# Joint Exhibit 16

EPA OALJ Docket No. FIFRA-HQ-2022-0002

AMVAC

August 24, 2018

Mr. Jordan Page
Risk Management and Implementation Branch III
Pesticide Re-evaluation Division (7508P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

**Subject:** **Submission of Reports and Quarterly Update in Support of Registration Review:**
**DCPA – (GDCI ID# 078701)**
**Special Study Guideline Requirement -- Comparative Thyroid Assay**

Dear Mr. Page:

Enclosed please find the following reports and updates, submitted in support of Registration Review of DCPA (aka Dacthal; chlorthal dimethyl):

- Validation of an Immunoassay Method for the Measurement of Thyroid Stimulating Hormone (TSH) in Rat Serum. Seavers, L. June 2018 (Envigo Study No. SL13SG).
- Validation of a Bioanalytical Method for the Determination of 3,3,5'-Triiodo-L-Thyronine (T3) and Thyroxine (T4) in Rat Serum using Liquid Chromatography with Tandem Mass Spectrometric Detection (LC-MS/MS). Peard, A. June 2018 (Envigo Study No. FF58YR).
- DCPA (Chlorthal Dimethyl): Dose Range Finding Pre-Natal Developmental Thyroid Study in Sprague-Dawley Rats by Oral Administration. Leggett, A. June 2018 (Envigo Study No. BDG0204).
- Summary Table of Thyroid Hormone Methods and Control Ranges – Sprague Dawley Rats, Charles River UK (Envigo).
- Study outline and design (Envigo Study Plan No. JW36WK).
- Comparative Thyroid Assay - Quarterly Update (dated 24-Aug-2018).

We have the methods developed now for DCPA in both rat milk and plasma and are undergoing the required validation studies currently. As soon as these are fully reported, we will send these in to EPA, together with our DCPA: Dose range finding pre and post-natal developmental thyroid study (including a PTU positive control group) in Sprague-Dawley rats by oral administration (Envigo Study Plan: JW36WK) Study Protocol for EPA's review and approval, before we commence the study.

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Note that this report is submitted in partial fulfillment of the Special Study Guideline requirement (ss-comparative thyroid) and additional reports will be submitted as soon as they become available. If you have questions or require additional information, please do not hesitate to contact me at (949) 221-6109 or jonw@amvac-chemical.com. Thank you for your attention to this matter.

Best regards,

Jon C. Wood
Sr. Regulatory Manager

ENVIGO

**Plan for completion of DCPA developmental thyroid studies:**

1) **DCPA (Chlorthal Dimethyl): Dose Range Finding Pre and Post Natal Developmental Thyroid Study in Sprague Dawley Rats by Oral Administration (Envigo Study: BDG0204).**

We need to rerun Phase I of this study because the rat Luminex immunofluorescence assay which was used at the time the study was performed was not able to detect quantifiable levels of T4 and T3 in plasma from rat fetuses: and these are critical endpoints on the study. The assays were validated to the lowest possible limits of detection taking into account the limited available scientific literature on this subject.

As Phases II and III of the study were scheduled to start after Phase I, we acted quickly and those phases were not performed and will be performed once the rerun of Phase I has been completed. Detection of T4 and T3 and TSH in the dams and TSH in the fetuses was successful using the Luminex assay.

In order to overcome this challenge Envigo has now developed an LC-MS MS assay with much lower detection limits (pg/ml) which has been proven to detect T4 and T3 in Control fetuses. The assay, which detects T4 and T3 simultaneously, has been satisfactorily validated for accuracy and precision and we also have 1 month frozen stability data and are currently investigating stability for longer periods of storage. The Luminex assay is also currently being validated for detection of TSH in serum so that all 3 hormones are assayed in the same medium, serum.

The rerun of Phase I was authorised by UK Home Office and the in life phase and thyroid hormone assays have been successfully completed as follows:

Animal arrival 22 February 2017.

Start of dosing on Day 6 after mating: 6 March 2017

Completion of in life phase: 26 March 2017

Thyroid hormone assay results issued: 19 May 2017

The results from Phase I have been reviewed by US EPA.

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envigo.com

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Submission of the following Reports and Table as per 2nd Quarterly update 2018.

Validation of an Immunoassay Method for the Measurement of Thyroid Stimulating Hormone (TSH) in Rat Serum. Seavers, L. June 2018 (Envigo Study Number SL13SG)

Validation of a Bioanalytical Method for the Determination of 3,3,5'-Triiodo-L-Thyronine (T3) and Thyroxine (T4) in Rat Serum using Liquid Chromatography with Tandem Mass Spectrometric Detection (LC-MS/MS). Peard, A. June 2018 (Envigo Study Number FF58YR)

DCPA (Chlorthal Dimethyl): Dose Range Finding Pre-Natal Developmental Thyroid Study in Sprague-Dawley Rats by Oral Administration. Leggett, A. June 2018 (Envigo Study Number BDG0204).

Table: Summary of Thyroid Hormone Methods and Control Ranges – Sprague Dawley Rats, Charles River UK (Envigo)

The following method validation studies are in progress:

DCPA: Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl (DCPA) in Rat Plasma ($K_2$EDTA) using Liquid Chromatography with Tandem Mass Spectometric Detection (LC-MS/MS). Envigo Study: DC87NT. Protocol Issued on 19 June 2018. Final Report scheduled for September 2018.

DCPA: Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl (DCPA) in Rat Milk using Liquid Chromatography with Tandem Mass Spectometric Detection (LC-MS/MS). Envigo Study: CH09GN. Protocol Issued on 19 June 2018. Final Report scheduled for September 2018.

The full draft study protocol will be submitted into EPA by October 2018 for EPA's review:

DCPA: Dose range finding pre and post-natal developmental thyroid study (including a PTU positive control group and milk investigation) in Sprague-Dawley rats by oral administration. (Envigo Study Number: JW36WK).

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**Testing on the new range-finding pre- and post-natal developmental thyroid study (Envigo Study No. JV36WK) study will proceed as soon as possible following authorisation to proceed is received from US EPA.**

The results will determine the doses for the definitive main pre and post natal developmental thyroid study (BDG0202) and the precise design and size of the study (i.e. if direct dosing of pups required) and if it is how many groups of pups will need to be dosed.

2) **DCPA (Chlorthal Dimethyl): Definitive Main Pre and Post Natal Developmental Thyroid Study in CD Rats by Oral Administration (Envigo Study:BDG0202)**

Testing will proceed as soon as possible once the range-finding pre- and post-natal developmental thyroid study (Envigo Study No. JV36WK) has been completed and all of the results from that study have been reviewed by US EPA and authorisation to proceed is received.

D. P. Myers 24 August 2018

Signed: David P Myers, BSc, PhD, IDT, Senior Toxicologist, Department of Toxicology

Test Facility:
ENVIGO CRS Limited
Eye
Suffolk
IP23 7PX
UK

Pages omitted

| Data Submission | | | | |
|---|---|---|---|---|
| **DCI Number: GDCI-078701-1140** | | | | |
| **Data Call-In Information** | | | | |
| Company Name | **AMVAC CHEMICAL CORPORATION** | | | |
| Company Address | **4695 MACARTHUR COURT, SUITE 1200 NEWPORT BEACH, CA 926601706** | | | |
| DCI Type | **Generic** | | | |
| Issued Date | **01/31/2013** | | | |
| 90-Day Response Deadline | **05/11/2013** | | | |
| CRM Information | **King, Marquea** | | | |
| Chemical Name | **DCPA (or chlorthal-dimethyl?)** | | | |
| Chemical Number | **078701** | | | |
| **Data Submission Information** | | | | |
| Tracking Number | **CDX_DCI_2018_000403** | | | |
| **DCI Level Documents** | | | | |
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180824 Signed Cover Letter DCPA Thyroid Study Qtrly Update and Reports.pdf** | **Transmittal Document** | **N.A.** | **N.A.** | **08/28/2018** |
| **EPA Product Registration Number(s)** | | | | |
| 5481-495 | | | | |
| **EPA Product Registration Documents: 5481-495** | | | | |
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI Waivers_Transmittal_DRAFT.pdf** | **General Correspondences** | **N.A.** | **N** | **02/23/2018** |
| **20180222 DCPA GDCI Waivers_870-1_signed.pdf** | **General Correspondences** | **N.A.** | **N** | **02/23/2018** |
| **Guideline Requirement Number(s)** | | | | |
| **Guideline Requirement Number - 835.1230** | | | | |
| Study Title | **Sediment and soil absorption/desorption for parent and degradates** | | | |
| Protocol | **N** | | | |
| Target Submission Date | **01/31/2014** | | | |
| Use Pattern | **A; B; C; II; K; U** | | | |
| Test Substance | **DEGR** | | | |
| Time Frame | **12 month(s)** | | | |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** | | | |
| Registrant Response | **N.A.** | | | |
| **Guideline Requirement Number - 835.1240** | | | | |
| Study Title | **Soil column leaching** | | | |
| Protocol | **N** | | | |
| Target Submission Date | **01/31/2014** | | | |
| Use Pattern | **A; B; C; II; K; U** | | | |
| Test Substance | **DEGR** | | | |

| | |
|---|---|
| Time Frame | **12 month(s)** |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 835.2120** | |
| Study Title | **Hydrolysis of parent and degradates as a function of pH at 25 C** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **DEGR** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 835.4100** | |
| Study Title | **Aerobic soil metabolism** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **DEGR** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 835.4200** | |
| Study Title | **Anaerobic soil metabolism** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **DEGR** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 835.4300** | |
| Study Title | **Aerobic aquatic metabolism** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.** |
| Registrant Response | **N.A.** |
| **Uploaded Documents** | |

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| 20180222 DCPA GDCI_Waiver 835.4300 Aerobic Aquatic Metabolism.pdf | Data Waiver Request | 50533511 | No CBI | 02/23/2018 |

| Guideline Requirement Number - 835.4400 | |
|---|---|
| Study Title | Anaerobic aquatic metabolism |
| Protocol | N |
| Target Submission Date | 01/31/2015 |
| Use Pattern | A; B; C; II; K; U |
| Test Substance | DEGR |
| Time Frame | 24 month(s) |
| Footnote(s) | 3. Test to be conducted with TPA degradate only. |
| Registrant Response | N.A. |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| 20180222 DCPA GDCI_Waiver 835.4400 Anaerobic Aquatic Metabolism.pdf | Data Waiver Request | 50533512 | No CBI | 02/23/2018 |

| Guideline Requirement Number - 835.6100 | |
|---|---|
| Study Title | Terrestrial field dissipation |
| Protocol | N |
| Target Submission Date | 01/31/2015 |
| Use Pattern | A; B; C; II; K; U |
| Test Substance | COMMENT |
| Time Frame | 24 month(s) |
| Footnote(s) | 2. Tests to be conducted with DCPA parent and TPA degradate. |
| Registrant Response | N.A. |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| 20180222 DCPA GDCI_Waiver 835.6100 Terrestrial Field Dissipation.pdf | Data Waiver Request | 50533513 | No CBI | 02/23/2018 |

| Guideline Requirement Number - 850.1010 | |
|---|---|
| Study Title | Aquatic invertebrate acute toxicity, test, freshwater daphnids |
| Protocol | N |
| Target Submission Date | 01/31/2014 |
| Use Pattern | A; B; C; II; K; U |
| Test Substance | COMMENT |
| Time Frame | 12 month(s) |
| Footnote(s) | 2. Tests to be conducted with DCPA parent and TPA degradate. |
| Registrant Response | N.A. |

**Guideline Requirement Number - 850.1025**

| | |
|---|---|
| Study Title | **Oyster acute toxicity test (shell deposition)** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>15. Preferred test species is Crassostrea virginica, Eastern oyster.** |
| Registrant Response | **N.A.** |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| **20180222 DCPA GDCI_Waiver 850.1025 Oyster Acute Toxicity Test (shell deposition).pdf** | **Data Waiver Request** | **50533502** | **No CBI** | **02/23/2018** |

**Guideline Requirement Number - 850.1035**

| | |
|---|---|
| Study Title | **Mysid acute toxicity test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>13. Preferred test species is Mysidopsis bahia, mysid shrimp.** |
| Registrant Response | **N.A.** |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| **20180222 DCPA GDCI_Waiver 850.1035 Mysid Acute Toxicity Test.pdf** | **Data Waiver Request** | **50533503** | **No CBI** | **02/23/2018** |

**Guideline Requirement Number - 850.1075**

| | |
|---|---|
| Study Title | **Fish acute toxicity test, freshwater and marine** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>16. Preferred test species are rainbow trout, Oncorhynchus mykiss and bluegill sunfish, Lepomis macrochirus (freshwater); and sheepshead minnow, Cyprinodon variegatus (estuarine/marine).** |
| Registrant Response | **N.A.** |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
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| | | | | |
|---|---|---|---|---|
| **20180222 DCPA GDCI_Waiver 850.1075 Fish Acute Toxicity Test, Freshwater and Marine.pdf** | **Data Waiver Request** | **50533504** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 850.1300** | |
|---|---|
| Study Title | **Daphnid chronic toxicity test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>14. Preferred test species is Daphnia magna.** |
| Registrant Response | **N.A.** |

| **Uploaded Documents** | | | | |
|---|---|---|---|---|
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI_Waiver 850.1300 Daphnid Chronic Toxicity Test.pdf** | **Data Waiver Request** | **50533505** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 850.1350** | |
|---|---|
| Study Title | **Mysid chronic toxicity test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>13. Preferred test species is Mysidopsis bahia, mysid shrimp.** |
| Registrant Response | **N.A.** |

| **Uploaded Documents** | | | | |
|---|---|---|---|---|
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI_Waiver 850.1350 Mysid Chronic Toxicity Test.pdf** | **Data Waiver Request** | **50533506** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 850.1400** | |
|---|---|
| Study Title | **Fish early-life stage toxicity test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>16. Preferred test species are rainbow trout, Oncorhynchus mykiss and bluegill sunfish, Lepomis macrochirus (freshwater); and sheepshead minnow, Cyprinodon variegatus (estuarine/marine).** |
| Registrant Response | **N.A.** |

| Uploaded Documents | | | | |
|---|---|---|---|---|
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI_Waiver 850.1400 Fish Early Life-Stage Toxicity Test.pdf** | **Data Waiver Request** | **50533507** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 850.1730** | |
|---|---|
| Study Title | **Fish BCF** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **DEGR** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **3. Test to be conducted with TPA degradate only.** |
| Registrant Response | **N.A.** |

| **Guideline Requirement Number - 850.2100** | |
|---|---|
| Study Title | **Avian acute oral toxicity test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **12. Preferred test species is redwing blackbird, Agelaius phoneiceus.** |
| Registrant Response | **N.A.** |

| **Guideline Requirement Number - 850.2300** | |
|---|---|
| Study Title | **Avian reproduction test** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **17. Preferred test species are mallard duck and Northern bobwhite quail.** |
| Registrant Response | **N.A.** |

| **Guideline Requirement Number - 850.4100** | |
|---|---|
| Study Title | **Terrestrial Plant Toxicity (Seedling Emergence)** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TEP** |
| Time Frame | **12 month(s)** |

| | |
|---|---|
| Footnote(s) | **20. Data are required for six species of dicots from at least four families, one species of which is soybean (Glycine max). Data are required for four species of monocots from at least two families, one species of which is corn (Zea mays). At least one of either the monocot or dicot species must be a root crop.<br>25. A Tier II study is required. A Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well. The purpose of a Tier II study is to establish both a definitive No Observed Adverse Effect Concentration (NOAEC), or alternatively, a concentration at which there is a 5% observed inhibition effect (IC05), to be used in a risk assessment and effects determination for endangered or threatened species (listed species), and a definitive IC25 (concentration at which there is a 25% observed inhibition effect) for assessing risk to non-listed nontarget plants. If any adverse effects are observed in a Tier I study and neither a definitive NOAEC nor a definitive IC05 value is available, then the Agency may have to presume in its effects determination, that DCPA "may affect" and is "likely to adversely affect" listed plant species.** |
| Registrant Response | **N.A.** |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| **20180222 DCPA GDCI_Waiver 850.4100 Terrestrial Plant Toxicity Tier 1 (Seedling Emergence).pdf** | **Data Waiver Request** | **50533510** | **No CBI** | **02/23/2018** |

**Guideline Requirement Number - 850.4150**

| | |
|---|---|
| Study Title | **Terrestrial plant toxicity, Tier 1 (vegetative vigor)** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>20. Data are required for six species of dicots from at least four families, one species of which is soybean (Glycine max). Data are required for four species of monocots from at least two families, one species of which is corn (Zea mays). At least one of either the monocot or dicot species must be a root crop.<br>25. A Tier II study is required. A Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well. The purpose of a Tier II study is to establish both a definitive No Observed Adverse Effect Concentration (NOAEC), or alternatively, a concentration at which there is a 5% observed inhibition effect (IC05), to be used in a risk assessment and effects determination for endangered or threatened species (listed species), and a definitive IC25 (concentration at which there is a 25% observed inhibition effect) for assessing risk to non-listed nontarget plants. If any adverse effects are observed in a Tier I study and neither a definitive NOAEC nor a definitive IC05 value is available, then the Agency may have to presume in its effects determination, that DCPA "may affect" and is "likely to adversely affect" listed plant species.** |
| Registrant Response | **N.A.** |

**Guideline Requirement Number - 850.4400**

| | |
|---|---|
| Study Title | **Aquatic plant toxicity test using Lemna spp. Tiers I and II** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>22. Data are required for a duckweed species.<br>24. A Tier II study is required. A Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well. The purpose of a Tier II study is to establish both a definitive No Observed Adverse Effect Concentration (NOAEC), or alternatively, a concentration at which there is a 5% observed inhibition effect (IC05), to be used in a risk assessment and effects determination for endangered or threatened species (listed species), and a definitive IC50 (concentration at which there is a 50% observed inhibition effect) for assessing risk to non-listed nontarget plants. If any adverse effects are observed in a Tier I study and neither a definitive NOAEC nor a definitive IC05 value is available, then the Agency may have to presume in its effects determination, that DCPA "may affect" and is "likely to adversely affect" listed plant species.** |

| | |
|---|---|
| Registrant Response | **N.A.** |

| **Uploaded Documents** | | | | |
|---|---|---|---|---|
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI_Waiver 850.4400 Aquatic Vascular Plant Toxicity Test, Tiers I_II (Lemna spp.).pdf** | **Data Waiver Request** | **50533508** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 850.5400** | |
|---|---|
| Study Title | **Algal toxicity, Tiers 1 and II** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **COMMENT** |
| Time Frame | **12 month(s)** |
| Footnote(s) | **2. Tests to be conducted with DCPA parent and TPA degradate.<br>21. Data are required for a freshwater green alga species, a freshwater diatom species, a marine diatom species, and a cyanobacterium (formerly known as blue-green algae).<br>24. A Tier II study is required. A Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well. The purpose of a Tier II study is to establish both a definitive No Observed Adverse Effect Concentration (NOAEC), or alternatively, a concentration at which there is a 5%observed inhibition effect (IC05), to be used in a risk assessment and effects determination for endangered or threatened species (listed species), and a definitive IC50 (concentration at which there is a 50%observed inhibition effect) for assessing risk to non-listed nontarget plants. If any adverse effects are observed in a Tier I study and neither a definitive NOAEC nor a definitive IC05 value is available, then the Agency may have to presume in its effects determination, that DCPA "may affect" and is "likely to adversely affect" listed plant species.** |
| Registrant Response | **N.A.** |

| **Uploaded Documents** | | | | |
|---|---|---|---|---|
| **File Name** | **File Type** | **MRID** | **CBI** | **Submitted Date** |
| **20180222 DCPA GDCI_Waiver 850.5400 Aquatic Non-Vascular Plant Toxicity Test, Tiers I_II (Algal species).pdf** | **Data Waiver Request** | **50533509** | **No CBI** | **02/23/2018** |

| **Guideline Requirement Number - 860.1300** | |
|---|---|
| Study Title | **Nature of the residue - plants, livestock** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **PAIRA** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **18. Nature of the residue for poultry only. The required poultry nature of the residue study will need supporting storage stability data for all DCPA residues of concern, unless the samples from the feeding study are analyzed within six months of collection.** |
| Registrant Response | **N.A.** |

| **Guideline Requirement Number - 860.1340** | |
|---|---|
| Study Title | **Residue analytical method** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |

| | |
|---|---|
| Test Substance | **Residue of Concern** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **7. Residue analytical method for livestock commodities only. The registrant has submitted a method for determining residues of DCPA and its metabolites that may be suitable but must be tested by an independent laboratory to ensure that it is useful.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 860.1380** | |
| Study Title | **Storage stability data** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TEP; res of concrn** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **11. Previously submitted data from several field trials did not include necessary information about storage intervals and conditions. This information is required to allow the Agency to evaluate data from the studies with MRID #s 00017975, 00018299, 00033087, 00038919, 00058377, 00058378, 00072099, 00090259, 00114643, 00114678, 00114679, 00114680, 00114681, 00121864, and 00130562.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 860.1480** | |
| Study Title | **Meat/milk/poultry/eggs** |
| Protocol | **N** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI; plant metab** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **23. Cattle feeding study. The required study will need supporting storage stability data for all DCPA residues of concern, unless the samples from the feeding study are analyzed within 30 days of collection.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 860.1900** | |
| Study Title | **Field accumulation in rotational crops** |
| Protocol | **N** |
| Target Submission Date | **01/31/2016** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TEP** |
| Time Frame | **36 month(s)** |
| Footnote(s) | **1. The scope of this requirement is dependent upon the registrant's intent to support the rotation of particular crops into areas previously treated with DCPA and the desired plantback interval(s) for these crops. Any crop without a registered use and for which the registrant wishes rotation to be allowed requires field trial data to determine a suitable tolerance level. A crop group approach, requiring data on representative commodities, may be appropriate if several crops within a group are to be rotated. For individual crops, testing must include the standard number of trials that would be needed to support tolerances for direct crop treatment, e.g., 20 trials for wheat. In its data submission, the registrant must indicate the crops it wishes to support for rotation and the corresponding proposed plant-back intervals.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 870.3465** | |
| Study Title | **90-day inhalation toxicity** |
| Protocol | **N** |

| | |
|---|---|
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 870.6200** | |
| Study Title | **Neurotoxicity screening battery** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **12 month(s)** |
| Footnote(s) | |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - 870.7800** | |
| Study Title | **Immunotoxicity** |
| Protocol | **N** |
| Target Submission Date | **01/31/2014** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **12 month(s)** |
| Footnote(s) | |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - SS-1066** | |
| Study Title | **Chronic Sediment - Hyalella Azteca** |
| Protocol | **Y** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **6. Test Method 100.4: Hyalella azteca 42-d Test for Measuring the Effects of Sediment-associated Contaminants on Survival, Growth, and Reproduction in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates EPA 600/R-99/064**<br>**8. Protocol must be submitted to the Agency for review and approval prior to study inception. The draft protocol must be submitted to the Agency within 90 days of receipt of this DCI.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - SS-1069** | |
| Study Title | **Chronic Sediment - Chironomus dilutus** |
| Protocol | **Y** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |

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|---|---|
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **5. Test Method 100.5: Life-cycle Test for Measuring the Effects of Sediment-associated Contaminants on Chironomus dilutus (formerly known as C. tentans) in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates EPA 600/R-99/064**<br>**9. Protocol must be submitted to the Agency for review and approval prior to study inception. The draft protocol must be submitted to the Agency within 90 days of receipt of this DCI** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - SS-1072** | |
| Study Title | **Chronic Sediment - Leptocheirus plumulosus** |
| Protocol | **Y** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **9. Protocol must be submitted to the Agency for review and approval prior to study inception. The draft protocol must be submitted to the Agency within 90 days of receipt of this DCI**<br>**19. Leptocheirus plumulosus in USEPA 2001 Method for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod Leptocheirus plumulosus EPA 600/R-0I/020** |
| Registrant Response | **N.A.** |

**Uploaded Documents**

| File Name | File Type | MRID | CBI | Submitted Date |
|---|---|---|---|---|
| **20180222 DCPA GDCI_Waiver SS-1072 [Chronic Sediment - Leptocheirus plumulosus].pdf** | **Data Waiver Request** | **50533501** | **No CBI** | **02/23/2018** |

| | |
|---|---|
| **Guideline Requirement Number - SS-1075** | |
| Study Title | **Avian Acute Inhalation** |
| Protocol | **Y** |
| Target Submission Date | **10/31/2013** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **9 month(s)** |
| Footnote(s) | **4. Test organism must be most sensitive avian species as shown in acute oral toxicity testing. Registrant must submit a protocol that includes an explanation of the choice of test species.** |
| Registrant Response | **N.A.** |
| **Guideline Requirement Number - SS-thyroid tox.** | |
| Study Title | **comparative thyroid toxicity study** |
| Protocol | **Y** |
| Target Submission Date | **01/31/2015** |
| Use Pattern | **A; B; C; II; K; U** |
| Test Substance | **TGAI** |
| Time Frame | **24 month(s)** |
| Footnote(s) | **10. Protocol must be submitted to the Agency for review and approval prior to study inception. The draft protocol must be submitted to the Agency within 90 days of receipt of this DCI.** |
| Registrant Response | **N.A.** |

| Uploaded Documents | | | | |
|---|---|---|---|---|
| File Name | File Type | MRID | CBI | Submitted Date |
| 20170817 DCPA Thyroid - PTU-Positive Control Report XJ05HV_cover memo signed.pdf | General Correspondences | N.A. | Y | 08/17/2017 |
| 100-TOX-063_XJ05HV Toxicology Report.pdf | Supplemental Study Data | 50357301 | No CBI | 08/17/2017 |
| Amvac DCPA update 24 August 2018.pdf | General Correspondences | N.A. | Y | 08/28/2018 |
| 20180824 DCPA Thyroid Study Qtrly Update and Reports.pdf | General Correspondences | N.A. | Y | 08/28/2018 |
| 100-TOX-072 DCPA Draft DRF Study Design.pdf | General Correspondences | N.A. | Y | 08/28/2018 |
| 100-TOX-070 Study Plan DCPA Dose range finding pre and post-natal developmental thyroid study (including a PTU positive control group and milk investigation) in.pdf | General Correspondences | N.A. | Y | 08/28/2018 |
| 100-TOX-066 Validation of a Bioanalytical Method for the Determination of 3,3,5'-Triiodo-Thyronine (T3) and Thyroxine (T4).pdf | Study | 50663601 | Confidential Attachment and Supplemental Claim | 08/28/2018 |
| 100-TOX-067 The Validation of a Immunoassay Method for the Measurement of Throid-Stimulating Hormone (TSH) in Rat Serum.pdf | Study | 50663602 | Confidential Attachments | 08/28/2018 |
| 100-TOX-068 DCPA (Chlorthal Dimethyl) Dose Range Finding.pdf | Study | 50663603 | Confidential Attachments | 08/28/2018 |

| Submitter Information | |
|---|---|
| Submitter | Eileen Rodriguez |
| Submitted Date | 08/28/2018 |

**From:** helpdesk@epacdx.net
**To:** Rodriguez, Eileen
**Subject:** CDX DCI Data Submission Transmitted to OPP
**Date:** Tuesday, August 28, 2018 11:04:19 AM

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Your Data Submission (GDCI-078701-1140) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_DCI_2018_000403.

Company Name: AMVAC CHEMICAL CORPORATION
Company Number: 5481

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

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