

# **Joint Exhibit 22**



December 17, 2020

Mr. James Douglass  
Risk Management and Implementation Branch III  
Pesticide Re-evaluation Division (7508P)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**Subject: Submission of Waiver Requests in Support of Registration Review  
DCPA – (GDCI ID# 078701)  
Response to EPA Memorandum dated October 16, 2020**

Dear Mr. Douglass:

Enclosed please find waiver requests submitted in further support of the subject Registration Review of Dacthal (DCPA). These requests are provided, in response to the Agency's memorandum dated October 16, 2020, to address certain OPPTS Guideline requirements for environmental fate and ecological effects related to data for the parent DCPA and degradate TPA.

#### Discussion of Outstanding Data Call-In Requirements

The scope of this response is limited to only those Guideline data requirements that are considered outstanding per the Agency's Notification dated 16-Oct-2020. It is our understanding that all data requirements not specifically listed below are considered either satisfied or are in review with the Agency.

Note that AMVAC previously submitted waiver requests (22-Feb-2018, MRID Nos. 505335 -01 to -13) for many of the outstanding data requirements discussed below. Since we have not received a response from the Agency, we have revisited, and in some cases refined, those earlier waiver requests, thereby rendering them somewhat obsolete.

- 835.4200 – Anaerobic Soil Metabolism (TPA)
- 835.4400 – Anaerobic Aquatic Metabolism (TPA)

Report enclosed titled 'Tetrachlorophthalic Acid (TPA) Anaerobic Terrestrial and Aquatic Metabolism Waiver Request' (AMVAC Report No. 100-REV-048, MRID No. [51398102](#))

- 835.4300 – Aerobic Aquatic Metabolism (TPA)

The Agency's rationale for not requiring further studies for DCPA also applies to TPA. Further, evidence has been provided that TPA is very stable and would not degrade during the course of a laboratory-based study.

- 835.6100 – Terrestrial Field Dissipation (DCPA)
- 835.6100 – Terrestrial Field Dissipation (TPA)

Report enclosed titled 'Dacthal (DCPA) Field Dissipation Waiver Request' (AMVAC Report No. 100-REV-047, MRID No. 51398101)

- 850.1025 – Oyster Acute Toxicity (shell deposition) (TPA)
- 850.1035 – Mysid Acute Toxicity (TPA)
- 850.1075 – Fish Acute Toxicity, Freshwater and Marine (TPA)
- 850.1350 – Mysid Chronic Toxicity (TPA)
- 850.4100 – Terrestrial Plant Toxicity Tier 1 (Seedling Emergence) (TPA)
- 850.4400 – Aquatic Vascular Plant Toxicity, Tiers 1, 2 (Lemna) (TPA)
- 850.4500 – Aquatic Non-Vascular Plant Toxicity Tier 1, 2 (Algal) (TPA)

Report enclosed titled 'Tetrachlorophthalic Acid (TPA): Selected Ecological Study Waiver Request' (AMVAC Report No. 100-REV-049, MRID No. 51398103)

- 850.1400 – Fish Early Life-Stage Toxicity

AMVAC has reviewed the Agency's most recent response (DER dated 17-Feb-2017, received 16-Oct-2020) concerning the submitted but rejected reports. On that basis, we will now initiate work to fulfill the Fish Early Life Stage study requirement for DCPA in early 2021.

Regarding this same study requirement for TPA, we are seeking a waiver for this work (Report enclosed).

- ss-1072 – Chronic Sediment (*Leptocheirus plumulosus*)

AMVAC wishes to remind the Agency of earlier discussions concerning the DCI requirement for conducting a chronic study on the sediment dwelling organism *Leptocheirus plumulosus*. As the Agency is aware, the specific requirements for conducting such a study have not been fully validated and for that reason, EPA requested that AMVAC conduct an acute study in the interim. AMVAC had agreed to this approach with the understanding that the acute study would fulfill the DCI study requirement for conducting a chronic study, assuming that the study, as expected, would demonstrate low toxicity. This understanding is based on the other two DCPA sediment dwelling organism tests that have been completed and submitted to EPA.

However, we have learned that EFED would not adopt this approach and insisted on retaining the requirement for the chronic study. Under such circumstances, AMVAC has chosen to await a specific DCI requirement for this acute study or will wait for confirmation that the chronic study guideline has been validated. Considering the very low toxicity associated with DCPA to aquatic organisms, AMVAC believes that this delay will not impact the Agency's conclusions concerning sediment dwelling organisms that can be made based on the available studies.

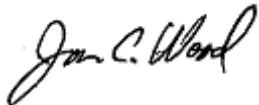
- ss-thyroid tox – Comparative Thyroid Assay

This is the only study currently in progress. We continue to provide the Agency with quarterly updates, the most recent submitted via email 09-Dec-2020.

Attached please find a Transmittal Document that lists the five reports submitted via CDX e-portal system (dated 17-Dec-2020).

As always, AMVAC welcomes the opportunity to meet (virtually) with the Agency to discuss the Registration Review of Dacthal. Meanwhile, if you have questions or require additional information, please do not hesitate to contact me at (949) 221-6109 or [jonw@amvac.com](mailto:jonw@amvac.com). Thank you for your patience and consideration in this matter.

Best regards,

A handwritten signature in black ink that reads "Jon C. Wood". The signature is written in a cursive, flowing style.

Jon C. Wood  
Sr. Regulatory Manager

## Transmittal Document

### Name and Address of Submitter:

**AMVAC Chemical Corporation**  
4695 MacArthur Court, Suite 1200  
Newport Beach, CA 92660-1868

### Company No. 5481

**Contact Person: Jon C. Wood**  
**Sr. Regulatory Manager**  
**(949) 221-6109**  
[jonw@amvac.com](mailto:jonw@amvac.com)

### Regulatory Actions:

Submission of waivers in support of Registration Review of Dacthal (GDCI ID# 078701).

**Transmittal Date:** December 17, 2020

### List of Submitted Studies:

Vol.#	Contents	Guideline No.	Study Report Title	MRID No.
1	GDCI Waiver	835.6100	Dacthal (DCPA) Field Dissipation Waiver Request (AMVAC Report No. 100-REV-047)	51398101
2	GDCI Waiver	835.4200 835.4400	Tetrachlorophthalic Acid (TPA) Anaerobic Terrestrial and Aquatic Metabolism Waiver Request (AMVAC Report No. 100-REV-048)	51398102
3	GDCI Waiver	850.1025 850.1035 850.1075 850.1350 850.1400 850.4100 850.4400 850.5400	Tetrachlorophthalic Acid (TPA): Selected Ecological Study Waiver Request (AMVAC Report No. 100-REV-049)	51398103
4	Study Report	850.1300	Chlorthal-dimethyl (DCPA) Reproduction Study with Daphnia magna, Report No. 1708/035-D2149 (AMVAC Ref. No. 100-REP-007)	51398104
5	Study Report	850.1075	Dacthal W-75: Acute Toxicity to Oncorhynchus mykiss, Report No. 1708/036-D1249 (AMVAC Report No. 100-ACT-111)	51398105

Attachments omitted