 1.12 – 10.7 – 101 – 1111 F: 0 – 1.10 – 12.0 – 120 – 1180	NOAEL (M/F) = 10.7 / 1.10 mg/kg/day LOAEL (M/F) = 101 / 12.0 mg/kg/day based on: ↑(m/f)– ALP
870.3100	90-Day oral toxicity (rat)	46817210 (2003)/ Acceptable/guideline ppm: 0 – 20 – 50 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 1.15 – 2.85 – 11.4 – 116 – 1192 F: 0 – 1.30 – 3.29 – 13.1 – 128 – 1320	NOAEL (F) = 13.1 mg/kg/day LOAEL (F) = 128 mg/kg/day based on: slight hepatotoxicity (↑(f) – periportal fatty change, hepatocellular hypertrophy, ↑wt [abs/rel(f)], ↑GGT

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3150	90-Day oral toxicity (mouse)	46817211 (2002)/ Acceptable/guideline ppm: 0 – 50 – 100 – 1000 – 10000 mg/kg/day: M: 0 – 6.01 – 11.9 – 123 – 1214 F: 0 – 7.13 – 14.7 – 145 – 1424	NOAEL (M/F) = 11.9 / 14.7 mg/kg/day LOAEL (M/F) = 123 / 145 mg/kg/day based on slight hepatotoxicity: (↑fatty change, hepatocellular hypertrophy, ↑ abs/rel wt [f])
870.3150	90-Day oral toxicity (dog)	46817212 and 46817242 (2003)/ Acceptable/guideline ppm: 0 – 100 – 2000 – 40000 mg/kg/day: M: 0 – 2.58 – 52.7 – 1076 F: 0 – 2.82 – 59.7 – 1135	NOAEL (M/F) = 2.58 / 2.82 mg/kg/day LOAEL (M/F) = 52.7 / 59.7 mg/kg/day based on clinical signs of toxicity (loose stool), shortened APTT, increased ALP and triglycerides, increased adrenal weights, and microscopic effects on the adrenal glands in females: adrenal: ↑(f) – cortical hypertrophy; ↑(f) – wt ↓(m/f) – APTT ↑ – [ALP(m/f), Triglycerides(f)]
870.3200	28/29-Day dermal toxicity (rat)	46817213 (2004)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	NOAEL = 100 mg/kg/day (systemic); 1000 mg/kg/day (local skin) LOAEL = 1000 mg/kg/day based on: liver: ↑(m/f)–periportal fatty change + ↑wt [abs/rel]; thyroid: ↑(f)–follicular cell hypertrophy ↓(f) –[Hct + MCV + MCH] ↓(f) – AST
870.3700a	Prenatal developmental in (rat)	46817215 and 46817241 (2003)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	**Maternal:** NOAEL = 10 mg/kg/day; LOAEL = 100mg/kg/day based on: liver: ↑wt[abs/rel]. **Developmental:** NOAEL >1000 mg/kg/day; LOAEL was not observed (>1000 mg/kg/day).
870.3700b	Prenatal developmental in (rabbit)	46817214 and 46817240 (2002)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	**Maternal:** NOAEL = 100 mg/kg/day; LOAEL = 1000 mg/kg/day based on: food consumption decreaseon last day of treatment (GD27-28) and loose stool **Developmental:** NOAEL >1000 mg/kg/day; LOAEL not observed (>1000 mg/kg/day)

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3800	Two-generation Reproduction and fertility effects (rat)	46817216 (2004)/ Acceptable/guideline ppm: 0 – 20 – 50 – 2000 – 20000 mg/kg/day (premating doses): Pm: 0 – 1.30 – 3.30 – 131 – 1307 Pf: 0 – 1.59 – 3.95 – 159 – 1577 F1m: 0 – 1.64 – 4.05 – 162 – 1636 F1f: 0 – 1.84 – 4.59 – 176 – 1808	**Parental/Systemic**: NOAEL (M/F) = 3.30 / 3.95 mg/kg/day; LOAEL (M/F) = 131/159 mg/kg bw/day based on: liver: ↑P/F1m–[brown pigment deposition + wt (rel)]; ↑Pf /F1f –[enlarged/dark-colored livers + hepatocyte hypertrophy + periportal fatty change + brown pigment deposition + wt]; thyroid: ↑P/F1 –[follicular cell hypertrophy]; ↑wt (abs Pm); kidney: ↑Pf –[tubular basophilic change + urinary casts]; ↑Pf /F1f – wt; ovary: ↑Pf –interstitial cell vacuolation; uterus: ↑wt (Pf); pituitary: ↓wt (F1); spleen: ↓wt (Pf /F1f) **Reproductive**: No effect of treatment on: precoital interval; mating, fertility, or gestation indices; or gestation duration in either generation. Furthermore, the numbers of primordial ovarian follicles in the 20,000 ppm F1 dams were comparable to controls. No effects were noted on estrous cycle duration or sperm parameters. The NOAEL is 20,000 ppm (1307/1577 mg/kg/day males/females, respectively). The LOAEL for reproductive toxicity was not observed. **Offspring:** NOAEL = 3.30 mg/kg/day; LOAEL = 131 mg/kg/day based on: liver: ↑–[hepatocyte hypertrophy, diffuse fatty change, brown pigment deposition, proliferation bile ducts; wt]; thyroid: ↑follicular cell hypertrophy; spleen + thymus: ↓wt; ↑eyeball enlargement
	One-generation reproduction study in rat	46817239 (2004)/Acceptable/nonguideline ppm: 0-50-200-2000-20,000 mg/kg/day: Pm: 0-3.25-12.91-127.2-1287 Pf: 0-3.84-14.97-148.9-1490	**Parental:** LOAEL is 2000 ppm (127.2/148.9 mg/kg/day in amles/females, respectively) bsed on effects on the liver, thyroid, and kidneys. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively). **Reproductive:** The LOAEL was not observed and the NOAEL is 20,000 ppm (1287/1490 mg/kg/day in males/females, respectively). **Offspring:** The LOAEL is 2000 ppm (127.2/148.9 mg/kg/day in males/females, respectively) based on effects on the eyes and liver; and on increased anogenital distance and delayed sexual maturation in the males. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively).

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
	Histopathology of the Eyes of Weanlings in a One-generation Reproduction Study in Rats	46817238/Acceptable/non-guideline ppm: 0-50-200-2000-20,000 mg/kg/day: Pm: 0-3.25-12.91-127.2-1287 Pf: 0-3.84-14.97-148.9-1490	**Offspring:** The LOAEL for offspring toxicity is 2000 ppm (127.2/148.9 mg/kg/day in males/females, respectively) bsed on confirmed microscopic effects on the eyes in both sexes. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively).
	Perinatal Ocular Toxicity Study in CD-1 Mice following exposure via diet	46817236/ non-guideline approx. 1000 mg/kg/day from day 6 post conception until lactation day 21	Eye lesions of viable pups were noted neither during the lactation period nor during the follow-up period lasting from PND 22-42. **Offspring:** The LOAEL for offspring toxicity is 4500/2000 ppm (equivalent to 1052.3 mg/kg/day) based on decreased pup body weights and body weight gains. The NOAEL was not established.
870.4100a	Chronic toxicity (rat)	46817217 (2004)/ Acceptable/guideline ppm: 0 – 20 – 50 – 2000 – 20000 mg/kg/day: M: 0 – 0.8 – 2.0 – 79.3 – 822 F: 0 – 1.0 – 2.4 – 97.5 – 998	NOAEL (F) = 2.4 mg/kg/day. LOAEL (F) = 97.5 mg/kg/day based on: hepatotoxicity (periportal fatty change, hepatocyte hypertrophy, ↑wt [abs/rel] and ↑GGT
870.4100b	Chronic toxicity (dog)	46817218 Acceptable/guideline ppm: 0 – 100 – 1500 – 20000 mg/kg/day: M: 0 – 2.21 – 35.2 – 484 F: 0 – 2.51 – 37.9 – 533	NOAEL (M/F) = 2.21 / 2.51 mg/kg/day. LOAEL (M/F) = 35.2 / 37.9 mg/kg/day based on: liver: ↑wt [abs m+f, rel(m)] ↓(m) – BWG and BW ↓ –[APTT(m/f), ↑(m/f) – ALP
870.4200a	Carcinogenicity (rat)	46817219 (2004)/ Acceptable/guideline ppm: 0 – 50 – 1000 – 20000 mg/kg/day: M: 0 – 1.70 – 33.9 – 705 F: 0 – 2.15 – 43.7 – 912	NOAEL (M/F) = 1.70 / 2.15 mg/kg/day. LOAEL (M/F) = 33.9 / 43.7 mg/kg/day based on: liver: ↑(m/f)– [periportal fatty change, hypertophy] ;↑wt [abs/rel(m/f)]; kidney: ↑(m/f)– chronic nephropathy; ↑wt [rel(f)] **No evidence of carcinogenicity**
870.4200b	Carcinogenicity (mouse)	46817220 (2004)/ Acceptable/guideline ppm: 0 – 50 – 1000 – 10000 mg/kg/day: M: 0 – 4.85 – 94 – 988 F: 0 – 4.44 – 93 – 937	NOAEL (M/F) = 4.85 / 4.44 mg/kg/day. LOAEL (M/F) = 94 / 93 mg/kg/day based on: hepatotoxicity (periportal fatty changes, hypertophy); thyroid changes (↑follicular cell hypertrophy with hydropic change, ↑large sized follicles) **No evidence of carcinogenicity**

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.5100	Gene mutation (in vitro bacteria)	46817221 Acceptable/guideline 0 – 3.86 – 11.6 – 34.7 – 104 – 313 µg/plate (w/o activation) 0 – 61.7 – 185 – 556 – 1,670 – 5,000 µg/plate (+ activation)	Negative
870.5100	Gene mutation (in vitro bacteria)	46817222 Unacceptable/guideline 0 – 16 – 50 – 158 – 500 – 1581 – 5000 µg /plate (+/- S9 activation) (conducted w/ NNI-0001 SC)	Negative
870.5300	Gene Mutation (*in vitro* mammalian V79)	46817224 Acceptable/guideline 0 – 7.5 – 15 – 30 – 60 - 120 – 240 µg/ml (+/ – activation)	Negative
870.5375	Mammalian Cytogenetics (*in vitro* CHL)	Acceptable/guideline 0 – 550 – 1100 – 2200 µg/ml (+ activation) 0 – (125-550) – (250-1100) – (500-2200) µg/ml; 6, 20, or 40 hrs exp. (w/o activation)	Negative
870.5395	Mammalian Cytogenetics (micronucleus mouse)	46817226 Acceptable/guideline 0 – 1000 – 2000 – 4000 mg/kg	Negative
870.5395	Mammalian Cytogenetics (micronucleus mouse)	46817225 Acceptable/guideline 0 – 500 – 1000 – 2000 mg/kg	Negative
870.6200a	Acute neurotoxicity screening battery	46817227 Acceptable/guideline mg/kg/day: 0 – 209 – 731 – 2213 (analytically determined)	NOAEL = 2213 mg/kg/day LOAEL = Not observed (>2213 mg/kg/day)
870.6300	Developmental neurotoxicity	46817228 Acceptable/non-guideline ppm: 0 – 120 – 1200 – 12000 ppm mg/kg/day (based on last 2 wks of gestation and 3 wks of lactation): 0 – 9.9 – 99.5 – 979.6	**Maternal:** NOAEL = 9.9 mg/kg/day LOAEL = 99.5 mg/kg/day based on: liver: ↑wt[abs/rel]. **Offspring:** NOAEL = 9.9 mg/kg/day LOAEL = 99.5 mg/kg/day based on ↑balanopreputial separation time: this LOAEL is also protective of adverse eye effects reported at 979.6 mg/kg/day (eye – [enlarged eyeball + exophthalamus + general ocular opacity(m)])

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.7485	Metabolism and pharmacokinetics - rat	46817229, 46817230 and 46817231 Acceptable/guideline	Oral absorption = 23.5/34.1% in m/f, respectively (average = 29%); see Section 3.2 Appendix A.3 for more information
870.7600	Dermal penetration (monkey)	46817234 Acceptable/non-guideline	Intravenous injection of [14C]NNI-0001resulted in excretion of a large fraction of the dosed radioactivity in feces. Total recoveries through 360 hours post-dose were 80.91% in feces, 7.78% in urine, and 4.11% in cage debris/rinse samples. Dermal application of [14C]NNI-0001 resulted in a negligible absorption of 0.02% at 8 hrs post-dose. The overall mean total recovery of radioactivity from excreta and from the application site was 105.15%, the majority of which was associated with the radioactivity recovered from the application site.
870.7800	4-week Immunotoxicity (plaque-forming assay in rat)	46817243 Acceptable/guideline ppm: 0 – 40 – 400 – 4000 mg/kg/day: M: 0 – 3.34 – 33.6 – 336.3 F: 0 – 4.0 – 38.4 – 358.8	NOAEL (M/F) = 336/358.8 mg/kg/day. No evidence of primary immunotoxicity
	Effects on Thyroid Hormones and Liver Enzymes in Female Rats	46817235 Acceptable/non-guideline ppm: 0-1000-10,000 mg/kg/day: 0-83-812	Study generally support this indirect effect on the thyroid via induction of enzymes in the liver. Direct effects on the liver included increases in organ weights, cytochrome P450, UDP-GT and EROD activities, and incidences of hepatocyte hypertrophy and vacuolation.
	In vitro Metabolism in rat, mouse, dog and human microsomes	46817232 Acceptable/Non-guideline	see Appendix A.3 for more information
	Toxicokinetic study in rats and mouse	46817233 Acceptable/Non-guideline	see Appendix A.3 for more information

*The studies designated as "Not Submitted" were included in the registrant's toxicity profile table, which in turn was in the registrant's human health risk assessment (MRID 46817252, p. 42); there are reported here in order to be as thorough, complete and inclusive as possible.

Appendix 4 – Ecological Effects Data

Ecological Effects Data Requirements for Flubendiamide					
Guideline #		Data Requirement	Formulation	MRID (Accession #)	Study Classification
71-1	850.2100	Avian Oral LD_{50}	Technical 480 SC	46817003 46817004	Acceptable Acceptable
71-2	850.2200	Avian Dietary LC_{50}	Technical Technical	46817005 46817006	Acceptable Acceptable
71-4	850.2300	Avian Reproduction	Technical Technical	46817007 46817008	Supplemental Acceptable
72-1	850.1075	Freshwater Fish LC_{50}	Technical Technical Technical Technical 480 SC 480 SC	46816937 46816939 46816940 46816941 46816942 46816943	Acceptable Acceptable Acceptable Acceptable Acceptable Acceptable
72-2	850.1010	Freshwater Invertebrate LC_{50}	Technical 24 WG 480 SC 480 SC Des-iodo	46816930 46816932 46816931 46816934 46816933	Acceptable Acceptable Acceptable Supplemental Acceptable
72-3(a)	850.1075	Estuarine/Marine Fish LC_{50}	Technical	46816938	Acceptable
72-3(b)	850.1025	Estuarine/Marine Mollusk EC_{50}	Technical	46816935	Acceptable
72-3(c)	850.1035 850.1045	Estuarine/Marine Shrimp LC_{50}	Technical	46816936	Acceptable
72-4(a)	850.1400	Freshwater Fish Early Life Stage	Technical	46816947	Acceptable
72-4(b)	850.1300 850.1350 850.1300	Aquatic Invertebrate Life-cycle	Technical Technical 480 SC	46816944 46816946 46816945	Supplemental Acceptable Acceptable
	850.1790	Benthic Organisms	Technical 24 WG 480 SC Des-iodo	46817022 46817014 46817013 46817023	Supplemental Acceptable Acceptable Supplemental
		Mesocosm Study	480 SC	46817002	Supplemental
72-5	850.1500	Freshwater Fish Life-Cycle	Technical	46816948	Unacceptable
122-1(a)	850.4100	Seed Germination/ Seedling Emergence Tier 1	24 WG 480 SC	46817034 46817036(a)	Acceptable Acceptable
		Herbicidal Toxicity Terrestrial plants Tier 2	480 SC	46817035	Supplemental, Non-guideline
122-1(b)	850.4150	Vegetative Vigor Tier 1	Technical 24 WG	46817036(b) 46817037	Acceptable Supplemental
122-2	850.4400	Aquatic Plant (Non-Vascular) Tier 1&II	Technical 480 SC	46817041 46817040	Acceptable Acceptable
122-2	850.4400	Aquatic Plant (Vascular) Tier 2	Technical	46817039	Acceptable

Ecological Effects Data Requirements for Flubendiamide					
Guideline #		Data Requirement	Formulation	MRID (Accession #)	Study Classification
123-1(a)	850.4225	Seed Germination/ Seedling Emergence Tier 2	24 WG	46817038	Acceptable
141-1	850.3020	Honey Bee Acute Contact LD_{50}	Technical 480 SC 480 SC WG 40	46817009 46817010 46817011 46817012	Acceptable Acceptable Acceptable Supplemental, Non-guideline
	850.6200	Acute Toxicity to Earthworms	Technical 480 SC Des-iodo	46817028 46817029 46817030	Supplemental Supplemental Supplemental
	850.6200	Chronic Toxicity to Earthworms	480 SC 24 WG	46817031 46817032	Supplemental Supplemental
141-2	850.3030	Honey Bee Residue on Foliage	NA	NA	NA
		Parasitoid Wasp	WG 40	46817020	Supplemental, Non-guideline
		Predatory Mite	WG 40	46817019	Supplemental, Non-guideline
		Ladybird Beetle (45 day study)	480 SC	46817015	Supplemental, Non-guideline
		Ladybird Beetle (Extended Study)	480 SC	46817016	Supplemental, Non-guideline
		Ladybird Beetle (Life Cycle Test)	480 SC	46817017	Supplemental, Non-guideline
		Parasitic Wasp (Side Effects Tests)	480 SC	46817021	Supplemental, Non-guideline
		White springtail (Reproduction Test)	480 SC	46817027	Supplemental
		Green lacewing (Extended Study)	480 SC	46817018	Supplemental

Appendix 5 – Environmental Fate Data

Environmental Fate Data Requirements for Flubendiamide				
Guideline #		Data Requirement	MRID #s	Study Classification
161-1	835.212	Hydrolysis	46816907	Acceptable
161-2	835.224	Photodegradation in Water	46816908	Acceptable
161-3	835.241	Photodegradation on Soil	46816909	Acceptable
161-4	835.237	Photodegradation in Air	NA[1]	NA
162-1	835.41	Aerobic Soil Metabolism	Parent: 46816910 Degradate:46816911	Acceptable Acceptable
162-2	835.42	Anaerobic Soil Metabolism	46816912	Supplemental
162-3	835.44	Anaerobic Aquatic Metabolism	46816914	Acceptable
162-4	835.43	Aerobic Aquatic Metabolism	46816913	Acceptable
163-1	835.1240 835.1230	Leaching-Adsorption/Desorption	Parent: 46816905 Degradate: 46816906	Supplemental Supplemental
163-2	835.141	Laboratory Volatility	NA	NA
163-3	835.81	Field Volatility	NA	NA
164-1	835.61	Terrestrial Field Dissipation	46816915 46816916 46816917	Acceptable Acceptable Acceptable
165-4	850.173	Accumulation in Fish	46816949 46817001	Acceptable Acceptable
		Quantum Yield in Water	46816919	Supplemental

[1] Not Available.

Appendix 6 – Bibliography

71-2 Avian Dietary Toxicity

MRID	Citation Reference
46817005	Bowers, L. (2005) Technical NNI 0001: A Subacute Dietary LC50 with Mallards. Project Number: AS720801, 201263. Unpublished study prepared by Bayer Corp. 41 p.

71-4 Avian Reproduction

MRID	Citation Reference
46817007	Sabbert, T. (2004) Effect of Technical NNI 0001 on Mallard Reproduction. Project Number: EBAM0221. Unpublished study prepared by Bayer Corp. 114 p.
46817008	Bowers, L. (2005) Effect of Technical NNI 0001 on Northern Bobwhite Reproduction. Project Number: AS741701, 201138. Unpublished study prepared by Bayer Corp. 143 p.

72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
46816937	Kern, M.; DeHann, R. (2004) Acute Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Static Conditions. Project Number: EBAM0390/AS811201, 200713. Unpublished study prepared by Bayer Corp. 42 p.
46816939	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Lepomis macrochirus). Project Number: E/280/2291/4, DOM/22043. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 49 p.
46816940	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Oncorhynchus mykiss). Project Number: DOM/22044, E/280/2292/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 75 p.
46816942	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Lepomis macrochirus). Project Number: E/280/2352/2, DOM/22081, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 42 p.
46816943	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Oncorhynchus mykiss). Project Number: E/280/2354/4, DOM/22082, 00789. Unpublished study prepared by Bayer Ag, Institute of Product

Info. & Residue Anal. 42 p.

72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
46816930	Dorgerloh, M. (2006) Acute Toxicity of NNI-0001 (tech.) in Water Fleas (Daphnia magna). Project Number: DOM/22041, E/320/2283/0, MR/391/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 39 p.
46816931	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 SC 480 to Water Fleas (Daphnia magna). Project Number: E/320/2284/1, DOM/22042. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.
46816932	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 WG 24 to the Waterflea Daphnia magna in a Static Laboratory Test System. Project Number: P/684/027017, MR/188/02, EBAMX018. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 58 p.
46816933	Dorgerloh, M. (2004) Acute Toxicity of NNI-0001-des-iodo to the Waterflea Daphnia magna. Project Number: DOM/23055, MR/029/04, E/320/2503/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.
46816934	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 SC 480 in the Waterflea Dahnia magna Under Different Feeding Conditions in a Static Laboratory Test System. Project Number: E/320/2849/8, EBAMX028, MR/188/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 59 p.

72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID	Citation Reference
46816935	Dionne, E. (2004) NNI-0001-Acute Toxicity to Eastern Oysters (Crassostrea virginia) Under Flow-Through Conditions. Project Number: AS881501, 13798/613, EBAM0380. Unpublished study prepared by Springborn Smithers Laboratories. 53 p.
46816936	Dionne, E. (2004) NNI-0001 - Acute Toxicity to Mysids (Americamysis bahia) Under Static Conditions. Project Number: 13798/6131, AS883101, EBAMO376. Unpublished study prepared by Springborn Smithers Laboratories. 49 p.
46816938	Banman, C.; Kern, M.; Lam, C. (2004) Acute Toxicity of NNI 0001 Technical to the Sheepshead Minnow (Cyprinodon variegatus) Under Static Conditions. Project Number: 200992, EBAM0370. Unpublished

study prepared by Bayer Corp. 31 p.

72-4 Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study

MRID	Citation Reference
46816944	Dorgerloh, M. (2003) Influence of NNI-0001 (Tech.) on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2267/3, DOM/22035, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 88 p.
46816945	Dorgerloh, M. (2003) Influence of NNI-0001 SC 480 on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2372/0, DOM/23001, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 81 p.
46816946	Putt, A. (2005) NNI-0001 - Life-Cycle Toxicity Test with Mysids (Americamysis bahia). Project Number: 13798/6156, EBAMO377. Unpublished study prepared by Springborn Smithers Laboratories. 89 p.
46816947	Kern, M; Lam, C. (2004) Early Life Stage Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions. Project Number: EBAMX005, 200995, AS841201. Unpublished study prepared by Bayer Corp. 86 p.

72-5 Life cycle fish

MRID	Citation Reference
46816948	Cafarella, M. (2005) NNI-0001 - The Full Life-Cycle Toxicity Test with Fathead Minnow (Pimphales promelas). Project Number: 13798/6155, EBAM0393. Unpublished study prepared by Springborn Smithers Laboratories. 141 p.

72-6 Aquatic org. accumulation

MRID	Citation Reference
46816949	Dorgerloh, M.; Weber, E. (2005) (Carbon 14)-NNI-0001-Bioconcentration and Biotransformation in Fish (Lepomis macrochirus). Project Number: DOM/23026, E/244/2330/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 156 p.

122-1 Seed Germination/Seedline Emergence and Vegetable Vigor

MRID	Citation Reference

46817036 Christ, M.; Lam, C. (2005) Tier I Seedling Emergence and Vegetative Vigor: Nontarget Phytotoxicity Study Using NNI-0001 480SC. Project Number: 201376, EBAMX007, EBAM0367. Unpublished study prepared by Bayer Corp. 62 p.

123-1 Seed germination/seedling emergence and vegitative vigor

MRID **Citation Reference**

46817038 Christ, M.; Lam, C. (2006) Tier II Seedling Emergence: Nontarget Phytotoxicity Study using NNI-0001 WG24. Project Number: EBAMX049. Unpublished study prepared by Bayer Corp. 32 p.

123-2 Aquatic plant growth

MRID **Citation Reference**

46817039 Kern, M.; Banman, C.; Lam, C. (2004) Toxicity of NNI 0001 Techncial to Duckweed (Lemna gibba G3) Under Static-Renewal Conditions. Project Number: EBAMX010, AS883701, 200604. Unpublished study prepared by Bayer Corp. 41 p.

132-1 Dissipation of Dislodgeable Foliar & Soil Residues

MRID **Citation Reference**

46817245 Fischer, D. (2006) NNI-0001 480 SC - Dislodgeable Foliar Residue on Sweet Corn and Grape Plant Foliage: Final Report. Project Number: RAAMY004, AM001/05DA, AM002/05D. Unpublished study prepared by Bayer Corp. 494 p.

161-1 Hydrolysis

MRID **Citation Reference**

46816907 Yamashita, A. (2001) Hydrolysis Study of NNI-0001: Final Report. Project Number: LSRC/A01/078A, GC/03, 01/0034. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 56 p.

161-2 Photodegradation-water

MRID **Citation Reference**

46816908 Motoba, K. (2005) Study on Aqueous Photolysis of NNI-0001: Final Report (Amended II). Project Number: GC/03, LSRC/A01/128A, 01/0036. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 88 p.

161-3 Photodegradation-soil

MRID	Citation Reference
46816909	Shepler, K. (2004) Photodegradation of [(Carbon 14)]NNI-0001 in/on Soil by Artificial Light. Project Number: 1050W/1, 1050W. Unpublished study prepared by PTRL West, Inc. 141 p.

162-1 Aerobic soil metabolism

MRID	Citation Reference
46816910	Babczinski, P.; Eberhardt, R. (2004) NNI-0001: Aerobic Soil Degradation/Metabolism in Four Different Soils. Project Number: MEF/04/280, M1251206/7, M/125/1206/7. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 123 p.
46816911	Fliege, R. (2004) [Phthalic Acid Ring-UL-(Carbon 14)]-and [Aniline Ring-UL-(Carbon 14)]-NNI-0001-des-iodo: Aerobic Soil Metabolism in Four Soils. Project Number: M1251289/8, MEF/04/388, M/125/1289/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 114 p.

162-2 Anaerobic soil metabolism

MRID	Citation Reference
46816912	Hellpointner, E. (2004) Anaerobic Degradation/Metabolism of NNI-0001 in Soil. Project Number: M1261225/9, MEF/04/067, M/126/1225/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 56 p.

162-3 Anaerobic aquatic metab.

MRID	Citation Reference
46816914	Mathew, A. (2005) [Phthalic Acid Ring-UL-(Carbon 14)]NNI-0001: Anaerobic Aquatic Metabolism. Project Number: AS042401, MEAM6026. Unpublished study prepared by Bayer Corp. 72 p.

163-1 Leach/adsorp/desorption

MRID	Citation Reference
46816905	Babczinski, P.; Heinemann, O. (2004) Adsorption/Desorption of NNI-0001 on Soils. Project Number: M1311243/5, MR/201/03, M/131/1243/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 75 p.

46816906 Volkel, W. (2005) Adsoprtion/Desorption of [(Carbon 14)]-NNI-001-DES-IODO on Soils. Project Number: 855843. Unpublished study prepared by RCC Umweltchemie Ag. 108 p.

164-1 Terrestrial field dissipation

MRID	Citation Reference
46816916	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Mississippi Soil, 2003. Project Number: 03EFAMY002, AS022102, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Bayer CropScience Mississippi Field Station. 186 p.
46816917	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Washington Soil, 2003. Project Number: 03EFAMY003, AS022103, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Agvise Inc. 192 p.

165-4 Bioaccumulation in fish

MRID	Citation Reference
46816949	Dorgerloh, M.; Weber, E. (2005) (Carbon 14)-NNI-0001-Bioconcentration and Biotransformation in Fish (Lepomis macrochirus). Project Number: DOM/23026, E/244/2330/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 156 p.

171-11 Tobacco Uses: Total Residues and Pyrolysis Products

MRID	Citation Reference
46817244	Ponte, M.; Schick, M. (2006) Tobacco Pyrolysis of [14-Carbon]NNI-0001. Project Number: 1426W/1, 1426W, RAAMX049. Unpublished study prepared by PTRL West, Inc. 94 p.

830.1550 Product Identity and composition

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. &

Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

46816904 Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1600 Description of materials used to produce the product

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1620 Description of production process

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.1650 Description of formulation process

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

46816904 Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1670 Discussion of formation of impurities

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1700 Preliminary analysis

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.

830.1750 Certified limits

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study

prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1800 Enforcement analytical method

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.6302 Color

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6303 Physical state

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6304 Odor

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6313 Stability to sunlight, normal and elevated temperatures, metals, and metal ions

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.6314 Oxidizing or reducing action

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6315 Flammability

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6316 Explodability

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A.

Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.6317 Storage stability of product

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6320 Corrosion characteristics

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7000 pH of water solutions or suspensions

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7050 UV/Visible absorption

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7100 Viscosity

MRID	Citation Reference

46816903 Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7200 Melting point/melting range

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7300 Density/relative density

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7370 Dissociation constant in water

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7560 Partition coefficient (n-octanol/water), generator column method

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7840 Water solubility: Column elution method, shake flask method

MRID	Citation Reference

46816902 Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7950 Vapor pressure

MRID	Citation Reference

46816902 Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

835.1240 Soil column leaching

MRID	Citation Reference

46816906 Volkel, W. (2005) Adsoprtion/Desorption of [(Carbon 14)]-NNI-001-DES-IODO on Soils. Project Number: 855843. Unpublished study prepared by RCC Umweltchemie Ag. 108 p.

835.2120 Hydrolysis of parent and degradates as a function of pH at 25 C

MRID	Citation Reference

46816907 Yamashita, A. (2001) Hydrolysis Study of NNI-0001: Final Report. Project Number: LSRC/A01/078A, GC/03, 01/0034. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 56 p.

835.2240 Direct photolysis rate of parent and degradates in water

MRID	Citation Reference

46816908 Motoba, K. (2005) Study on Aqueous Photolysis of NNI-0001: Final Report (Amended II). Project Number: GC/03, LSRC/A01/128A, 01/0036. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 88 p.

835.2410 Photodegradation of parent and degradates in soil

MRID	Citation Reference

46816909 Shepler, K. (2004) Photodegradation of [(Carbon 14)]NNI-0001 in/on Soil by Artificial Light. Project Number: 1050W/1, 1050W. Unpublished study prepared by PTRL West, Inc. 141 p.

835.4100 Aerobic soil metabolism

MRID	Citation Reference
46816910	Babczinski, P.; Eberhardt, R. (2004) NNI-0001: Aerobic Soil Degradation/Metabolism in Four Different Soils. Project Number: MEF/04/280, M1251206/7, M/125/1206/7. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 123 p.
46816911	Fliege, R. (2004) [Phthalic Acid Ring-UL-(Carbon 14)]-and [Aniline Ring-UL-(Carbon 14)]-NNI-0001-des-iodo: Aerobic Soil Metabolism in Four Soils. Project Number: M1251289/8, MEF/04/388, M/125/1289/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 114 p.

835.4200 Anaerobic soil metabolism

MRID	Citation Reference
46816912	Hellpointner, E. (2004) Anaerobic Degradation/Metabolism of NNI-0001 in Soil. Project Number: M1261225/9, MEF/04/067, M/126/1225/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 56 p.

835.4300 Aerobic aquatic metabolism

MRID	Citation Reference
46816913	Sneikus, J. (2004) Aerobic Degradation and Metabolism of NNI-0001 in the Water/Sediment System. Project Number: M1511248/2, MEF/414/03, M/151/1248/2. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 91 p.

835.4400 Anaerobic aquatic metabolism

MRID	Citation Reference
46816914	Mathew, A. (2005) [Phthalic Acid Ring-UL-(Carbon 14)]NNI-0001: Anaerobic Aquatic Metabolism. Project Number: AS042401, MEAM6026. Unpublished study prepared by Bayer Corp. 72 p.

835.6100 Terrestrial field dissipation

MRID	Citation Reference
46816915	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in California Soil, 2003. Project Number: 03EFAMY001, AS022101. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and

Bayer CropScience. 187 p.

46816916 Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Mississippi Soil, 2003. Project Number: 03EFAMY002, AS022102, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Bayer CropScience Mississippi Field Station. 186 p.

46816917 Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Washington Soil, 2003. Project Number: 03EFAMY003, AS022103, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Agvise Inc. 192 p.

835.6200 Aquatic field dissipation

MRID	Citation Reference

46817033 Sommer, H. (2002) Method for the Determination of NNI-0001 in Test Water from Aquatic Toxicity Test by HPLC-UV. Project Number: MR/391/02, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 12 p.

850.1010 Aquatic invertebrate acute toxicity, test, freshwater daphnids

MRID	Citation Reference

46816930 Dorgerloh, M. (2006) Acute Toxicity of NNI-0001 (tech.) in Water Fleas (Daphnia magna). Project Number: DOM/22041, E/320/2283/0, MR/391/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 39 p.

46816931 Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 SC 480 to Water Fleas (Daphnia magna). Project Number: E/320/2284/1, DOM/22042. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.

46816932 Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 WG 24 to the Waterflea Daphnia magna in a Static Laboratory Test System. Project Number: P/684/027017, MR/188/02, EBAMX018. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 58 p.

46816933 Dorgerloh, M. (2004) Acute Toxicity of NNI-0001-des-iodo to the Waterflea Daphnia magna. Project Number: DOM/23055, MR/029/04, E/320/2503/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.

46816934 Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 SC 480 in the Waterflea Dahnia magna Under Different Feeding Conditions in a Static Laboratory Test System. Project Number: E/320/2849/8, EBAMX028,

MR/188/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 59 p.

850.1025 Oyster acute toxicity test (shell deposition)

MRID	Citation Reference
46816935	Dionne, E. (2004) NNI-0001-Acute Toxicity to Eastern Oysters (Crassostrea virginia) Under Flow-Through Conditions. Project Number: AS881501, 13798/613, EBAM0380. Unpublished study prepared by Springborn Smithers Laboratories. 53 p.

850.1035 Mysid acute toxicity test

MRID	Citation Reference
46816936	Dionne, E. (2004) NNI-0001 - Acute Toxicity to Mysids (Americamysis bahia) Under Static Conditions. Project Number: 13798/6131, AS883101, EBAMO376. Unpublished study prepared by Springborn Smithers Laboratories. 49 p.

850.1075 Fish acute toxicity test, freshwater and marine

MRID	Citation Reference
46816937	Kern, M.; DeHann, R. (2004) Acute Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Static Conditions. Project Number: EBAM0390/AS811201, 200713. Unpublished study prepared by Bayer Corp. 42 p.
46816938	Banman, C.; Kern, M.; Lam, C. (2004) Acute Toxicity of NNI 0001 Technical to the Sheepshead Minnow (Cyprinodon variegatus) Under Static Conditions. Project Number: 200992, EBAM0370. Unpublished study prepared by Bayer Corp. 31 p.
46816939	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Lepomis macrochirus). Project Number: E/280/2291/4, DOM/22043. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 49 p.
46816940	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Oncorhynchus mykiss). Project Number: DOM/22044, E/280/2292/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 75 p.
46816941	Yamazaki, I. (2003) Acute Toxicity Test of NNI-0001 to Carp. Project Number: GC/01, LSRC/T02/126A, 02/0145. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 30 p.

46816942 Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Lepomis macrochirus). Project Number: E/280/2352/2, DOM/22081, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 42 p.

46816943 Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Oncorhynchus mykiss). Project Number: E/280/2354/4, DOM/22082, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 42 p.

850.1300 Daphnid chronic toxicity test

MRID	Citation Reference

46816944 Dorgerloh, M. (2003) Influence of NNI-0001 (Tech.) on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2267/3, DOM/22035, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 88 p.

46816945 Dorgerloh, M. (2003) Influence of NNI-0001 SC 480 on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2372/0, DOM/23001, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 81 p.

850.1400 Fish early-life stage toxicity test

MRID	Citation Reference

46816946 Putt, A. (2005) NNI-0001 - Life-Cycle Toxicity Test with Mysids (Americamysis bahia). Project Number: 13798/6156, EBAMO377. Unpublished study prepared by Springborn Smithers Laboratories. 89 p.

46816947 Kern, M; Lam, C. (2004) Early Life Stage Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions. Project Number: EBAMX005, 200995, AS841201. Unpublished study prepared by Bayer Corp. 86 p.

850.1500 Fish life cycle toxicity

MRID	Citation Reference

46816948 Cafarella, M. (2005) NNI-0001 - The Full Life-Cycle Toxicity Test with Fathead Minnow (Pimphales promelas). Project Number: 13798/6155, EBAM0393. Unpublished study prepared by Springborn Smithers Laboratories. 141 p.

850.1730 Fish BCF

MRID	Citation Reference
46816949	Dorgerloh, M.; Weber, E. (2005) (Carbon 14)-NNI-0001-Bioconcentration and Biotransformation in Fish (Lepomis macrochirus). Project Number: DOM/23026, E/244/2330/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 156 p.

850.1850 Aquatic food chain transfer

MRID	Citation Reference
46817001	Weber, E.; Dorgerloh, M. (2005) [Aniline-UL-(Carbon 14)]-NNL-0001-desidio: Bioconcentration, Depuration and Determination of Residues in Fish (Lepomis macrochirus). Project Number: DOM/24023, E/244/2683/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 111 p.

850.1950 Field testing for aquatic organisms

MRID	Citation Reference
46817002	Heimbach, F.; Arnold, M.; Brumhard, B. (2005) Biological Effects and Fate of NNI-0001 SC 480 in Outdoor Mesocosm Ponds. Project Number: HBF/BT/06, E/413/2434/1. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. and Fraunhofer Institute for Molecular. 349 p.

850.2100 Avian acute oral toxicity test

MRID	Citation Reference
46817003	Barfknecht, R. (2003) Acute Oral Toxicity for Northern Bobwhite Quail (Colinus virginianus): NNI-0001. Project Number: E/204/2295/4, BAR/LD/044. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 32 p.
46817004	Barfknect, R. (2004) Acute Oral Toxicity for Bobwhite Quail (Colinus virginianus): NNI-0001 SC 480. Project Number: E/204/2717/3, BAR/LD/057. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 24 p.

850.2200 Avian dietary toxicity test

MRID	Citation Reference
46817005	Bowers, L. (2005) Technical NNI 0001: A Subacute Dietary LC50 with

Mallards. Project Number: AS720801, 201263. Unpublished study prepared by Bayer Corp. 41 p.

46817006 Barfknecht, R. (2003) NNI-0001 Tech.: 5-Day-Dietary LC50 Bobwhite Quail (Colinus virginianus). Project Number: BAR/LC014, E/295/2268/4. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 33 p.

850.2300 Avian reproduction test

MRID	Citation Reference

46817008 Bowers, L. (2005) Effect of Technical NNI 0001 on Northern Bobwhite Reproduction. Project Number: AS741701, 201138. Unpublished study prepared by Bayer Corp. 143 p.

850.2500 Field testing for terrestrial wildlife

MRID	Citation Reference

46817012 Nguyen, D.; Gosch, H. (2005) Effect on Bombus terrestris of NNI 0001 WG 24 and Decis Protech used at the Maximum Dose in Greenhouse Tomatoes. Project Number: 201492. Unpublished study prepared by Bayer Cropscience Gmbh. 36 p.

46817024 Wolf, C. (2006) Residues in Arthropod Prey of Birds and Mammals After the Application of NNI 0001 SC 480 (Active Substance NNI 0001) in a German Vineyard: Final Report. Project Number: WFC/FS/011, E/308/2687/4. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 89 p.

46817027 Frommholz, U. (2005) NNI-0001 SC 480: Influence on the Reproduction of the Collembola species Folsomia Candida Test in Artificial Soil. Project Number: E/314/2/870/5, LKC/COLL/40/05. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 26 p.

850.3020 Honey bee acute contact toxicity

MRID	Citation Reference

46817009 Barth, M. (2002) Acute Toxicity of NNI-0001 a.i. to the Honeybee Apis Mellifera L. under Laboratory Conditions: Final Report. Project Number: 02/10/48/035. Unpublished study prepared by Biochem Agrar, Lab fuer Biologische und Chemische. 30 p.

46817010 Barth, M. (2002) Acute Toxicity of NNI-0001 SC 480 to the Honeybee Apis Mellifera L. under Laboratory Conditions: Final Report. Project Number: 01/10/48/034, 02/10/48/034. Unpublished study prepared by Biochem Agrar, Lab fuer Biologische und Chemische. 29 p.

46817015 Waltersdorfer, A. (2004) Toxicity to the Ladybird Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an Extended Laboratory Test Including Exposure to and Oral Uptake of NNI-0001 SC 480. Project Number: CW03/029. Unpublished study prepared by Bayer Cropscience Gmbh. 27 p.

850.3040 Field testing for pollinators

MRID	Citation Reference
46817011	Schur, A. (2006) Assessment of Side Effects of NNI-0001 SC 480 on the Honey Bee (Apis mellifera L.) in the Semi-Field: Final Report. Project Number: 20051108/01/BZEU. Unpublished study prepared by GAB Biotechnologie Gmbh. 115 p.

850.4100 Terrestrial plant toxicity, Tier 1 (seeding emergence)

MRID	Citation Reference
46817034	Nguyen, D.; Gosch, H. (2005) Non-Target Terrestrial Plants: An Evaluation of the Effects of NNI-0001 WG 24 in the Seedling Emergence and Growth Test (Tier 1). Project Number: SE04/14, SE04/14/TIER/1. Unpublished study prepared by Bayer Cropscience Gmbh. 17 p.
46817035	Lechelt-Kunze, C. (2002) NNI-0001 SC 480: Pre - and Post - Emergence Screening for Herbicidal Activity. Project Number: LKC/NTPSCR/05/02. Unpublished study prepared by Bayer Cropscience Gmbh. 14 p.

850.4150 Terrestrial plant toxicity, Tier 1 (vegetative vigor)

MRID	Citation Reference
46817035	Lechelt-Kunze, C. (2002) NNI-0001 SC 480: Pre - and Post - Emergence Screening for Herbicidal Activity. Project Number: LKC/NTPSCR/05/02. Unpublished study prepared by Bayer Cropscience Gmbh. 14 p.
46817036	Christ, M.; Lam, C. (2005) Tier I Seedling Emergence and Vegetative Vigor: Nontarget Phytotoxicity Study Using NNI-0001 480SC. Project Number: 201376, EBAMX007, EBAM0367. Unpublished study prepared by Bayer Corp. 62 p.
46817037	Nguyen, D.; Gosch, H. (2005) Non-Target Terrestrial Plants: An Evaluation of the Effects of NNI-0001 WG 24 in the Vegetative Vigor Test (Tier 1). Project Number: VV04/14, VV04/14/TIER/1. Unpublished study prepared by Bayer Cropscience Gmbh. 17 p.

850.4400 Aquatic plant toxicity test using Lemna spp. Tiers I and II

MRID	Citation Reference
46817039	Kern, M.; Banman, C.; Lam, C. (2004) Toxicity of NNI 0001 Techncial to Duckweed (Lemna gibba G3) Under Static-Renewal Conditions. Project Number: EBAMX010, AS883701, 200604. Unpublished study prepared by Bayer Corp. 41 p.
46817040	Dorgerloh, M. (2005) Pseudokirchneriella subcapitata Growth Inhibition Test with NNI-0001 SC 480. Project Number: DOM/24031, 00789, MR/391/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 53 p.

850.5400 Algal toxicity, Tiers 1 and II

MRID	Citation Reference
46817041	Yamazaki, I. (2003) Algal Growth Inhibition Test of NNI-0001: Final Report. Project Number: GC/01, 02/0128, LSRC/T02/121A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 30 p.

860.1000 Background

MRID	Citation Reference
46817114	Muprhy, J. (2005) NNI-0001 480 SC - Magnitude of the Residue in/on Tobacco. Project Number: RAAMX048. Unpublished study prepared by Bayer Corp., Bayer CropScience Midwest Field Technology Station and Bayer Research Farm. 131 p.

860.1300 Nature of the residue - plants, livestock

MRID	Citation Reference
46817043	Baker, F.; Kimmel, E.; Estigoy, L. (2002) A Metabolism Study with [(Carbon 14)]-NNI-0001 on Apples. Project Number: 1027W/2, 1027W. Unpublished study prepared b: PTRL West, Inc. and Excel Research Services, Inc. 390 p.
46817044	Motoba, K. (2002) Metabolism Study of NNI-0001 in Cabbage: Final Report (Amended I). Project Number: GB/03, 01/0101, LSRC/M02/011A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 83 p.
46817045	Motoba, K. (2005) Metabolism Study of NNI-0001 in Cherry Tomato: Final Report (Amended II). Project Number: GB/03, 01/0069, LSRC/M01/122A. Unpublished study prepared by Nihon Nohyaku Co.,

Ltd. 97 p.

46817046 Krolski, M.; Nguyen, T. (2005) The Metabolism of NNI-0001 in Corn. Project Number: AS041602/MEAMX009, AS041601/MEAMX010. Unpublished study prepared by Bayer Corp. 121 p.

46817047 Weber, H.; Koester, J.; Justus, K. (2005) [Aniline-UL-(Carbon 14)]NNI-0001: Absorption, Distribution, Excretion, and Metabolism in the Lactating Goat. Project Number: MEF/03/173, M51819123, M/181/9123/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 254 p.

46817048 Koester, J.; Justus, K.; Brueckner, H. (2005) [Phthalic-acid-UL-(Carbon 14)]NNI-0001: Absorption, Distribution, Excretion, and Metabolism in the Lactating Goat. Project Number: M11819129, MEF/04/173, M/181/9129/1. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 185 p.

46817049 Koester, J.; Justus, K. (2004) Metabolism of [Aniline-UL-(Carbon 14)]NNI-0001 in the Laying Hen. Project Number: M81819126, MEF/04/055, M/181/9126/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 158 p.

46817050 Koester, J.; Justus, K.; Brueckner, H. (2005) Metabolism of [Phthalic-Acid-UL-(Carbon 14)]NNI-0001 in the Laying Hen. Project Number: M51819132, MEF/04/159, M/181/9132/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 151 p.

860.1340 Residue analytical method

MRID	Citation Reference
46816928	Netzband, D.; Yin, J. (2006) Independent Laboratory Validation of "Method 00838 (MR-134/03) for the Determination of NNI-0001 and NNI-0001-des-iodo in Drinking and Surface Water by HPLC-MS/MS". Project Number: RAAMX098, MR/134/03, 000838. Unpublished study prepared by Bayer Corp. 78 p.
46817101	Billian, P.; Wolters, A. (2006) Analytical Method 00816/M002 for the Determination of Residues of NNI-0001 and its Des-Iodo Metabolite A-1 in/on Plant Material by HPLC-MS/MS Using Stable-Labelled Internal Standards. Project Number: P602030522, 00816/M002, MR/121/03. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 103 p.
46817102	Reiner, H. (2005) Extraction Efficiency Testing of the Residue Method for the Determination of NNI-0001 Residues in Corn Using Aged Radioactive Residues. Project Number: M9991366/3, MEF/04/0465. Unpublished study prepared by Bayer Ag, Institute of Product Info. &

Residue Anal. 41 p.

46817103 Class, T. (2005) Independent Laboratory Validation of Method 00816/M001 for the Determination of Residues of NNI-0001 and Its Des-Iodo Metabolite A-1 in/on Plant Material by HPLC-MS/MS: Demonstration of a LC/MS/MS Confirmatory Method. Project Number: P/866/G, P612050563, P/B/866/G. Unpublished study prepared by PTRL Europe Gmbh. 50 p.

46817104 Billian, P. (2005) Analytical Method 00912 for the Determination of Residues of NNI-0001 and its Metabolite A14 in/on Muscle, Liver and Kidney, Milk, Fat and Poultry Egg by HPLC-MS/MS. Project Number: MR/149/04, 00912, P603040541. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 177 p.

46817105 Justus, K.; Brueckner, H. (2005) [Phthalic acid-UL-(Carbon 14)] NNI-0001: Extraction Efficiency of the Residue Analytical Method for the Determination of NNI-0001 and NNI-0001-Iodophthalimide in Animal Tissues, Milk, and Eggs Using Aged Radioactive Residues. Project Number: M9991432/7, MEF/04/526. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 65 p.

46817106 Anspach, T. (2005) Independent Laboratory Validation of the Bayer CropScience Method No. 00912 for the Determination of Residues of NNI-001 and its Metabolite A-14 in/on Muscle, Fat and Poultry Egg by HPLC-MS/MS: Final Report. Project Number: BAY/0512V, G05/0019, P683050565. Unpublished study prepared by Dr. Specht and Partner. 100 p.

47263101 Billian, P. (2007) Confirmation Method for Analytical Method 00816/M002 for the Determination of Residues of NNI-001 and its des-iodo Metabolite A-1 in/on Plant Material by HPLC-MS/MS Using Stable-Labelled Internal Standards. Project Number: P682070621, MR/07/300, M/290991/01/1. Unpublished study prepared by Bayer CropScience AG. 17 p.

47263102 Rotzoll, N. (2007) Independent Laboratory Validation of the Bayer CropScience Method 00816/M002 for the Determination of NNI-0001 (Flubendiamide) and its Metabolite NNI-001-desiodo in Plant Matrices: Final Report. Project Number: BAY/0705V, G07/0117, P612070622. Unpublished study prepared by Eurofins Analytik GmbH. 72 p.

860.1360 Multiresidue method

MRID	Citation Reference
46817107	Wilson, T. (2006) Testing of NNI-0001 and Two Metabolites Through the FDA Multiresidue Methods as Described in the FDA Pesticide Analytical Manual (PAM) I, Appendix II, Updated 1/94. Project

Number: RAAMY017, 49859. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 95 p.

860.1380 Storage stability data

MRID	Citation Reference
46817108	Billian, P. (2005) Storage Stability of NNI-0001 in/on Tomato (Fruit), Cotton (Oil), Wheat (Grain), Head Cabbage (Head), Bean (Bean with Pod) and Citrus (Fruit) for 18 Months. Project Number: P642030518, MR/064/03, BCS/RD/D/ROCS. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 37 p.
46817109	Billian, P. (2005) Storage Stability of NNI-0001-Des-Iodo in/on Tomato (Fruit), Plant Oil, Wheat (Grain), Head Cabbage (Head), Bean (Bean With Pod) and Citrus (Fruit) for 18 Months. Project Number: P642030520, BCS/RD/D/ROCS, MR/086/03. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 37 p.
46817110	Murphy, I. (2006) Storage Stability of NNI-0001 and A-1 (NNI-0001-Desiodo) in Various Crop Matrices. Project Number: RAAMY002, AM050804B/NNI/A1, AM060207A/34. Unpublished study prepared by Bayer Corp. 250 p.

860.1480 Meat/milk/poultry/eggs

MRID	Citation Reference
46817111	Billian, P.; Auer, S.; Eberhardt, R. (2005) NNI-0001: Dairy Cattle Feeding Study. Project Number: MR/030/05, P673050562, BCS/RD/D/ROCS. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 200 p.
46817112	Billian, P.; Eberhardt, R. (2005) NNI-0001: Feeding Study Laying Hens (Gallus gallus domesticus). Project Number: P673050566, BR/031/05, BCS/RD/D/ROCS. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 292 p.

860.1500 Crop field trials

MRID	Citation Reference
46817113	Krolski, M.; Harbin, A. (2006) NNI-0001 480 SC - Magnitude of the Residue in/on Field and Sweet Corn. Project Number: RCAMY004. Unpublished study prepared by Bayer Corp., Bayer CropScience Midwest Field Technology Station and Bayer Research Farm. 455 p.
46817114	Muprhy, J. (2005) NNI-0001 480 SC - Magnitude of the Residue in/on Tobacco. Project Number: RAAMX048. Unpublished study prepared by

Bayer Corp., Bayer CropScience Midwest Field Technology Station and Bayer Research Farm. 131 p.

46817115 Beedle, E. (2006) NNI-0001 480 SC - Magnitude of the Residue on Cotton. Project Number: RCAMY002. Unpublished study prepared by Bayer Corp., Texas A & M Food Protein Research & and GLP Technologies. 244 p.

46817116 Lenz, C. (2006) NNI-0001 480 SC - Magnitude of the Residue on Grape. Project Number: RCAMY016. Unpublished study prepared by Bayer Corp., Crop Management Strategies, Inc. and A.C.D.S. Research, Inc. 152 p.

46817117 Xu, T.; Mackie, S. (2005) NNI-001 480 SC - Magnitude of the Residue on Pome Fruit (Apple and Pear). Project Number: RCAMY009. Unpublished study prepared by: Bayer Corp., A.C.D.S. Research, Inc. and Ag Research Associates. 354 p.

46817118 Helfrich, K.; Sandra, J.; Mackie, W. (2006) NNI-0001 480 SC - Magnitude of the Residue on Stone Fruit (Crop Group 12: Cherries, Plums, and Peaches). Project Number: RCAMY011. Unpublished study prepared by Bayer Corp., Crop Management Strategies, Inc. and Agsearch. 357 p.

46817119 Pither, K.; Mackie, S. (2006) NNI-0001 480 SC - Magnitude of the Residue on Tree Nuts (Almonds and Pecan). Project Number: RCAMY014. Unpublished study prepared by Bayer Corp., South Texas Ag Research, Inc. and Crop Guard Research, Inc. 245 p.

46817120 Fischer, D. (2005) NNI-0001 24 WG - Magnitude of the Residue in/on Fruiting Vegetables (Crop Group 8; Including Residue Reduction Information). Project Number: RCAMY006. Unpublished study prepared by Bayer Corp. 300 p.

46817121 Fischer, D. (2005) NNI-0001 24 WG - Magnitude of the Residue in/on Head and Stem Brassica (Crop Subgroup 5A; Including Residue Reduction Information). Project Number: RCAMY001. Unpublished study prepared by Bayer Corp., Bayer CropScience and South Texas Ag Research, Inc. 301 p.

46817122 Fishcher, D. (2005) NNI-0001 24 WG - Magnitude of the Residue in/on Leafy Brassica Greens (Crop Subgroup 5B; Including Residue Reduction Information). Project Number: RCAMY001/1, 00816/M002. Unpublished study prepared by Bayer Corp., Bayer CropScience and South Texas Agricultural Research. 274 p.

46817123 Dacus, S.; Harbin, A. (2006) NNI-0001 24 WG - Magnitude of the Residue in/on Leafy Vegetables - (Crop Group 4; Including Residue Reduction Information). Project Number: RCAMY008, 00816/M002. Unpublished study prepared by Bayer Corp., Syntech Research and GLP

Research & Consulting. 449 p.

46817124 Zimmer, D.; Dacus, S. (2006) NNI-0001 24 WG - Magnitude of the Residue in/on Cucurbit Vegetables - Crop Group 9 (Including Reduction Information). Project Number: RCAMY015, 00816/M002. Unpublished study prepared by Bayer Corp., GLP Research & Consulting and South Texas Ag Research, Inc. 336 p.

46817125 Lenz, C. (2005) NNI-0001 480 SC - Magnitude of the Residue in/on Field Corn Grain, Corn Aspirated Grain Fractions, and Corn Processed Commodities. Project Number: RCAMY005, 00816/M002, AM050207B/NNI. Unpublished study prepared by Bayer Corp. and Texas A & M Research Center. 209 p.

860.1520 Processed food/feed

MRID	Citation Reference
46817125	Lenz, C. (2005) NNI-0001 480 SC - Magnitude of the Residue in/on Field Corn Grain, Corn Aspirated Grain Fractions, and Corn Processed Commodities. Project Number: RCAMY005, 00816/M002, AM050207B/NNI. Unpublished study prepared by Bayer Corp. and Texas A & M Research Center. 209 p.
46817126	Murphy, J. (2006) NNI-0001 480 SC - Magnitude of the Residue on Cotton Processed Commodities. Project Number: RCAMY003, AM051128AD/NNI/A1, AM051128AD/NN1. Unpublished study prepared by Bayer Corp. and GLP Technologies. 137 p.
46817127	Lenz, C. (2005) NNI-0001 480 SC - Magnitude of the Residue on Grape Processed Commodities. Project Number: RCAMY017, AM050404ABC/NNI/A1, AM050404ABC/NNI. Unpublished study prepared by Bayer Corp., National Food Laboratory, Inc. and Excel Research Services, Inc. 150 p.
46817128	Lenz, C. (2006) NNI-0001 480 SC - Request for Waiver of the Study of the Magnitude of the Residue in/on Soybean Processed Commodities from a Rotational Crop of Soybeans. Project Number: RAAMY014, 00816/M002. Unpublished study prepared by Bayer Corp. and Texas A & M Food Protein Research &. 76 p.
46817129	Lenz, C. (2006) NNI-0001 480 SC - Request for Waiver of the Study of the Magnitude of the Residue in/on Wheat Processed Commodites from a Rotation Crop of Wheat. Project Number: RAAMY007, 00816/M002. Unpublished study prepared by Bayer Corp. 68 p.
46817130	Helfrich, K.; Mackie, S. (2005) NNI-0001 480 SC: Magnitude of the Residue on Apple Processed Commodities. Project Number: RCAMY010, 00816/M002, AM041216C/NNI/A1. Unpublished study

prepared by Bayer Corp., National Food Laboratory, Inc. and Qualls Agricultural Laboratories, I. 195 p.

46817131 Helfrich, K.; Mackie, S. (2006) NNI-0001 480 SC: Magnitude of the Residue on Plum Processed Commodities. Project Number: RCAMY012, AM050104A/NNI/A1, AM050104A/NNI. Unpublished study prepared by Bayer Corp. and National Food Laboratory, Inc. 126 p.

46817132 Fischer, D. (2005) NNI-0001 24 WG - Magnitude of the Residue in/on Tomatoes and Tomato Processed Commodities. Project Number: RCAMY007, 00816/M002, MG6880. Unpublished study prepared by Bayer Corp. and National Food Laboratory, Inc. 233 p.

860.1850 Confined accumulation in rotational crops

MRID	Citation Reference

46817133 Reiner, H. (2004) Metabolism of [Aniline Ring-UL-(Carbon 14)] NNI-0001 in Confined Rotational Crops. Project Number: MEF/009/03, M/1031192/7. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 212 p.

46817134 Reiner, H. (2004) Metabolism of [Phthalic Acid Ring-UL-(Carbon 14)] NNI-0001 in Confined Rotational Crops. Project Number: MEF/008/03, M/1301191/6. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 214 p.

860.1900 Field accumulation in rotational crops

MRID	Citation Reference

46817135 Fischer, D. (2006) NNI-0001 480 SC - Magnitude of the Residue in Barley (Rotational Crop Tolerance). Project Number: RAAMY009, AM051115A/NNI, AM051115/NNI/A1. Unpublished study prepared by Bayer Corp. 192 p.

46817136 Fischer, D. (2006) NNI-0001 480 SC - Magnitude of the Residue in Mustard Greens When Planted as a Roational Crop Following Treatment of Cotton, Squash, or Sweet Corn With NNI-0001 480 SC at the Maximum Proposed Label Specifications (Limited Rotational Crop). Project Number: AS19MG01, RCAM1000, AM/002/P05/01. Unpublished study prepared by Bayer Corp. 186 p.

46817137 Xu, T.; Fischer, D. (2006) NNI-0001 480 SC - Magnitude of the Residue in Sorghum (Rotational Crop Tolerance). Project Number: RAAMY012, 00816/M002, AM050315BC/NNI. Unpublished study prepared by Bayer Corp., South Texas Ag. Research and Shoffner Farm Research. 194 p.

46817138 Duah, F.; Harbin, A. (2006) NNI-0001 480 SC - Magnitude of the Residue in Soybeans (Rotational Crop Tolerance). Project Number: RAAMY013, 00816/M002, AM050309AB/NNI. Unpublished study prepared by Bayer Corp., Agvise Inc. and Agresources, Inc. 275 p.

46817139 Fischer, D. (2006) NNI-0001 280 SC - Magnitude of the Residue in Turnips When Planted as a Rotational Crop Following Treatment of Cotton, Squash, or Sweet Corn with NNI-0001 480 SC at the Maximum Proposed Label Specifications (Limited Rotational Crop). Project Number: AS19TU01, RCAM1005, AM/002/P05/01. Unpublished study prepared by Bayer Corp. and South Texas Ag. Research. 211 p.

46817140 Fischer, D. (2006) NNI-0001 480 SC - Magnitude of the Residue in Wheat (Rotational Crop Tolerance). Project Number: RAAMY008, 00816/M002, AM050412ABC/NNI/A1. Unpublished study prepared by Bayer Corp. and Qualls Agricultural Laboratories, I. 251 p.

46817141 Fischer, D. (2006) NNI-0001 480 SC - Magnitude of the Residue in Wheat When Planted as a Rotational Crop Following Treatment of Cotton, Squash, Mustard Greens, or Sweet Corn with NNI-0001 480 SC at the Maximum Proposed Label Specifications (Limited Rotational Crop). Project Number: RCAM1010, AS19WH01, AM/002/P05/01. Unpublished study prepared by Bayer Corp. 281 p.

870.1000 Acute toxicity testing--background

MRID	Citation Reference

46817236 Langewische, F. (2006) Perinatal Ocular Toxicity Study in CD-1 Mice Following Exposure Via Diet: NNI-0001. Project Number: AT02781, TXAMX036, T2073354. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 191 p.

870.1100 Acute oral toxicity

MRID	Citation Reference

46817142 Horiuchi, K. (2003) Acute Oral Toxicity Study of NNI-0001 in Rats: Final Report. Project Number: GA/01, 02/0004, LSRC/T02/026A. Unpublished study prepared by Nihon Nohyaku Co., Ltd., Agvise Inc. and Agro-Tech, Inc. 22 p.

46817143 Schungel, M. (2004) Acute Toxicity in the Rat After Oral Administration: NNI-0001 480 SC. Project Number: AT01182, TXAM0190, T/8074098. Unpublished study prepared by Bayer CropScience LP. 25 p.

46817144 Eiben, R. (2004) Acute Toxicity in the Rat After Oral Administration: NNI-0001 24 WG. Project Number: AT01622, T/3074651, ID64005/04.

Unpublished study prepared by Bayer Ag Pflanzenschutz-Entwicklung. 23 p.

870.1200 Acute dermal toxicity

MRID	Citation Reference
46817145	Horiuchi, K. (2003) Acute Dermal Toxicity Study of NNI-0001 in Rats: Final Report. Project Number: GA/01, 02/0005, LSRC/T02/027A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 22 p.
46817146	Schungel, M. (2004) NNI-0001 480 SC: Acute Toxicity in the Rat After Dermal Application. Project Number: T/9074099, TXAM0195, AT01183. Unpublished study prepared by Bayer CropScience LP. 26 p.
46817147	Eiben, R. (2004) Acute Toxicity in the Rat After Dermal Application: NNI-0001 24 WG. Project Number: AT01623, T/4074652, TXAMX025. Unpublished study prepared by Bayer Ag Pflanzenschutz-Entwicklung. 26 p.

870.1300 Acute inhalation toxicity

MRID	Citation Reference
46817148	Wesson, C. (2004) NNI-0001: Acute Inhalation Toxicity (Nose Only) Study in the Rat. Project Number: 289/119. Unpublished study prepared by Safepharm Laboratories Ltd. 46 p.
46817149	Pauluhn, J. (2004) NNI-0001 480 SC: Acute Inhalation Toxicity in Rats. Project Number: TXAM0185, T5073302, AT01263. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 67 p.
46817150	Christenson, W. (2006) Justification for Waiving an Acute Inhalation Toxicity Study With the 24WG Formulation of NNI-0001 Technical. Project Number: 201490. Unpublished study prepared by Bayer CropScience LP. 5 p.

870.2400 Acute eye irritation

MRID	Citation Reference
46817201	Horiuchi, K. (2004) Eye Irritation Study of NNI-0001 in Rabbits: Final Report. Project Number: GA/02, 02/0031, LSRC/T02/065A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 26 p.
46817202	Schungel, M. (2004) NNI-0001 480 SC: Acute Eye Irritation on Rabbits. Project Number: AT01509, T0074379, TXAM0175. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.
46817203	Schungel, M. (2005) NNI-0001 24 WG: Acute Eye Irritation on Rabbits.

Project Number: AT01758, T/9074396, TXAMX028. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.

870.2500 Acute dermal irritation

MRID	Citation Reference
46817204	Horiuchi, K. (2004) Skin Irritation Study of NNI-0001 in Rabbits: Final Report. Project Number: GA/02, 02/0030, LSRC/T02/064A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 21 p.
46817205	Schungel, M. (2004) NNI-0001 480 SC: Acute Skin Irritation/Corrosion on Rabbits: Final Report. Project Number: T/9074378, AT01500. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 19 p.
46817206	Schungel, M. (2005) NNI-0001 24 WG: Acute Skin Irritation/Corrosion on Rabbits. Project Number: AT01752, TXAMX029, T/8074395. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.

870.2600 Skin sensitization

MRID	Citation Reference
46817207	Horiuchi, K. (2004) Skin Sensitization Study of NNI-0001 in Guinea Pigs (Maximization Test): Final Report. Project Number: GA/03, 02/0003, LSRC/T03/077A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 47 p.
46817208	Vohr, H. (2004) NNI-0001 480 SC: Study for the Skin Sensitization Effect in Guinea Pigs (Buehler Patch Test). Project Number: AT01492, TXAM0202. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 29 p.
46817209	Vohr, H. (2004) NNI-0001 24 WG: Study for the Skin Sensitization Effect in Guinea Pigs (Buehler Patch Test). Project Number: AT01645, TXAMX031, T/7074150. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 26 p.

870.3100 90-Day oral toxicity in rodents

MRID	Citation Reference
46817210	Enomoto, A. (2003) NNI-0001: Repeated Dose 90-Day Oral Toxicity Study in Rats: Final Report. Project Number: IET/01/0013. Unpublished study prepared by Institute of Environmental Toxicology. 780 p.
46817211	Takeuchi, Y. (2002) NNI-0001: Repeated Dose 90-Day Oral Toxicity Study in Mice: Final Report. Project Number: IET/01/0049. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 258 p.

870.3150 90-day oral toxicity in nonrodents

MRID	Citation Reference
46817212	Kuwahara, M. (2003) NNI-0001: Repeated Dose 90-Day Oral Toxicity Study in Dogs: Final Report. Project Number: IET/01/0062. Unpublished study prepared by Institute of Environmental Toxicology. 300 p.

870.3200 21/28-day dermal toxicity

MRID	Citation Reference
46817213	Krotlinger, F. (2004) 30-Day Toxicity Study in the Rat by Dermal Administration: NNI-0001. Project Number: AT01704, TXAM0026, T/6073709. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 275 p.

870.3700 Prenatal developmental toxicity study

MRID	Citation Reference
46817214	Takahashi, K. (2002) NNI-0001: Teratogenicity Study in Rabbits: Final Report. Project Number: IET/01/0128. Unpublished study prepared by Institute of Environmental Toxicology. 126 p.
46817215	Aoyama, H. (2003) NNI-0001: Teratogenicity Study in Rats: Final Report. Project Number: IET/02/0036. Unpublished study prepared by Institute of Environmental Toxicology. 117 p.
46817240	Takahashi, K. (2001) NNI-0001: Preliminary Teratogenicity Study in Rabbits: Final Report. Project Number: IET/01/0030. Unpublished study prepared by Institute of Environmental Toxicology. 96 p.
46817241	Aoyama, H. (2002) NNI-0001: Preliminary Teratogenicity Study in Rats: Final Report. Project Number: IET/01/0113. Unpublished study prepared by Institute of Environmental Toxicology. 93 p.

870.3800 Reproduction and fertility effects

MRID	Citation Reference
46817216	Hojo, H. (2004) NNI-0001: Reproductive Toxicity Study in Rats: Final Report. Project Number: IET/01/0127. Unpublished study prepared by Institute of Environmental Toxicology. 617 p.

870.4100 Chronic toxicity

MRID	Citation Reference

46817217 Enomoto, A. (2004) NNI-0001: Repeated Dose 1-Year Oral Toxicity Study in Rats: Final Report. Project Number: T/8016, IET/01/0079. Unpublished study prepared by Institute of Environmental Toxicology. 986 p.

46817218 Kuwahara, M. (2004) NNI-0001: 52-Week Chronic Toxicity Study in Dogs: Final Report. Project Number: IET/02/0035. Unpublished study prepared by Institute of Environmental Toxicology. 415 p.

870.4200 Carcinogenicity

MRID	Citation Reference

46817219 Enomoto, A. (2004) NNI-0001: Carcinogenicity Study in Rats: Final Report. Project Number: IET/02/0035, T/8059. Unpublished study prepared by Institute of Environmental Toxicology. 691 p.

46817220 Takeuchi, Y. (2004) NNI-0001: Carcinogenicity Study in Mice: Final Report. Project Number: IET/01/0126, T/8019. Unpublished study prepared by Institute of Environmental Toxicology. 648 p.

870.5100 Bacterial reverse mutation test

MRID	Citation Reference

46817221 Inagaki, K. (2003) Bacterial Reverse Mutation Test of NNI-0001: Final Report (Amendment 1). Project Number: GA/08, 02/0017, LSRC/T02/018A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 39 p.

46817222 Herbold, B. (2004) NNI-0001 480 SC: Salmonella/Microsome Test Plate Incorporation and Preincubation Method. Project Number: AT01237, T/3073247, TXAMM004. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 53 p.

870.5375 In vitro mammalian chromosome aberration test

MRID	Citation Reference

46817223 Miyahana, K. (2004) In Vitro Chromosome Aberration Test of NNI-0001 in Cultured Chinese Hamster Cells: Final Report. Project Number: GA/08, 02/0116. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 32 p.

46817224 Herbold, B. (2003) NNI-0001: V79/HPRT-Test In Vitro for the Detection of Induced Forward Mutations. Project Number: T/2071518, AT00460. Unpublished study prepared by Bayer Ag Inst. of Toxicology.

36 p.

870.5395 Mammalian erythrocyte micronucleus test

MRID	Citation Reference
46817225	Miyahana, K. (2003) Micronucleus Test of NNI-0001 in Mice: Final Report. Project Number: GA/08, 02/0020, LSRC/T02/089A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 33 p.
46817226	Herbold, B. (2005) NNI-001: Micronucleus-Test on the Male Mouse. Project Number: TXAMX034, AT01775, T/0073947. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 49 p.

870.6200 Neurotoxicity screening battery

MRID	Citation Reference
46817227	Gilmore, R.; Lake, S. (2003) An Acute Oral Neurotoxicity Screening Study with Technical Grade NNI-0001 in Fischer 344 Rats. Project Number: 02/N12/LC, 200489. Unpublished study prepared by Bayer Corp. 445 p.

870.6300 Developmental neurotoxicity study

MRID	Citation Reference
46817228	Sheets, L.; Gilmore, R.; Hoss, H. (2006) A Developmental Neurotoxicity Screening Study with Technical Grade NNI-0001 in Wistar Rats. Project Number: 04/D72/VK, 201448. Unpublished study prepared by Bayer Corp. 1136 p.

870.7485 Metabolism and pharmacokinetics

MRID	Citation Reference
46817229	Motoba, K. (2005) Absorption, Distribution, Metabolism and Excretion of Radiolabeled NNI-0001 Following a Single Oral Administration to Male and Female Rats: Final Report (Amended I). Project Number: GB/01, 03/0022, LSRC/M04/115A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 142 p.
46817230	Motoba, K. (2005) Absorption, Distribution, Metabolism and Excretion of [phthalic ring (U)-(Carbon 14)] NNI-0001 Following 14 Repetitive Oral Administration to Male and Female Rats: Final Report (Amended I). Project Number: GB/01, 03/0222, LSRC/M04/114A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 81 p.
46817231	Motoba, K. (2004) Biliary Excretion Study of [phthalic Ring-(U)-

(Carbon 14)] NNI-0001 Following a Single Oral Administration to Male and Female Rats: Final Report. Project Number: GB/01, 01/0151, LSRC/M04/107A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 167 p.

46817232 Motoba, K. (2004) In Vitro Metabolism Study of NNI-0001: Final Report. Project Number: GB/05, 03/0181, LSRC/M04/184A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 57 p.

46817233 Motoba, K. (2005) Toxicokinetics of NNI-0001: Concentration in Selected Organs, Tissues and Plasma Following Repetitive Daily Administration to Rats and Mice: Final Report. Project Number: GA/25, 05/0230, LSRC/M05/248A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 62 p.

870.7600 Dermal penetration

MRID	Citation Reference

46817234 Bomann, W. (2005) A Study to Determine the Dermal Absorption of NNI-0001 SC 480 when Administered Dermally to Male Rhesus Monkeys: Final Report. Project Number: VCBZ/0111/03/742, 201134, 03C/B29/TL. Unpublished study prepared by Charles River Laboratories. 131 p.

870.7800 Immunotoxicity

MRID	Citation Reference

46817243 Krotlinger, F.; Vohr, H. (2005) Project: NNI-0001: Immunotoxicity Study in Rats - Plaque Assay (4-Weeks Administration by Diet). Project Number: AT02098, TXAMM002, T1073902. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 149 p.

875.1300 Inhalation exposure--outdoor

MRID	Citation Reference

46817247 Standart, V. (2006) Occupational Exposure & Safety Assessment for Mixers/Loaders, Applicators and Reentry Workers During Use of . Project Number: 201475. Unpublished study prepared by Bayer CropScience LP. 27 p.

875.2100 Foliar dislodgeable residue dissipation

MRID	Citation Reference

46817246 Hoag, R.; Belcher, T. (2004) Renounce 20 WP - Dislodgeable Foliar

Residue and Worker Re-entry Following Application to Sweet Corn: Final Report. Project Number: CY251601, CY264601, RCBDY032. Unpublished study prepared by Bayer Corp. and Morse Laboratories, Inc. 667 p.

875.2400 Dermal exposure

MRID	Citation Reference
46817246	Hoag, R.; Belcher, T. (2004) Renounce 20 WP - Dislodgeable Foliar Residue and Worker Re-entry Following Application to Sweet Corn: Final Report. Project Number: CY251601, CY264601, RCBDY032. Unpublished study prepared by Bayer Corp. and Morse Laboratories, Inc. 667 p.

875.2500 Inhalation exposure

MRID	Citation Reference
46817246	Hoag, R.; Belcher, T. (2004) Renounce 20 WP - Dislodgeable Foliar Residue and Worker Re-entry Following Application to Sweet Corn: Final Report. Project Number: CY251601, CY264601, RCBDY032. Unpublished study prepared by Bayer Corp. and Morse Laboratories, Inc. 667 p.

850.7100 Data reporting for environmental chemistry methods

MRID	Citation Reference
46816925	Seymour, R.; Beck, D. (2005) Independent Laboratory Validation of "Method 00849 for the Determination of Residues of NNI-0001, NNI-0001-des-iodo, NNI-0001-3-OH, NNI-0001-3-OH-hydroxyperfluoroalkyl and NNI-0001-Benzoic Acid in Soil and Sediment by HPLC-MS/MS". Project Number: RAAMX006, 00849. Unpublished study prepared by Bayer Corp. 76 p.
46816928	Netzband, D.; Yin, J. (2006) Independent Laboratory Validation of "Method 00838 (MR-134/03) for the Determination of NNI-0001 and NNI-0001-des-iodo in Drinking and Surface Water by HPLC-MS/MS". Project Number: RAAMX098, MR/134/03, 000838. Unpublished study prepared by Bayer Corp. 78 p.
46816929	Netzband, D.; Yin, J. (2006) Determination of NNI-0001 and NNI-0001-des-iodo in Drinking and Surface Water by LC/MS/MS. Project Number: AM/003/W06/01. Unpublished study prepared by Bayer Corp. 27 p.

850.1790 Chironomid Sediment Toxicity Test

MRID	Citation Reference
46817013	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 SC 480 to Larvae of Chironomus riparius in a Static Laboratory Test System. Project Number: EBAMX024, E/322/2846/6. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 53 p.
46817014	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 WG 24 to Larvae of Chironomus riparius in a Static Laboratory Test System. Project Number: EBAMX023, E/322/2844/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 53 p.
46817022	Dorgerloh, M. (2003) Chironomus riparius 28-Day Chronic Toxicity Test with the NNI-0001 (Tech.) in a Water-Sediment System Using Spiked Water. Project Number: DOM/23005, E/416/2340/0, MR/188/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 102 p.
46817023	Dorgerloh, M. (2004) Chironomus riparius 28-Day Chronic Toxicity Test with NNI-0001-des-iodo in a Water-Sediment System Using Spiked Water. Project Number: DOM/23069, E/416/2518/7, 00838. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 130 p.

850.6200 Earthworm subchronic toxicity test

MRID	Citation Reference
46817028	Kunze, C. (2002) NNI-0001 (Tech.): Acute Toxicity to Earthworms (Eisenia fetida). Project Number: E/310/2293/0, LKC/RG/406/02, RG/11/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 14 p.
46817029	Lechelt-Kunze, C. (2004) NNI-0001 SC 480: Acute Toxicity to Earthworms (Eisenia fetida) Tested in Artificial Soil. Project Number: E/310/2772/2, RG/18/04, LKC/RG/A/35/04. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 22 p.
46817030	Lechelt-Kunze, C. (2004) NNI-0001-des-iodo: Acute Toxicity to Earthworms (Eisenia fetida) Tested in Artificial Soil with 5% Peat: Amended Report. Project Number: E/310/2564/1, LKC/RG/A/21/04. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 23 p.
46817031	Luhrs, U. (2002) NNI-0001 SC480: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil: FInal Report. Project Number: 14421022. Unpublished study prepared by Institut fuer

Biologische Analytik und Consulting IBACON. 33 p.

46817032 Lechelt-Kunze, C. (2005) NNI-0001 WG 24: Effects on Survival, Growth and Reproduction on the Earthworm Eisenia fetida Tested in Artificial Soil. Project Number: E/312/2847/7, LKC/RG/R/11/05, RG/19/05. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 39 p.

850.7100 Data reporting for environmental chemistry methods

MRID	Citation Reference

46817042 Barfknecht, R. (2006) Dissipation of the Active Substance NNI-0001 from Exposed Grass After a Spray Application with NNI-0001 SC 480. Project Number: E/308/2949/5, BAR/FS/027. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 37 p.

Non-Guideline Study

MRID	Citation Reference

46816900 Bayer CropScience LP and Nichino America, Inc. (2006) Submission of Product Chemistry, Residue, Fate, Environmental Fate and Toxicity Data in Support of the Application for Registrations of NNI-0001 Techncial, NNI-0001 480 SC and NNI-0001 24 WG, and the Petition for Tolerance of Flubendiamide on Corn (Field Corn, Pop Corn, Sweet Corn, and Corn Grown for Seed), Cotton, Tobacco, Tree Fruit, Nut, and Vine Crops and Vegetable Crops. Transmittal of 49 of 201 Studies.

46816918 Hellpointner, E. (2003) Calculation of the Chemical Lifetime of NNI-0001 in the Troposphere. Project Number: M1451332/9, MEF/362/03. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 13 p.

46816919 Hellpointner, E. (2004) Determination of the Quantum Yield and Assessment of the Environmental Half-life of the Direct Photodegradation in Water: NNI-0001. Project Number: M1431261/8, MEF/099/03, M/143/1261/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 35 p.

46816920 Hellpointner, E. (2003) Determination of the Quantum Yield and Assessment of the Environmental Half-life of the Direct Photodegradation in Water: NNI-0001-Des-Iodo. Project Number: M1431300/2, MEF/214/03, M/143/1300/2. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 32 p.

46816921 Hellpointner, E. (2004) Determination of the Quantum Yield and Assessment of the Environmental Half-Life of the Direct Photo-degradation in Water: NNI-0001-3-OH-hydroxyperfluoroalkyl (A10).

Project Number: M1431306/8, MEF/275/03, M/143/1306/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.

46816922 Babczinski, P. (2004) Outdoor Soil Degradation of [(Carbon 14)]NNI-001. Project Number: MEF/04/418, M1251280/9, M/125/1280/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 126 p.

46816923 Brumhard, B. (2006) Determination of the Storage Stability of NNI-0001, NNI-0001-des-iodo, NNI-0001-3-OH, NNI-0001-3-OH-Hydrxyperfluoroalkyl and NNI-0001-Benzoic Acid in Soil. Project Number: P641030027, MR/06/014. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 80 p.

46816924 Brumhard, B. (2004) Analytical Method 00849 for the Determination of Residues of NNI-0001, and its Metabolites NNI-0001-des-iodo, NNI-0001-3-OH, NNI-0001-3-OH-Hydroxyperfluroalkyl and NNI-0001-Benzoic Acid in Soil and Sediment by HPLC-MS/MS. Project Number: P601030020, MR/202/03, 00849. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 94 p.

46816926 Seymour, R.; Beck, D. (2004) NNI-0001: Analytical Method AM-001-S04-01 for Determination of Residues of NNI-0001, NNI-0001-des-iodo, NNI-0001-3-OH, NNI-0001-3-OH-Hydroxyperfluoroalkyl and NNI-0001-Benzoic Acid in Soil and Sediment by HPLC-MS/MS. Project Number: AM/001/S04/01. Unpublished study prepared by Bayer Corp. 38 p.

46816927 Brumhard, B. (2004) Analytical Method 00838 (MR-134/03) for the Determination of NNI-0001-des-iodo in Drinking and Surface Water by HPLC-MS/MS. Project Number: P684/037058, MR/134/03, 00838. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 28 p.

46817000 Bayer Cropscience LP and Nichino America, Inc. (2006) Submission of Fate, Environmental Fate and Toxicity Data in Support of the Application for Registration of NNI-0001 Technical, NNI-0001 480 SC, NNI-0001 24 WG and the Petition for Tolerance of Flubendiamide for Use in/on Corn, Cotton, Tobacco, Tree Fruit, Vegetable Crops, Nut and Vine Crops. Transmittal of 50 Studies.

46817016 Moll, M. (2005) Effects of NNI-0001 SC 480 on the Ladybird Beetle Coccinella septempunctata, Extended Laboratory Study -Aged Residue Test- :Final Report. Project Number: 24321013. Unpublished study prepared by Institut fuer Biologische Analytik und Consulting IBACON. 46 p.

46817017 Maus, C. (2002) Evaluation of the Effects of NNI-0001 SC 480 on the Life Cycle of Ladybird Beetles (Coccinella septempunctata) under

Extended Laboratory Conditions. Project Number: E/398/2289/1, MAUS/CS004. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 38 p.

46817018 Waltersdorfer, A. (2004) Toxicity to the Green Lacewing Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) Using an Extended Laboratory Test: NNI-0001 SC 480 Water Miscible Suspension Concentrate. Project Number: CW03/030. Unpublished study prepared by Bayer Cropscience Gmbh. 26 p.

46817019 Waltersdorfer, A. (2005) Toxicity to the Predatory Mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) in the Laboratory: NNI-0001 24 WG Water Dispersible Granules. Project Number: CW05/025. Unpublished study prepared by Bayer Cropscience Gmbh. 34 p.

46817020 Waltersdorfer, A. (2005) Toxicity to the Parasitoid Wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braconidae) in the Laboratory: NNI-0001 24 WG Water Dispersible Granules. Project Number: CW05/021. Unpublished study prepared by Bayer Cropscience Gmbh. 25 p.

46817021 Fussell, S. (2002) A Rate-Response Laboratory Test to Determine the Effects of NNI-0001 SC 480 on the Parasitic Wasp, Aphidius rhopalosiphi. Project Number: BAY/02/5. Unpublished study prepared by Mambo-Tox Ltd. 26 p.

46817025 Anderson, J. (2002) Influence of NNI-0001 SC 480 on Glucose Stimulated Respiration in Soils. Project Number: AJO/233002, 2749, E/330/2277/4. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 21 p.

46817026 Anderson, J. (2002) Influence of NNI-0001 SC 480 on the Microbial Mineralization of Nitrogen in Soils. Project Number: E/337/2278/2, AJO/233102, 2750. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 17 p.

46817100 Bayer CropScience LP and Nichino America (2006) Submission of Residue and Toxicity Data in Support of the Application for Registrations of Flubendiamide, NNI-0001 480 SC and NNI-0001 24 WG and the Petition for Tolerance of Flubendiamide on Corn (Field Corn, Pop Corn, Sweet Corn, and Corn Grown for Seed), Cotton, Tobacco, Tree Fruit, Nut and Vine Crops and Vegetable Crops. Transmittal of 50 of 200 Studies.

46817200 Bayer CropScience LP and Nichino America, Inc. (2006) Submission of Toxicity, Fate, Environmental Fate, Residue, Exposure and RiskData in Support of the Application for Registration of NNI-0001 Technical, NNI-0001 480 SC, NNI-0001 24 WG and the Petition for Tolerance of Flubendiamide for Use on Corn, Cotton, Tobacco, Tree Fruit, Nut and Vine Crops and Vegetable Crops. Transmittal of 52 of 202 Studies.

46817235 Amanuma, T. (2005) Effect of NNI-0001 Administration on the Thyroid-Related Hormones and Liver Drug-Metabolizing Enzymes in Female F-344 Rats. Project Number: GA/11, 02/0162, LSRC/T05/041A. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 118 p.

46817237 Freyberger, A. (2003) NNI-0001: Studies on Interactions with Iodothyronine Deidinase Type I in Vitro. Project Number: AT00471, T2071996. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.

46817238 Takeuchi, Y. (2005) NNI-0001: One-Generation Reproductive Toxicity Study in Rats Histopathological Examination of the Eyes of Weanlings: Final Report. Project Number: IET/04/0075. Unpublished study prepared by Institute of Environmental Toxicology. 50 p.

46817239 Hojo, H. (2004) NNI-0001: One-Generation Reproductive Toxicity Study in Rats: Final Report. Project Number: IET/03/0013. Unpublished study prepared by Institute of Environmental Toxicology. 354 p.

46817242 Kuwahara, M. (2001) NNI-0001: Repeated Dose 28-Day Oral Toxicity Study in Dogs: Final Report. Project Number: IET/01/0019. Unpublished study prepared by Institute of Environmental Toxicology. 115 p.

46817248 Sabbagh, G. (2006) Aquatic Exposure Assessment for NNI-0001. Project Number: MEAMY002. Unpublished study prepared by Bayer Corp. 67 p.

46817249 Sabbagh, G. (2006) Screening Level Drinking Water Exposure Assessment for the Use . Project Number: MEAMY001. Unpublished study prepared by Bayer CropScience LP. 52 p.

46817250 Lenz, C. (2006) Aggregate Dietary Exposure to NNI-0001 and Assessment of Potential Risk. Project Number: RGAMY004. Unpublished study prepared by Bayer CropScience LP. 71 p.

46817251 Hall, T.; Sabbagh, G.; Kelly, I. (2005) Environmental Fate and Ecological Risk Assessment for NNI-0001. Project Number: EBAMP027. Unpublished study prepared by Bayer CropScience LP. 94 p.

46817252 Buckelew, L.; Larochelle, D.; Christenson, R.; et al. (2006) NNI-0001 (Flubendamide): Human Health Risk Assessment for Use on Corn, Cotton, Tobacco, Tree Nut, Vine Crops and Vegetable Crops. Project Number: G201491, M/268723/01/1. Unpublished study prepared by Bayer CropScience LP. 117 p.

47263100 Nichino America, Inc. (2007) Submission of Residue Data in Support of the Application for Registration of NNI-0001 Technical. Transmittal of 2 Studies.

47325300 Bayer CropScience (2008) Submission of Public Interest Data in Support of the Application for Registration of NNI-0001 Technical. Transmittal of 1 Study.

47325301 Nelson, J.; Speas, J.; Kelly, I.; et al. (2008) Public Interest Document Supporting the Registration of Flubendiamide (NNI-0001) to Control Commercially Important Lepidoptera Pests in Corn, Cotton, Tobacco, Leafy Vegetables and Vegetable, Tree Fruit, Nut and Vine Crops. Project Number: PID/BAY06JN23. Unpublished study prepared by ABG, Inc. 135 p.

EXHIBIT 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

JUL 24 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC) (DP# 427644) and BCS White Paper (DP# 427994)

FROM: Colwell A. Cook, Ph. D., Entomologist C.A.Cook
Biological Analysis Branch

Donald Atwood, Ph.D., Entomologist Signature for D.A.
Science Information and Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Arnet Jones, Chief Carl Chen for Arnet Jones
Biological Analysis Branch

Diann Sims, Chief Steve Jacobs for D. Sims
Science Information and Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Carmen Rodia, Risk Manager Reviewer
Richard Gebken, Risk Manager
Deborah McCall, Branch Chief
Invertebrate and Vertebrate Branch 2
Registration Division (7504 P)

Product Review Date: July 1, 2015

Summary

Flubendiamide is an insecticide which was conditionally registered in 2008. As part of their continued registration Bayer CropScience submitted a Flubendiamide Benefits Analysis document (EPA MRID No. 49533001). The registrant used a combination of a private pesticide market survey of growers, Arthropod Management Tests, trade journal articles, university

extension IPM websites, and expert opinions to support claims of the benefits of flubendiamide. In general, BEAD uses the same sources to conduct pesticide benefits assessments, and agrees with the registrant's findings. BEAD agrees with Bayer CropScience findings that flubendiamide plays a role in integrated pest management and insecticide resistance management based upon the following characteristics: specificity to Lepidopteran larvae; non-systemic but translaminar properties; and no to low impacts on beneficial arthropods. Bayer CropScience has determined that the main alternatives to flubendiamide will be synthetic pyrethroids. BEAD found that in crops such as alfalfa and soybeans, synthetic pyrethroids are the most used insecticides and growers will likely use them if flubendiamide were not available for use. But for other crops, such as almonds and peppers, growers are using other pesticides like methoxyfenozide and chlorantraniliprole, and these are the most likely replacements for flubendiamide. BEAD is unable to determine if multiple applications of the alternatives are required to control the primary target pests, as comparative product performance analyses were not conducted for this review.

Review of Bayer CropScience Benefits Analysis

Bayer CropScience (BCS) submitted a document (EPA MRID No. 49533001) to support their claim that flubendiamide is valuable both in integrated pest management (IPM) and insecticide resistance management (IRM) strategies. Flubendiamide has been registered on over 200 crops. BCS provided information on the general benefits of flubendiamide then examined 15 crops in more detail. The crops were selected either because the pounds of flubendiamide applied to the crop was relatively high, or the crop had a high percentage of acres treated with flubendiamide (Table 1). These crops also represent different EPA crop groups and therefore represent the other crops in those groups. BCS selected: soybean, almonds, pistachio, peanuts, tobacco, alfalfa, cotton, tomato, pepper, grape, watermelon, broccoli, lettuce, snap bean, and strawberry.

Table 1. Average Pounds of Flubendiamide Applied Annually in Crops Selected by BCS, and the Average Percent of Crops Treated with Flubendiamide.

Crop	Average Pounds A.I. Applied Annually (2011-2013)	Average Acres Treated (2011-2013)	Average Percent of Crop Treated (2011-2013)
Alfalfa	3,000	33,400	0.2
Almond	14,000	130,000	14
Broccoli	<100	1,700	1
Cotton	2,900	46,700	0.4
Grapes, Table	<500	3,500	4
Lettuce	1,100	34,300	13
Peanut	5,000	65,600	6
Pepper	<500	12,000	15
Pistachio	1,500	12,000	5
Snap Beans	<500	3,200	1
Soybean	59,000	960,000	1
Strawberry	<100	1,200	2
Tobacco	7,000	88,000	26
Tomato	1,300	30,000	9
Watermelon	1,000	18,000	14

BEAD Proprietary Data, 2011-2013.

Flubendiamide is in the Insecticide Resistance Action Committee's (IRAC) Mode of Action (MOA) Group 28, the diamides or ryanodine receptor modulators. In addition to flubendiamide, this group contains chlorantraniliprole and cyantraniliprole. Diamides have both nerve and muscle effects on insects and there is no known cross resistance to alternative modes of action (IRAC, 2015).

Company data provided by BCS demonstrate that flubendiamide is a unique diamide in that it is more selective to Lepidopteran larvae than chlorantraniliprole and cyantraniliprole. The labels for chlorantraniliprole and cyantraniliprole include larger pest lists than the flubendiamide label. These other pests include grasshoppers, leafhoppers, thrips, beetles, and flies, in addition to Lepidoptera.

BCS asserts that providing a pesticide in a different mode of action group is important to insecticide resistance management. This agrees with IRAC (2015) recommendations of rotating insecticides with different modes of action to manage resistance. This rotation decreases the selection pressure on pest species to reduce the likelihood of developing resistance. However, since flubendiamide is not the only diamide, it does not have a unique mode of action, so chlorantraniliprole and cyantraniliprole may be used equally for resistance management.

Non-systemic

Flubendiamide, unlike the other diamides, is not systemic in the plant. Data provided by the registrant does not find any movement of the pesticide in the xylem or phloem of the plants. However, it will move from the top of a leaf to the underside, in a process known as

translamination. Because of this translaminar property, flubendiamide does not have the residual activity of systemic insecticides, but it is more residual than pyrethroids. Information from extension entomologists and in several of the Arthropod Management Test results demonstrated that flubendiamide was effective for two to three weeks. This was longer than the pyrethroids, but shorter than the systemic chlorantraniliprole. Entomologists favor translamination over systemic insecticides (such as chlorantraniliprole and cyantraniliprole) as it reduces selection pressure on the pest insects and fits well in both IRM and IPM strategies. BEAD agrees that the translaminar characteristic is unique to flubendiamide and makes it very suitable for IRM and IPM strategies in many crops (BCS, 2015).

Specificity to Lepidopterans

BCS provided results of numerous experiments published in the Arthropod Management Tests from 2007 to 2013. The results indicated that flubendiamide was very effective at controlling various Lepidopteran larvae in their selected crops. Some of the tests were conducted on other insects, such as earwigs, which showed that chlorantraniliprole and pyrethroids reduced those populations, but flubendiamide had no effect on non-Lepidopteran arthropods.

BCS (2015) also submitted articles from trade publications, such as Southeast Farm Press and Delta Farm Press. The articles highlighted information from University researchers and extension agents, many of whom wrote letters to support that flubendiamide is very specific to the Lepidopteran pests in their crops, and is also less likely to impact non-target insects and cause secondary pest outbreaks.

BEAD concurs that these data from the Arthropod Management Test as well as the information from University entomologists support the registrant's conclusion that flubendiamide is specific and effective against Lepidopteran larval pests in the selected crops.

Protecting Beneficials

In addition to Arthropod Management Test results, BCS (2015) submitted company data on the effects of flubendiamide on several beneficial arthropods. Results indicated little to no mortality on many beneficial insects such as ladybird beetles, soldier beetles, predatory mirid bugs, predatory mites, and various parasitoid wasps. One study indicated that first instar ladybird beetles were moderately harmed, but not all studies had the same result (BCS, 2015). Several of the experts mentioned that an early field application of flubendiamide allowed for the build-up of predators and parasitoids which prevents the Lepidopteran pests from building up too high populations later in the season. This IPM strategy eliminates the potential of a second insecticide application (BCS, 2015). The use of beneficials and parasitoids to manage pest populations is an important component of IPM. BEAD agrees with BCS that flubendiamide is relatively protective of beneficial arthropods, and does play a role in IPM.

Alternative Insecticides in Selected Crops

BCS (2015) identified the most likely alternatives to flubendiamide on 15 use sites it analyzed in more detail (Table 1). Soybeans were selected b/c they represent the largest (highest) user of

flubendiamide in terms of total pounds applied annually. Other crops, like almonds, were selected because much of the crop is treated with flubendiamide. Other crops were selected because they are representative of similar crops of agronomic conditions. BEAD agreed that crops BCS selected are representative of the 200 crops for which flubendiamide is registered. BEAD analyzed the available usage data for soybean, almond, peppers, tobacco, peanuts, and alfalfa to verify the alternative analyses that BCS conducted and reached similar conclusions. BEAD did not conduct a comparative product performance analysis and is unable to quantify whether multiple applications of alternatives would be necessary to control target pests in the respective crops.

Soybeans

Lepidopteran pests are important pests of soybeans. Nearly 63 percent of soybean acres nationwide are treated annually for these pests, and as much as 75 percent of soybeans in the Southeast are treated (BCS 2015). Information provided by extension entomologists (BCS 2015) indicate that in much of the southeastern states, corn earworm and soybean looper are the primary Lepidopteran pests. The available usage data suggests that tobacco budworm and armyworm complex are also important Lepidopteran pests in soybeans in terms of acres treated (Proprietary Data, 2011-2013). Flubendiamide is used to control Lepidopteran pests on about 1 percent of U.S. soybeans; however, this use accounts for nearly 50 percent of the total amount of flubendiamide used in agriculture (Table 1). Since very little soybean acreage is treated with flubendiamide, BEAD concludes that it does not provide much benefit to soybean growers, but recognizes that this use is important to the registrant since it consists of the most pounds applied.

BCS (2015) identified that nationwide, lambda-cyhalothrin and bifenthrin (synthetic pyrethroids) are the primary insecticides in soybean acres targeting Lepidopteran pests, and that more flubendiamide is used in the Southeast soybean production area than in other areas of the country (Table 2 summarizes alternatives mode of actions). Caterpillars are more of a problem in the Southeast than in the rest of the U.S. BEAD's analysis of the available pesticide usage data determined that synthetic pyrethroids were the lead insecticides targeting Lepidopteran larvae. BEAD's analysis also shows that the majority of flubendiamide is applied to Southeast soybeans. Other insecticides used include diflubenzuron, methoxyfenozide, and chlorantraniliprole, but these are applied to fewer acres than flubendiamide. (Proprietary Data, 2011-2013).

BEAD thinks that the synthetic pyrethroids are the probable alternatives to flubendiamide in soybeans because they are currently used more, they are broader-spectrum (so will target more pest species), and are less expensive than the other chemistries. However, synthetic pyrethroids are known to cause secondary pest problems (e.g., mites) because they are broad-spectrum insecticides, and are known to kill many beneficial arthropods, thus requiring multiple insecticide applications to maintain control. In their letters of support, several extension entomologists mentioned that growers who used flubendiamide did not have to apply additional insecticides to control caterpillars later in the growing season because the predators kept the populations in check (BCS, 2015). Therefore, if flubendiamide were not available for use, soybean growers currently using flubendiamide would need to make multiple insecticide applications if they used synthetic pyrethroids to control Lepidopteran pests in soybeans.

Table 2. IRAC Mode of Actions for Insecticides Targeting Lepidoptera Identified in this Document.

Group Number	Mode of Action	Chemical Type	Example Chemical(s)
1B	Acetylcholinesterase Inhibitor	Organophosphates	Acephate
3A	Sodium Channel Modulators	Pyrethroids	Bifenthrin, Cyhalothrin, Cypermethrin
5	Nicotinic Acetylcholine Receptor Allosteric Modulators	Spinosyns	Spinetoram Spinosad
11A	Microbial Disruptors of Insect Midgut	*Bacillus thuringiensis*	*Bacillus thuringiensis*
15	Inhibitors of Chitin Biosynthesis, Type 0	Benzoylureas	Diflubenzuron
18	Ecdysone Receptor Agonists	Diacyl-hydrazines	Methoxyfenozide
22A	Voltage-dependent Sodium Channel Blockers	Indoxacarb	Indoxacarb
28	Ryanodine Receptor Modulators	Diamides	Chlorantraniliprole Cyantraniliprole Flubendiamide

Almonds

Almonds constitute the second largest user of flubendiamide in terms of pounds applied, and on average, nearly 14 percent of the crop was treated with flubendiamide annually between 2011-2013 (Table 1), indicating high benefits to flubendiamide in almonds. The main Lepidopteran pests targeted by insecticide applications are navel orangeworm and peach twig borer, about 40 percent of insecticide applications target these pests (BCS, 2015). BCS (2015) determined that methoxyfenozide, bifenthrin, and chlorantraniliprole are the top three insecticides used to control Lepidopteran pests in almonds, followed by flubendiamide (Table 2). BEAD's usage analysis had similar results, but determined that more almonds were treated with bifenthrin, then methoxyfenozide, followed by chlorantraniliprole (Proprietary Data, 2011-2013). Bifenthrin, a synthetic pyrethroid, could be the main alternative to flubendiamide in almonds. However, methoxyfenozide, an insect growth regulator, or chlorantraniliprole, another diamide, are more likely to be chosen by growers, as data suggest almond growers are selecting more IPM friendly insecticides (BCS, 2015). IRM would still be possible if rotation occurred between these chemistries. BCS (2015) provided data showing that flubendiamide is less expensive than methoxyfenozide and chlorantraniliprole, so growers choosing them may incur higher costs.

Peppers

The main Lepidopteran pests on peppers are armyworms. On average, about 47 percent of insecticide applications are used to control these pests in peppers (BCS, 2015). While less than 500 pounds of flubendiamide were applied to peppers on average between 2011 and 2013, nearly 15 percent of pepper acres were treated with flubendiamide (Table 1). Therefore, pepper

growers are finding flubendiamide to be beneficial. BCS (2015) identified the main alternatives to be spinetoram, chlorantraniliprole, methoxyfenozide, zeta-cypermethrin, and cyfluthrin (Table 2). BEAD's usage analysis identifies these same chemicals to be the primary insecticides for these pests (Proprietary Data, 2011-2013). BEAD thinks that pepper growers currently using flubendiamide are likely to select chlorantraniliprole, another diamide, to replace flubendiamide, because the data indicate pepper growers are choosing more IPM friendly insecticides, even though they are more expensive than synthetic pyrethroids (BCS, 2015; Proprietary Data, 2011-2013).

Tobacco

About 6,000 pounds of flubendiamide were applied annually to tobacco on average between 2011 and 2013, and about 26 percent of tobacco acres were treated (Table 1), indicating that flubendiamide has high benefits to tobacco growers. The primary Lepidopteran pests are tobacco budworm and tobacco hornworm. BCS identified flubendiamide as the second most used insecticide, after chlorantraniliprole, then followed by spinosyn and lambda-cyhalothrin. BEAD's usage analysis found that the top insecticides targeting these pests are acephate, *Bacillus thuringiensis*, chlorantraniliprole, flubendiamide, and spinosyn (Table 2) (Proprietary Data, 2011-2013). Growers currently using flubendiamide are choosing an IPM and IRM compatible insecticide; therefore, if flubendiamide were not available for use, BEAD thinks growers would likely choose chlorantraniliprole or spinosyn over an organophosphate or synthetic pyrethroid, which are not compatible with IPM and IRM strategies.

Peanuts

On average, over the years 2011-2013, about 5,000 pounds of flubendiamide were applied to about 6 percent of peanut acres grown (Table 1). BCS' and BEAD's usage analysis determined that the most used Lepidopteran insecticides on peanuts are diflubenzuron, bifenthrin, and lambda-cyhalothrin. BCS found that methoxyfenozide was the fourth most used insecticide for control of Lepidopteran pests (Table 2), whereas BEAD found that esfenvalerate, another synthetic pyrethroid was the fourth most used insecticide. BCS thinks that synthetic pyrethroids would likely replace flubendiamide to control Lepidopteran pests in peanuts. Since data indicate that many acres are treated with synthetic pyrethroids, BEAD agrees that peanut growers are likely to choose them to replace flubendiamide. Not only will growers likely have to make multiple insecticide applications to replace flubendiamide since synthetic pyrethroids are broad spectrum insecticides and their use can cause secondary pest problems (e.g. mites), but synthetic pyrethroids use the same mode of action, thereby limiting IRM strategies.

Alfalfa

Nearly 60 percent of insecticides applied to alfalfa target Lepidopteran pests. On average, over the years 2011-2013, about 4,000 pounds of flubendiamide were applied to less than one percent of alfalfa acres grown (Table 1). BCS (2015) found that the insecticides with the highest usage on alfalfa are lambda-cyhalothrin, cyfluthrin, z-cypermethrin, and indoxacarb (Table 2). BEAD's usage analysis had similar results but with a slightly different ranking. The most likely alternatives to flubendiamide are the synthetic pyrethroids. Synthetic pyrethroids are broad-

spectrum insecticides and tend to result in population explosions of secondary pests, since all the beneficial arthropods are killed. If current flubendiamide users switched to synthetic pyrethroids, the absence of predators and parasitoids will allow pest populations to increase, resulting in more applications of insecticides, but this would be on a very small percent of alfalfa acres.

Conclusions

While there are some differences in BCS' and BEAD's analysis of the potential alternatives to flubendiamide, they are minor. The reliance on synthetic pyrethroids reduces the ability to manage IRM by using insecticides with different modes of action. IPM strategies try to employ specific insecticides that target the pests while allowing beneficial arthropods to survive. Synthetic pyrethroids are broad spectrum insecticides and do not fit well with most IPM practices. BEAD agrees with BCS that synthetic pyrethroids are the likely alternatives to flubendiamide in alfalfa, peanuts, and soybeans; but these crops have very few acres treated with flubendiamide, and consequently little benefit to those growers. However, based on its analysis of the available usage data, BEAD thinks that growers of almonds, peppers, and tobacco that have chosen to use IPM friendly flubendiamide, are likely to continue to select IPM friendly alternatives, such as insect growth regulators (e.g., diflubenzuron, methoxyfenozide), other diamides (e.g., chlorantraniliprole, cyantraniliprole), and spinosyns (e.g., spinetoram). In addition, these crops have higher acres treated with flubendiamide indicating higher benefits.

References

BCS. 2015. Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC). EPA MRID No. 49533001.

BEAD Proprietary Data, 2011-2013.

Insecticide Resistance Action Committee. 2015. Mode of Action. Available at: http://www.irac-online.org/modes-of-action/ Accessed: June 22, 2015.

EXHIBIT 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

APR 15 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Memorandum:

SUBJECT: BEAD Public Interest Finding for Flubendiamide to Control Lepidoptera Pests on Corn, Cotton, Tobacco, Leafy Vegetables, Fruiting Vegetables, and Vine (DP 348894)

FROM: Don Atwood, Entomologist
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Arnet Jones, Chief 4/15/08
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Carmen Rodia, Environmental Protection Specialist
Insecticide Branch
Registration Division (7505P)

PRP Review: April 2, 2008

SUMMARY:

BEAD has reviewed the data submission in support of a Public Interest Finding for the proposed uses of flubendiamide on corn (sweet and field), cotton, tobacco, tree fruit, nuts, vegetables (leafy and fruiting), and vine crops and has concluded that registration of this new active ingredient would be in the public interest. However, it should be noted that no efficacy data were submitted for vine crops and BEAD can therefore only assume similar levels of control as noted for the other crops. As a unique new chemistry with a novel mode of action, flubendiamide should play an important role in resistance management and therefore prolong the effective life of currently registered insecticides used to control lepidopterous pests of the aforementioned crops.

BACKGROUND:

Flubendiamide is a new insecticide which specifically targets immature lepidoptera pests. It represents a new class of insecticide, pthalmic acid diamides. Flubendiamide works by activating the ryanodine receptor which regulates muscle and nerve activities by modifying levels of calcium in these cells. Ryanodine receptor activation results in rapid cessation of feeding followed by death and also exhibits residual larvicidal activity. Flubendiamide exhibits no cross-resistance with conventional insecticides and should therefore provide a new tool for management of lepidopteran insecticide resistance.

The registrant (Bayer) is proposing labeling to use flubendiamide on corn, cotton, tobacco, leafy vegetables, fruiting vegetables, and vine crops to control lepidopterous pests. Pests for which flubendiamide is recommended are listed in Table 1.

Table 1. Recommended lepidopterous pests targeted for control with flubendiamide.

Crop	**Lepidopterous Pest**
Corn (field, pop, sweet, and seed)	Armyworms (beet, fall, yellowstriped, and true), black cutworm, corn earworm, corn borer (European and Southwestern), Western bean cutworm
Cotton	Armyworms (beet, fall, yellowstiped, and true), cotton leafworm, looper (cabbage and soybean), and saltmarsh caterpillar
Tobacco	Tobacco budworm, tobacco hornworm
Pome Fruit (apple, crabapple, loquat, mayhaw, pear, oriental pear, and quince)	Codling moth, eyespotted bud moth, fruitworm (green and loconobia), leafroller (obliquebanded, pandemic, redbanded, and variegated), lesser appleworm
Stone Fruit (apricot, sweet cherry, tart cherry, nectarine, peach, Chickasaw plum, damson plum, and Japanese plum, plumcot, and prune)	Green fruitworm, learollers (oblique banded, pandemic, redbanded, and variegated)
Tree nut (almond, beech nut, brazil nut, cashew, chestnut, chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachio, walnut (black and English)	Fall webworm, hickory shuckworm, naval orangeworm, peach twig borer, pecan nut casebearer, walnut caterpillar
Grape (American bunch grape, muscadine grape, and vinifera grape	Cutworm, grape leaffolder, grape leaf skelotonizer, omnivorous leafroller, orange tortrix

The registrant's claims to support a Public Interest Finding fall into three categories: comparative efficacy, resistance management and integrated pest management programs. Bayer's chief arguments center on flubendiamide being a new chemistry with wide efficacy against

Lepidoptera pests which makes it a valuable tool for inclusion in an integrated pest management program for the management of insect resistance. This implies that flubendiamide is not only effective as a stand-alone insecticide but will also extend the effective life of other insecticides on the submitted crops.

COMPARATIVE EFFICACY:

The registrant claims that flubendiamide is efficacious against a wide range of lepidopterous pests and is equivalent in efficacy to the industry standards for control of the target pests. Tables 2–9 provide a synopsis of comparative efficacy studies submitted by the registrant in support of the Public Interest Finding. While the registrant submitted efficacy data over a wide range of flubendiamide application rates, the following table only considers the most effective flubendiamide application rate. Overall, BEAD found that flubendiamide does provide superior or equivalent control to the crop specific standard insecticides across all registrant supported crops. However, comparative efficacy data were not provided for grapes, therefore BEAD assumes similar efficacy as were noted for the other crops. In addition, the registrant submission also indicates that flubendiamide exhibits good residual activity. This efficacy data indicate that flubendiamide could play an important role as a rotational insecticide to prevent or lessen insecticide resistance in the target pest populations.

Table 2. Comparative Efficacy (% control) of Flubendiamide and Alternative Insecticides on corn.

Crop	Pest	Days after application	Flubendiamide	Spinosad	Best Pyrethroid
corn	Fall armyworm	2-8	80%	72%	70%
		10-22	88%	44%	62%
	Black cutworm	1-14	98%	78%	84%
	Corn borer	6-26	98%		88%
	Corn earworm	2-25	73%	73%	66%

Table 3. Comparative Efficacy (% reduction in damage) of Flubendiamide and Alternative Insecticides on cotton.

Crop	Pest	Flubendiamide	Best Pyrethroid
Cotton	Bollworm/budworm	80%	82%
	Beet armworm	81%	81%
	Soybean looper	62%	62%
	Cabbage looper	68%	68%
	Spodotera sp.	100%	n/a

Table 4. Comparative Efficacy (% control) of Flubendiamide and Alternative Insecticides on tobacco.

Crop	Pest	Days after application	Flubendiamide	Best Pyrethroid
Tobacco	Tobacco buworm	4	81%	61%
		11	94%	61%
		46	100%	59%
	Tobacco hornworm	3	90%	83%
		7	86&	63%
		14	89%	73%

Table 5. Comparative Efficacy (% control) of Flubendiamide and Alternative Insecticides on apple.

Crop	Pest	Flubendiamide	Spinosad	Azinphos methyl	methoxyfenozide	Standard[a]
Apple	Oblique band leafroller	92%	70%	88%	82%	
	Codling moth (eastern)	80%				92%
	Codling moth (western)	62%				82%

[a] Standards include: Guthion Calypso and Programs with Actar, Assail, Calypso, Guthion, Intrepid, Rimon, Spintor

Table 6. Comparative Efficacy (% control) of Flubendiamide and Alternative Insecticides on almond and pistachio.

Crop	Pest	Fluben diamid e	Azinphos methyl	Chlorpyrifos
Almond and Pistachio	Navel orangeworm	80%	78%	66%

Table 7. Comparative Efficacy (% control) of Flubendiamide and Alternative Insecticides on brassica.

Crop	Pest	Days after application	Flubendiamide	Spinosad	Indoxicarb	Methoxyfenozide	Best Pyrethroid
Brassica	Diamondback moth	5-8	98%	98%	82%	100%	76%
		12-16	94%	94%			62%
	Imported cabbageworm	5-8	90%	90%	100%	86%	94%
		12-16	92%	80%	30%	84%	34%
	Cabbage looper	5-8	90%	90%	90%	100%	96%
		12-16	92%	82%	74%	88%	100%
	Beet armyworm		100%	100%			50%

Table 8. Comparative Efficacy (% reduction in damage) of Flubendiamide and Alternative Insecticides on tomato.

Crop	Pest	Flubendiamide	Spinosad	Indoxicarb	Emamectin Benzoate or (methoxyfenozide)	Methomyl	Best Pyrethroid
Tomato	Tomato fruitworm	94%	64%	81%	76%	14%	70%
	Beet armyworm	95%	83%	n/a	(93%)	91%	68%

Table 9. Comparative Efficacy (% damaged fruit) of Flubendiamide and Alternative Insecticides on pepper.

Crop	Pest	Flubendiamide	Spinosad	Best Pyrethroid
Pepper	European corn borer	13%	32%	14%

RESISTANCE MANAGEMENT:

According to the registrant, flubendiamide is a novel insecticide from the new chemical class of pthalic acid diamides. Flubendiamide has a mode of action different from currently registered insecticides and exhibits no cross resistance with the standard insecticides currently used to control lepidopterous pests on the proposed target crops (See Tables 2 – 9 for standard insecticides). The availability of a new insecticide with a unique mode of action will be useful to

growers for resistance management purposes particularly for pests known for rapid development of insecticide resistance (e.g. Diamondback moth on brassica). BEAD believes that flubendiamide could play a substantial role in managing insect pesticide resistance.

INTEGRATED PEST MANAGEMENT PROGRAMS:

The registrant submission shows that flubendiamide is a highly selective insecticide. Flubendiamide exhibits low toxicity to beneficial insects (predators and parasites) and honey bees. Flubendiamide has a better toxicity profile than most insecticides currently targeted to control lepidopterous pests in the target crops (e.g. spinosad, indoxicab, emamectin benzoate, methomyl and the synthetic pyrethroids). In addition, due to the selective nature of this insecticide, flubendiamide should not result in the flaring of secondary pest populations. Weighing these factors, BEAD believes that flubendiamide can be a valuable tool in development of integrated pest management programs.

CONCLUSIONS:

As flubendiamide is a novel chemistry, BEAD believes that it can be an important tool as a rotational insecticide to limit or prevent resistance development. As such, flubendiamide can also be expected to extend the useful life of other currently registered insecticides. BEAD's analysis of the submitted material indicates that flubendiamide provides Lepidoptera control equivalent or superior to the insecticides currently being used for pest control in the evaluated crops. Furthermore, the low toxicity to insect predators and honey bees should make flubendiamide an important component in integrated pest management programs.

EXHIBIT 9

ENVIRONMENTAL PROTECTION AGENCY

[OPP-38509; FRL-3846-4]

Existing Stocks of Pesticide Products; Statement of Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; statement of policy.

SUMMARY: This Statement summarizes the policies that will generally guide EPA in making individual decisions concerning whether, and under what conditions, the Agency will permit the continued sale, distribution, and use of existing stocks of pesticide products whose registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are amended, cancelled, or suspended. Although most of the policies reflected in this Statement have already been applied by the Agency on a case-by-case basis, EPA now intends to formalize these policies and is soliciting comments from interested persons. If, after reviewing any comments, EPA determines that changes to this Statement are warranted, the Agency will issue a revised Statement of Policy in the Federal Register.

DATES: The policies announced in this Statement are currently in effect. The Agency will review any comments on these policies received by the Agency on or before August 26, 1991. After reviewing such comments, the Agency may issue a revised Statement of Policy.

ADDRESSES: By mail, submit comments to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. In person, deliver comments to: Rm. 246, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Martha Lamont, Special Review and Reregistration Division (H7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location and telephone number: Special Review Branch, rm. 31L3, Crystal Station 1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8033.

SUPPLEMENTARY INFORMATION: The general statement of policy on existing stocks of pesticide products whose registrations under FIFRA are amended, cancelled, or suspended follows.

GENERAL STATEMENT OF POLICY

Table of Contents

I. Application

This Statement of Policy applies to determinations the Agency will make concerning existing stocks of pesticide products whose registrations have been amended, cancelled, or suspended pursuant to sections 3, 4, or 6 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA). This Statement also applies to existing stocks of products sold or distributed under a supplemental distributor agreement. It is the responsibility of the registrant to notify such distributors of any applicable existing stock provisions.

For purposes of this Statement, existing stocks are defined as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the action.

This Statement establishes general principles which the Agency generally will apply in determining whether and under what conditions to allow the sale and use of existing stocks. In general, if there are significant risk concerns associated with a cancelled pesticide, the Agency will make a case-by-case determination as to whether to allow the continued sale or use of existing stocks of the pesticide. The Agency will not allow continued sale, distribution, or use of such a pesticide unless the benefits associated with such sale, distribution, or use exceed the risks.

Where there are no significant risk concerns associated with the cancellation of a pesticide, the Agency will generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant. A registrant will generally be allowed to continue to sell existing stocks for 1 year after the date cancellation is requested, or 1 year after the date the registrant has ceased to comply with the responsibilities that are placed upon registrants, whichever date is sooner.

This policy will be implemented on the date of publication of this notice. Because registrants were unaware of the policies contained in this notice, the Agency has decided to provide a 6-month "grace period" before certain aspects of this Policy become fully effective. Specifically, in cases where the Agency has not identified any significant risk concerns, the Agency will allow registrants of products cancelled on or before December 26, 1991 to continue to sell or distribute existing stocks at least until December 26, 1991, notwithstanding the fact that application of the policies set forth in this statement might result in a shorter existing stocks period or an outright prohibition against the sale or distribution by the registrant of any existing stocks.

II. Applicable Statutory Provisions

Under FIFRA section 3, a pesticide product must be registered with EPA before it may be sold or distributed in commerce. EPA may not register a pesticide unless, among other things, it first determines that the product and its use will not cause unreasonable adverse effects on the environment. Once a pesticide product is registered, FIFRA provides a number of different mechanisms for changing the status of a registration. These mechanisms can be grouped into three categories: Changes requested by a registrant; changes imposed by EPA for failure to comply with various obligations imposed upon registrants; and changes imposed by EPA because of a determination by the Agency that use of the pesticide product results in unreasonable adverse effects to man or the environment.

A registrant may request at any time, for any reason, to voluntarily cancel a registration (FIFRA section 6(f)) or to amend the terms and conditions of the registration, most frequently by amending the pesticide product label (FIFRA sections 3(f) and 6(f)). Voluntary amendments to registration can include, among other things, adding or deleting uses, increasing or decreasing application rates, changing the formulation of a pesticide, or changing the label language (such as changing directions for use, warning statements, etc.).

Other changes in registration status are the result of Agency action because of the failure of a registrant to fulfill

certain responsibilities adequately. Each registrant has a continuing obligation to ensure that its registered products comply with the standards for registration. Note that the the term "registration" includes reregistration (see FIFRA section 2(z)). As part of this obligation, a registrant may be required to submit to EPA additional information which the Agency considers necessary to support continued registration. See FIFRA section 3(c)(2)(B). Failure to submit information required by the Agency pursuant to section 3(c)(2)(B) may result in the suspension of a registration until the information is provided.

In addition, registrants of pesticide products containing active ingredients first registered before November 1, 1984, must demonstrate, under FIFRA section 4, that their products meet the current standards for registration and should be reregistered. Failure to comply with certain provisions of section 4 can result in the cancellation or suspension of pesticide registrations. For example, registrations may be cancelled if a registrant fails to pay fees mandated by section 4(i) or fails to provide EPA with certain information during the early stages of the reregistration process (see FIFRA sections 4(d)(5), 4(e)(3) and 4(i)(7)(C)). Failure by registrants to supply other information required during reregistration may result in the suspension of registrations until the required information is provided to EPA (see, e.g., FIFRA sections 4(d)(6) and 4(f)(3)).

If a registration is a conditional registration, the Agency may also take action to cancel the registration pursuant to FIFRA section 6(e) if the registrant fails to meet any of the conditions imposed upon the product at the time of registration.

Finally, changes in the status of a registration may be mandated by EPA to assure that the product or its use does not result in unreasonable adverse effects on the environment. The Agency may reevaluate a pesticide at any time. If EPA determines that a pesticide product (without change in its terms of registration) no longer meets the standard for registration, the Agency may propose cancellation of the product under FIFRA section 6(b) or propose to classify the product for restricted use. Such Agency proposals may at times allow changes in the terms of registration (such as the deletion of particular uses or addition of specified protective measures) as alternatives to cancellation or change in classification. If the Agency determines that use may result not only in unreasonable adverse effects but in an "imminent hazard," EPA may initiate action to suspend the pesticide registration during the pendency of cancellation proceedings (FIFRA section 6(c)).

It is a violation of FIFRA section 12(a)(1)(A) to sell or distribute any pesticide that has been cancelled or suspended, except to the extent that sale or distribution is authorized by EPA. It is also a violation of FIFRA section 12(a)(2)(J) and (K) to violate the terms of a suspension or cancellation order. Thus, unless expressly permitted by the Agency, distribution or sale of existing stocks of cancelled or suspended pesticides is unlawful. Use of such existing stocks, on the other hand, is not unlawful unless specifically prohibited by the Agency in a cancellation or suspension order.

If a pesticide is cancelled under section 6(b) or section 6(e), FIFRA provides in section 6(a)(1) and (e) that the Administrator may permit the continued sale and use of existing stocks of the cancelled pesticide "to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of (FIFRA) and will not have unreasonable adverse effects on the environment." FIFRA section 2(bb) defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, in determining whether to permit distribution, sale, or use of existing stocks of pesticides cancelled under sections 6(b) or 6(e), EPA must apply the same risk/benefit considerations that are applicable to other Agency actions under FIFRA (except that such considerations would be limited to the context of allowing distribution, sale, or use of existing stocks).

FIFRA does not specify a standard for the Agency to apply in determining whether to allow the distribution, sale, and use of existing stocks of pesticide products cancelled voluntarily pursuant to FIFRA section 6(f) or for failure of the registrant to comply with the requirements of section 4. The Agency has decided to make existing stocks determinations with respect to products cancelled under sections 4 and 6(f) based upon whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. In determining whether such distribution, sale, or use would be consistent with the purposes of FIFRA, the Agency will first determine whether there are any significant risk concerns associated with the cancelled product. If there are such risk concerns, the Agency will generally require a risk/benefit analysis before allowing the sale, distribution, or use of existing stocks. If there are no significant risk concerns, the Agency will generally not require a risk/benefit analysis before making an existing stocks determination.

In the case of suspension of pesticide registrations for failure to submit data, FIFRA has explicitly provided the Agency with broad discretion in the area of existing stocks. Section 3(c)(2)(B) provides that the Administrator may make such provisions for the sale and use of existing stocks of a pesticide whose registration is suspended for failure to submit data as EPA "deems appropriate."

As to existing stocks of pesticides that have had their registrations amended, the Agency generally considers sale or distribution of a pesticide bearing a label or containing a formula other than the label or formula currently approved by the Agency to be a violation of FIFRA section 12(a)(1)(B), (C), or (E). The Agency has, however, established regulations (at 40 CFR 152.130) which provide for the continued sale of a product bearing previously approved labeling for certain periods of time depending upon the nature of the amendment. These regulations do not apply to changes in composition. The Agency will treat sale and distribution of products containing a previously accepted formula that is different from the currently accepted formula in the manner described in unit III.C (Amendments of Registration) of this Policy Statement.

III. General Policies Applicable to All Existing Stocks

This Policy Statement contains the general policies that the Agency intends to apply in making determinations concerning the sale or use of existing stocks of pesticides, as defined in unit I (Application) of this statement. In any individual case, the Agency will consider additional factors if appropriate. To the extent that a particular action or cancellation can fit into more than one category discussed below, EPA will generally select the most restrictive existing stocks provision that may apply. Whenever an existing stocks provision is issued, the Agency reserves the right to amend that provision on its own initiative or at the request of any interested person (either by allowing additional time to sell or use stocks or by placing additional restrictions on the sale or use of existing

stocks) if later circumstances warrant. Finally, unless an existing stocks provision stipulates otherwise, any sale or use of existing stocks must be in accordance with the previously approved label and labeling on, or accompanying, the product.

A. Cancelled Pesticides

In determining what existing stocks provision is appropriate with respect to a pesticide whose registration has been cancelled, the Agency generally will base its determination on the total circumstances affecting the cancelled registration. The actual mechanism triggering cancellation will not always be the controlling factor. Instead, the Agency generally will focus on three factors: (1) Whether there are significant potential risks which raise a question as to whether the use of the cancelled pesticide results in unreasonable adverse effects on man or the environment (this category consists primarily of cancellations where the registration is the subject of a notice of intent to cancel issued pursuant to section 6(b) or a special review initiated pursuant to 40 CFR part 154); (2) whether the registrant of the cancelled pesticide has failed to meet an obligation of registration (such as payment of fees under section 4, or submission of data required under section 3(c)(2)(B), 3(c)(7), or (4); and (3) whether the Agency has taken some regulatory position with respect to the cancelled registration (such as issuance of a Registration Standard, Label Improvement Program, or a document describing the reregistration status of a pesticide or active ingredient). Consideration of these factors in a particular case may suggest differing provisions for the sale, distribution, or use of existing stocks. In such situations, the Agency generally will apply the most restrictive existing stocks provision to the cancelled product.

1. *Cancellations where the Agency has identified particular risk concerns.* Whenever a pesticide registration is cancelled, the Agency will determine whether there are significant potential risk concerns associated with the use of the pesticide. If there are such concerns, the Agency generally will make a case-by-case determination as to whether to allow continued distribution, sale, or use of existing stocks of the cancelled pesticide. This likely will be the case whether a product is cancelled by Agency mandate after issuance of a risk-based notice of intent to cancel, whether the product is cancelled because of the registrant's failure to comply with the reregistration requirements of section 4, or whether the cancellation was requested voluntarily by the registrant.

In most cases, the Agency will not permit continued distribution, sale, or use of existing stocks of a cancelled pesticide raising risk concerns unless it can be demonstrated that the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks. A risk/benefit analysis for existing stocks purposes is somewhat different from the analysis that is performed by the Agency in determining whether or not to cancel a registration. In making existing stocks determinations, the Agency may consider any or all of the following criteria, to the extent that information is provided or available:

a. The quantity of existing stocks at each level of the market (i.e., in possession of registrants, distributors, retailers, end-users, etc.)

b. The risks resulting from the use of such stocks. The examination of risk may take into account the limited nature of use of existing stocks where relevant (such as where limited use might result in a level of exposure that may not result in much risk). In many cases, however, it may turn out that the risks posed by use of existing stocks will be similar or identical to the risks posed by continued registration (such as, for example, where the risk is primarily an acute risk from single exposure). In assessing the risks posed by use of existing stocks, the Agency will, to the extent possible, also consider the risks posed by likely alternatives (if any).

c. The benefits resulting from the use of such stocks. In considering the benefits of existing stocks, the Agency may consider the short-term problems (if any) in switching to alternatives, including the length of time before which such alternatives could be available to retailers and users and any hardships that might be presented to users before alternatives are available. The consideration of benefits may also include (insofar as it affects existing stocks) the type of analysis of benefits that the Agency performs in its other risk/benefit analyses (i.e., whether alternatives are available, how any such alternatives compare in terms of cost and efficacy, and what the economic effects to the user will be if the cancelled product is unavailable).

d. The dollar amount users and others have already spent on existing stocks (which would be lost if distribution, sale, or use were not permitted).

e. The risks and costs of disposal or alternative disposition of the pesticide if distribution, sale, or use are not permitted. The Agency may assess whether existing stocks could be used for other purposes. If disposal appears likely, the Agency may consider relevant aspects of disposal, including the nature, feasibility, and cost of proper disposal of the cancelled product.

f. The practicality of implementing restrictions on distribution, sale, or use of existing stocks. For instance, it may be that in some circumstances the Agency would allow continued use of a product because the product could not, as a practical matter, be retrieved.

In addition to the factors listed above, the Agency may consider any other information relevant to either the risks posed by, or the benefits resulting from, the sale and use of existing stocks.

In performing a risk/benefit analysis the Agency will consider all information and/or comments from registrants and interested persons regarding existing stocks that are received in response to public documents that the Agency issues in the course of its regulatory process. For example, where an active ingredient is in special review, the Agency will often issue a Preliminary Determination (position document (PD) 2/3) and request public comment on all proposed regulatory actions. Where a registrant's request for voluntary cancellation is received prior to initiation of special review, but while one is under consideration, the Agency will publish a notice in the **Federal Register** acknowledging receipt of the request and may solicit public comments regarding existing stocks provisions.

If registrants or others indicate that there is an interest in the continued sale or use of existing stocks of cancelled pesticides raising risk concerns, and if information is provided to the Agency to support such distribution, sale, or use, the Agency will generally conduct an analysis of the risks and benefits of the distribution, sale, and use of existing stocks. If information is not provided to the Agency or no interest in continued sale, distribution, or use is expressed to the Agency, the Agency will generally not conduct a risk/benefit analysis and will not permit any sale, distribution, or use of existing stocks.

While a risk/benefit analysis will be an important factor in the Agency's determination of whether or not to allow distribution, sale, and use of existing stocks of cancelled pesticides raising risk concerns, the Agency must also determine that further distribution, sale, or use would be consistent with the purposes of FIFRA. There may be unusual circumstances where the Agency will place restrictions on the distribution, sale, and use of existing

stocks beyond those limits otherwise identified in a risk/benefit analysis (e.g., to prevent stockpiling by distributors and users).

In addition, in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of the Act, the Agency will generally look at the circumstances surrounding the cancellation. If a cancellation is the result of a final Agency action after a special review and a hearing pursuant to section 6(b), the Agency is unlikely to allow continued sale or distribution (and quite possibly, use) of the cancelled pesticide. In such circumstances, registrants, other distributors, and users of the pesticide have had ample notice of the Agency's intentions and sufficient time to take appropriate steps accordingly (such as to procure alternatives, not stockpile large quantities of the pesticide involved, use up stocks already on hand, etc.). On the other hand, where a voluntary cancellation occurs well before the Agency could take final action (i.e., prior to the completion of a special review or in lieu of a hearing under section 6(b)), the Agency may take into consideration the shorter period of notice sellers and users may have had before cancellation, the degree to which the registrant's actions accelerated the removal of the pesticide from the market, and whether the cancellation would have occurred at all without an existing stocks provision.

In a special review situation, the Agency will publish its final determination on whether to allow any sale, distribution, or use of existing stocks of cancelled pesticides, and if so, what conditions to place on such sale, distribution, or use, as part of the Final Determination (PD 4) and any other documents the Agency may issue either with or subsequent to the issuance of the PD 4 (such as notices of intent to cancel, cancellation orders, etc.). If a chemical raising a risk concern is cancelled without issuance of a Notice of Final Determination at the conclusion of a special review, the Agency will include a final existing stocks determination in a cancellation order. Existing stocks determinations contained in cancellation orders will be enforced under section 12(a)(2)(K) or 12(a)(1)(A) of FIFRA.

The Agency may allow the continued sale, distribution, and use of existing stocks of a voluntarily cancelled product raising risk concerns without performing a risk/benefit analysis if similar products with substantial share of the market remain on the market. For example, if a registration raising risk concerns is cancelled voluntarily, the Agency may examine whether the cancelled registration comprises a significant share of the market for the particular active ingredient and use pattern, and the circumstances surrounding the cancellation. If the cancelled registration does not comprise a significant share of the market, a prohibition on existing stocks would not be likely to significantly reduce environmental risks, because similar products would continue to be sold and used. Further, the Agency believes that it makes sense to encourage the early, voluntary cancellation of registrations when risk concerns arise.

If such an early cancellation is truly voluntary (i.e., the registration is not facing imminent cancellation or suspension), the Agency may allow the registrant to sell and distribute existing stocks for 1 year without performing a detailed risk/benefit analysis, and may allow other persons to distribute, sell, and use existing stocks until the stocks are exhausted. The Agency does not believe it should penalize registrants, distributors, or users in cases where a registrant voluntarily cancels a registration before other registrants are compelled to do so. Moreover, it is unlikely that a detailed risk/benefit analysis would yield a different result; so long as similar registrations comprising a predominant share of the market remain, it is unlikely that distribution, sale, or use of existing stocks of a relatively small volume of cancelled product would significantly (if at all) increase the risk of any unreasonable adverse effect on the environment.

On the other hand, if registrations constituting a dominant share of the market are cancelled, and the Agency does not believe that the remaining registrants can fill the previous demand for the product, the Agency will generally not allow continued sale, distribution, or use of existing stocks unless a risk/benefit analysis supporting such sale, distribution, or use is performed.

In cases where the Agency allows continued sale and use of existing stocks of cancelled products raising risk concerns because of the continuing nature of other registrations, it should be understood that the existing stocks allowance may be amended if the conditions concerning the registrations of the remaining products change. (The Agency in all cases reserves the right to amend existing stocks provisions where appropriate.) If other registrations are cancelled or amended during an existing stocks period for a voluntarily cancelled product, and the Agency establishes restrictions on existing stocks of these other registrations or requires relabeling of product made prior to the amendment, the Agency will likely impose similar restrictions on the existing stocks of the earlier voluntarily cancelled registration.

2. *Cancellations where a registrant has failed to comply with an obligation of registration.* This category consists of cancellations where the Agency does not have significant risk concerns with respect to the cancelled pesticide, but where the registrant has failed to respond appropriately to an obligation of registration. In these situations, the Agency has no particular reason to believe that continued distribution, sale, or use of the cancelled product would result in unreasonable adverse effects on the environment.

If a cancellation is not triggered by section 6(b) or 6(e) of FIFRA, the Agency is not required to perform a risk/benefit analysis before determining whether to allow continued sale, distribution, or use of existing stocks. Unless there are significant risk concerns associated with the cancelled pesticide, the Agency generally does not intend to perform such an analysis. Even where a cancellation is triggered by section 6(b) or 6(e), the Agency generally intends to make existing stocks decisions for cancelled products without performing a detailed risk/benefit analysis if there are no significant risk concerns associated with the cancelled pesticide. EPA believes it would be a poor use of resources to perform such an analysis when the Agency is not aware of any risk/benefit considerations that would serve as a basis for cancelling a registration. The Agency believes it highly unlikely that any analysis of risks and benefits of products not raising significant risk concerns would result in prohibition of distribution, sale, or use of existing stocks.

EPA does, however, believe that where registrants of cancelled products have failed to comply with requirements of registration, the nature of noncompliance with the particular obligation involved should be taken into account in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. Since such noncompliance does not itself raise concerns of unreasonable adverse effects on the environment, EPA will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may

place some restrictions on sale or use if inventories are not exhausted in a reasonable period of time). In the case of the noncompliant registrant, however, EPA will generally apply the policies set forth below in determining whether to allow continued sale and distribution. Those policies would generally prohibit a registrant from selling or distributing existing stocks more than 1 year from the date the registrant first failed to comply with an obligation of registration.

In any given case, multiple existing stocks dates might apply if a registrant has failed to comply with more than one obligation of registration. In such circumstances, the most restrictive date will generally apply, regardless of the triggering mechanism for cancellation. For example, if a registrant of a cancelled product failed to pay a maintenance fee due on March 1, 1990, and a reregistration fee due on June 1, 1990, the registrant would likely not be allowed to sell or distribute any existing stocks of the product after March 1, 1991 (regardless of whether the product was actually cancelled for failure to pay maintenance fees or reregistration fees).

a. *Failure to pay maintenance fees.* FIFRA section 4(i)(5) requires all registrants to pay annually by March 1st certain maintenance fees for registrations. Failure to pay such fees may result in the cancellation of a registration by order without a hearing (although the cancellation itself does not become effective until the Agency issues the cancellation order). If a maintenance fee is not paid for any given year, the Agency will generally not allow a registrant to continue to sell or distribute existing stock of a cancelled product for more than 1 year after the date when payment to support the cancelled registration was due, regardless of when the actual cancellation occurs. For example, if a registrant fails to pay a maintenance fee due March 1, 1991, to support a particular registration, and the registration is later cancelled, the Agency will generally not allow that registrant to sell or distribute existing stocks of the pesticide after March 1, 1992.

b. *Failure to pay reregistration fees.* FIFRA section 4(i) also requires some registrants to pay a reregistration fee (either in one or two deposits). This fee is to be apportioned among the applicable registrants on the basis of market share information that registrants are required to submit to the Agency. Failure to submit market share information or to pay an appropriate fee can lead to cancellation of a registration by order without a hearing (FIFRA section 4(i)(7)(C)). If a registrant fails to pay the appropriate reregistration fee or submit the required market share information, and an applicable product is later cancelled, a registrant will generally not be allowed to sell or distribute existing stocks of the cancelled product more than 1 year after the date the market share data or fee were due.

c. *Failure to file information during reregistration.* FIFRA section 4 establishes a five-phased process for reregistration activities. If a registrant elects to pursue reregistration, a registrant may have to commit to supply, and then supply, information to the Agency during Phases 2, 3, 4, and 5 (sections 4(d), (e), (f), and (g)). Failure to provide appropriate commitments or information can result in suspension or cancellation of a registration. If a registrant fails to comply fully with any particular phase of reregistration, and an affected product is later cancelled, the Agency will generally not allow a registrant to sell or distribute existing stocks of the cancelled product more than 1 year after the date that a registrant commitment for that particular product was due. For example, if an initial Phase 3 response is due from a registrant on July 24, 1991, the registrant fails to submit an adequate response, and the product is later cancelled, the Agency will generally not allow the registrant to sell existing stocks of the product after July 24, 1992.

Registrants will not be penalized for voluntarily cancelling a product at the beginning of any particular phase of reregistration (i.e., a registrant who cancels as of the commitment date will have a full year from the commitment date to sell or distribute existing stocks). Noncompliance in any phase, however, will generally be treated as if the registrant had requested voluntary cancellation at the beginning of the phase.

Agency policy with respect to existing stocks of suspended products that failed to comply with the requirements of reregistration are discussed later in this document.

d. *Failure to comply with the terms of a conditional registration.* FIFRA section 3(c)(7) allows the Agency to issue registrations before all applicable supporting data are provided. Such registrations, however, are conditional upon submission of the missing data in a timely manner (and upon compliance with any other conditions contained in the registration at the time of issuance). Failure to comply with the terms of a conditional registration can lead to issuance of a notice of intent to cancel under section 6(e).

Where a conditional registration is cancelled (and the Agency has not identified significant risk concerns), the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant. For purposes of this analysis, conditions of registration can be categorized as "general" conditions or "specific" conditions. A general condition, frequently applied to conditional registrations issued pursuant to FIFRA section 3(c)(7)(A) (i.e., registrations issued to products that are identical or substantially similar in chemical composition and use to one or more existing registered products), requires a registrant to submit required data when all other registrants of the similar product are required to do so. Such a general condition neither establishes specific data requirements nor specific dates; the condition is generally triggered by issuance of a data call-in notice. On the other hand, some conditional registrations, particularly those issued pursuant to FIFRA section 3(c)(7)(B) and (C) (i.e., conditional registrations of products containing new chemicals or bearing significant new uses), contain conditions requiring the submission of specified studies or information by specified dates. Where data requirements and submission dates are specifically identified in the conditional registration, such requirements are considered "specific" conditions.

The Agency will treat the failure to comply with a general condition of a conditional registration in the same manner as a failure by a registrant to comply with the terms of any other data call-in. If a registrant of a conditional registration with a general condition to submit data upon request does not thereafter submit data after issuance of a data call-in, and the registration is cancelled for any reason, the registrant would generally be allowed to continue to sell or distribute existing stocks for 1 year after either the day the 90-day response to the data call-in was due or the date at which the registrant ceased to remain in compliance with the terms of the data call-in, whichever date is later. (See unit III.A.3 below).

On the other hand, if a registrant of a conditional registration fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any sale and use of existing stocks if the registration is cancelled. Accordingly, the Agency does

not anticipate allowing a registrant to sell or distribute existing stocks of cancelled products that were conditionally registered if the registrant fails to demonstrate compliance with any specific requirements set forth in the conditional registration.

3. *Cancellation of products while subject to data call-in notices under section 3(c)(2)(B).* Section 3(c)(2)(B) allows the Agency to require data from registrants. Registrants are required to make an initial response to data call-in notices in 90 days, and thereafter to submit the required data in accordance with the schedule established by the Agency. Failure to respond appropriately can result in the suspension of any registration subject to the data call-in.

Similar to reregistration, data call-in notices require a commitment from a registrant to supply data, and the timely submission of data, to maintain an active registration. Accordingly, the Agency will generally not allow registrants to sell existing stocks of cancelled products more than 1 year after the date a 90-day response to a data call-in notice is due unless the registrant remains in compliance with the terms of the notice. For example, if a registrant commits to submit a 3-year study and the product registration is thereafter cancelled upon request by the registrant pursuant to section 6(f) 9 months after the 90-day response date, sale and distribution of existing stocks by the registrant will be permitted for no more than 3 months (1 year from the 90-day response date). However, if a product subject to a data call-in is cancelled and the registrant can demonstrate full compliance with the requirements of the data call-in up to a certain date, the Agency will likely allow the registrant to continue to sell and distribute existing stocks for 1 year from the date that compliance ended. For example, if the registrant had contracted with a lab to perform a 3-year study, the lab had commenced work, and the registrant instructed the lab to cease work 6 months later, the registrant would generally be allowed to sell and distribute existing stocks of cancelled products for 1 year from the date the lab was asked to cease work on the required study. The Agency will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may place restrictions if such stocks are not exhausted in a reasonable time).

The preceding discussion assumes that data generated under the data call-in have not disclosed significant potential risks associated with the product. Registrants should be advised that voluntary cancellation of a product during a data call-in response period does not excuse the registrant from compliance with the requirements of FIFRA section 6(a)(2) to report to the Administrator any information regarding unreasonable adverse effects on the environment.

4. *Cancellation of registrations subject to reregistration requirements and label improvement programs.* In the case of a registration subject to a Label Improvement Program (LIP) or determination resulting from decisions made during reregistration, the Agency has determined that the registration of the product may continue, provided that certain changes are made to the terms of registration (generally involving the product label). If a product subject to an LIP or reregistration requirement is cancelled, whether voluntarily or upon action by the Agency (e.g., for failure to pay fees), the Agency will generally not allow a registrant or any other person to sell or distribute existing stocks unless such sale or distribution is consistent with the terms of the LIP or reregistration determination.

For example, if an LIP states that registrants may not sell or distribute a product after January 1, 1992, without a certain label change and states that other persons may not sell or distribute product without the new label after January 1, 1994, and a product subject to the LIP is voluntarily cancelled on July 1, 1991, the registrant of the cancelled product will not be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1992, unless the existing stocks are relabeled to be in compliance with the LIP. Similarly, no other persons would likely be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1994, unless the stocks were in compliance with the terms of the LIP.

5. *Other voluntary cancellations.* If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call-ins, and the registration is not subject to a Registration Standard, Label Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted.

B. Suspended Pesticides

FIFRA provides for two different types of suspension. Under section 6(c), EPA may suspend a pesticide registration if use of the pesticide results in an imminent hazard. Under section 3(c)(2)(B), EPA may suspend a registration if a registrant fails to submit required data to the Agency in a timely fashion. Section 4(d)(6) and 4(f)(3) provide for suspensions pursuant to section 3(c)(2)(B) if registrants fail to make timely progress of data development to meet commitments for data submission, tests are not initiated within 1 year after issuance of a Phase 4 data call-in notice, or data are not submitted by the due date.

Where a pesticide is suspended because of an imminent hazard, EPA will apply the policies applicable to cancellations where the Agency has identified significant risk concerns. The Agency is highly unlikely to allow significant sale, distribution, or use of pesticides suspended because of imminent hazard concerns.

Where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement, the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension. Registrants who sell or distribute a pesticide which has been suspended under FIFRA section 3(c)(2)(B) will be in violation of FIFRA section 12(a)(2)(J). Unlike imminent hazard suspensions, the Agency does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement unless risk concerns were identified.

C. Amendments of Registrations

The Agency has promulgated regulations (at 40 CFR 152.130) dealing with the sale or distribution of products bearing labeling other than the labeling currently approved by the Agency. Section 152.130(c) of the CFR states that the Agency will "normally" allow registrants to sell products bearing old labeling for 18 months after Agency approval of a revised label and allow others to sell products bearing the old label until all such products are sold, if the product labeling is amended "on the initiative of the registrant." Section 152.130(d) goes on to say that if a

revision is the result of a Registration Standard, Label Improvement Program, or notice concluding a Special Review, the Agency may establish alternate dates after which product sold by a registrant, or sold by others, must bear currently approved labeling.

The regulations do not address the issue of time periods for sale of products bearing a different composition or packaging from that currently approved by the Agency. The Agency believes that if the composition or packaging is required to be changed by the Agency, the policies expressed below concerning label changes should apply. However, if the composition or packaging of a product is changed by a registrant voluntarily, the Agency will generally allow registrants to sell or distribute product for 18 months after the Agency approves the change; other persons will generally be allowed to sell product using the old composition or packaging until all such product is sold.

Changes in labeling made at the behest of the Agency are covered by paragraph (d) rather than paragraph (c) of 40 CFR 152.130. Thus, if label changes are imposed in a document issued during Phase 5 of reregistration (under FIFRA section 4(g)(2)(A)) or if label revisions (or other changes) are in part attributable to concerns that the product may pose unreasonable adverse effects without the change, the Agency may impose appropriate restrictions on the sale or distribution of products not only by the registrant but by others in the distribution chain as well ("channels of trade" dates).

The Agency believes that, although such channels of trade dates may be relatively lengthy, they are necessary to effective enforcement, serving as a form of "closure" on old labeling. In the Agency's enforcement experience, products bearing old labels can be found in channels of trade far longer than foreseen. Besides enforcement difficulties, lack of an absolute cutoff point for needed label changes prolongs inconsistency among similar products, leading to confusion among users as to what label instructions are correct. More importantly, the lack of a channels of trade date creates uncertainty that product labels actually represent current and protective standards. Under FIFRA, the assurance of risk reduction depends heavily on expectations that labeling instructions will be followed. Uncertainty that such compliance is occurring and inconsistency among labels can frustrate efforts by both the Agency and registrants to effect real and consistent risk reduction. Accordingly, in each label change either imposed by the Agency, or attributed in part to risk concerns under review by the Agency, EPA intends to impose both a date for introduction of new labeling into channels of trade (a registrant sale and distribution date), and a date for removing old labeling from channels of trade. Except in the case of labeling changes imposed through Special Review, EPA is unlikely to impose restrictions upon use of product bearing old labeling.

The exact restrictions that the Agency may impose will, of course, depend upon the particular circumstances involved. Nonetheless, the Agency can identify certain principles it generally will apply to label changes directed by the Agency. Label changes directed by the Agency are currently imposed under three specific activities:

1. *The Special Review Process.* Special reviews often culminate in an Agency determination that use of the pesticide without labeling changes would cause unreasonable adverse effects. Also, registrants of pesticides in special review may propose label changes prior to the conclusion of a special review to reduce the risks that are the focus of the review. When label changes are approved in such situations, existing stocks provisions will be determined on a case-by-case basis. In determining what provisions are appropriate, the Agency may consider any or all of the following factors:

a. The nature of the risk posed by the pesticide.

b. The nature of the labeling change required.

c. Whether an amendment to effect the labeling change was submitted in a timely manner.

d. The potential adverse effects associated with continued sale of product not bearing the revised labeling.

e. The volume and location of affected products in the distribution chain.

f. The feasibility, expense, and effectiveness of either requiring relabeling of existing stocks, or of restricting sale and distribution of product not bearing the revised labeling.

2. *Reregistration of current products.* Under FIFRA section 4(g), Phase 5 of the reregistration scheme requires that products containing active ingredients first registered before November 1, 1984, be reregistered. The Agency anticipates that labeling changes (amendments) will likely be required upon issuance of a document stating the Agency's determination of the reregistrability of an active ingredient under FIFRA section 4(g)(2)(A). This Reregistration Eligibility Document (RED) will ask for label changes to be submitted within one of two timeframes—normal or expedited.

In the first instance, the reregistration process envisioned in Phase 5 will normally encompass changes in labeling, composition, or packaging. These changes will be of a more routine nature, or will depend upon the development of product-specific data, such as acute toxicity or efficacy data. Dates for submission of labeling, timeframes for Agency review of labeling changes, and existing stocks provisions will be specified in the RED. Generally, submission of labeling changes will be required 8 months from the date of submission of the RED, and Agency review will be completed 6 months following submission. Registrants will generally be permitted to sell or distribute products bearing old labeling (or composition or packaging) for 1 year after the timeframe established in the RED for Agency approval, and persons other than registrants will generally be permitted to sell or distribute those products for an additional 24 months. Thus, existing stocks dates for sale and distribution of products bearing old labeling will generally be 26 months from the date of issuance of the RED for registrants and 50 months from the date of issuance of the RED for persons other than registrants.

In the second instance, the Agency may require expedited labeling changes if it has significant concerns about the risks of the active ingredient that do not warrant placing it into the Special Review process, but that labeling changes could mitigate. Although EPA believes this situation will be rare, nonetheless the significance of Agency concerns will dictate early submission and review of labeling, and relatively short existing stocks provisions. Existing stocks timeframes will be established case-by-case, depending on the number of products involved, the number of label changes needed, and other factors.

3. *The Label Improvement Program (LIP).* An LIP provides a framework for upgrading labeling that is unconnected with reregistration, and can be initiated at any time that circumstances warrant. The LIP was established to provide a mechanism for the Agency to target a particular labeling problem or a group of products having a common label element and to implement a labeling solution uniformly for all affected products. In that respect it should be viewed as neither active ingredient-specific nor product-specific, but rather "problem-specific." Fundamental to this approach is that the program does not depend upon the development or

interpretation of data, such as is required for reregistration. With such a cross-cutting but focussed approach, the LIP generally endeavors to impose labeling requirements that can be specified exactly or with a minimum of variability. Although labeling may be required to be submitted and reviewed in a LIP, EPA's preferred approach is to obtain agreement via certification that registrants will make the changes. Thus, registrants can rapidly begin implementing the changes in products they distribute and sell. EPA anticipates that any submission of labeling or certification would be required in a comparatively short time after issuance of the LIP. Unless the LIP is a singularly complex one or involves large numbers of products or registrants, submissions of labeling or certifications will normally be required within 3 months. Registrants will generally be allowed to sell or distribute products bearing old labeling for 1 year after issuance of the LIP and persons other than registrants for 3 years after issuance of the LIP.

The Agency acknowledges the impact multiple and frequent required label changes have in escalating registrant costs, potentially disrupting the distribution chain, and creating user confusion. EPA will make every effort to consolidate labeling efforts resulting from reregistration with those that may be under way from LIPs or from parallel regulatory activities.

Interested persons are invited to sumbit written comments on this notice of statement of policy on or before December 26, 1991. Comments must bear a notation indicating the document control number, (OPP–38509). Written comments should be addressed to the Public Docket and Freedom of Information Section, Field Operations Division, at the address given above.

Dated: June 17, 1991.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 91–14958 Filed 6–25–91; 8:45 am]

BILLING CODE 6560–50–F

EXHIBIT 10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thursday, July 31, 2008

CERTIFIED MAIL: (Article Number 7008 0150 0002 6191 4899)

Ms. Danielle A. Larochelle,
Registration Product Manager,
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: Application for a New Section 3 Registration of Flubendiamide with Associated Tolerance NNI-0001 Technical (EPA File Symbol 71711-EA); NNI-0001 24 WG (EPA File Symbol 264-RNEA); NNI-0001 480 SC (EPA File Symbol 264-RNEL); and Tolerance Petition No. 6F7065

Dear Ms. Larochelle:

The products referred to above will be acceptable for registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, provided that Bayer CropScience LP (Bayer), as authorized agent for Nichino America, Inc. (Nichino), agree/concur with the following conditions of registration and provided that the Director of the Office of Pesticide Programs concurs with the registration:

1. The subject products will be conditionally registered for a period of five (5) years from the date of the "Notice of Registration." In addition, this regulatory action will establish permanent tolerances in primary crops for residues of flubendiamide.

2. Bayer, as authorized agent for Nichino, will generate/submit acceptable data listed in the following tables, in accordance with 40 CFR §158, as follows:

Guideline Number	Title of Study	Date Due
Non-Guideline	**Small-Scale Run-Off/Vegetative Buffer Strip Study** - A run-off study is requested to determine the magnitude of the parent, flubendiamide, retained in buffer strips of various widths.	July 31, 2010
NOTE: Bayer will submit a final protocol for the small-scale run-off/vegetative buffer strip study on or before January 31, 2009. Bayer will submit one (1) progress report by December 31, 2009 and a final report on or before July 31, 2010.		
Non-Guideline	**Monitoring Program** –If risk assessment, based on the results from the small-scale run-off/vegetative buffer strip study and additional available data indicates that there are still risk concerns, there will be a need to conduct monitoring of receiving waters within watersheds where flubendiamide will be used.	July 31, 2012
NOTE: Bayer will submit to EPA a final protocol for the monitoring program on or before March 1, 2010. Bayer will revise the protocol for the monitoring study, as necessary, within one (1) month following receipt of the Agency's decision that a monitoring program is necessary.		

The Agency believes that the efficacy of vegetative buffers for flubendiamide use is uncertain. Open literature and Bayer-conducted studies on compounds with similar characteristics to flubendiamide provide information that permits an estimation of the impact of such buffers on the risk picture. A confirmatory small-scale run-off/vegetative buffer strip study with flubendiamide would allow the Agency to quantitatively consider the impact of such buffer strips on risk reduction in critical use areas. It is recommended that the protocol for the referenced study, like in past cases, be a product of a dialogue between EPA and Bayer scientists. Such dialogue, the protocols arising from it and assessment of supporting literature, should be mindful of the need to address

vulnerable use patterns and sites as well as a variety of buffer conditions. The buffer conditions used for this study should support potential mitigation enforceable by label language if, in the future, they are demonstrated to achieve meaningful reductions in off-site transport and aquatic organism risk of the pesticide.

The Agency will make use of the results of the small-scale run-off/vegetative buffer strip study in refining the aquatic exposure and risk assessment.[1] If the employment of the data from the small-scale run-off/vegetative buffer strip study, together with other available date, result in the Agency's conclusion that there are no risk concerns, then no further work, including the monitoring program, need be conducted. However, if risk concerns remain, then the other areas of critical uncertainty in the modeling assumptions must be considered. In this case, there is considerable uncertainty in the application of the EXAMS pond scenario for chemicals with suspected aquatic system accumulation. Additional information on the actual potential for the pesticide to build up in receiving waters would address the uncertainty associated with current model limitations.

3. The Environmental Fate and Effects risk assessment (copy enclosed), suggests that both flubendiamide and its NNI-0001-des-iodo (des-iodo) degradate will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates. The available mesocosm data does not provide evidence to refute these conclusions. No degradation pathway was identified for des-iodo. As such, Bayer will commit to generate and submit the following data (studies) on the des-iodo degradate to determine if Agency assumptions of chemical stability are appropriate:

Guideline Number	Title of Study	Date Due
161-1	**Hydrolysis** – A hydrolysis study is requested to establish the significance of chemical hydrolysis as a route of degradation for des-iodo and to identify, if possible, the hydrolytic products formed to provide initial information on whether they may exhibit structures that may potentially adversely affect non-target organisms.	October 30, 2010
162-4	**Aerobic Aquatic Metabolism** – An aerobic aquatic metabolism study is requested to assist in determining the effects of des-iodo on aerobic conditions in water and sediments during the period of dispersal of des-iodo throughout the aquatic environment and to compare rates and formation of metabolites. The data from this study would provide the aerobic aquatic input parameter for PRZM/EXAMS; therefore, potentially reducing modeling uncertainty.	October 30, 2010

4. For the submitted GLN 860.1850 Confined Rotational Crop studies (MRIDs 46817133 and 46817134), Bayer will submit extraction and analysis dates of samples in order to confirm that samples were extracted and analyzed within the stated intervals (or within 6 months of harvest). Otherwise, additional storage stability data may be required by EPA.

5. Nichino America Inc. (Nichino) (or some other person who consents to Nichino's reliance on the data) understands and agrees that the time-limited registration of the flubendiamide technical product shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment.

6. The EPA and Nichino (or some other person who consents to Nichino's reliance on the data) agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide technical product, as well as Nichino's (or some other person who consents to Nichino's reliance on the data) generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:

   (a) Nichino (or some other person who consents to Nichino's reliance on the data) shall submit all data identified in paragraphs 2-4, on or before July 31, 2012, according to the schedules set forth in those paragraphs.

[1] The goal of the vegetative buffer strip study is to determine how much of a buffer is necessary to prevent both flubendiamide applied to a field and des-iodo formed in the field from accumulating to levels in aquatic environments that pose risk to freshwater benthic invertebrates. Therefore, showing "that the level of the des-iodo degradate leaving the field (prior to reaching the buffer) is insignificant," would be insufficient justification to remove "the 15 foot buffer requirement.

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Nichino (or some other person who consents to Nichino's reliance on the data) by January 31, 2013. EPA scientists and Bayer scientists, as agents for Nichino, shall engage in dialogue about the data and the Agency's conclusions.

(c) By September 1, 2013, the EPA shall either: (1) Approve the registration of the flubendiamide technical product unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Nichino will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide technical product.

(d) If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Nichino will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

(e) No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide technical product registration could meet the standards for registration set forth in section 3(c)(5) of FIFRA, and Nichino agrees in writing to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination.

7. Bayer understands and agrees that the time-limited registration of the flubendiamide end-use products shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment. In addition, this regulatory action will establish permanent tolerances in primary crops for residues of flubendiamide.

8. The EPA and Bayer (or some other person who consents to Bayer's reliance on the data) agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide end-use products, as well as Bayer's (or some other person who consents to Bayer's reliance on the data) generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:

(a) Bayer (or some other person who consents to Bayer's reliance on the data) shall submit all data identified in paragraphs 2-4, on or before July 31, 2012, according to the schedules set forth in those paragraphs.

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Bayer (or some other person who consents to Bayer's reliance on the data) by January 31, 2013. EPA scientists and Bayer scientists shall engage in dialogue about the data and the Agency's conclusions.

(c) By September 1, 2013, the EPA shall either: (1) Approve the registration of the flubendiamide end-use products unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Bayer will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide end-use products.

(d) If, after EPA's review of the data as set forth in 8(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Bayer will submit a request for voluntary cancellation of the flubendiamide end-use product registrations. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

(e) No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide end-use product registrations could meet the standards for registration set forth in section 3(c)(5) of FIFRA, and Bayer agrees in writing to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination.

The "Notice of Registration" will be issued under separate cover when you have agreed in writing to the conditions stated within this letter. **Further, this letter DOES NOT constitute registration, and the products MAY NOT be lawfully marketed until they are registered.**

Nichino and Bayer should recognize that if EPA issues any technical and/or end-use product registration pursuant to the requirements of section 3(c)(7)(C) of FIFRA, such registration will contain any conditions that are a necessary component of EPA's findings that the statutory requirements for issuing a registration are met. Any such registration will provide that Nichino's or Bayer's release for shipment of any product pursuant to any such registration signals Nichino's or Bayer's acceptance of all of those conditions. If either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void. If either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions, EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA.

If you have any questions regarding anything in this letter, please contact Mr. Carmen J. Rodia, Jr. directly at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

Lois A. Rossi, Director
Registration Division (7505P)

Bayer CropScience LP hereby concurs with the time-limited conditional registration of the new insecticide flubendiamide under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as outlined in this preliminary acceptance letter, dated July 31, 2008.

Margaret Cheung 7/31/08
CONCUR DATE

DO NOT CONCUR DATE

Enclosures:
Copy of Human Health Effects Risk Assessment for Flubendiamide, dated April 3, 2008
Copy of Environmental Fate and Effects Risk Assessment for Flubendiamide, dated June 23, 2008
Copy of Public Interest Finding for Flubendiamide, dated April 15, 2008
Copy of Acute Toxicity Review for NNI-0001 Technical, dated October 12, 2007
Copy of Acute Toxicity Review for NNI-0001 24 WG, dated July 15, 2007
Copy of Acute Toxicity Review for NNI-0001 480 SC, dated October 12, 2007
Copy of Product Chemistry Review for NNI-0001 Technical, dated October 24, 2007
Copy of Product Chemistry Review #1 for NNI-0001 24 WG, dated October 18, 2007
Copy of Product Chemistry Review #2 for NNI-0001 24 WG, dated January 25, 2008
Copy of Product Chemistry Review for NNI-0001 480 SC, dated October 19, 2007

071711-00026 D366875
000264-01026 D366877
000264-01025 D366878
PP# 6F7065 D366884

EXHIBIT 11

71711-26 08/01/2008 1/4

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
71711-26	AUG 0 1 2008

Term of Issuance:
Conditional

Name of Pesticide Product:
NNI-0001 Technical

Name and Address of Registrant (include ZIP Code):

Nichino America, Inc.
c/o Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7) provided that you:

1. Make the following change to the label:

   a. Change the product registration number to "EPA Reg. No. 71711-26"

(continued on page 2)

Signature of Approving Official:	Date:
Refer to Page #2. Richard J. Gebken, Product Manager (10) Insecticide Branch, Registration Division (7505P)	AUG 0 1 2008

EPA Form 8570-6

2. Submit two (2) copies of t.. .inal printed labeling before releasing the).. .uct for shipment.

Your release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.

A stamped "Accepted" copy of the label for this product is enclosed for your records.

Sincerely yours,

Richard J. Gebken,
Product Manager (10)
Insecticide Branch,
Registration Division (7505P)

Enclosures: Copy of label for NNI-0001 Technical stamped "Accepted," dated August 1, 2008
071711-00264 D366875

NNI-0001 Technical

For Use in the Manufacture of Insecticides

ACTIVE INGREDIENT:

Flubendiamide* (*N*²-[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-*N*¹-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide)..... **97.76%**

OTHER INGREDIENTS:..... **2.24%**

Total:..... **100.00%**

*CAS Number: 272451-65-7

EPA Reg. No. 71711-26 **EPA Est. No.**

KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF INHALED	• Move the person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

For medical emergencies, health concerns, or pesticide incidents, you may call the Bayer CropScience Emergency Response toll free number 24 hours a day at 1-800-334-7577.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if inhaled, swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes and chemical-resistant gloves. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may be used only for formulation into an insecticide for:

1. the following uses:
   Terrestrial Food and Feed Crops: Brassica (Cole) Leafy Vegetables, Corn (Field Corn, Pop Corn, Sweet Corn, Silage, and Corn Grown for Seed), Cotton, Cucurbit Vegetables, Fruiting Vegetables, Grapes, Leafy Vegetables (except Brassica), Okra, Pome Fruit, Stone Fruit, Tobacco, and Tree Nuts.
2. uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and
3. uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

Do not store for more than 30 consecutive days at an average daily temperature exceeding 100° F. Keep container tightly closed when not in use. Avoid cross contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into the processing equipment. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Nichino America, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NICHINO AMERICA, INC. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Nichino America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NICHINO AMERICA, INC. DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT NICHINO AMERICA, INC.'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

Nichino America, Inc.
4550 New Linden Hill Road
Suite 501
Wilmington, DE 19808

264-1025 8/01/2008 1/12

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
264-1025	AUG 0 1 2008

Term of Issuance:
Conditional

Name of Pesticide Product:
NNI-0001 480 SC

Name and Address of Registrant (include ZIP Code):

Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7) provided that you:

1. Make the following change to the label:

    a. Change the product registration number to "EPA Reg. No. 264-1025"

(continued on page 2)

Signature of Approving Official:	Date:
Refer to Page #2. Richard J. Gebken, Product Manager (10) Insecticide Branch, Registration Division (7505P)	AUG 0 1 2008

EPA Form 8570-6

2. Submit two (2) copies of the final printed labeling before releasing the product for shipment.

Your release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.

A stamped "Accepted" copy of the label for this product is enclosed for your records.

Sincerely yours,

Richard J. Gebken,
Product Manager (10)
Insecticide Branch,
Registration Division (7505P)

Enclosures: Copy of label for NNI-0001 480 SC stamped "Accepted," dated August 1, 2008
000264-01025 D366878

GROUP	28	INSECTICIDE

NNI-0001 480 SC

ACTIVE INGREDIENT:

Flubendiamide (N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide)..... **39%**

OTHER INGREDIENTS: **61%**

NNI-0001 480 SC contains 4 pounds of flubendiamide per US gallon (480 grams per liter). **TOTAL:** **100%**

EPA Reg. No. 264-1025 **EPA Est. No.**

STOP - Read the label before use
KEEP OUT OF REACH OF CHILDREN
CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

For medical emergencies, health concerns, or pesticide incidents, you may call the Bayer CropScience Emergency Response toll free number 24 hours a day at 1-800-334-7577.

NOTE TO PHYSICIAN: No specific antidote is known. Treat symptomatically.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves (such as Natural Rubber). If you want more options, follow the instructions for Category A on the EPA chemical-resistance category selection chart.
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

ACCEPTED
August 1, 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 264-1025

ENGINEERING CONTROLS STATEMENT

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands thoroughly before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Ground Water Advisory

Flubendiamide and its degradate NNI-0001-des-iodo have properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.

Surface Water Advisory

Flubendiamide and its degradate NNI-0001-des-iodo may also impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. These chemicals are classified as having a medium potential for reaching both surface water and aquatic sediment via runoff several months or more after application. A vegetative buffer strip as required under the Directions for Use will reduce the potential for loading of flubendiamide and its degradate NNI-0001-des-iodo from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the same area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

BUFFER ZONES

Vegetative Buffer Strip

Construct and maintain a minimum 15-foot wide vegetative filter strip of grass or other permanent vegetation between field edge and down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).

Only apply products containing flubendiamide onto fields where a maintained vegetative buffer strip of at least 15 feet exists between the field edge and down gradient aquatic habitat.

For guidance, refer to the following publication for information on constructing and maintaining effective buffers: *Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services.* USDA, 2000. Fort Worth, Texas. 21 pp. http://www.in.csusda/v/technical/agronom/newconbuf.pdf

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours following application.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil or water, is: coveralls, chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, or viton, and shoes plus socks.

GENERAL INFORMATION

NNI-0001 480 SC is a Suspension Concentrate formulation. The active ingredient contained in NNI-0001 480 SC is active by insect larval ingestion leading to a rapid cessation of feeding followed by death of the insect. Application should be timed to coincide with early threshold level in a developing larval population. Thorough coverage of all plant parts is required for optimum performance.

RESISTANCE MANAGEMENT

NNI-0001 480 SC contains an active ingredient with a novel mode of action. Studies to determine cross-resistance with NNI-0001 480 SC linked to other commercial insecticide have demonstrated no cross-resistance. However, repeated use of any crop protection product may increase the development of resistant strains of pests, including insects and mites. Rotation to another product with a different mode of action is recommended.

APPLICATION GUIDELINES

For all insects, timing of application should be based on careful scouting and local thresholds.

Foliar Spray Applications

Ground applications: A minimum of 10 gallons of diluted product/A.

Aerial applications: A minimum of 5 gallons of diluted product/A. Aerial applications made to dense canopies may not provide sufficient coverage of lower leaves to provide acceptable pest control. Under these conditions, the higher rate of NNI-0001 480 SC specified in the crop/pest specific tables within the Directions for Use section of this label may be necessary for optimum pest control.

Chemigation applications (see use in Chemigation Systems directions below) should be made as concentrated as possible. For best results apply at 100% input/travel speed, for center pivots or 0.10 inch (2,716 gallons) up to 0.15 inch (4,073 gallons) of water/A, for other systems. Higher labeled rates of NNI-0001 480 SC may be necessary for chemigation applications.

CHEMIGATION SYSTEMS

NNI-0001 480 SC may be applied through irrigation systems only on those crops listed under Recommended Applications where application through irrigation systems is recommended.

Types of Irrigation Systems: Apply NNI-0001 480 SC only through sprinkler, including center pivot, lateral move, side roll, or overhead solid set irrigation systems. Do not apply NNI-0001 480 SC through any other type of irrigation system.

GENERAL DIRECTIONS FOR ALL RECOMMENDED TYPES OF IRRIGATION SYSTEMS

Uniform Water Distribution and System Calibration: The irrigation system must provide uniform distribution of treated water. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water. The system must be calibrated to uniformly apply the rates specified. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

Chemigation Monitoring: A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Drift: Do not apply when wind speed favors drift beyond the area intended for treatment.

Required System Safety Devices: The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Using Water from Public Water Systems: Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), back flow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection. The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock

Cleaning the Chemical Injection System: In order to accurately apply pesticides, the chemical injection system must be kept clean; free of chemical or fertilizer residues and sediments. Refer to your owner's manual or ask your equipment supplier for the cleaning procedure for your injection system.

Flushing the Irrigation System: At the end of the application period, allow time for all lines to flush the pesticide through all nozzles before turning off irrigation water. To ensure the lines are flushed and free of pesticides, a dye indicator may be injected into the lines to mark the end of the application period.

Equipment Area Contamination Prevention: It is recommended that nozzles in the immediate area of control panels, chemical supply tanks, pumps and system safety devices be plugged to prevent chemical contamination of these areas

Center-Pivot and Automatic-Move Linear Systems: Inject the specified dosage per acre continuously for one complete revolution or move of the system. DO NOT USE END GUNS. The system should be run at maximum speed.

Solid Set and Manually Controlled Linear Systems: Injection should be during the last 30 to 60 minutes of regular irrigation period or as a separate 30 to 60 minute application not associated with a regular irrigation. Adjust end guns to keep treated water on the treated area in a uniform manner

SPRAY DRIFT REDUCTION MANAGEMENT

Do not apply when wind speed favors drift beyond the area intended for treatment. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions. Avoiding spray drift is the responsibility of the applicator.

Importance of Droplet Size:

An important factor influencing drift is droplet size. Small droplets (<150 - 200 microns) drift to a greater extent than large droplets. Within typical equipment specifications, applications should be made to deliver the largest droplet spectrum that provides sufficient control and coverage. Use only Medium or coarser spray nozzles (for ground and non-ULV aerial application) according to ASAE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.

Ground Applications:

Wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application. For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two (2) rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.

Aerial Applications:

The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75% of the wing span or 80% rotor diameter. Flight speed and nozzle orientation must be considered in determining droplet size. Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety. When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Making applications at the lowest height that is safe reduces the exposure of the droplets to evaporation and wind.

Wind Speed Restrictions:

Drift potential increases at wind velocities of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors, including droplet size, canopy and equipment specifications determine drift potential at any given wind speed. Only apply this product if the wind direction favors on-target deposition. Do not apply when wind velocity exceeds 15 mph and avoid gusty and windless conditions. Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

Restrictions During Temperature Inversions:

Do not make ground applications during temperature inversions. Drift potential is high during temperature inversions. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain close to the ground and move laterally in a concentrated cloud. Temperature inversions are characterized by stable air and increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by mist or ground fog; however, if fog is not present, inversions can also be indentified by the movement of smoke from a ground source. Smoke that layers and moves laterally near the ground surface in a concentrated cloud (under low wind conditions) indicated an inversion, while smoke that moves upward and rapidly dissipates indicated good vertical mixing.

MIXING INSTRUCTIONS

COMPATIBILITY

NNI-0001 480 SC is physically and biologically compatible with many registered pesticides and fertilizers or micronutrients. When considering mixing NNI-0001 480 SC with other pesticides, or other additives, first contact your supplier for advice. For further information, contact your local Bayer Representative. If you have no experience with the combination you are considering, you should conduct a test to determine physical compatibility. To determine physical compatibility, add the recommended proportions of each chemical with the same proportion of water, as will be present in the chemical supply tank, into a suitable container, mix thoroughly and allow to stand for five minutes. If the combination remains mixed, or can be readily re-mixed, the mixture is considered physically compatible.

ORDER-OF-MIXING

NNI-0001 480 SC may be used with other recommended pesticides, fertilizers and micronutrients. The proper mixing procedure for NNI-0001 480 SC alone or in tank mix combinations with other pesticides is:

1) Fill the spray tank 1/4 to 1/3 full with clean water;
2) While recirculating and with the agitator running, add any products in PVA bags **(See Note)**. Allow time for thorough mixing;
3) Continue to fill spray tank with water until 1/2 full;
4) Add any other wettable powder (WP) or water dispersible granule (WG) products;
5) Add the required amount of NNI-0001 480 SC, and any other "flowable" (FL or SC) type products;
6) Allow enough time for thorough mixing of each product added to tank;
7) If applicable, add any remaining tank mix components: emulsifiable concentrates (EC), fertilizers and micronutrients.
8) Fill spray tank to desired level and maintain constant agitation to ensure uniformity of spray mixture.

NOTE: Do not use PVA packets in a tank mix with products that contain boron or release free chlorine. The resultant reaction of PVA and boron or free chlorine is a plastic that is not soluble in water or solvents.

ROTATIONAL CROP STATEMENT

Treated areas may be replanted with any crop specified on this label as soon as practical following the last application.

ROTATIONAL PLANT-BACK INTERVALS[1]

Immediate plant-back: Brassica (Cole) Leafy Vegetables, Corn (Field, Pop, and Sweet), Cotton, Cucurbit Vegetables, Fruiting Vegetables, Leafy Vegetables (except Brassica), Okra, Tobacco

30-Day plant-back: Alfalfa, Barley, Buckwheat, Clover, Grasses, Millet (pearl), Millet (proso), Oats, Root Crops (Root, Tuber, and Bulb Vegetables), Rye, Sorghum, Soybeans, Teosinte, Triticale, Wheat

9-Month plant-back: All other crops

[1] Cover Crops for soil building or erosion control may be planted at any time, but do not graze or harvest for food or feed.

FIELD CROPS

Recommended Applications: Apply specified dosage of NNI-0001 480 SC as needed for control. For best results, treatment should be made when insect populations begin to build and before a damaging population becomes established. Rate selected for use should depend on stage of pest development at application, pest infestation level, plant size and density of plant foliage. Thorough coverage of plant foliage is recommended for optimum product performance. NNI-0001 480 SC may be applied by air, ground equipment or through overhead irrigation systems as designated in the CHEMIGATION statement in the Application Recommendations section of this label. Please contact your local Bayer CropScience representative or Pest Control Advisor for specific recommendations by crop.

CORN (FIELD CORN, POP CORN, SWEET CORN, and CORN GROWN FOR SEED)

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Armyworms (including beet, fall, yellowstriped, and true)	1.0 - 3.0
Black cutworm	
Corn earworm	
European corn borer	
Southwestern corn borer	
Western bean cutworm	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): Green forage and silage - **1 day**; Sweet corn – **1 day**; Grain or stover – **28 days**.

Do not apply more than **3 fl oz per acre (0.094 lb ai/A) per 3-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**

Do not apply more than 4 times per crop season

Minimum application volume: 10.0 GPA – ground, 5.0 GPA – aerial application.

Application should be timed to coincide with early threshold level in a developing larval population.

See CHEMIGATION statement in *Application Guidelines* section of this label.

COTTON

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Armyworms (including beet, fall, yellowstriped, and true)	
Cotton leafworm	1.0 - 2.0
Cotton leaf perforator	
Loopers (including cabbage and soybean)	
Saltmarsh caterpillar	
Cotton bollworm	2.0 - 3.0
Tobacco budworm	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **28 days.**

Do not apply more than **3.0 fl oz per acre (0.094 lb ai/A) per 5-day interval.**

Do not apply more than **9.0 fl oz per acre (0.282 lb ai/A) per crop season.**

Do not apply more than 3 times per crop season.

Minimum application volume: 10.0 GPA – ground; 5.0 GPA – aerial application.

Application should be timed to coincide with early threshold level in a developing larval population.

See CHEMIGATION statement in *Application Guidelines* section of this label.

TOBACCO

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Tobacco budworm	1.0 - 3.0
Tobacco hornworm	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-harvest Interval (PHI): **14 days.**

Do not apply more than **3 fl oz per acre (0.094 lb ai/A) per 5-day interval.**

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season.**

Do not apply more than 4 times per crop season.

Minimum application volume: 10.0 GPA – ground; 5.0 GPA – aerial application

Application should be timed to coincide with early threshold level in a developing larval population.

See CHEMIGATION statement in *Application Guidelines* section of this label.

TREE FRUIT, NUT, AND VINE CROPS

Recommended Applications: Apply specified dosage of NNI-0001 480 SC as needed for control. For best results, treatment should be made when insect populations begin to build and before a damaging population becomes established. Recommended application rates within this label are based on full-size mature trees and vines. Thorough coverage of plant foliage and fruit is recommended for optimum product performance. Please contact your local Bayer CropScience representative or Pest Control Advisor for specific recommendations by crop.

POME FRUIT

Crops of Crop Groups 11 including: Apple, Crabapple, Loquat, Mayhaw, Pear, Oriental pear, Quince

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Codling moth (West of the Rockies) *For use against low to moderate infestations in conjunction with alternate control measures such as in established mating disruption blocks.*	5.0
Codling moth (East of the Rockies) Eyespotted bud moth Green fruitworm Lacanobia fruitworm Leafrollers (including obliquebanded, pandemic, redbanded, and variegated) Lesser appleworm	3.0 - 5.0

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-Harvest Interval (PHI): **14 days**.

Do not apply more than **5.0 fl oz per acre (0.156 lb ai/A) per 7-day interval**.

Do not apply more than **15.0 fl oz per acre (0.468 lb ai/A) per crop season**.

Do not apply more than 3 times per crop season.

Minimum application volumes: 100 GPA – ground application. Aerial application is prohibited.

Application should be timed to coincide with early threshold level in a developing larval population.

STONE FRUIT

Crops of Crop Group 12 including: Apricot, Cherry [sweet and tart], Nectarine, Peach, Plum [includes Chickasaw plum, Damson plum, and Japanese plum], Plumcot, Prune (fresh and dried)

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Green fruitworm	2.0 - 4.0
Leafrollers (including obliquebanded, pandemic, redbanded, and variegated)	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-Harvest Interval (PHI): **7 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Do not apply more than 3 times per crop season.

Minimum application volumes: 50 GPA – ground application. Aerial application is prohibited.

Application should be timed to coincide with early threshold level in a developing larval population.

TREE NUT CROPS

Crops of Crop Group 14 including: Almond, Beech Nut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filbert, Hickory Nut, Macadamia Nut, Pecan, Walnut (black and English)

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Fall webworm	2.0 - 4.0
Hickory shuckworm	
Naval orangeworm	
Peach twig borer	
Pecan nut casebearer	
Walnut caterpillar	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-Harvest Interval (PHI): **14 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 7-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) percrop season**.

Do not apply more than 3 times per crop season.

Minimum application volumes: 50 GPA – ground application. Aerial application is prohibited.

Application should be timed to coincide with early threshold level in a developing larval population.

GRAPE

Including American bunch grape, Muscadine grape, and Vinifera grape

PESTS CONTROLLED	RATE PER APPLICATION fluid ounces/Acre
Cutworm	2.0 - 4.0
Grape Leaffolder	
Grape leaf skelotonizer	
Omnivorous leafroller	
Orange tortrix	

Notes

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 12 hours.

Pre-Harvest Interval (PHI): **7 days**.

Do not apply more than **4.0 fl oz per acre (0.125 lb ai/A) per 5-day interval**.

Do not apply more than **12.0 fl oz per acre (0.375 lb ai/A) per crop season**.

Do not apply more than 3 times per crop season.

Minimum application volumes: 50 GPA – ground application. Aerial application is prohibited.

Application should be timed to coincide with early threshold level in a developing larval population.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE

Do not store for more than 30 consecutive days at an average daily temperature exceeding 100° F. If allowed to freeze, shake well to ensure the product is homogenous before use. Store in original container and out of the reach of children, preferable in a locked storage area. Avoid cross contamination with other pesticides.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

[---------- is a registered trademark of Bayer.]

PRODUCED FOR

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)
http://www.bayercropscience.us

NNI-0001 480 SC (PENDING) Changes Made 07-24-08

EXHIBIT 12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Thursday, July 18, 2013

CERTIFIED MAIL: (Article Number 7008 3230 0000 9482 3609)

Mr. George J. Sabbagh, Ph.D.
Registration Product Manager, Herbicides
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Extension of Registration Expiration Date for Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Mr. Sabbagh:

The purpose of this letter is to officially state that the registration expiration date (July 31, 2013) for all of the referenced flubendiamide products is being extended. This additional time will allow Bayer CropScience, LP (BCS) sufficient time to complete the 3-year monitoring program required by the original conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008 (copy attached). BCS will continue monitoring/reporting its findings according to the agreed upon reporting schedule through the remainder of the 3rd year of monitoring.

As of July 31, 2012, BCS, as the authorized agent for Nichino America, Inc., has submitted all data required by the original conditions of registration for flubendiamide. Please note that all of the original conditions of registration for flubendiamide, as outlined in the referenced preliminary acceptance letter, are still in effect. **The registration expiration date for flubendiamide is being extended out to August 31, 2015.** During this extension, BCS will complete the 3rd (final) year of the monitoring program for flubendiamide and submit a final report by December 31, 2014. This will allow EPA sufficient time to review the final monitoring report for flubendiamide.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely yours,

FOR Carmen J. Rodia, Jr.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

cc: *Ms. Anna Armstrong, Nichino America, Inc.*

Attachment: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*

000264-01025 BELT™ SC Insecticide
000264-01026 SYNAPSE™ WG Insecticide
071711-00026 FLUBENDIAMIDE Technical
071711-00032 VETICA® Insecticide
071711-00033 TOURISMO® Insecticide

EXHIBIT 13

From: Rodia, Carmen <Rodia.Carmen@epa.gov>
Sent: Tuesday, August 04, 2015 3:49 PM
To: Nancy Delaney; Charlotte Sanson; Dan Dyer
Cc: Lewis, Susan; Herndon, George; Rosenblatt, Daniel; Gebken, Richard
Subject: DRAFT List of Required Additional Studies for Flubendiamide

Good afternoon Nancy, Charlotte and Dan, as a follow-up to our most recent teleconference call on Thursday, July 30, 2015, I am submitting to Bayer a DRAFT list of the items that the Registration Division presented to Bayer in order to address the uncertainties related to flubendiamide.

New Data:

Guideline Number	Title of Study	Date Due
Non-Guideline	Bayer must conduct an expanded suite of stream/pond water monitoring representative of all current outdoor uses that are listed on the existing flubendiamide labels. The Agency and Bayer will collaborate on establishing monitoring sites using available modeling tools on a more refined geographic and use site basis to identify likely areas where accumulation of flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates will be a factor under shorter durations of pesticide use.	**[DATE]**
NOTE: The focus of monitoring on areas predicted to be of accumulation concern over shorter durations of pesticide use will develop a data set in a more rapid and economical manner to test the findings of the available modeling supporting risk assessment for flubendiamide. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
Non-Guideline	To be consistent with current Agency policy concerning an effect data set for pollinators, honeybee adult oral acute (OECD 213) and chronic (non-guideline) as well as larval acute (OECD 237) and chronic (non-guideline) studies would constitute the baseline data set for pollinators. Because data with parasitoid hymenopterans and the effects in semi-field studies suggest that developmental and chronic endpoints are of potential concern for flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates, the bee larval acute study and the larval chronic study must be performed. These studies may be performed in tiers.	**[DATE]**
NOTE: There presently are acute adult toxicity studies with honeybees and bumble bees as well as parasitoid wasps for flubendiamide. The honeybee testing included acute contact studies with adults as well as a semi-field study. The data showed minimal toxicity to adults and only transient effects on brood development and flight intensity under semi-field conditions, with recovery. Bumblebee studies were comprised of greenhouse exposure to treated tomatoes, and no effects were observed. The available parasitoid wasp studies showed effects on survival and reproduction. Given the above data summary, it is doubtful that the additional adult data will be materially important. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
850-1010	Acute water only toxicity testing with ephemeropteran (mayfly) species	**[DATE]**
850-1010	Acute water only toxicity testing with plecopteram (stonefly) species	**[DATE]**
850-1010	Acute water only toxicity testing with tricopteran (caddisfly) species	**[DATE]**
NOTE: The underlying claim of receptor specificity for terrestrial arthropods has only limited data to support its application to aquatic systems. To address this area of uncertainty, Bayer must conduct the above referenced water only acute invertebrate studies to provide additional confirmation that receptor specificity of the compound will not affect benthic/epibenthic macroinvertebrate species commonly used to determine biologically-based water quality. Bayer must submit a draft protocol for the above referenced studies for review by the Agency on or before **[DATE]**.		
Non-Guideline	Bayer must conduct sediment toxicity testing with the following additional species (*Hyalella azteca* and *Leptocheirus plumulosa*).	**[DATE]**

NOTE: The existing dataset for sediment organism toxicity addresses a single species (*Chironomus tentans*) to emergence (OPPTS GLN 28-d). Again, as in the case of water only testing, there is considerable uncertainty in the representation of this single species as an adequate surrogate for the variety of in-faunal species. To address this uncertainty, and be consistent with current EPA sediment testing policy, Bayer must conduct the above referenced sediment toxicity testing. To the extent possible by protocol, these studies should continue through developmental periods commensurate with the available chironomid testing and involve spiked sediment as opposed to overlying water. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
Non-Guideline	A two-year, multi-season sampling, biomonitoring effort that provides comparison of benthic macroinvertebrate community analysis with appropriate reference sites should be provided. This effort should address a variety of use sites and be targeted to areas of high proposed flubendiamide projected use and high field runoff potential. This monitoring should be for flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates.	**[DATE]**
NOTE: Bayer must conduct a biomonitoring study to provide confirmation that any residues observed in the monitoring study, as compared to the aforementioned laboratory toxicity studies, is not associated with adverse benthic community effects *in situ*. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		

I would also like to remind Bayer of a number of administrative items that will need to be completed as soon as possible in order to help us all move toward this potential path forward. Among the items presented to Bayer last week were the following:

- Bayer must withdraw the following list of submitted PRIA applications in writing well in advance of August 31, 2015:

Registration/Petition Numbers	Description of Applications	Affected Decision Numbers
71711-26 (FLUBENDIAMIDE TECHNICAL)	R170/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493617, 495233, and 495235
264-1025 (BELT SC Insecticide)	R170.2/R170.3/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493618, 495242, and 495244
PP #4F8283	R170/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493619

- Prior to August 31, 2015, the PRIA conclusion date for the submitted R350 application to increase the PHI on tobacco (EPA Reg. No. 264-1025 (BELT SC Insecticide; Decision No. 491208) must be renegotiated for completion by HED in 2016;
- Bayer will agree not to submit any additional Section 3 outdoor uses during the potential 3 year extension of the time-limited registrations for flubendiamide;
- Bayer will reduce all applications on all 5 flubendiamide product labels to 1 application per crop season as part of label amendments that will be submitted to the Agency;
- Bayer will remove aerial applications on all 5 flubendiamide product labels;
- Bayer will agree to submit progress reports on the additional data capture every six (6) months to the Agency during the potential 3 year extension of the time-limited registrations for flubendiamide;
- Prior to August 31, 2015, Bayer and the Agency will sign a new preliminary acceptance letter outlining all of these items as well as the additional data that are listed above; and
- All additional data must completed by the end of the 2nd year of the potential 3 year extension in order to provide EFED with adequate time to review the submitted additional data.

Please review the above information and use it as the basis of Bayer's upcoming proposal to continue the registration of flubendiamide beyond its current August 31, 2015 expiration date. These are our initial broad thoughts, and let's plan to talk later this week to finalize! We are still looking forward to hearing from Bayer for potential dates/times for the Jack Housenger meeting. If you have any questions, please contact me directly. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.
Environmental Protection Specialist
U.S. EPA, Office of Pesticide Programs,
Registration Division, Invertebrate & Vertebrate Branch 2
1200 Pennsylvania Avenue, NW (7504P)

Washington, DC 20460-0001
(703) 306-0327 (tel)
(703) 308-0029 (fax)
Rodia.Carmen@epa.gov

EXHIBIT 14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wednesday, August 26, 2015

CERTIFIED MAIL: (Article Number 7008 3230 0000 9474 2849)

Mrs. Nancy Delaney
Regulatory Manager
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Extension of Registration Expiration Date for Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Mrs. Delaney:

Bayer CropScience LP (BCS), on its behalf and as an agent for Nichino America, Inc., submitted a request to U.S. Environmental Protection Agency (EPA) on August 20, 2015 for an administrative extension to December 10, 2015 for the registration of the flubendiamide products listed above under Section 3 (c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This extension will provide time for BCS and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty within EPA's Environmental Fate and Effects Division's (EFED) ecological risk assessment. The existing registration expiration date (August 31, 2015) for all of the above referenced flubendiamide products is being extended. **In direct response to BCS' request, the registration expiration date for flubendiamide is extended to December 10, 2015.**

As of July 31, 2012, BCS has submitted all data required by the original conditions of registration for flubendiamide. Please note that all of the original conditions of registration for flubendiamide, as outlined in the preliminary acceptance letter for flubendiamide dated July 31, 2008 (copy attached), are still in effect.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov* or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at *Gebken.Richard@epa.gov*.

Sincerely yours,

Richard J. Gebken
Product Manager (10)
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)

Attachments: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*
Copy of BCS Request for Extension of Registration Expiration Date for Flubendiamide

cc: *Ms. Lydia Cox, Nichino America, Inc.*

000264-01025 BELT™ SC Insecticide
000264-01026 SYNAPSE™ WG Insecticide
071711-00026 FLUBENDIAMIDE Technical
071711-00032 VETICA® Insecticide
071711-00033 TOURISMO® Insecticide

EXHIBIT 15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL
SAFETY AND
POLLUTION
PREVENTION

PC Code: 121027
DP Barcode: 427543
Date: September 16, 2015

MEMORANDUM

SUBJECT: Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment Endangered Species Effects Determination for Methoxyfenozide

TO: Bonnie Adler, Chemical Review Manager
Jill Bloom, Team Leader
Linda Arrington, Branch Chief
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

FROM: Mary Clock-Rust, Biologist
Karen Milians, Ph.D., Chemist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P**)**

REVIEWED BY: Thomas Steeger, Ph.D., Senior Science Advisor
Jim Carleton, Ph.D., Senior Scientist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P**)**

APPROVED BY: Jean Holmes, DVM, MPH, Branch Chief
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P**)**

The Environmental Fate and Effects Division (EFED) has completed a preliminary risk assessment for the insecticide methoxyfenozide. EFED's analysis has determined that the use of methoxyfenozide has the potential for direct effects on Federally listed threatened/endangered (hereafter referred to as "listed") and non-listed freshwater invertebrates following acute exposure, and on listed and non-listed freshwater and estuarine/marine invertebrates following chronic exposure. Acute risk to listed estuarine/marine invertebrates is also possible for the majority of methoxyfenozide uses evaluated. The likelihood of direct adverse effects on birds, terrestrial-phase amphibians, reptiles, mammals, fish, aquatic-phase amphibians, and terrestrial and aquatic plants

from exposure to methoxyfenozide as a result of the registered uses is expected to be low. However, the extent to which other taxa that depend on aquatic invertebrate species may be indirectly affected is uncertain. Finally, data are incomplete but available lines of evidence suggest that methoxyfenozide risk to terrestrial and aquatic plants is likely to be low.

The potential for direct adverse effects to adult honey bees (*Apis mellifera*) is considered low. A review of submitted field studies on honey bee brood development and colony survival (including overwintering) does not indicate that honey bee brood (larvae/pupae) are adversely affected by exposure to the compound, although uncertainties were noted in the submitted toxicity data. A recently submitted laboratory-based acute toxicity study on larval honey bees raises new concerns. Using the new toxicity data combined with default exposure and larval food consumption rates from the *Guidance for Assessing Pesticide Risks to Bees* (US EPA, 2014) results in risk estimates that exceed EFED's levels of concern (LOC) for honey bee larvae.

Uncertainties

Although methoxyfenozide is intended to act specifically on immature stages of insects within the order Lepidoptera (moths/butterflies), there is uncertainty about the extent to which larval stages of other insects (excluding honey bees) may be affected, since the compound acts as an ecdysone agonist and is intended to induce premature molts thereby resulting in death of the target organism. There are also concerns for beneficial lepidopterans that co-occur in areas where methoxyfenozide is used.

No data are available to assess the potential for adverse effects on terrestrial plants or to aquatic vascular plants from exposure to methoxyfenozide; however, toxicity data available for aquatic non-vascular plants did not indicate any adverse effects from exposure up to the solubility limit of the compound (3.3 mg/L). Also, terrestrial and vascular aquatic plant data on tebufenozide, another ecdysone agonist in the same chemical class as methoxyfenozide, suggest that methoxyfenozide toxicity to terrestrial and aquatic plants is likely to be low. Further, no reports of plant damage resulting from exposure to methoxyfenozide have been recorded in EFED's incident databases. Given the mode of action of these compounds, it is uncertain whether any analogous pathways (*i.e.*, ecdysone receptors) exist in plants.

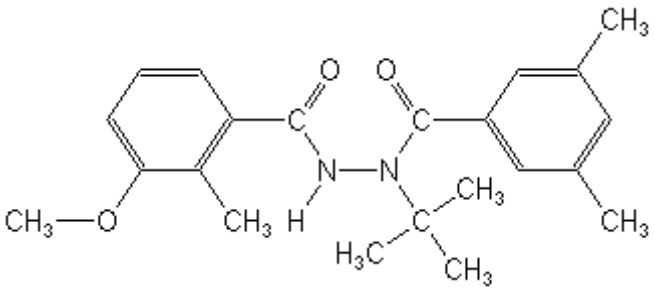
For uses where the retreatment interval (RTI) was not specified, a three-day interval was assumed. The RTI was not specified on two labels, EPA Reg, # 62719-442 (corn) and EPA Reg. # 62719-666 (peanuts).

Although whole colony studies are available for methoxyfenozide and did not demonstate any consistent long-term adverse effects on brood development, a laboratory-based chronic toxicity study with larval honey bees, in which exposure conditions can be more readily controlled, would increase the confidence in risk conclusions and help to address uncertainties regarding repeated direct exposure of larvae to methoxyfenozide. Specifically, a 21-day larval honey bee toxicity study extending through adult emergence would be informative.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

Environmental Fate and Ecological Risk Assessment for Registration Review of Methoxyfenozide.



Methoxyfenozide

CAS Registry No: 161050-58-4 PC Code: 121027

Prepared by: Mary Clock-Rust, Biologist Karen Milians, Ph.D., Chemist	U.S. Environmental Protection Agency Office of Pesticide Programs Environmental Fate and Effects Division Environmental Risk Branch IV 1200 Pennsylvania Ave., NW Mail Code 7507P Washington, DC 20460
Reviewed by: Jean Holmes D.V.M, Branch Chief Thomas Steeger, Ph.D., Senior Science Advisor Jim Carleton, Ph.D., Senior Scientist	

September 16, 2015

Executive Summary

The preliminary risk assessment (PRA) in support of Registration Review for methoxyfenozide, examines the risks to wildlife associated with the compound's labeled uses. The risk assessment is based on the best available scientific and commercial information on the use, environmental fate and transport, and ecological effects of methoxyfenozide on non-target organisms.

Methoxyfenozide is a dibenzoyl hydrazine insecticide which acts as an insect growth regulator (IGR) and registered for use on a variety of agricultural as well as non-agricultural sites across the US. The chemical is an agonist for the invertebrate molting hormone, ecdysone, and induces a precocious incomplete molt in invertebrates, particularly lepidopterans (butterflies/moths).

Methoxyfenozide may be applied using ground, aerial, conventional spray or chemigation application methods. Single application rates range from 0.16 lb a.i./A (for cotton and peanuts) to a maximum of 0.40 lb a.i./A (for cotton). Use sites include citrus, cotton, fruiting vegetables (Crop Group 1B), globe artichokes, bushberries (Crop Group 13-07B), corn, peanuts, grapes, stone fruits (Crop Group 12-12) and tree nuts (Crop Group 14-12; including almonds, walnuts, and other nuts). Annual maximum application rates across all methoxyfenozide use sites do not exceed 1.0 lb a.i./acre/year. The technical registrant for this pesticide is Dow AgroSciences (DAS).

The compound is considered very persistent and moderately mobile based on a soil aerobic metabolism half-lives range from 336 to 1100 days; organic carbon partition coefficient (K_{oc}) range from 219 to 922 mL/g_{oc}; and, a log octanol-water partition coefficient (K_{ow}) of 3.72. Once applied, methoxyfenozide has the potential to move off the site of application by leaching, erosion and runoff where it can accumulate in aquatic systems.

While methoxyfenozide is expected to persist in the environment and move to surface water via runoff and erosion based on laboratory studies, a monitoring study was recently completed which showed no apparent accumulation of methoxyfenozide in sediment and water at any of the monitoring sites under the conditions tested. Furthermore, bioconcentration data with both fish and invertebrates indicate that the compound does not bioconcentrate appreciably (BCF range: 1.1 – 22.1X) and it depurates relatively quickly once organisms are no longer exposed. Available data indicate that for both freshwater and estuarine/marine fish, the toxicity of methoxyfenozide appears limited by its solubility in water (3.3 mg a.i./L) and at this concentration, no adverse effects (*i.e.*, mortality or sublethal effects) were observed on fish following acute exposure.

EFED's analysis has determined that all of the registered uses of methoxyfenozide have the potential to result in direct adverse effects to freshwater and estuarine/marine invertebrates. Specifically, federally listed threatened/endangered (hereafter referred to as "listed") and non-listed freshwater invertebrates are at risk following acute exposure to methoxyfenozide, and listed and non-listed aquatic freshwater and estuarine/marine invertebrates following chronic exposure. Acute risk to listed estuarine/marine invertebrates is also possible for the majority of registered methoxyfenozide use sites that are in close proximity to these environments. A low likelihood of direct adverse effects to birds, terrestrial-phase amphibians, reptiles, mammals, fish, aquatic-phase amphibians, and terrestrial and aquatic plants is expected from exposure to methoxyfenozide as a

result of the registered uses. However, there is the potential for indirect effects on taxa that depend on aquatic invertebrate species for prey and/or habitat, although the magnitude and likelihood of indirect effects are uncertain.

There are data to indicate that lepidopteran species of terrestrial invertebrates are sensitive to methoxyfenozide, consistent methoxyfenozide's use in controlling lepidopteran pests (such as the corn root worm, cabbage moth, diamond back moth). While available acute toxicity data do not indicate potential risk to adult honey bees, a laboratory-based study indicates that larval honey bees may be sensitive to methoxyfenozide following a single (acute) exposure. Screening-level risk quotient (RQ) values exceed the acute risk level of concern (LOC) for honey bee larvae, although refined RQ values based on measured residue levels in pollen/nectar are below the acute risk LOC. Field-based studies of whole colonies fed methoxyfenozide-spiked diets did not exhibit any consistent, long-term adverse effect on brood development and/or colony overwintering capacity. Laboratory-based chronic toxicity data for larval honey bees would increase the confidence in risk conclusions and address uncertainties about methoxyfenozide risk to terrestrial invertebrates and lead to more robust risk conclusions. Specifically, a 21-day larval bee toxicity study extending through adult emergence would help to address uncertainties.

1.0 Problem Formulation

The problem formulation sets the objectives for the risk assessment and provides a plan for analyzing the data and characterizing the risk (USEPA 1998a). EFED completed the preliminary problem formulation for the environmental fate, ecological risk, endangered species, and drinking water exposure assessments to be conducted as part of the Registration Review of methoxyfenozide (USEPA, 2013b).

The following section summarizes the key points of that document and discusses any differences between the analysis outlined in the preliminary problem formulation and the analysis conducted in this risk assessment.

1.1 Nature of Regulatory Action

The risk assessment is conducted as part of the Agency's Registration Review process for pesticide active ingredients. The Registration Review process was established under the Food Quality Protection Act (FQPA 1996).

2. Nature of Chemical Stressor

Methoxyfenozide, 3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide (CAS No. 161050-58-4), belongs to the diacylhydrazine class of insecticides that interfere with the binding of the endogenous steroidal molting hormone 20-hydroxyecdysone with its nuclear receptor protein complex. As such, methoxyfenozide is referred to as an ecdysteroid (ecdysone) agonist[1]. Exposure of sensitive organisms (pests including fruit worm, diamond back moth, corn root worm, leaf roller, armyworm, grapevine moth and other

[1] Shimizu *et al.*, 1997.

USE SCENARIO (PRZM scenario used; rate modeled in kg/ha)		Estimated Environmental Concentrations (EECs, ppb)				
		Application Method	Peak	96-hour	21-day	60-day
Globe Artichoke	CA lettuce, 0.28 x 4 applic @ 7-d interval	aerial	144	144	143	142
Grass, forage fodder hay	OR Grass seed x 8 applic @ 3-d interval	aerial	37.4	37.3	37.1	36.7
	FL turf, 0.07 x 8 applic @ 3-d interval	aerial	20.5	20.4	20.2	19.9
Bushberries	OR berries, 0.07 x 3 applic @ 7-d interval	aerial	13.2	13.1	13.0	12.9
	OR berries, 0.28 x 3 applic @ 7-d interval	aerial	52.7	52.6	52.2	51.6
Peanuts	NC peanuts, 0.09 x 3 applic @ 3-d interval	aerial	27.6	27.6	27.4	27.0
	NC peanuts, 0.18 x 3 applic @ 7-d interval	aerial	54.5	54.4	54.0	53.4
Corn	MS corn, 0.07 x 17 applic @ 3-d interval	aerial	144	144	143	141
	MS corn, 0.28 x 4 applic @ 3-d interval	aerial	130	130	127	127
Grapes[2]	NY grapes, 0.13 x 5 applic @ 3-d interval	aerial	63.9	63.8	63.5	63.1
	NY grapes, 0.26 x 5 applic @ 4-d interval	aerial	141	141	140	139
Tree nuts (almond, pistachio)	CA almond, 0.25 x 4 applic @ 3-d interval	aerial	66.0	65.8	65.3	64.3
	CA almond, 0.43 x 4 applic @ 10-d interval	aerial	101	101	100	99
	GA pecans, 0.13 x 8 applic @ 8-d interval	aerial	72.3	72.1	71.7	70.7

[1]Refer to the modeling results for NC cotton scenario in Appendix F
[2] Although methoxyfenozide is not registered for use on grapes in NY, this scenario was used for modeling purposes.
Bolded value represents the highest EDWC for methoxyfenozide

3.2.2.4 Aquatic Exposure Monitoring

Methoxyfenozide was not included in monitoring conducted by the U. S. Geological Survey (USGS) National Water Quality Assessment (NAWQA) program nor in the California Department of Pesticide Regulation (CDPR) Surface Water Database (CDPR 2003).

Because methoxyfenozide is very persistent, moderately mobile and may accumulate in the aquatic environment following repeated applications, the Agency recommended surface water and sediment studies using a representative sample of water bodies in high use areas (based on DAS record sales, growers and state and county government records). These studies were intended to determine whether multiple years of use would result in evidence of accumulation of methoxyfenozide residues in water and/or sediment in areas that represent vulnerable fields (prone to runoff). Samples for determining methoxyfenozide residues were collected over a two-year period (2012 and 2013) in two lotic (flowing) water bodies and five lentic (standing) water bodies in each of the following states: California, Mississippi, and Michigan.

The maximum concentration of methoxyfenozide detected in lotic surface water samples was 1.31 µg/L, found in Mississippi. The maximum concentration detected in lentic waters was 0.845 µg/L, in a pond in Michigan. The maximum concentration of methoxyfenozide in benthic sediments (31 µg/kg) was detected in Michigan. No apparent accumulation of methoxyfenozide was observed in sediment at any monitoring sites after years of use. There are deficiencies of the monitoring study such as analytical methods slightly modified (ECMs reported in the study differed from the one submitted to the Agency) and one sampling site was changed with an alternate sampling point.

It may not be appropriate to make a direct comparison from the results of the monitoring study with the values obtained in modeling (using SWCC) because the frequency of sampling in the monitoring study may not have captured the peak concentration. Additionally, SWCC model simulates the impact of daily weather on the treated agricultural field, and resulting concentrations in an adjacent farm pond over a defined period (here, thirty years). During this time, pesticide is washed-off of the field into the water-body by twenty to forty rainfall/runoff events per year. Each new addition of pesticide mass from each runoff event adds to the existing pesticide mass in the pond from previous runoff and/or spray-drift events. Since methoxyfenozide is known to be persistent in aquatic environments, the mass of the pesticide accumulates in the pond from one year to the next. In the SWCC model, the yearly simulated peaks are not independent of each other but are temporally auto-correlated, meaning that the "1-in-10 year EECs" obtained from model post-processing are in part functions of the simulation duration. As a result, SWCC results likely overestimate concentrations in streams and various other kinds of water bodies, as over the course of thirty years, some loss of methoxyfenozide is expected due to washout, dispersion, burial of sediment and other dissipative processes that aren't simulated. In particular, methoxyfenozide concentrations in lotic (flowing) water bodies are not expected to accumulate at such a high concentrations from year to year because of downstream advective removal. **Table 8** below details the results of the monitoring study conducted by DAS.

Table 8: Summary of the Methoxyfenozide Sediment and Surface Water Monitoring Study

Site	Concentration of methoxyfenozide in surface water (µg/L), (Number of samples analyzed)		Concentration of methoxyfenozide in sediment (µg/kg), (Number of samples analyzed)	
	Lotic	Lentic	Lotic	Lentic
California	ND-1.01 (88)[1]	ND-0.0502 (20)	ND (8)	ND (20)
Mississippi	ND-1.31 (55)[2]	ND-0.233 (20)	ND (8)	ND (20)

Michigan	ND (36)[3]	ND-0.845 (23)	ND (4)	ND-31.0 (23)

LOQ=0.050 µg/L and LOD= 0.015µg/L in surface water and LOD= 3 µg/kg in sediment.
ND =below detection limit
[1]87, 7- day composite samples and 1, 28-day composite sample
[2]47, 7- day composite samples and 8, 28-day composite samples
[3]22, 7- day composite samples and 14, 28-day composite samples

OPP is not aware of any other monitoring programs in which methoxyfenozide is an analyte.

3.2.3 Measures of Terrestrial Exposure

Exposure to terrestrial organisms was assessed based on the registered uses of methoxyfenozide. Dietary exposure to birds and mammals was assessed using the T-REX model[2]. Terrestrial plant exposure was estimated using the TerrPlant model[13].

3.2.3.1. Ingestion of Foliar Residues by Birds and Mammals

Terrestrial wildlife exposure estimates are typically calculated for the dietary exposure of birds and mammals. Avian exposures are considered surrogates for exposures to terrestrial-phase amphibians and reptiles. For exposure to terrestrial organisms, such as birds and mammals, pesticide residues on food items are estimated, based on the assumption that organisms are exposed to pesticide residues in a given exposure use pattern. For methoxyfenozide, application methods for the registered uses include aerial, broadcast, banded, and directed spray of liquid formulations for all crops.

T-REX[14] (Version 1.5.2) is used to calculate upper-bound dietary EECs for estimating exposure to birds and mammals resulting from the registered uses of methoxyfenozide. A one year time period is simulated, and the default foliar dissipation half-life of 35 days was used for modeling the registered uses. An example printout from the T-REX model is provided in **Appendix D**.

Table 9: Input Parameters for Deriving Terrestrial EECs for Methoxyfenozide Labeled Uses (T-REX).

Use Site	Application Rate (lbs a.i./A)	Minimum Reapplication Interval (days)[1]	Number of Applications
Citrus	0.25	14	4
Cotton[3]	0.4	10	4
Fruiting Vegetables	0.25	7	4
Globe Artichokes	0.25	7	4
Bushberries	0.25	7	3
Corn	0.25	NS[2]	4
Peanuts	0.16	7	3

[13] http://www.epa.gov/oppefed1/models/terrestrial/index.htm
[14] USEPA. 2014. T-REX Version 1.5.2 (Terrestrial Residue Exposure). http://www.epa.gov/oppefed1/models/terrestrial/#trex (last accessed 02.24/15)

EXHIBIT 16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tuesday, December 8, 2015

Mrs. Nancy Delaney
Regulatory Manager
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Extension of Registration Expiration Date for Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Mrs. Delaney:

Bayer CropScience LP (BCS), on its behalf and as an agent for Nichino America, Inc., submitted a request to the U.S. Environmental Protection Agency (EPA) on December 4, 2015, requesting an extension of the registrations listed above to December 18, 2015. These products are currently time-limited registrations under Section 3 (c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) with an expiration date of December 10, 2015.

In response to the BCS' request, the registration expiration date of December 10, 2015 is extended to December 18, 2015, to provide additional time for BCS and EPA to discuss areas of uncertainties.

All of the original conditions of registration for these flubendiamide products as outlined in the preliminary acceptance letter for flubendiamide dated July 31, 2008 (copy attached) are still in effect.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov* or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at *Gebken.Richard@epa.gov*.

Sincerely yours,

Richard J. Gebken
Product Manager (10)
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)

Attachments: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*
Copy of BCS Request for Extension of Registration Expiration Date for Flubendiamide, dated December 4, 2015

cc: *Ms. Lydia Cox, Nichino America, Inc.*

000264-01025 BELT™ SC Insecticide
000264-01026 SYNAPSE™ WG Insecticide
071711-00026 FLUBENDIAMIDE Technical
071711-00032 VETICA® Insecticide
071711-00033 TOURISMO® Insecticide

EXHIBIT 17

DATA EVALUATION RECORD
FRESHWATER SEDIMENT *Chironomus riparius* EMERGENCE TEST

1. **CHEMICAL:** Flubendiamide — PC Code: 027602

2. **TEST MATERIAL:** NNI-0001-des-iodo — Purity: 99.3%

3. **CITATION:**

Authors: Dorgerloh, M.
Title: *Chironomus riparius* 28-day Chronic Toxicity Test with NNI-0001-des-iodo in a Water-Sediment System using Spiked Water
Study Completion Date: November 22, 2004
Laboratory: Bayer CropScience AG
Development-Ecotoxicology
40789 Monheim, Germany
Sponsor: Bayer CropScience AG
Portfolio Management, Project Management/Project Planning
40789 Monheim am Rhein, Germany
Laboratory Report ID: DOM 23069; Project ID E 416 2518-7
MRID No.: 468170-23

4. **REVIEWED BY:** John Marton, Staff Scientist, Cambridge Environmental, Inc.

Signature: John Marton **Date:** 07/30/07

APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental Inc.

Signature: Teri S Myers **Date:** 08/02/07

5. **APPROVED BY:** Holly Galavotti, Biologist, ERB1

Signature: Holly Galavotti **Date:** 5/21/08

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Chironomus riparius*
Age of Test Organism: 1st instar (L1) larvae, 2 to 3 days post-hatch
Definitive Test Duration: 28 days
Study Method: Static with aeration
Type of Concentrations: Initial nominal overlying water and TWA (pore and overlying water)

7. CONCLUSIONS:

Results Synopsis:

Percent Emergence:
28-day NOAEC: 4.00 µg ai/L
28-day LOAEC: 8.00 µg ai/L
EC_{50}: 20 µg ai/L 95% C.I.: 18-24 µg ai/L
Probit slope: 4.07±0.664

Male Development Rate:
28-day NOAEC: 16.00 µg ai/L
28-day LOAEC: 32.00 µg ai/L
EC_{50}: >32.00 µg ai/L

Female Development Rate:
28-day NOAEC: 16.00 µg ai/L
28-day LOAEC: 32.00 µg ai/L
EC_{50}: >32.00 µg ai/L

Assessment endpoints: percent emergence and development rate
Endpoints affected: percent emergence and development rate

8. ADEQUACY OF THE STUDY:

A. Classification: Supplemental

B. Rationale: This study followed methods described in the proposal for a new OECD Guideline 219: "Sediment-Water Chironomid Toxicity Test Using Spiked Water" (December 2002), and was not submitted to fulfill any current U.S. EPA data requirement.

C. Reparability: N/A

9. MAJOR GUIDELINE DEVIATIONS:

1. Overlying water was spiked, prefer that the sediment is spiked.

2. Sediment was not analyzed for degradate NNI-0001 des-iodo levels.

10. SUBMISSION PURPOSE: To assess the toxicity of the degradate NNI-0001 des-iodo to the chironomid in a water spiked water-sediment system for the purpose of new chemical

registration (PRIA).

11. MATERIALS AND METHODS

Stability of Compound Under Test Conditions: Overlying water and pore water samples from the surrogate vessels prepared at 0.25, 4.00 and 32.0 µg ai/L (one vessel per interval) were analyzed at 0 (1 hour), 7, and 28 Days and analyzed for NNI-0001-des-iodo. Residues associated with the overlying water were decreased from 82% of nominal concentrations at Day 0 to 32% of nominal concentrations by Day 28. Concentrations in the pore water did not exceed 0.7% of nominal concentrations. No test material was detected in the negative or solvent controls.

Nominal Initial Conc. Applied to Water (µg ai/L)	Day	Analytical Results of NNI-0001-des-iodo In Overlying Water and Pore Water Sample			
		Pore Water		Overlying Water	
		µg ai/L	% of Nominal	µg ai/L	% of Nominal
Control	0, 7, 28	<0.05	N/A	<0.05	N/A
Solvent Control	0, 7, 28	<0.05	N/A	<0.05	N/A
0.25	0	<0.05	N/A	0.199	80
	7	<0.05	N/A	0.156	62
	28	<0.05	N/A	0.119	48
4.00	0	0.135	0.2	3.20	80
	7	0.363	0.7	2.31	58
	28	0.217	0.4	0.914	23
32.0	0	1.18	0.3	27.6	86
	7	5.98	1.4	18.7	58
	28	2.07	0.5	8.52	27

Storage conditions of test chemical: <5°C, dark

Physicochemical properties of NNI-0001-des-iodo.

Parameter	Values	Comments
Water solubility at 20°C	~0.42 mg/L	
Vapour pressure	Not reported	
UV adsorption	Not reported	
pKa	Not reported	
Kow	Not reported	

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound.

A. Test Organisms/Acclimation

Guideline Criteria	Reported Information
Species *Chironomus riparius*	*Chironomus riparius*
Source	In-house laboratory culture originally obtained from the University of Sheffield (UK) in autumn 1991.
Culture Conditions A reproduction and oviposit chamber should consist of an adult area, sufficiently large to allow swarming (minimum 30 x 30 x 30 cm), and an oviposit area. Crystallizing dishes or larger containers with a thin layer of quartz sand (5 to 10 mm) or Kieselgur (thin layer to a few mm) spread over the bottom and containing suitable water to a depth of several cm are suitable as an oviposit area. Environmental conditions: temperature 20±2°C; 16:8 hours light:dark (intensity ca. 1000 lux); air humidity ca. 60%	For breeding, the midges were kept in cages (60 x 60 x 55 cm) with gauze on each side of the cage. A glass basin (45 cm x 55 cm x 10 cm), made of inert plastic, was set on the bottom of each cage, and the bottom of the basin was covered with a thin layer of silica and 2- to3-cm of reconstituted water (Elendt M7). The water was gently aerated. To begin each culture, two to four egg masses are placed into the prepared basin. The cultures were maintained at 20 ± 2°C and a 16:8 hour light:dark photoperiod.
Egg Mass Acclimation Period Four to five days before test initiation freshly laid egg masses should be taken from cultures and maintained separately in culture medium, temperature change should not exceed 2°C per day.	Fresh egg masses were incubated in small dishes with test medium. The temperature was not reported.
Age of Test Larvae First instar (1 to 4 days post-hatch with confirmation)	1st instar (L1), 2-3 days post-hatch
Food Green algae (e.g., *Scenedesmus subspicatus, Chlorella vulgaris*) or flaked fish food as a ground powder, suspension, or filtrate	Hatched chironomus larvae were fed green algae and an aqueous suspension of a vegetable fish food (Tetra Phyll®).

Guideline Criteria	Reported Information
Health of parent culture stock Were parent chironomids in good health during the culture period?	Not reported.

B. Test System

Guideline Criteria	Reported Information
Type of Test System Static (static-renewal or flow-through of overlying water is evaluated on a chemical-specific basis). Distilled or deionized water may be added to overlying water once daily as needed to maintain volume.	Static with aeration. Once a week, test beakers were refilled with deionized water up to the mark (indicating 380 mL of overlying water) to replicate water lost by evaporation. Additional test vessels (with chironomids) were used for chemical analysis of the test item on days 0 and 7 (single additional replicate for the negative and solvent controls, and two additional replicates for the 0.25, 4.00 and 32.0 µg ai/L levels). For chemical analysis on day 28, one beaker of the four beakers for biological evaluations was used. Therefore, the method for analytical sampling did not affect volume, biological load, or test concentration. A further replicate of each test concentration was prepared (with chironomids) to measure the temperature, pH, and oxygen content in the overlying water during the study.

Guideline Criteria	Reported Information
Test Water Soft reconstituted water or water from a natural source is preferred. Dechlorinated tap water may be used if the test organism will survive in it for the duration of the culturing and testing without showing signs of stress.	Elendt M7 medium was prepared with deionized water 7 days prior to test initiation; a detailed chemical composition was provided. Alkalinity, hardness and ammonium were measured in the negative control and 32.0 µg ai/L treatment levels on Days 0 and 28. Alkalinity ranged from 213.6-284.8 mg $CaCO_3$/L, total hardness ranged from 302.6-338.2 mg $CaCO_3$/L and ammonium ranged from 1.3-16.2 mg/L.
Test Sediment Formulated (reconstituted, artificial, or synthetic) sediment is recommended. Content of sediment by dry weight: 5% peat (dry) (pH 5.5-6.0) or alpha-cellulose, 75% quartz sand (>50% in size range of 50-200 microns), 20% kaolinite clay (kaolinite content ca. 30%), $CaCO_3$ 0.05-0.1%). Moisture content 30-50%, TOC 2% (±0.5%) and pH 6.5 - 7.5. Natural sediment can be used if it is fully characterized, unpolluted, and free of organisms that might compete with or consume chironomids. (If solvent other than water will be used, sand content of artificial sediment is adjusted accordingly.)	Formulated (artificial) sediment was prepared on a dry weight basis 7 days before the start of the exposure period: 74% fine quartz sand (68.2% with a particle size of 0.05-0.2 mm) 5.0% dried, finely-ground peat (sphagnum peat, pH 2-4) 20% kaolin (kaolinite content of about 36%, pH 7) *ca.* 1% calcium carbonate to adjust the pH value to 7 ± 0.5. Sediment characterization: TOC: 2.5% Moisture content: 31.4% pH: 6.6 CEC (meq/100 g sediment): 7.4
Sediment Conditioning Artificial sediment: 7 days in flowing dilution water prior to test initiation, chambers may be aerated	Prepared sediment was equilibrated for 7 days prior to test initiation.

Guideline Criteria	Reported Information
Introduction of Test Organisms Twenty-four hours prior to test initiation aeration of chambers is stopped and organisms are added to the chambers. Aeration should not resume for at least 24 hours. At test initiation, the test substance is spiked into the overlying water column.	On day -1, test organisms were introduced into the equilibrated test vessels five at a time, until each replicate test vessel contained 20 larvae. On Day 0 the test substance was applied just below the water surface with a pipette. The bottom of the test vessels were covered with a 1.5-cm layer of sediment. Gentle mixing of the water ensured homogenous distribution without disturbing the sediment. Dilution water (0.38 L) was added over the sediment layer with the aid of a sheet to avoid disturbance of the sediment. The sheet was removed following flooding. The final water height was 6.0 cm. Vessels were gently aerated throughout the study.
Solvents If used, minimal (i.e., #0.1 ml/l) and same concentration in all treatments. Suitable solvents are acetone, ethanol, methanol, elthylene glycol monoethyl ether, ethylene glycol dimethyl ether, dimethylformamide or triethylene glycol. (OECD guidelines also allows use of dispersants: Cremophor RH40, Tween 80, methycellulose 0.01%, and HCO-40)	DMF, 16.3 mg test substance was dissolved in 50 mL DMF to obtain the stock solution. The stock solution was stirred on a magnetic stirrer for 2 minutes. To obtain the application solution, 1.180 mL of the stock solution was made up to 1 L with M7 medium and was stirred on a magnetic stirrer for 2 minutes.
Water Temperature 20°C ± 2°C (Should not deviate between vessels by more than 1°C.)	19.2-19.5°C
pH Sediment: 7.0 ± 0.5 Interstitial Water: Overlying Water: 6.0 to 9.0 (Should not vary by more than 1 unit during test)	Sediment: Not determined Interstitial Water: Not determined Overlying Water: 8.4-8.7

Guideline Criteria	Reported Information
TOC Sediment: 2 ± 0.5% Overlying Water: 2 mg/L	Sediment: 2.5% (determined prior to introduction into vessels) Overlying Water: Not determined
Ammonia Interstitial Water: Overlying Water:	Interstitial Water: Not determined Overlying Water: 1.3-1.7 mg/L on day 0 and 15.7-16.2 mg/L on day 28 (as measured in the control and highest treatment level)
Total Water Hardness 200 mg/L as $CaCO_3$ (prefer 160 to 180 mg/L as $CaCO_3$)	302.6-338.2 mg/L as $CaCO_3$ on days 0 and 28 (as measured in the control and highest treatment level)
Dissolved Oxygen 60% air saturation value throughout test	≥8.2 mg/L (≥91% saturation)
Aeration Aeration (ca. one bubble/sec) is allowed except for when larvae are being added and for at least 24 hours after introduction of test organisms to a test chamber. If one test chamber is aerated all test chambers must be treated the same.	Continuously at a rate of *ca.* 2 bubbles/sec through Pasteur pipettes.
Test Vessels or Compartments 1. Material: Glass, No. 316 stainless steel, teflon or perfluorocarbon plastics 2. Size: Sediment depth of 1.5- 3 cm and the depth ratio of sediment to water should be ca. 1:4, must not be >1:4; 600 ml beaker with 8 cm diameter	Material: glass Size: 600 mL; 1.5-cm layer of sediment and 6-cm laboratory dilution water depth (380 mL). The height ratio was 1:4 sediment to overlying water.
Covers Test vessels should be covered with a glass plate.	Test vessels were covered with clear plastic plates to prevent evaporation
Photoperiod 16 hours light, 8 hours dark (Light intensity 500 to 1000 lux)	16 hours light, 8 hours dark Light intensity ~800 lux

Guideline Criteria	Reported Information
Food Green algae (e.g., *Scenedesmus subspicatus, Chlorella vulgaris*) or flaked fish food as a ground powder, suspension, or filtrate	Tetra Phyll® ornamental fish food suspension (1 g Tetra Phyll® per 20 mL water)
Food Concentration and Frequency Preferably feed daily but at least 3 times per week. day 1 to 10: 0.25-0.5 mg per larvae per day remainder of test: 0.5-1 mg per larvae per day (keep to a minimum, should not accumulate on sediment surface, cause overlying water to be cloudy or cause drop in DO)	At least 3 times per week 1 mg Tetra Phyll® per larvae day every 1 to 3 days

C. Test Design

Guideline Criteria	Reported Information
Duration *Chironomus riparius*: 28 days (if midges emerge early the test can be terminated after a minimum of 5 days after emergence of the last adult in the control).	28 days

Guideline Criteria	Reported Information
Nominal Concentrations Negative control, solvent control (if a solvent was used) and at least 5 test concentrations. (Note exception to dilution factors described below can be made for shallow slope responses but minimum number of test concentrations may need to be increased)	Negative control, solvent control, 0.25, 0.50, 1.00, 2.00, 4.00, 8.00, 16.0 and 32.0 µg ai/L
ECx endpoint: test concentrations should bracket ECx and span the environmental concentration range. Dilution factor should not be greater than two between exposure concentrations.	ECx endpoint: N/A.
NOAEC/LOAEC endpoint: factor between concentrations must not be greater than 3.	NOAEC/LOAEC endpoint: A nominal factor rate of 2.0 was used.
Number of Test Organisms** ECx endpoint: 60 larvae per treatment level; 3 replicates per treatment level	ECx endpoint: N/A
NOAEC/LOAEC endpoint: at least 80 larvae per treatment level with at least 4 replicates per treatment level (adequate power to detect a 20% difference, Type I error rate 5%)	NOAEC/LOAEC endpoint: 80 larvae per treatment level with 4 replicates per treatment level.
**(Optional) If data on 10-day growth and survival are needed additional replicates (number based on ECx or NOEC/LOEC endpoint determination) should be included at test initiation..	**(Optional) 10-day growth data were not collected.
Test organisms randomly or impartially assigned to test vessels?	Organisms were randomly assigned to test containers.

Guideline Criteria	Reported Information
Overlying Water Parameter Measurements 1. Dissolved oxygen should be measured daily in all test chambers. 2. Temperature and pH should be measured in all test chambers at the start and end of the test and at least once a week during the test. 3. Temperature should be monitored at least hourly throughout the test in one test chamber. 4. Hardness and ammonia should be measured in the controls and one test chamber at the highest concentration at the start and end of the test.	1. Dissolved oxygen was measured twice weekly in the supplemental replicate vessels prepared for each treatment level. 2. Temperature and pH were measured once per week in the supplemental replicate vessels prepared for each treatment level. 3. Criteria not required in OECD 219 guidance. 4. Hardness and ammonia levels were measured in one control and one 32.0-mg ai/kg vessel at study initiation and termination.
Chemical Analysis-Overlying Water At a minimum must be analyzed at test initiation (i.e., one hour after introduction of test substance into the test chamber) and at the end of the test in at least the highest concentration and one lower concentration.	The overlying water of the three surrogate vessels prepared at the control, solvent control 0.25, 4.00 and 32.0 µg ai/L levels were analyzed at 0 (before addition of larvae), 7, and 28 days.
Interstitial Water and Sediment Isolation Method Centrifugation (e.g., 10,000 g and 4 EC for 30 min) is recommended. If test substance is demonstrated not to adsorb to filters, filtration may be acceptable.	Overlying water was decanted carefully. The wet sediment of each beaker was filtered by vacuum (glass micro fiber filter, mesh size 1.0 µm) and the filtrate (pore water) was analyzed.
Chemical Analysis-Interstitial Water At a minimum must be analyzed at the end of the test in at least the highest concentration and one lower concentration.	The isolated pore water of the three surrogate vessels prepared at the control, solvent control, 0.25, 4.00 and 32.0 levels were analyzed at 0 (before addition of larvae), 7, and 28 days.

Guideline Criteria	Reported Information
Chemical Analysis-Bulk Sediment At a minimum must be analyzed at the end of the test in at least the highest concentration and one lower concentration.	Analysis of the sediment was not conducted. OECD guidance states that sediment analysis may not be necessary if the partitioning of the test substance between water and sediment has been demonstrated in a separate water/sediment study under similar conditions. No such study was reported.

12. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes. This study was conducted in compliance with the GLP standards of the OECD and German Chemical Law (ChemG). It also meets the USEPA-FIFRA Good Laboratory Standards (40 CFR Part 160) as well as the GLP standards of the Japanese Ministry of Agriculture, Forestry and Fishereies (JMAFF, 11 Nohsan No. 6283 from Oct. 1999) with the exception that recognized differences exist between the GLP principles/standards of OECD and the GLP principles/standards of FIFRA and JMAFF.
Control Mortality <30%	Yes
Did chironomids emerge in controls between day 12 and 23?	Yes. Emergence was first observed on Day 14 for both controls and was done by Days 22 and 23 in the negative and solvent controls, respectively.
Control Emergence Mean emergence between 50-70%	Negative control – 82.5% emergence (66/80) Solvent control – 83.8% emergence (67/80)

Guideline Criteria	Reported Information
Data Endpoints Emergence Test (28 day) - Number alive - Time to emergence - Number of emerged male and female midges - Number of visible pupae that have failed to emerge - Number of egg masses deposited - Observations of other effects, abnormal behavior, or appearance or clinical signs (e.g., leaving sediment, unusual swimming) Growth and Survival (10-day) (Optional) - Number alive - Instar level of surviving larvae - Dry weight (ash free) per test chamber of surviving larvae by instar level	Emergence Test (28 day) - Number emerged; differentiated by sex - Development rate - Time to emergence - Number of dead larvae, pupae and midges which failed to emerge (visible) - Observations of other effects (i.e., sediment avoidance) Growth and Survival (10-day) (Optional) N/A
Raw data included?	Yes

Effects Data

Table 1. Summary of NNI-0001-des-iodo effects on *Chironomus riparius* emergence success and sex ratio

Toxicant Concentration				Initial No.	Total Number Emerged [c]			Mean Sex Ratio[d] (%)		% Inhibition in Emergence[e]
Nominal Overlying Water (µg ai/L)	TWA Concentrations [a]				♂	♀	Total	♂	♀	
	Overlying Water (µg ai/L)	Sediment[b]	Pore Water (µg ai/L)							
Negative control	<LOQ	N/A	<LOQ	80	38	28	66	57.6	42.4	N/A
Solvent control	<LOQ	N/A	<LOQ	80	35	32	67	52.2	47.8	-1.5
0.25	<LOQ	N/A	<LOQ	80	31	31	62	50.0	50.0	6.1
0.50	Not analyzed			80	33	34	67	49.3	50.7	-1.5
1.00	Not analyzed			80	27	33	60	45.0	55.0	9.1
2.00	Not analyzed			80	29	34	62	46.0	54.0	4.5
4.00	1.90	N/A	0.280	80	30	35	65	46.2	53.8	1.5
8.00	Not analyzed			80	29	26	55	52.7	47.3	16.7*
16.00	Not analyzed				25	19	44	56.8	43.2	33.3*
32.00	16.0	N/A	3.91	80	5	8	13	38.5	61.5	80.3*

[a] Reviewer-calculated time-weighted average for NNI-0001-des-iodo residues (from both overlying and pore water samples; refer to associated Excel spreadsheet). The LOQ for aqueous samples was 0.05 µg/L; when test material was <LOQ, ½ of the LOQ (0.0250 µg ai/L) was used in the TWA calculations.

[b] Samples were not collected from the sediment for analytical verification.

[c] Reviewer-calculated from the raw data

[d] $ER_{♂}$ = number of emerged males/number of emerged larvae; $ER_{♀}$ = number of emerged females/number of emerged larvae; reviewer-calculated.

[e] Reviewer-calculated relative to the negative control

N/A- Not Applicable

* Significant difference in percent emergence (% not emerged as calculated by the study author) from the pooled control (α=0.05).

Table 2. Summary of NNI-0001-des-iodo effects on *Chironomus riparius* development time and rate.

Toxicant Concentration				Days to First Emergence[b]	Mean Development Rate[c] (1/day)	% Inhibition in Mean Development Rate
Nominal Overlying Water (µg ai/L)	TWA Concentrations [a]					
	Overlying Water (µg ai/L)	Sediment[b]	Pore Water (µg ai/L)			
Negative control	<LOQ	N/A	<LOQ	14	0.057	N/A
Solvent control	<LOQ	N/A	<LOQ	14		
0.25	<LOQ	N/A	<LOQ	14	0.057	0.0
0.50	Not analyzed			14	0.056	1.8
1.00	Not analyzed			15	0.058	-1.8
2.00	Not analyzed			15	0.058	-1.8
4.00	1.90	N/A	0.280	15	0.057	0.0
8.00	Not analyzed			14	0.058	-1.8
16.00	Not analyzed			15	0.059	-3.5
32.00	16.0	N/A	3.91	16	0.053	7.0

[a] Reviewer-calculated time-weighted average for NNI-0001-des-iodo residues (from both overlying and pore water samples; refer to associated Excel spreadsheet). The LOQ for aqueous samples was 0.05 µg/L; when test material was <LOQ, ½ of the LOQ (0.0250 µg ai/L) was used in the TWA calculations.

[b] Reviewer-determined from summarized data tables. Does not represent mean days to first emergence.

[c] Mean development rate $= \sum_{i=1}^{m} \frac{f_i x_i}{n_e}$ where: i = index of inspection interval; m = maximum number of inspection intervals; f_i = number of midges emerged in the inspection interval i; n_e = total number of midges emerged; and

$x_i = 1 / \left(day_i - \frac{l_i}{2} \right)$ which is the development rate of the midges emerged in interval i; day_i = inspection day (days since application); and l_i = length of inspection interval i (days, 1 day in this study)

N/A- Not Applicable

Toxicity Observations: The Chi-square test indicated no statistically-different distribution (in number emerged) between sexes compared to the assumption of 50% females and 50%

males. Therefore, males and females were pooled for all further endpoint calculations to increase statistical power. Statistically-significant reductions in emergence were observed compared to the pooled controls at the 8.00, 16.00 and 32.00 µg ai/L treatment levels. No statistically-significant effects were observed in development rate.

No abnormal observations (dead larvae, pupae or midges) were observed in the controls or in the 0.25-16.00 µg ai/L treatment levels. At the highest treatment level, 32.00 µg ai/L, dead midges were observed on Days 17, 20, 21 and 23 and dead larvae/pupae were observed on Days 18, 19, 20 and 22. As these findings were observed in test concentrations clearly above the NOAEC (for emergence rates), they did not affect the outcome of the study.

B. Statistical Results (From Study Report)

Midge emergence, sex ratio, and development rate were statistically analyzed.

Midge emergence was evaluated as the percentage of midges that failed to emerge for each test level. Negative and solvent control emergence and development rate data were compared using a two-sided Chi-square 2 x 2 Table test (alpha = 0.05); no significant differences were observed, and the data were pooled for subsequent comparisons. Threshold concentrations (NOAEC) for emergence were determined using the Williams Multiple Sequential t-test Procedure (alpha = 0.05, one-sided).

The statistical distribution between sexes compared to the assumption of 50% males and 50% females were judged by a Chi-square 2 x 2 Contingency Table test. No significant effects were observed in sex distribution, and therefore, development rate data were reported using combined sexes.

For both endpoints, a range-to-standard-deviation-ratio test on Normal Distribution was tested (α=0.05) to test correspondence with normal distribution and Cochran's Test was conducted to test homogeneity of variance. Both the normality and homogeneity tests were passed, hence the use of a parametric multiple test.

For all endpoints, effective concentrations (ECx) were calculated using probit analysis.

Results were reported in terms of nominal initial overlying water concentrations.

Most sensitive endpoint: percent emergence

Endpoint	Methods	EC_{50} (95% CI) (µg ai/L)	NOAEC (µg ai/L)	LOAEC (µg ai/L)
28-d Percent Emergence (Pooled Sex)	Williams	18.6 (15.7-22.1)	4.00	8.00
28-d Development Rate (Pooled Sex)	Williams	>32.0	16.0	32.0
10-d Survival (Optional)	---	---	---	---
10-d Growth (Optional)	---	---	---	---

13. VERIFICATION OF STATISTICAL RESULTS

Statistical Method(s): Analyzed endpoints included percent emergence of the combined sexes, male development rate and female development rate. First, data from the negative and solvent control groups for all endpoints were compared using a Student's t-test to determine if a significant difference existed between the two controls; no differences were detected between the controls for any of the analyzed endpoints. Next, treatment data were tested for normality using Chi-square and Shapiro-Wilks tests and for homogeneity of variance using Hartley and Bartlett tests. As all data sets met these assumptions of ANOVA, NOAEC and LOAEC values were determined using the parametric Dunnetts' t-test (or Bonferroni's t-test for unequal replicates) and Williams' test via Toxstat Statistical software. The ECx values (with 95% C.I.) and probit slopes were determined using the probit analysis via Nuthatch Statistical software. All analyses were conducted using the nominal overlying water concentrations (µg ai/L). The mean replicate growth rate values for both males and females were multiplied by 10 by the reviewer in order to avoid treatment means of 0 within Toxstat.

Summary of Statistical Methods used for NOAEC/LOAEC Analyses.

Endpoint	Solvent vs Dilution Control		NOAEC/LOAEC	
	Method	Diff [1] (%)	Method	Diff [2] (%)
28-d Percent Emergence (Pooled sexes)	Student's t-test	-1.5%	Williams	1.5
28-d Development Rate- Male	Student's t-test	1.6%	Bonferroni	-0.8
28-d Development Rate- Female	Student's t-test	3.3%	Bonferroni	-2.8
10-d Survival (Optional)	N.D.	N.D.	N.D.	N.D.
10-day Dry Weight (Optional)	N.D.	N.D.	N.D.	N.D.

[1] Difference between the mean dilution water and solvent control responses.
[2] Difference between the dilution water and NOAEC concentration treatment.
N.D.- Not Determined

Most sensitive endpoint: Percent Emergence (combined sexes)

Verification Statistical Endpoint Values[a].

Statistical Endpoint	28-Day Emergence	28-Day Dev. Rate- Male	28-Day Dev. Rate- Female	10-D Survival	10-D Dry Weight
NOAEC	4.00	16.00	16.00	ND	ND
LOAEC	8.00	32.00	32.00	ND	ND
IC_{50} (95% C.I.)	20 (18-24)	>32.00	>32.00	ND	ND
Slope (Standard Error)	4.07±0.664	N/A	N/A	ND	ND

[a] Results are based on nominal initial overlying water concentrations (µg ai/L).
The 10-Day Survival and Dry Weight were not assessed

14. REVIEWER'S COMMENTS:

The reviewer's conclusions were more conservative than those of the study author as the reviewer detected significant inhibitions in male and female development rate at the highest treatment level relative to the negative control. Therefore, the reviewer's results are reported in the Conclusions section of this DER.

Overlying water and pore water samples from the surrogate vessels (one vessel per interval) were analyzed at 0, 7, and 28 days and analyzed for residues of NNI-0001-des-iodo for TWA calculations. However, as actual concentrations were not determined for each treatment level, results were reported in terms of initial nominal overlying water levels.

A detailed statistical report was provided in the study. Development rate data were assessed not only for combined sexes, but also for individual sexes. As assessment of the sex ratio percentages were not statistically different, only combined-sex data were reported within the study. However, the reviewer analyzed both data sets separately as both were readily available.

Overlying and pore water samples were analyzed by direct injection of the samples into an HPLC-MS/MS instrument. The mass spectrometric detector showed linear response in the concentration range of 0.042 µg/L to 12.5 µg/L for NNI-0001 in surface water with a correlation coefficient of 0.9995 and in the concentration range of 0.041 µg/L to 12.3 µg/L for NNI-0001-des-iodo in surface water with a correlation coefficient of 0.9997.

The MS/MS detection of NNI-0001 and NNI-0001-des-iodo were slightly affected by the matrix. The peak area of NNI-0001 in a surface water sample containing 0.5 µg/L was reduced to approximately 82% of the corresponding peak area in milli-Q-water. The peak area of NNI-0001-des-iodo in a surface water sample containing 0.5 µg/L was reduced to approximately 83% of the corresponding peak area in milli-Q-water.

The reviewer calculated the time-weighted average concentrations for the nominal 0.25, 4.00 and 32.00 µg ai/L treatment levels using the following equation:

$$C_{TWA} = \frac{\left(\frac{C_1 + C_0}{2}\right)(t_1 - t_0) + \left(\frac{C_2 + C_1}{2}\right)(t_2 - t_1) + \left(\frac{C_{n-1} + C_2}{2}\right)(t_{n-1} - t_2) + \left(\frac{C_n + C_{n-1}}{2}\right)(t_n - t_{n-1})}{t_n}$$

where:

C_{TWA} is the time-weighted average concentration,

C_j is the concentration measured at time interval j (j = 0, 1, 2,...n)

t_j is the number of hours (or days or weeks, units used just need to be consistent in the equation) of the test at time interval j

(e.g., t_0 = 0 hours (test initiation), t_1 =24 hours, t_2 =96 hours)

The experimental work began on March 5, 2004. The biological and analytical portions of the study were completed on April 9, 2004 and April 26, 2004. An initial definitive test was initiated on October 31, 2003; however, the chosen test concentrations did now show enough dose-related effects. The results from this test were not included in the study report.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL ANALYSIS:

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORM

t-test of Solvent and Blank Controls Ho:GRP1 MEAN = GRP2 MEAN

GRP1 (SOLVENT CRTL) MEAN =	82.5000	CALCULATED t VALUE =	-0.3612
GRP2 (BLANK CRTL) MEAN =	83.7500	DEGREES OF FREEDOM =	6
DIFFERENCE IN MEANS =	-1.2500		

TABLE t VALUE (0.05 (2), 6) = 2.447 NO significant difference at alpha=0.05
TABLE t VALUE (0.01 (2), 6) = 3.707 NO significant difference at alpha=0.01

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	2.412	8.712	13.752	8.712	2.412
OBSERVED	0	13	12	11	0

Calculated Chi-Square goodness of fit test statistic = 7.7586
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

Shapiro Wilks test for normality

D = 2693.750

W = 0.964

Critical W (P = 0.05) (n = 36) = 0.935
Critical W (P = 0.01) (n = 36) = 0.912

Data PASS normality test at P=0.01 level. Continue analysis.

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

Hartley test for homogeneity of variance

Calculated H statistic (max Var/min Var) = 22.75
Closest, conservative, Table H statistic = 281.0 (alpha = 0.01)

Used for Table H ==> R (# groups) = 9, df (# reps-1) = 3
Actual values ==> R (# groups) = 9, df (# avg reps-1) = 3.00

Data PASS homogeneity test. Continue analysis.

NOTE: This test requires equal replicate sizes. If they are unequal
but do not differ greatly, the Hartley test may still be used
as an approximate test (average df are used).

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

Bartletts test for homogeneity of variance

Calculated B statistic = 8.58
Table Chi-square value = 20.09 (alpha = 0.01)
Table Chi-square value = 15.51 (alpha = 0.05)

Average df used in calculation ==> df (avg n - 1) = 3.00
Used for Chi-square table value ==> df (#groups-1) = 8

Data PASS homogeneity test at 0.01 level. Continue analysis.

NOTE: If groups have unequal replicate sizes the average replicate size is
used to calculate the B statistic (see above).

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	8	14925.000	1865.625	18.699
Within (Error)	27	2693.750	99.769	
Total	35	17618.750		

Critical F value = 2.31 (0.05,8,27)
Since F > Critical F REJECT Ho:All groups equal

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	neg control	82.500	82.500		
2	0.25	77.500	77.500	0.708	
3	0.50	83.750	83.750	-0.177	
4	1.00	75.000	75.000	1.062	
5	2.00	78.750	78.750	0.531	
6	4.00	81.250	81.250	0.177	
7	8.00	68.750	68.750	1.947	
8	16.00	55.000	55.000	3.894	*
9	32.00	16.250	16.250	9.380	*

Dunnett table value = 2.53 (1 Tailed Value, P=0.05, df=24,8)

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	neg control	4			
2	0.25	4	17.869	21.7	5.000
3	0.50	4	17.869	21.7	-1.250
4	1.00	4	17.869	21.7	7.500
5	2.00	4	17.869	21.7	3.750
6	4.00	4	17.869	21.7	1.250
7	8.00	4	17.869	21.7	13.750
8	16.00	4	17.869	21.7	27.500
9	32.00	4	17.869	21.7	66.250

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	neg control	4	82.500	82.500	82.500
2	0.25	4	77.500	77.500	80.625
3	0.50	4	83.750	83.750	80.625
4	1.00	4	75.000	75.000	78.333
5	2.00	4	78.750	78.750	78.333
6	4.00	4	81.250	81.250	78.333
7	8.00	4	68.750	68.750	68.750
8	16.00	4	55.000	55.000	55.000
9	32.00	4	16.250	16.250	16.250

% Emergence (pooled sex), Day 28; ug ai/L
File: 7023pe Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
neg control	82.500				
0.25	80.625	0.265		1.71	k= 1, v=27
0.50	80.625	0.265		1.79	k= 2, v=27
1.00	78.333	0.590		1.81	k= 3, v=27
2.00	78.333	0.590		1.82	k= 4, v=27
4.00	78.333	0.590		1.83	k= 5, v=27
8.00	68.750	1.947	*	1.84	k= 6, v=27
16.00	55.000	3.894	*	1.84	k= 7, v=27
32.00	16.250	9.380	*	1.84	k= 8, v=27

s = 9.988
Note: df used for table values are approximate when v > 20.

Estimates of EC%

Parameter	Estimate	95% Bounds Lower	95% Bounds Upper	Std.Err.	Lower Bound /Estimate
EC5	8.0	5.4	12.	0.087	0.67
EC10	9.9	7.0	14.	0.073	0.71
EC25	14.	11.	18.	0.051	0.79
EC50	20.	18.	24.	0.031	0.87

Slope = 4.07 Std.Err. = 0.664

Goodness of fit: p = 0.84 based on DF= 6.0 27.

7023PE : % Emergence (pooled sex), Day 28; ug ai/L

Observed vs. Predicted Treatment Group Means

Dose	#Reps.	Obs. Mean	Pred. Mean	Obs. -Pred.	Pred. %Control	%Change
0.00	4.00	82.5	79.1	3.43	100.	0.00
0.250	4.00	77.5	79.1	-1.57	100.	3.59e-13
0.500	4.00	83.8	79.1	4.68	100.	2.73e-09
1.00	4.00	75.0	79.1	-4.07	100.	4.88e-06
2.00	4.00	78.8	79.1	-0.321	100.	0.00202
4.00	4.00	81.3	78.9	2.34	99.8	0.200
8.00	4.00	68.8	75.2	-6.43	95.1	4.93
16.0	4.00	55.0	52.6	2.43	66.5	33.5
32.0	4.00	16.3	16.7	-0.482	21.2	78.8

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORM

t-test of Solvent and Blank Controls Ho:GRP1 MEAN = GRP2 MEAN

GRP1 (SOLVENT CRTL) MEAN =	0.6150	CALCULATED t VALUE =	0.7746
GRP2 (BLANK CRTL) MEAN =	0.6050	DEGREES OF FREEDOM =	6
DIFFERENCE IN MEANS =	0.0100		

TABLE t VALUE (0.05 (2), 6) = 2.447 NO significant difference at alpha=0.05
TABLE t VALUE (0.01 (2), 6) = 3.707 NO significant difference at alpha=0.01

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	2.345	8.470	13.370	8.470	2.345
OBSERVED	0	12	13	10	0

Calculated Chi-Square goodness of fit test statistic = 6.4478
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

```
Shapiro Wilks test for normality
--------------------------------------------------------------------------------

D =    0.019

W =    0.949

Critical W (P = 0.05) (n = 35) = 0.934
Critical W (P = 0.01) (n = 35) = 0.910
--------------------------------------------------------------------------------

Data PASS normality test at P=0.01 level. Continue analysis.


Male development rate, Day 28; ug ai/L
File: 7023md        Transform: NO TRANSFORMATION

Hartley test for homogeneity of variance
--------------------------------------------------------------------------------

Calculated H statistic (max Var/min Var) =   73.50
Closest, conservative, Table H statistic =  281.0  (alpha = 0.01)

Used for Table H ==>     R (# groups) =   9,    df (# reps-1) =       3
Actual values    ==>     R (# groups) =   9,    df (# avg reps-1) =   2.89
                                                (average df used)

--------------------------------------------------------------------------------

Data PASS homogeneity test. Continue analysis.

NOTE: This test requires equal replicate sizes. If they are unequal
      but do not differ greatly, the Hartley test may still be used
      as an approximate test (average df are used).


Male development rate, Day 28; ug ai/L
File: 7023md       Transform: NO TRANSFORMATION

Bartletts test for homogeneity of variance
--------------------------------------------------------------------------------

Calculated B statistic =   15.82
Table Chi-square value =   20.09  (alpha = 0.01)
Table Chi-square value =   15.51  (alpha = 0.05)

Average df used in calculation  ==>   df (avg n - 1) =   2.89
Used for Chi-square table value ==>   df (#groups-1) =   8
--------------------------------------------------------------------------------

Data PASS homogeneity test at 0.01 level. Continue analysis.

NOTE: If groups have unequal replicate sizes the average replicate size is
      used to calculate the B statistic (see above).

Male development rate, Day 28; ug ai/L
File: 7023md        Transform: NO TRANSFORMATION

                                ANOVA TABLE
--------------------------------------------------------------------------------

SOURCE            DF              SS                MS              F
--------------------------------------------------------------------------------
```

Between	8	0.0068	0.0008	1.143
Within (Error)	26	0.0193	0.0007	
Total	34	0.0261		

Critical F value = 2.32 (0.05,8,26)
Since F < Critical F FAIL TO REJECT Ho:All groups equal

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

BONFERRONI T-TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	neg control	0.615	0.615		
2	0.25	0.600	0.600	0.802	
3	0.50	0.608	0.608	0.401	
4	1.00	0.620	0.620	-0.267	
5	2.00	0.623	0.623	-0.401	
6	4.00	0.610	0.610	0.267	
7	8.00	0.613	0.613	0.134	
8	16.00	0.620	0.620	-0.267	
9	32.00	0.570	0.570	2.227	

Bonferroni T table value = 2.68 (1 Tailed Value, P=0.05, df=26,8)

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

BONFERRONI T-TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	neg control	4			
2	0.25	4	0.050	8.2	0.015
3	0.50	4	0.050	8.2	0.007
4	1.00	4	0.050	8.2	-0.005
5	2.00	4	0.050	8.2	-0.007
6	4.00	4	0.050	8.2	0.005
7	8.00	4	0.050	8.2	0.003
8	16.00	4	0.050	8.2	-0.005
9	32.00	3	0.054	8.8	0.045

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	neg control	4	0.615	0.615	0.615
2	0.25	4	0.600	0.600	0.613
3	0.50	4	0.608	0.608	0.613

4	1.00	4	0.620	0.620	0.613
5	2.00	4	0.623	0.623	0.613
6	4.00	4	0.610	0.610	0.613
7	8.00	4	0.613	0.613	0.613
8	16.00	4	0.620	0.620	0.613
9	32.00	3	0.570	0.570	0.570

Male development rate, Day 28; ug ai/L
File: 7023md Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
neg control	0.615				
0.25	0.613	0.093		1.71	k= 1, v=26
0.50	0.613	0.093		1.79	k= 2, v=26
1.00	0.613	0.093		1.81	k= 3, v=26
2.00	0.613	0.093		1.82	k= 4, v=26
4.00	0.613	0.093		1.83	k= 5, v=26
8.00	0.613	0.093		1.84	k= 6, v=26
16.00	0.613	0.093		1.84	k= 7, v=26
32.00	0.570	2.166	*	1.84	k= 8, v=26

s = 0.027
Note: df used for table values are approximate when v > 20.

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORM

t-test of Solvent and Blank Controls Ho:GRP1 MEAN = GRP2 MEAN

GRP1 (SOLVENT CRTL) MEAN =	0.5350	CALCULATED t VALUE =	1.5275
GRP2 (BLANK CRTL) MEAN =	0.5175	DEGREES OF FREEDOM =	6
DIFFERENCE IN MEANS =	0.0175		

TABLE t VALUE (0.05 (2), 6) = 2.447 NO significant difference at alpha=0.05
TABLE t VALUE (0.01 (2), 6) = 3.707 NO significant difference at alpha=0.01

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

Chi-square test for normality: actual and expected frequencies

INTERVAL	<-1.5	-1.5 to <-0.5	-0.5 to 0.5	>0.5 to 1.5	>1.5
EXPECTED	2.345	8.470	13.370	8.470	2.345
OBSERVED	0	11	13	11	0

Calculated Chi-Square goodness of fit test statistic = 6.2117
Table Chi-Square value (alpha = 0.01) = 13.277

Data PASS normality test. Continue analysis.

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

Shapiro Wilks test for normality

D = 0.006

W = 0.969

Critical W (P = 0.05) (n = 35) = 0.934
Critical W (P = 0.01) (n = 35) = 0.910

Data PASS normality test at P=0.01 level. Continue analysis.

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

Hartley test for homogeneity of variance

Calculated H statistic (max Var/min Var) = 14.75
Closest, conservative, Table H statistic = 281.0 (alpha = 0.01)

Used for Table H ==> R (# groups) = 9, df (# reps-1) = 3
Actual values ==> R (# groups) = 9, df (# avg reps-1) = 2.89
(average df used)

Data PASS homogeneity test. Continue analysis.

NOTE: This test requires equal replicate sizes. If they are unequal
but do not differ greatly, the Hartley test may still be used
as an approximate test (average df are used).

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

Bartletts test for homogeneity of variance

Calculated B statistic = 6.40
Table Chi-square value = 20.09 (alpha = 0.01)
Table Chi-square value = 15.51 (alpha = 0.05)

Average df used in calculation ==> df (avg n - 1) = 2.89
Used for Chi-square table value ==> df (#groups-1) = 8

Data PASS homogeneity test at 0.01 level. Continue analysis.

NOTE: If groups have unequal replicate sizes the average replicate size is
used to calculate the B statistic (see above).

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	8	0.0043	0.0005	2.500

Within (Error)	26	0.0060	0.0002
Total	34	0.0103	

Critical F value = 2.32 (0.05,8,26)
Since F > Critical F REJECT Ho:All groups equal

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

BONFERRONI T-TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	neg control	0.535	0.535		
2	0.25	0.528	0.528	0.750	
3	0.50	0.525	0.525	1.000	
4	1.00	0.540	0.540	-0.500	
5	2.00	0.540	0.540	-0.500	
6	4.00	0.543	0.543	-0.750	
7	8.00	0.545	0.545	-1.000	
8	16.00	0.545	0.545	-1.000	
9	32.00	0.507	0.507	2.623	

Bonferroni T table value = 2.68 (1 Tailed Value, P=0.05, df=26,8)

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

BONFERRONI T-TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	neg control	4			
2	0.25	4	0.027	5.0	0.007
3	0.50	4	0.027	5.0	0.010
4	1.00	4	0.027	5.0	-0.005
5	2.00	4	0.027	5.0	-0.005
6	4.00	4	0.027	5.0	-0.008
7	8.00	4	0.027	5.0	-0.010
8	16.00	4	0.027	5.0	-0.010
9	32.00	3	0.029	5.4	0.028

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	neg control	4	0.535	0.535	0.538
2	0.25	4	0.528	0.528	0.538
3	0.50	4	0.525	0.525	0.538
4	1.00	4	0.540	0.540	0.538

5	2.00	4	0.540	0.540	0.538
6	4.00	4	0.543	0.543	0.538
7	8.00	4	0.545	0.545	0.538
8	16.00	4	0.545	0.545	0.538
9	32.00	3	0.507	0.507	0.507

Female development rate, Day 28; ug ai/L
File: 7023fd Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
neg control	0.538				
0.25	0.538	0.233		1.71	k= 1, v=26
0.50	0.538	0.233		1.79	k= 2, v=26
1.00	0.538	0.233		1.81	k= 3, v=26
2.00	0.538	0.233		1.82	k= 4, v=26
4.00	0.538	0.233		1.83	k= 5, v=26
8.00	0.538	0.233		1.84	k= 6, v=26
16.00	0.538	0.233		1.84	k= 7, v=26
32.00	0.507	2.446	*	1.84	k= 8, v=26

s = 0.015
Note: df used for table values are approximate when v > 20.