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

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 21, 2022

Mr. Jon C. Wood
AMVAC Chemical Corporation
4695 MacArthur Court, Suite 1200
Newport Beach, CA 92660

VIA E-MAIL, RETURN RECEIPT REQUESTED
**Subject: Suspension of Registration of Pesticide Product (EPA Registration Number 5481-495) for Failure to Comply with the Data Call-In (GDCI-078701-1140, issued January 31, 2013)**

Dear Mr. Wood:

This letter gives you notice that the EPA pesticide product registration number 5481-495, also listed in **Attachment I**, containing the active ingredient dimethyl tetrachloroterephthalate (DCPA), will be suspended 30 days from your receipt of this letter unless you take steps within that time to prevent this Notice from automatically becoming a final and effective order of suspension. This action is being taken pursuant to the Agency's authority under Section 3(c)(2)(B)(iv) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Upon becoming a final and effective order of suspension, any violation of the order will be an unlawful act under section 12(a)(2)(J) of FIFRA. In addition, any distribution or sale of a pesticide whose registration is suspended is an unlawful act under section 12(a)(1)(A) of FIFRA.

You are receiving this Notice of Intent to Suspend because you have failed to comply with the terms of the Data Call-In (DCI) notice cited above, issued pursuant to section 3(c)(2)(B) of FIFRA. Although AMVAC has provided updates about the statuses of given studies, multiple data requirements from the DCI remain outstanding. In a letter dated October 16, 2020[1], the Agency reminded AMVAC of the October 1, 2022 statutory deadline for EPA to complete registration review, as well as its original intent to use available data to complete the risk assessments necessary to reach a registration review decision by this deadline. However, due to these outstanding DCI data requirements, including but not limited to a study of the thyroid toxicity of DCPA, the Agency is not able to complete a human health risk assessment. Specifically, due to the lack of data examining the fetal thyroid toxicity of DCPA, the Agency is not able to complete a scientifically robust and defensible human health risk assessment. Preliminary data evaluated by EPA provides evidence that the fetus is potentially more sensitive to thyroid function compared to the mother in animal studies. Given the potential fetal sensitivity, EPA has concerns for exposures to pregnant females. Applying a standard uncertainty factor (typically a ten-fold factor) to account for these missing data may not be health

[1] *Notification of Outstanding Data Requirements, and Anticipated Registration Review Schedule for DCPA* (sent via email October 16, 2020).

protective based on EPA's review of these preliminary data. (See *DCPA. A Review of the Existing Thyroid Toxicity Data and Residual Uncertainty Related to the Lack of a Definitive Comparative Thyroid Assay*, DP[2] 464520, for the Agency's concerns about thyroid toxicity).

The factual background and status of outstanding DCI requirements leading to issuance of this Notice is provided in the Explanatory Appendix (Attachment III) to this Notice. The affected product and the requirement(s) which you failed to satisfy are listed and described in the following three attachments:

- Attachment I: Products List
- Attachment II: List of Outstanding Data
- Attachment III: Explanatory Appendix

The suspension of the registration of EPA product registration number 5481-495, also listed in Attachment I, will become final 30 days from your receipt of this Notice unless you or another person adversely affected by this Notice request a hearing, or you satisfy the outstanding data requirements listed in Attachment II.

**Request a Hearing**

You may avoid suspension under this Notice if you or another person adversely affected by this Notice properly requests a hearing within 30 days of your receipt of this Notice. If you request a hearing, it will be conducted in accordance with the requirements of section 6(d) of FIFRA and the Agency's Procedural Regulations in 40 CFR Part 164, to the extent applicable. The procedures for filing a request for a hearing are described below.

Section 3(c)(2)(B), however, provides that the only allowable issues which may be addressed at the hearing are whether you have failed to take the actions which are the bases of this Notice and whether the Agency's decision regarding the disposition of existing stocks is consistent with FIFRA. Therefore, no substantive allegation or legal argument concerning other issues, including but not limited to the Agency's original decision to require the submission of data or other information, the need for or utility of any of the required data or other information or deadlines imposed, any allegations of errors or unfairness in any proceedings before an arbitrator, and the risks and benefits associated with continued registration of the affected product, may be considered in the proceeding. The Administrative Law Judge shall by order dismiss any objections which have no bearing on the allowable issues which may be considered in the proceeding.

Section 3(c)(2)(B)(iv) of FIFRA provides that any hearing must be held and a determination issued within 75 days after receipt of a hearing request. This 75-day period may not be extended unless all parties in the proceeding stipulate to such an extension. If a hearing is properly requested, the Agency will issue a final order at the conclusion of the hearing governing the suspension of your product(s).

[2] DP = Data Product number: a sequentially-generated identifier assigned by the Agency to internal work requests.

A request for a hearing pursuant to this Notice must:

1) include specific objections which pertain to the allowable issues which may be heard at the hearing,
2) identify the registrations for which a hearing is requested, and
3) set forth all necessary supporting facts pertaining to any of the objections which you have identified in your request for a hearing.

If a hearing is requested by any person other than the registrant, that person must also state specifically why he asserts that he would be adversely affected by the suspension action described in this Notice.

Instructions for filing a request for a hearing are available at www.epa.gov/alj. You may file your request for a hearing electronically by clicking on the link to "E-file using the electronic filing system," or choose an alternative filing option by clicking on the link to "File by courier, mail or personal delivery." If you intend to use the electronic filing system, EPA advises that you register in advance because there may be a 1-2 business day delay between when you register and when you will be able to upload documents into the system.

An additional copy of your request for a hearing should be sent to the signatory listed below. The request must be **received** by the Hearing Clerk by the 30th day from your receipt of this Notice in order to be legally effective. The 30-day time limit is established by FIFRA and cannot be extended for any reason. Failure to meet the 30-day time limit will result in automatic suspension of your registration by operation of law and, under such circumstances, the suspension of the registration for your affected product will be final and effective at the close of business 30 days after your receipt of this Notice and will not be subject to further administrative review.

The Agency's Rules of Practice at 40 CFR 164.7 forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives.

Accordingly, the following EPA offices, and the staffs thereof, are designated as judicial staff to perform the judicial function of EPA in any administrative hearings on this Notice of Intent to Suspend: the Office of the Administrative Law Judges, the Office of the Environmental Appeals Board, the Administrator, the Deputy Administrator, and the members of the staff in the immediate offices of the Administrator and Deputy Administrator. In addition, the Administrator may designate specific individuals in the immediate office of the Administrator and the Office of General Counsel as judicial staff for particular hearings. None of the persons designated as the judicial staff shall have any ex parte communication with trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

**Satisfy Outstanding Data Requirements**

- You may also avoid suspension if, within 30 days of your receipt of this Notice, the Agency determines that you have taken appropriate steps to comply with the section

3(c)(2)(B) Data Call-In Notice. In order to avoid suspension under this option, you must satisfy the outstanding data requirements described in Attachment II, List of Outstanding Data Requirements, for the affected product by submitting all required supporting data/information described in Attachment II and in the Explanatory Appendix (Attachment III) by the following methods in order of Agency preference:

- **CDX Portal**

  Data may be submitted through CDX via the DCI application of the Pesticide Submission Portal (PSP). This is the preferred method. If you have a CDX account with access to the PSP, you may follow the link below to access your DCI(s): https://cdx.epa.gov/.

  A user guide is available for instructions on what to do if you do not have a CDX account (page 16 in the link below) or if you need to add PSP to your account (page 55 in the link below): https://cdx.epa.gov/content/documents/PSP/OPP_CDX_Pesticide_Submission_Portal Registration_UserGuidev1.0p.pdf.

- **Email**

  Submissions may be emailed to the address of the Chemical Review Manager associated with the case.

For you to avoid automatic suspension under this Notice, the Agency must also determine within the applicable 30-day period that you have satisfied the requirements that are the bases of this Notice and so notify you in writing. You should submit the necessary data/information as quickly as possible for there to be any chance the Agency will be able to make the necessary determination in time to avoid suspension of your product registration.

**Terms of Suspension Order**

The suspension of the registration of your company's product pursuant to this Notice will be rescinded when the Agency determines you have complied fully with the requirements which were the bases of this Notice. Such compliance may only be achieved by submission of the data/information described in the attachments to the CDX online submission portal or the appropriate Chemical Review Manager for the product's chemical case by email.

Your product will remain suspended, however, until the Agency determines you are in compliance with the requirements which are the bases of this Notice and so informs you in writing.

After the suspension becomes final and effective, the registrant subject to this Notice, including all supplemental registrants of the product registrant listed in Attachment I, cannot legally distribute, sell, use (including use to formulate another pesticide product), offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product listed in Attachment I, except for the purpose of disposal in accordance

with all applicable federal, state and local requirements. Any distribution or sale, by the registrant subject to this Notice, of a pesticide whose registration is suspended, is an unlawful act under section 12(a)(1)(A) of FIFRA. Any other violation of the suspension order, including use to formulate another pesticide product, is an unlawful act under section 12(a)(2)(J) of FIFRA.

Persons other than the registrant subject to this Notice, may continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product listed in Attachment I.

Nothing in this Notice authorizes any person to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product listed in Attachment I in any manner which would have been unlawful prior to the suspension.

You are reminded that it is your responsibility as the basic registrant to notify all supplemental distributors of your products listed in Attachment I that this suspension action also applies to their supplementary registered products. Note, too, that you can be held liable for violations committed by your supplemental distributors.

If you have any questions about the requirements and procedures set forth in this suspension notice or in the subject section 3(c)(2)(B) Data Call-In Notice, please contact James Douglass, the Chemical Review Manager, at douglass.james@epa.gov (preferred) or 202-566-2343.

Sincerely,

Mary Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
(via email at reaves.elissa@epa.gov)

**Attachments:**
Attachment I - Product List
Attachment II - List of Outstanding Data Requirements
Attachment III - Explanatory Narrative

**Attachment I – Product List**

Case Name: 0270 - DCPA (or chlorthal-dimethyl)
PC Code and Chemical Name: 078701 - DCPA (or chlorthal-dimethyl)
Test materials: DCPA and/or TPA (tetrachlorophthalic acid)

EPA Registration Number: 5481-495
Product Name: TECHNICAL CHLORTHAL DIMETHYL

**Attachment II - List of Outstanding Data Requirements**

| *Fate Data* | | |
|---|---|---|
| **OCSPP Guideline Number** | **Study Name (test material)** | **Due Date (from DCI)** |
| 835.4200 | Anaerobic soil metabolism (TPA) | 01/31/2015 |
| 835.4300 | Aerobic aquatic metabolism (TPA) | 01/31/2015 |
| 835.4400 | Anaerobic aquatic metabolism (TPA) | 01/31/2015 |
| *Ecological Effects Data* | | |
| **OCSPP Guideline Number** | **Study Name (test material)** | **Due Date (from DCI)** |
| 850.1350 | Chronic toxicity mysid (DCPA) | 01/31/2014 |
| 850.1350 | Chronic toxicity mysid (TPA) | 01/31/2014 |
| 850.1400 | Fish early life-stage (bluegill sunfish) (DCPA) | 01/31/2014 |
| 850.1400 | Fish early life-stage (sheepshead minnow) (DCPA) | 01/31/2014 |
| 850.1400 | Fish early life-stage (rainbow trout) (TPA) | 01/31/2014 |
| 850.1400 | Fish early life-stage (bluegill sunfish) (TPA) | 01/31/2014 |
| 850.1400 | Fish early life-stage (sheepshead minnow) (TPA) | 01/31/2014 |
| 850.2100 | Acute avian oral toxicity (passerine species) (DCPA) | 01/31/2014 |
| 850.4100 | Seedling Emergence (DCPA) [lettuce only] | 01/31/2014 |
| 850.4500 (formerly 850.5400) | Algal toxicity test, Tier I/II (TPA) [marine diatom only] | 01/31/2014 |
| Non-guideline | Chronic Sediment toxicity - *Chironomus* (DCPA) | 01/31/2015 |
| Non-guideline | Chronic Sediment toxicity - *Leptocheirus* (DCPA) | 01/31/2015 |
| *Human Health Data* | | |
| **OCSPP Guideline Number** | **Study Name (test material)** | **Due Date (from DCI)** |
| 860.1300 | Nature of the residue: poultry | 01/31/2015 |
| 860.1340 | Residue analytical method: livestock commodities | 01/31/2015 |
| 860.1480 | Meat/milk/poultry/eggs | 01/31/2015 |
| 860.1900 | Field accumulation in rotational crops | 01/31/2016 |
| Non-guideline | Comparative thyroid study (DCPA) | 01/31/2015 |

**Attachment III - Explanatory Appendix**

On January 31, 2013, the Agency issued the Data Call-In Notice GDCI-078701-1140 pursuant to FIFRA Section 3(c)(2)(B), which required the registrants of products containing DCPA used as an active ingredient to develop and submit certain data. The data were determined to be necessary to satisfy the registration review requirements of FIFRA Section 3(g). Failure to comply with the requirements of the registration review DCI constitute grounds for suspension under FIFRA Section 3(c)(2)(B)(iv).

Communications between the Agency and AMVAC concerning the outstanding data requirements, listed in Attachment II, that occurred after issuance of the DCI are summarized in the following table.

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| 835.4200 | Anaerobic soil metabolism | TPA | 01/31/2015 | 6 - citing a study | 04/29/2013 - AMVAC cited an existing study (MRID[4] 114651) to satisfy guideline 835.4200.<br><br>02/07/2017 - The Agency classified the study cited by AMVAC for guideline 835.4200 (MRID 114651) as supplemental, but required further data be submitted to satisfy this requirement (DP 413736).<br><br>10/16/2020 - The Agency sent AMVAC a letter via email that alerted it to outstanding DCI data requirements for guideline 835.4200. The Agency also solicited a response from AMVAC concerning its plans to satisfy the requirements identified in the letter.<br><br>12/17/2020 - AMVAC submitted a data waiver request (MRID | Waiver request (MRID 51398102) denied (DP 461053); data remain outstanding. A new anaerobic soil metabolism study must be of sufficient duration to reliably derive a half-life for TPA. |

[3] The DCI requires that the registrant respond to the DCI by specifying how it intends to address each data requirement. This column indicates how AMVAC responded directly after receiving the DCI.
[4] MRID = Master Record Identification number: a sequentially-generated identifier assigned by the Agency to external submissions.

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 51398102) for guideline 835.4200. The request was premised on evidence of the stability of TPA in anaerobic environments (from unidentified study data and the open literature).<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398102) for guideline 835.4200 (DP 461053). | |
| 835.4300 | Aerobic aquatic metabolism | TPA | 01/31/2015 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 835.4300.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 835.4300 (DP 413333).<br><br>10/16/2020 - The Agency sent AMVAC a letter via email that alerted it to outstanding DCI data requirements for guideline 835.4300. The Agency also solicited a response from AMVAC concerning its plans to satisfy these requirements identified in the letter.<br><br>12/17/2020 - AMVAC disputed the Agency's rationale for denying the waiver request for this data requirement. | Waiver request (MRID 49115401) denied (DP 413333); The Agency does not consider AMVAC's 12/17/20 correspondence to provide any additional evidence supporting the waiver of this data requirement. Data remain outstanding and are needed to reduce exposure uncertainties. |
| 835.4400 | Anaerobic aquatic metabolism | TPA | 01/31/2015 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 835.4400. The waiver request was premised on | Waiver request (MRID 51398102) denied (DP 461053); data remain outstanding. The anaerobic aquatic metabolism study must be of sufficient |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | the use of DCPA data in place of the same type of data for TPA.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 835.4400 (DP 413364). The Agency did not inform AMVAC of the denial until 3/17/17.<br><br>02/22/2018 – AMVAC responded to the denial by requesting that the Agency reconsider the waiver request after reviewing pending data from other TPA metabolism studies (MRID 50533512).<br><br>10/16/2020 - The Agency sent AMVAC a letter via email that alerted it to outstanding DCI data requirements for guideline 835.4400. The Agency also solicited a response from AMVAC concerning its plans to satisfy the requirements identified in the letter.<br><br>12/17/2020 - AMVAC submitted another data waiver request (MRID 51398102) for guideline 835.4400. The request was premised on evidence of the stability of TPA in anaerobic environments (from unidentified study data and the open literature).<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398102) for guideline | duration to reliably derive a half-life for TPA. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 835.4400 based on anticipated uncertainty in the assessment of environmental exposure in the absence of the data (DP 461053). | |
| 850.1350 | Aquatic invertebrate life-cycle, estuarine/marine mysid | DCPA | 01/31/2014 | 1 - developing data | 01/29/2014 – AMVAC submitted data (MRID 49307512) for guideline 850.1350 (DP 420871).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data submitted for guideline 850.1350 (MRID 49307512) was in review (DP 420871).<br><br>04/2022 - The Agency reviewed the data submitted by AMVAC for guideline 850.1350 (MRID 49307512) and determined further data was needed (DP 420871). | Some data have been submitted (MRID 49307512); further data are required (DP 420871) and remain outstanding. A definitive No Observed Adverse Effect Concentration (NOAEC) could not be established in the study as dose-responsive effects on male weight and length were observed at all doses. |
| 850.1350 | Aquatic invertebrate life-cycle, estuarine/marine mysid | TPA | 01/31/2014 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 850.1350.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 850.1350 (DP 413381).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1350 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement. | Waiver request (MRID 51398103) denied (DP 461052); data remain outstanding. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 12/17/2020 - AMVAC submitted another data waiver request (MRID 51398103) for guideline 850.1350.<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398103) for guideline 850.1350 (DP 461052). | |
| 850.1400 | Fish early life-stage (bluegill sunfish) | DCPA | 01/31/2014 | 4 - submitting existing data | 04/29/2013 – AMVAC expressed intent to submit existing data for guideline 850.1400.<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1400 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC communicated that it was commencing studies to satisfy guideline 850.1400 "in early 2021." No further timeframe was provided. | AMVAC is developing data, which remain outstanding. |
| 850.1400 | Fish early life-stage (sheepshead minnow) | DCPA | 01/31/2014 | 4 - submitting existing data | 04/29/2013 – AMVAC expressed intent to submit existing data for guideline 850.1400.<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1400 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement. | AMVAC is developing data, which remain outstanding. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 12/17/2020 - AMVAC communicated that it was commencing studies to satisfy guideline 850.1400 "in early 2021." No further timeframe was provided. | |
| 850.1400 | Fish early life-stage (rainbow trout) | TPA | 01/31/2014 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 850.1400.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 850.1400 (DP 413382).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1400 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC submitted another data waiver request (MRID 51398103) for guideline 850.1400.<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398103) for guideline 850.1400 (DP 461052). | Waiver request (MRID 51398103) denied (DP 461052); data remain outstanding. |
| 850.1400 | Fish early life-stage (bluegill sunfish) | TPA | 01/31/2014 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 850.1400. | Waiver request (MRID 51398103) denied (DP 461052); data remain outstanding. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 850.1400 (DP 413382).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1400 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC submitted another data waiver request (MRID 51398103) for guideline 850.1400.<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398103) for guideline 850.1400 (DP 461052). | |
| 850.1400 | Fish early life-stage (sheepshead minnow) | TPA | 01/31/2014 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 850.1400.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 850.1400 (DP 413382).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline 850.1400 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning | Waiver request (MRID 51398103) denied (DP 461052); data remain outstanding. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC submitted another data waiver request (MRID 51398103) for guideline 850.1400.<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398103) for guideline 850.1400 (DP 461052). | |
| 850.2100 | Acute avian oral, passerine species | DCPA | 01/31/2014 | 1 - developing data | 03/27/2013 – Protocol for guideline 850.2100 requested by the Agency via phone conversation.<br><br>04/29/2013 - AMVAC submitted protocol for guideline 850.2100 (DP 413328).<br><br>02/29/2014 - The Agency asked AMVAC to use the approved Huntingdon Life Sciences (HLS) passerine acute protocol for guideline 850.2100.<br><br>03/6/2014 - AMVAC agreed to use the approved HLS passerine acute protocol and requested a submission deadline extension to 10/30/2014 for guideline 850.2100.<br><br>09/30/2014 – AMVAC submitted data (MRID 49477601) for guideline 850.2100.<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data submitted for | Some data have been submitted (MRID 49477601); further data are required (DP 423300) and remain outstanding. Per OCSPP guideline 850.2100, the passerine study should have tested up to the maximum expected environmental concentration on food items. A dose-based study may not be feasible due to the high dose levels that need to be tested; therefore, testing may need to switch to the dietary-based test paradigm. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | guideline 850.2100 (MRID 49477601) was in review (DP 423300).<br><br>04/2022 - The Agency reviewed the data submitted by AMVAC for guideline 850.2100 (MRID 49477601) and determined further data was needed (DP 423300). | |
| 850.4100 | Tier I Plant tox - Seedling Emergence | DCPA | 01/31/2014 | 1 - developing data | 01/29/2014 – AMVAC submitted data for guideline 850.4100 (MRID 49307513).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data submitted for guideline 850.4100 (MRID 49307513) was in review (DP 420873).<br><br>04/2022 - The Agency reviewed the data submitted by AMVAC for guideline 850.4100 (MRID 49307513) and determined further data was needed for lettuce only (DP 420873). | Some data have been submitted (MRID 49307513); further data are required for lettuce only (DP 420873) and remain outstanding. |
| 850.4500 (formerly 850.5400) | Algal tox test, Tier I/II (marine diatom only) | TPA | 01/31/2014 | 9 - request for waiver of data | 04/29/2013 - AMVAC submitted data waiver request (MRID 49115401) for guideline 850.4500.<br><br>03/21/2014 - The Agency denied data waiver request from AMVAC (MRID 49115401) for guideline 850.4500 (DP 413393).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for guideline | Waiver request granted for freshwater diatom species and cyanobacterium only.<br><br>Waiver request (MRID 51398103) denied for marine diatom species only (DP 461052); data remain outstanding for marine diatom species only. |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| | | | | | 850.4500 was outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC submitted another data waiver request (MRID 51398103) for guideline 850.4500 (DP 461052).<br><br>03/03/2021 - The Agency contacted AMVAC to request two studies that were incorrectly cited in its data waiver request (MRID 51398103) for guideline 850.4500.<br><br>03/10/2021 - AMVAC provided two studies requested by the Agency on 03/03/2021 (MRID 51499401 and MRID 51499402) that were incorrectly cited in AMVAC's data waiver request for guideline 850.4500 (MRID 51398103).<br><br>01/25/2022 - DER for MRID 51499401 available (DP 461052). Study was classified supplemental with no additional data recommended for freshwater green algae species.<br><br>04/2022 - The Agency denied AMVAC's data waiver request (MRID 51398103) for guideline 850.4500 for marine diatom species only (DP 461052). | |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
|---|---|---|---|---|---|---|
| 860.1300 | Nature of the residue: poultry | DCPA | 01/31/2015 | 7 - deleting uses | 04/29/2013 - In its 90-day response to the DCI (MRID 49115401), AMVAC requested a waiver of guideline 860.1300 after deletion of alfalfa uses.<br><br>10/23/2013 - The Agency responded via memorandum (DP 413176) to AMVAC's waiver request for guideline 860.1300 made in its 90-day DCI response (MRID 49115401): Once the DCPA residues in corn and soybean as rotated crops have been determined (guideline 860.1900) in conjunction with possible soil drift contributions, a dietary burden can be estimated for poultry. If the dietary burden results in sufficiently low anticipated secondary residues in poultry tissue and eggs, a poultry metabolism study would be unnecessary.<br><br>07/31/2014 - AMVAC received the Agency's 10/23/2013 memorandum (DP 413176).<br><br>04/2020 - AMVAC has neither submitted data to satisfy guideline 860.1300 nor amended its product labels in a manner that obviates the need for the data called in under guideline 860.1300. | Data remain outstanding. |
| 860.1340 | Residue analytical method: livestock commodities | DCPA | 01/31/2015 | 7 - deleting uses | 04/29/2013 - In its 90-day response to the DCI (MRID 49115401), AMVAC requested a waiver of guideline 860.1340 after deletion of ruminant commodities. | Data remain outstanding. |

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| | | | | | 10/23/2013 - The Agency responded via memorandum (DP 413177) to AMVAC's waiver request for guideline 860.1340 made in its 90-day DCI response (MRID 49115401): Once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed (guideline 860.1900), a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then a livestock residue analytical method would not be necessary.<br><br>07/31/2014 - AMVAC received the Agency's 10/23/2013 memorandum (DP 413177).<br><br>04/2020 - AMVAC has neither submitted data to satisfy guideline 860.1340 nor amended its product labels in a manner that obviates the need for the data called in under guideline 860.1340. | |
| 860.1480 | Meat/milk/ poultry/eggs: ruminants | DCPA | 01/31/2015 | 7 - deleting uses | 04/29/2013 - In its 90-day response to the DCI (MRID 49115401), AMVAC requested a waiver of guideline 860.1480 after deletion of alfalfa, white potatoes, and peas.<br><br>10/23/2013 - The Agency responded via memorandum (DP 413202) to AMVAC's waiver request for guideline 860.1480 made in its 90- | Data remain outstanding. |

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| | | | | | day DCI response (MRID 49115401): Once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed, a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then a ruminant feeding study would not be necessary.<br><br>07/31/2014 - AMVAC received the Agency's 10/23/2013 memorandum (DP 413202).<br><br>04/2020 - AMVAC has neither submitted data to satisfy guideline 860.1480 nor amended its product labels in a manner that obviates the need for the data called in under guideline 860.1480. | |
| 860.1900 | Field accumulation in rotational crops | DCPA | 01/31/2016 | 5 - upgrading a study | 04/29/2013 - In its 90-day response to the DCI (MRID 49115401), AMVAC requested to satisfy guideline 860.1900 by upgrading a study.<br><br>10/23/2013 - The Agency responded via memorandum (DP 413218) to AMVAC's study upgrade request for guideline 860.1900 made in its 90-day DCI response (MRID 49115401): The Agency concluded that AMVAC had not submitted additional rotational crop data nor proposed any label restrictions that would obviate the need for rotational | Data remain outstanding. |

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| | | | | | crop tolerances. Furthermore, AMVAC must specify its intentions as to which crops are to be allowed in rotation with the crops on the label(s) and the desired plant back intervals (PBIs) for rotated crops.<br><br>01/29/2014 - In its 12-month response to the DCI (MRID 49307500), AMVAC provided additional storage stability data for guideline 860.1900.<br><br>07/07/2014 - The Agency responded via memorandum (DP 420907) to AMVAC's study upgrade for guideline 860.1900 made in its 12-month DCI response (MRID 49307500): the data submitted by AMVAC were not responsive to the DCI; additional field trials on rotated crops to determine the appropriate tolerance for residues of DCP A on those rotated crops remained outstanding.<br><br>07/30/2014 – AMVAC received Agency memorandum dated 07/07/2014 (DP 420907) stating data for guideline 860.1900 remained outstanding.<br><br>07/31/2014 - AMVAC received Agency memorandum dated 10/23/2013 (DP 413218) stating data remained outstanding. | |

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| | | | | | 08/11/2014 – In response to Agency memoranda, AMVAC submitted residue chemistry justifications (no MRID) for guideline 860.1900.<br><br>02/17/2015 - The Agency responded to AMVAC's submission from 08/11/2014 (DP 423450). The Agency concluded that rotation to a crop with an established tolerance for residues of DCPA (40 CFR 180.185) is permitted with a minimum plant back interval of 8 months; rotation to any other crop is not permitted. All labels for DCPA use on agricultural crops should be modified to reflect the appropriate rotational crop restrictions. Provided that the correct label modifications are made, additional field rotational crop data are not needed and the guideline 860.1900 data requirement will be considered fulfilled for DCPA. If rotation to crops without current tolerances for DCPA is desired, full rotational crop studies may be performed at the desired plant back intervals for those crops so that appropriate tolerance levels may be determined.<br><br>04/2020 - AMVAC has neither submitted data to satisfy guideline 860.1900 nor amended its product labels in a manner that obviates the need for the data called in under guideline 860.1900. | |

| OCSPP Guideline # | Study Name | Test Substance | Due Date | DCI Response Code[3] | Summary of Correspondence | Current Status |
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| ss-1069 | Chronic Sediment - *Chironomus dilutus* | DCPA | 01/31/2015 | 1 - developing data | 04/29/2013 - AMVAC submitted protocol for special study-1069.<br><br>03/20/2014 - The Agency reviewed protocol submitted by AMVAC for special study-1069 and described protocol revisions that it expected AMVAC to incorporate in its final report for this study (DP 413321).<br><br>10/20/2014 – AMVAC received the Agency's review dated 03/20/2014 (DP 413321).<br><br>12/15/2014 – AMVAC notified the Agency that the final protocol report for special study 1069 would be submitted by 06/15/2016.<br><br>03/19/2015 – The Agency confirmed with AMVAC via email that special study 1069 may proceed as described.<br><br>03/18/2016 – AMVAC submitted data (MRID 49865802) for special study 1069 (DP 432681).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data submitted for special study 1069 (MRID 49865802) was in review (DP 432681).<br><br>04/2022 - The Agency reviewed the data submitted by AMVAC for special study 1069 (MRID | Some data have been submitted (MRID 49865802); further data are required (DP 432681) and remain outstanding. The Agency determined that the statistically significant inhibitions observed for treatments compared to the negative control were likely the effect of the solvent and not actually an effect of the test substance. |

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| | | | | | 49865802) and determined further data were needed (DP 432681). | |
| ss-1072 | Chronic Sediment - *Leptocheirus plumulosus* | DCPA | 01/31/2015 | 1 - developing data | 04/29/2013 - AMVAC submitted protocol for special study-1072.<br><br>03/20/2014 - The Agency reviewed the protocol submitted by AMVAC for special study-1072 and described protocol revisions that it expected AMVAC to incorporate in its final report for this study (DP 413319).<br><br>10/20/2014 – AMVAC received the Agency's review dated 03/20/2014 (DP 413319).<br><br>12/15/2014 - AMVAC notified the Agency that further method development for special study-1072 was needed, and that an update would be provided on 03/31/2015.<br><br>03/30/2015 – AMVAC notified the Agency that further method development for special study-1072 was needed, and that an update would be provided in September 2015.<br><br>09/22/2015 – AMVAC notified the Agency that further method development for special study-1072 was needed, and that an update would be provided in March 2016.<br><br>03/15/2016 – AMVAC submitted a data waiver request (MRID 49865803) for special study-1072. | Data remain outstanding (DP 437397). |

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| | | | | | 06/27/2016 - The Agency denied the waiver request (MRID 49865803) for special study 1072 (DP 432677). As an alternative, the Agency allowed guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates, DCPA) to proceed to determine whether the full 28-day study would be required. Allowing AMVAC to conduct the 10-day guideline 850.1740 study instead of the 28-day study did not constitute a change in the Agency's policy or data requirements. The 28-day study will remain an outstanding DCI requirement since it includes effects on growth and reproduction which are not part of the 10-day study.<br><br>07/18/2016 – AMVAC received Agency response to its waiver request (DP 432677).<br><br>10/16/2020 - The Agency communicated to AMVAC in a letter via email that data for special study-1072 were outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement.<br><br>12/17/2020 - AMVAC communicated that it will await either a specific data requirement for the alternative acute study or confirmation that the chronic study | |

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| | | | | | guideline has been validated, but it would not be commencing studies to satisfy the requirements for special study 1072.<br><br>04/2022 - The Agency reiterated that AMVAC may proceed with guideline 850.1740 (spiked whole sediment 10-day toxicity test, saltwater invertebrates, DCPA), the results of which would allow the Agency to determine whether further data would be needed to satisfy the data requirements for special study 1072 (DP 437397). Since no estuarine/marine acute or chronic study data are available to address the requirements of special study-1072, the data remain outstanding. | |
| ss-thyroid tox. | Comparative thyroid study | DCPA | 01/31/2015 | 1 - developing data | A detailed list of the submission information is provided in a separate table titled ***Submission Information for Comparative Thyroid Study*** below. | Definitive CTA data remain outstanding. |

| ***Submission Information for Comparative Thyroid Study*** | |
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| Date | Description |
| 04/29/2013 | AMVAC submitted four initial Comparative Thyroid Assay (CTA) study protocols as part of its 90-day response to the DCI:<br>• DCPA(Chlorthal Dimethyl): Single and Repeat Exposure Dose Range Finding Study in Male and Female Juvenile Crl:CD(SD) Rats by Oral Gavage Administration (HLS Enquiry # 53284).<br>• DCPA (Chlorthal Dimethyl): Single Dose Comparative Thyroid and Thyroid Hormone Study in Young Adult and 11 Day Old Juvenile CD Rats by Oral Gavage Administration (HLS Enquiry # 53284/34).<br>• DCPA (Chlorthal Dimethyl): Repeat Dose Comparative Thyroid and Thyroid Hormone Study in Young Adult and 11 Day Old Juvenile CD Rats by Oral Gavage Administration (HLS Enquiry # 53284/35).<br>• DCPA (Chlorthal Dimethyl): Gestational Exposure Comparative Thyroid and Thyroid Hormone Study in the CD Rat by Oral Administration (HLS Enquiry # 53284/36). |
| 11/19/2013 | The Agency reviewed the four CTA study protocols submitted by AMVAC on 04/29/2013 (DP 413170). The protocols were deemed inadequate. The Agency recommended that a new protocol for a range-finding study for juvenile (PND 11) rats be drafted and submitted for Agency review before any thyroid assays were performed. The Agency also recommended that the range-finding study on young adult rats be submitted for Agency review. The Agency recommended that AMVAC consider the Agency's 2005 guidance document: Thyroid Assays in Pregnant Animals, Fetuses and Postnatal Animals, and Adult Animals and consult with the Agency prior to revision of the protocols. |
| 11/26/2014 | AMVAC submitted an additional revised comparative thyroid protocol:<br>• HLS Study# BDG0203. |
| 03/19/2015 | A conference call was held between the Agency and AMVAC to discuss the revised protocol. Points discussed included:<br>• No acute treatment (single exposure study) was needed.<br>• Repeat dosing range was adequate.<br>• Positive control (PTU) should be included.<br>• ADME/time course inclusion: discussion of 2 hours vs. 24 hours duration should be provided.<br>• Standard curves for thyroid hormone measures were required to be submitted with the final study.<br>• The gestational protocol should be integrated with the post-natal protocol for one study (all four protocols should be in one). |
| 04/01/2015 | AMVAC submitted revised comparative thyroid toxicity study protocols:<br>• Definitive Main Pre and Post Natal Developmental Thyroid Study in CD Rats by Oral Administration (Envigo study: BDG0202).<br>• DCPA (Chlorthal Dimethyl): Dose Range Finding Pre and Post Natal Developmental Thyroid Study in Sprague Dawley Rats by Oral Administration (Envigo Study: BDG0204).<br>• HLS Study # HLS1095. |

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| 04/16/2015 | The Agency found the protocols submitted by AMVAC on 04/01/2015 to be adequate (DP 424915). The Agency further recommended that AMVAC submit the positive control data and the results from the dose range-finding study before beginning a definitive CTA study. |
| 06/29/2015 | The Agency recommended that AMVAC conduct a special thyroid assay in pregnant animals, fetuses, postnatal animals, and adult animals (TXR#0057165). |
| 01/25/2017 | AMVAC updated the Agency via email about the CTA study status; explained delays with the study; and estimated a final report submission to the Agency by the end of 2018. |
| 03/17/2017 | The Agency requested that AMVAC send quarterly updates on its CTA study status. |
| 05/2017 | AMVAC began submitting semi-regular quarterly updates on the status of its CTA efforts. |
| 08/17/2017 | AMVAC submitted a positive control study (MRID 50357301). |
| 11/16/2017 | The Agency recommended that the new range-finding study incorporate all aspects such that the results would directly determine the dose levels, time points, and the potential for DCPA to be transferred in the milk avoiding the necessity of the direct dosing of pups in the definitive study (DP 444017). |
| 06/29/2018 | AMVAC submitted a pre-natal developmental thyroid dose range finding study (MRID 50663603). |
| 09/17/2019 | The Agency provided AMVAC with its review of the dose range-finding study plan submitted by AMVAC (Envigo Study No. JW36WK). The Agency recommended that the final study report contain internal standards and calibration curves. In reference to the immunoassay, the Agency recommended that the testing facility provide method validation data for the assessment of thyroid hormones to demonstrate similar results as those indicated by the manufacturer. (DP 420813). |
| 03/19/2020 | The Agency concluded that the updated protocol submitted by the registrant for the range-finding study (study # PM86YP) was adequate with the additional recommendations made at that time (DP 456384). |
| 06/23/2020 | AMVAC projected delivery of the dose range-finding final report at the end of December 2020 via email. |
| 08/06/2020 | AMVAC projected delivery of the dose range-finding final report at the end of March 2021 via email. |
| 10/16/2020 | The Agency communicated to AMVAC in a letter via email that data for the definitive CTA were outstanding. In this letter, the Agency solicited a response from AMVAC concerning its plans to satisfy the outstanding requirement. |
| 12/17/2020 | AMVAC communicated that it is developing data to satisfy the definitive CTA data requirements. |
| 03/25/2021 | AMVAC submitted a draft dose range-finding report for the CTA (Covance: PM86YP/8441782) and a protocol for the comprehensive CTA (Covance: 8432592) via the portal, and courtesy copies via email. |
| 05/27/2021 | AMVAC submitted the range-finding report for the CTA (MRID 51591701) and requested the review of the protocol for the main CTA assay by the end of June 2021. |
| 07/15/2021 | The Agency provided AMVAC with comments on the main CTA assay (Covance: 8432592) concerning dose selection and recommendations for the definitive CTA (DP 462323). |

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| 08/20/2021 | AMVAC provided responses to the Agency's review of the definitive CTA study protocol (Labcorp: 8432592), via email. |
| 01/26/2022 | AMVAC indicated that the in-life portion of the main CTA assay (initiated July 2021) was completed in August- September 2021, and projected delivery of CTA final report to the Agency at the end of June 2022, via email. |
| 02/07/2022 | The Agency requested supporting information for the CTA range-finding study, via email. |
| 02/09/2022 | The Agency requested additional supporting information (historical control thyroid hormone data).<br><br>AMVAC provided supporting information for the CTA range-finding study requested by the Agency on 02/07/2022. |
| 02/15/2022 | AMVAC provided supporting information (historical control thyroid hormone data) requested by the Agency on 02/09/2022, via email. |