

SETTLEMENT AGREEMENT

This Settlement Agreement embodies the agreement reached between the United States Environmental Protection Agency Office of Pesticide Programs (“OPP”) and AMVAC Chemical Corporation (“AMVAC”) to resolve a Notice of Intent to Suspend AMVAC’s Technical Chlorthal Dimethyl registration (EPA Reg. No. 5481-495) issued by the Agency on April 28, 2022, alleging that AMVAC failed to take appropriate steps in response to a January 31, 2013, Data Call-In Notice.

The undersigned parties, OPP and AMVAC, hereby stipulate and agree as follows:

WHEREAS, on January 31, 2013, OPP issued Generic Data Call-In Notice ID# GDCI-078701-1140 requiring submission of certain data determined by OPP to be necessary to support continued registration of products containing dimethyl tetrachloroterephthalate (“DCPA”) as an active ingredient;

WHEREAS, among the data required to be generated and submitted under the Data Call-In were studies addressing data requirements listed in Attachment A to this Settlement Agreement;

WHEREAS, AMVAC’s product, Technical Chlorthal Dimethyl (EPA Reg. No. 5481-495), is subject to the requirements of the Data Call-In Notice;

WHEREAS, AMVAC has been engaged with OPP concerning the requirements of the Data Call-In Notice and has fulfilled numerous data requirements contained therein through submission of data and other information;

WHEREAS, on April 28, 2022, OPP issued a Notice of Intent to Suspend (“NOITS”) based on AMVAC’s alleged failure to take appropriate steps in response to the Data Call-In Notice;

WHEREAS, after issuance of the NOITS, AMVAC requested a hearing by filing a hearing request with OPP, thus initiating a proceeding under FIFRA Section 3(c)(2)(B), Section 6(d), and 40 C.F.R. Part 164;

WHEREAS, the Grower-Shipper Association of Central California; J&D Produce; Ratto Bros., Inc.; and Huntington Farms separately requested a hearing as interested parties but have no obligation to comply with the Data Call-In Notice, and no obligations under this Settlement Agreement;

WHEREAS, prior to the hearing in this matter, as set forth in status updates filed on December 23, 2022 and January 18, 2023, *see* Dkts. 44, 53, OPP determined that eleven of the twenty data requirements identified in the NOITS were either satisfied or no longer formed a basis for OPP’s assertion that suspension was warranted, as set forth in those updates;

WHEREAS, in view of the status updates referenced in the prior clause, the hearing focused on the nine remaining data requirements identified in Attachment A to this Settlement Agreement;

WHEREAS, on May 16, 2023, following a hearing held January 24 through January 25, 2023, Chief Administrative Law Judge Susan L. Biro entered an Initial Decision and Order in Docket No. FIFRA-HQ-2022-0002 finding that AMVAC had not taken appropriate steps within the time required in response to the DCI, based on the evidence presented at the hearing, and that OPP's determination with respect to the disposition of existing stocks was consistent with FIFRA;

WHEREAS, on May 31, 2023, the Environmental Appeals Board granted AMVAC and OPP's Joint Motion to extend the deadline for exceptions to the Initial Decision and an appeal brief to facilitate settlement discussions;

WHEREAS, the Parties agree that this Settlement Agreement is not an admission of any wrongdoing or unlawful conduct by AMVAC, nor does it reflect a change in OPP's position that a basis exists for suspension of the registration of AMVAC's product. The Parties agree that this Agreement is a compromise and settlement of the claims in the NOITS;

WHEREAS, to avoid further litigation of the issues resulting in and from the issuance of the NOITS, AMVAC and OPP have reached this Settlement Agreement, the terms and conditions of which are set out in the following paragraphs. Given these circumstances, further litigation in this matter would not be an efficient use of AMVAC or OPP resources.

I. DEFINITIONS

A. For the purposes of this Settlement Agreement, the following terms are defined as below:

1. The terms "Data Call-In Notice" or "DCI" refer to Generic Data Call-In Notice ID# GDCI-078701-1140 issued by OPP on January 31, 2013. The Data Call-In Notice required, inter alia, the generation and submission of data responsive to the data requirements listed in Attachment A to this Settlement Agreement. This Settlement Agreement does not affect or apply to any other data requirements imposed by the Data Call-In Notice.
2. The terms "Notice of Intent to Suspend" or "NOITS" refer to the Notice of Intent to Suspend issued by OPP on April 28, 2022.
3. The term "sell or distribute" or its grammatical equivalent shall have the same meaning as set forth in section 2(gg) of FIFRA.
4. The phrase "substantial accordance with applicable requirements of the DCI" or any grammatical equivalent thereof shall mean that particular data, together with any reports or other documents setting forth or discussing that data, were generated and/or prepared in a manner consistent with all requirements for such data referenced and/or described in the DCI. Unless OPP determines that deviations from the OCSPP Guidelines or protocols, or other issues affect the scientific validity of submitted data, OPP will consider the submission to be in substantial accordance with applicable requirements of the DCI.

II. STATUS OF EPA REG. NO. 5481-495

A. EPA Reg. No. 5481-495 shall be suspended as of the date of the EAB's Final Decision and Order entering this Settlement Agreement, which shall constitute a suspension order under FIFRA Section 3(c)(2)(B).

B. EPA Reg. No. 5481-495 shall remain suspended pursuant to the terms of the EAB's Final Decision and Order entering this Settlement Agreement (and the terms and conditions governing the disposition of existing stocks incorporated therein) until the registration is reinstated under the terms of this Settlement Agreement.

III. AMVAC'S COMMITMENT TO SUBMIT DATA

A. AMVAC commits to continue generating data and to complete and submit related reports to OPP as specified in Attachment A to this Settlement Agreement.

B. The expected dates shown for the submittal of final reports for each study as shown on Attachment A are based on the most recent information available from the performing laboratories at the time of entry of this Settlement Agreement.

C. Submission of a request that the Agency waive a data requirement under 40 C.F.R. § 158.45, or any other assertion that data are not required, shall not be in substantial accordance with any applicable requirement of the DCI.

IV. OPP DATA REVIEW PROCEDURE

A. Following submittal of a final report subject to this Agreement, OPP shall have 90 days to conduct an initial screen to determine whether that data is in substantial accordance with applicable requirements referenced in the DCI and to notify AMVAC of its determination, except that in the case of the last final report submitted by AMVAC subject to this Settlement Agreement, OPP shall have 75 days instead of 90.

1. The expiration of any period set forth in this Settlement Agreement shall be determined consistent with the timing rules in 40 C.F.R. § 164.6(a).

2. The "day of the act ... from which the [period] begins to run" for application of those rules shall be the day on which AMVAC completes a submission to OPP in compliance with Section VII.A., not, in the case of final reports, the date indicated in Attachment A for expected submittal of data.

B. If OPP notifies AMVAC that submitted data passes the initial screen within the period identified in Section IV.A., or if OPP fails to provide any notification to AMVAC within the same period, the submitted data shall be deemed to be in substantial accordance with applicable requirements referenced in the DCI for purposes of reinstatement.

C. If OPP finds within the period established in Section IV.A that submitted data do not pass the initial screen, OPP shall, within that period, notify AMVAC of the reasons for this finding and shall provide AMVAC with an opportunity to submit additional information to address the

reasons specified in the notice.

D. If AMVAC submits additional information pursuant to Section IV.C., OPP shall re-evaluate the submitted data together with the additional information, to determine if the data and additional information collectively passes the initial screen.

1. OPP shall have 45 days to re-evaluate the combined information from the date of submittal of any additional information, consistent with Section IV.A, and notify AMVAC whether the combined information is sufficient, consistent with Section IV.B. If OPP finds that it is not, it shall provide an explanation and a further opportunity to supplement consistent with Section IV.C. This process shall be repeated until a submittal is deemed to pass the screen.

2. If OPP does not timely provide notification concerning the effect of additional information within any 45-day re-evaluation period established in this Section, this shall have the same effect as a lack of timely notification under Section IV.B.

E. For the avoidance of doubt, even if OPP advises AMVAC that submitted data is in substantial accordance with applicable requirements referenced in the DCI and thus passes the initial screen, or fails to timely notify AMVAC otherwise, such action (or inaction) shall not preclude OPP from later determining that any study or related submission must be replaced, repeated, or supplemented and that an order of suspension is warranted, or from initiating any other proceeding authorized by FIFRA, provided that, any order of suspension based on such later determination may occur only after issuance of a new Notice of Intent to Suspend pursuant to 7 U.S.C. § 136a(c)(2)(B)(iv) and exhaustion of AMVAC's rights under that provision.

F. AMVAC and OPP shall work cooperatively in the implementation of this Settlement Agreement and in the exchange of information as needed to accomplish the review process set forth above in an efficient manner. OPP shall, in good faith, provide notification required under this Section IV as soon as practicable following AMVAC's submission of a final report.

V. CONDITIONS FOR REINSTATEMENT

A. Within five days after the last final report subject to this Settlement Agreement has been determined (or deemed) to be in substantial accordance with applicable requirements referenced the DCI, pursuant to Section IV.B of this Settlement Agreement, OPP shall reinstate EPA Reg. No. 5481-495. Reinstatement shall be effective immediately upon AMVAC's receipt of notice from OPP concerning reinstatement.

B. OPP shall issue a public notice concerning reinstatement shortly after providing notice to AMVAC.

VI. RETENTION OF JURISDICTION; ENFORCEMENT

A. The Environmental Appeals Board shall retain jurisdiction to enforce this Settlement Agreement and to adjudicate any disputes between AMVAC and OPP arising under it, and AMVAC and OPP agree not to challenge such exercise of jurisdiction.

B. AMVAC and OPP will meet and confer prior to either filing any motion to enforce or

adjudicate a dispute under this Settlement Agreement. AMVAC and OPP consent to the procedure for disposition of any such motion set out in 40 C.F.R. § 164.60.

C. AMVAC will not challenge in any forum in any manner the entry of a Final Decision and Order of the EAB provided that it incorporates the terms of this Settlement Agreement.

D. AMVAC agrees that, for the purposes of FIFRA Sections 12, 13, and 14, any failure by it to comply with the suspension of EPA Reg. No. 5481-495, or the provisions concerning existing stocks of EPA Reg. No. 5481-495, as implemented by the Final Decision and Order shall constitute a violation of FIFRA.

E. AMVAC reserves its right to challenge any final decision of the EAB enforcing or interpreting this Settlement Agreement under this Section, or any other decision finding that a violation of FIFRA has occurred in connection with this Settlement Agreement or otherwise, in other fora.

VII. SUBMISSION OF DATA; NOTICES

A. Each report, notice, or other information required to be exchanged under this Settlement Agreement shall be submitted, if to OPP, through the Central Data Exchange (“CDX”) system, with an accompanying notification email sent to the current Chemical Review Manager informing OPP of the submission, unless OPP provides alternate direction in writing in advance for a particular submittal. Copies of the receipt received from CDX, and the associated tracking number, shall be provided to the current Chemical Review Manager. If CDX is not accepting submissions at the time a submission attempt is made, then AMVAC’s obligations under this Section shall be satisfied by sending an email to the current Chemical Review Manager (along with the document(s)) which were to be submitted through CDX) advising that issues were encountered with the submittal.

B. Each report, notice, or other information required to be exchanged under this Settlement Agreement shall be submitted, if to AMVAC, to: AMVAC’s regulatory manager for DCPA (niamhm@amvac.com) and VP of Regulatory Affairs (annet@amvac.com).

The foregoing SETTLEMENT AGREEMENT is HEREBY AGREED to by the undersigned,

United States Environmental Protection
Agency Office of Pesticide Programs

AMVAC Chemical Corporation (“AMVAC”)

By: _____

By: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Attachment A

| Guideline Reference | Study Requirement | Expected Report Submission |
|----------------------------------|--|---|
| 850.1400/TPA (sheepshead minnow) | Fish ELS | September 30, 2023 |
| 850.1400/TPA (bluegill sunfish) | Fish ELS | See Note ^a |
| 850.1400/TPA (rainbow trout) | Fish ELS | See Note ^a |
| 850.1350/TPA | Chronic Mysid (marine) | August 31, 2023 |
| 850.4500/TPA | Algal Tox (marine diatom) | MRID 52122002 submitted March 17 th 2023 ^c |
| SS-1072/DCPA | Initial Guideline 850.1740 acute 10-day study | July 31, 2023 |
| SS-1072/DCPA | Chronic Sediment (Leptocheirus) | See Note ^a |
| 835.4200/TPA | Anaerobic Soil Metab. | July 31, 2023 ^b |
| 835.4300/TPA | Aerobic Aqua. Metab. | July 31, 2023 ^b |
| 835.4400/TPA | Anaerobic Aqua. Metab. | July 31, 2023 ^b |

^a OPP shall retain discretion and authority to require completion of the 850.1400/TPA bluegill sunfish and/or rainbow trout studies following review of the 850.1400/TPA sheepshead minnow study, and of the chronic leptocheirus special study following review of the Guideline 850.1740 acute 10-day leptocheirus study, but the requirement for later submission of these additional studies shall not impact reinstatement of EPA Reg. No. 5481-495 pursuant to this Settlement Agreement. Upon notification by EPA that any of these studies must be completed, AMVAC commits to complete the stud(ies) and submit final report(s) within 365 days of EPA's notification. EPA notification for the need of these stud(ies) may occur after completion of the initial screen discussed in Section IV of this Settlement Agreement.

^b Date shown is for initial final reports based on 120-day data for the soil study and 100-day data for the aquatic studies. AMVAC commits to run studies out to 365 days for all studies per OPP direction and provide a corresponding update to the final report, but reinstatement of EPA Reg. No. 5481-495 pursuant to this Settlement Agreement relates to completion and submission of the 120/100 day final reports.

^c OPP shall conduct its initial screen of this final report within 60 days of the effective date of this Settlement Agreement, rather than the 90 days from submission provided by Section IV.A of this Settlement Agreement.