

Petitioner AMVAC

Exhibit 42



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.



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,

A handwritten signature in black ink that reads "Jon C. Wood". The signature is written in a cursive style with a large, prominent "J" and "W".

Jon C. Wood
Sr. Regulatory Manager

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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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 (K₂EDTA) using Liquid Chromatography with Tandem Mass Spectrometric 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 Spectrometric 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.

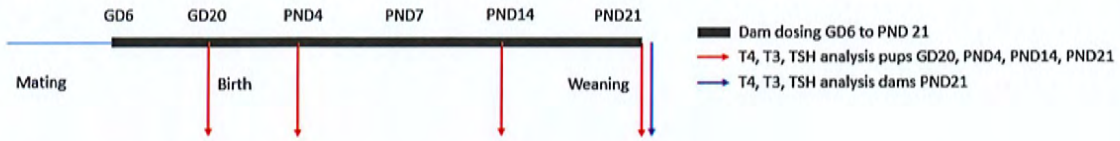
 24 August 2018

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

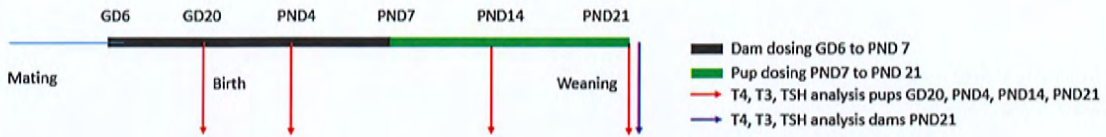
Test Facility:
ENVIGO CRS Limited
Eye
Suffolk
IP23 7PX
UK

DCPA draft DRF study design

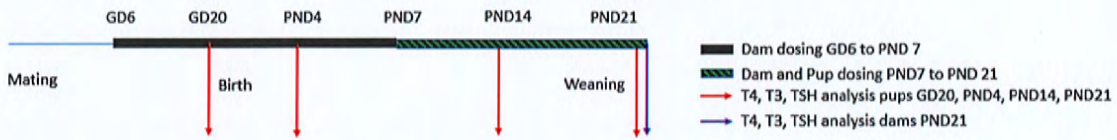
Treatment A – Evaluation of effects of maternal treatment only on thyroid



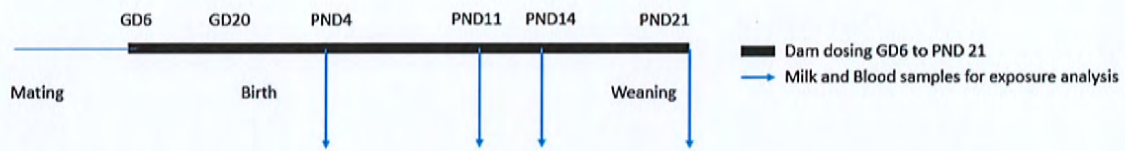
Treatment B – Evaluation of maternal and direct pup exposure on thyroid



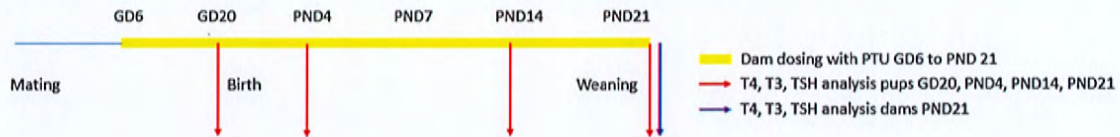
Treatment C – Evaluation of maternal and direct pup exposure on thyroid, dual exposure



Treatment D – Satellite groups for milk and plasma exposure analysis



Treatment E – PTU positive control – demonstration of laboratory competency



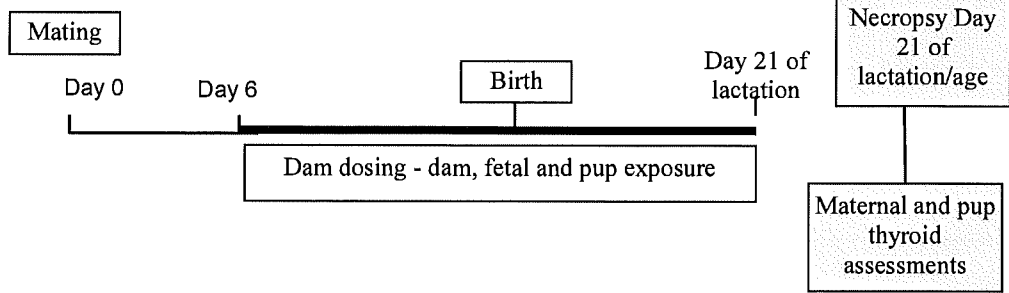
STUDY PLAN: JW36WK

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.

Treatment groups	<p><u>Phase I – Exposure in plasma and milk investigations</u> Treatment arm A – Milk and plasma exposure analysis Groups 1-5 (Control and DCPA): One control group and 0.01, 0.1, 1 or 10 mg/kg/day groups, each comprising 5 mated females. Dams dosed on Day 6 after mating to Day 21 of lactation.</p> <p><u>Phase II – Developmental thyroid evaluations</u> Treatment arm B – Evaluation of effects of maternal treatment only on thyroid Groups 6-10 (Control and DCPA): One control group and 0.01, 0.1, 1 or 10 mg/kg/day groups, each comprising 5 mated females. Dams dosed on Day 6 after mating to Day 21 of lactation.</p> <p>Treatment arm C – Evaluation of maternal and direct pup exposure on thyroid Groups 11-15 (Control and DCPA): One control group and 0.01, 0.1, 1 or 10 mg/kg/day groups, each comprising 5 mated females. Dams dosed on Day 6 after mating to Day 7 of lactation, with directed dosing of the pups from Day 7 to Day 21 of age.</p> <p>Treatment arm D – Evaluation of maternal and direct pup exposure on thyroid, dual exposure Groups 16-20 (Control and DCPA): One control group and 0.01, 0.1, 1 or 10 mg/kg/day groups, each comprising 5 mated females. Dams dosed on Day 6 after mating to Day 14 of lactation, with directed dosing of the pups from Day 7 to Day 21 of age.</p> <p>Treatment arm E – Evaluation of positive control effects on thyroid Group 21 (2.0 mg/kg/day PTU positive control group): Comprising 5 mated females. Group 21 (2.0 mg/kg/day PTU positive control group): Dams dosed on Day 6 after mating to Day 20 of lactation.</p>
Study structure	For logistical reasons, the study will be performed in two phases: Phase I will comprise Groups 1-5 and Phase II will comprise Groups 6-21. Females in Phase II will be paired for mating 12 weeks after pairing on Phase I.

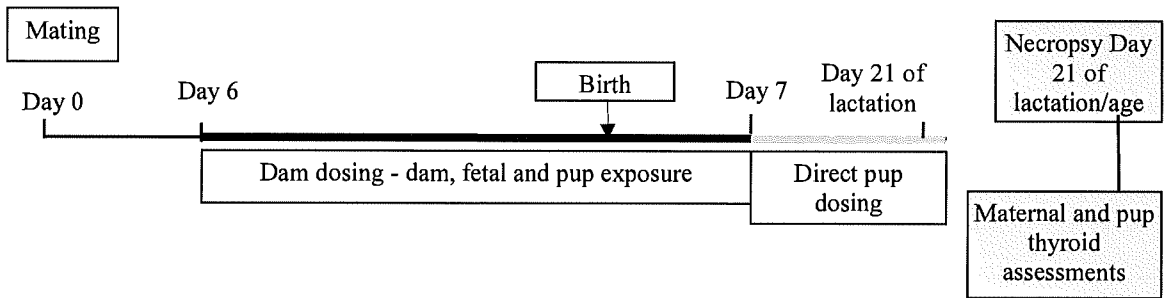
Study design:

Phase I Treatment arm A: Groups 1-5* and Phase II Treatment arm B: Groups 6-10

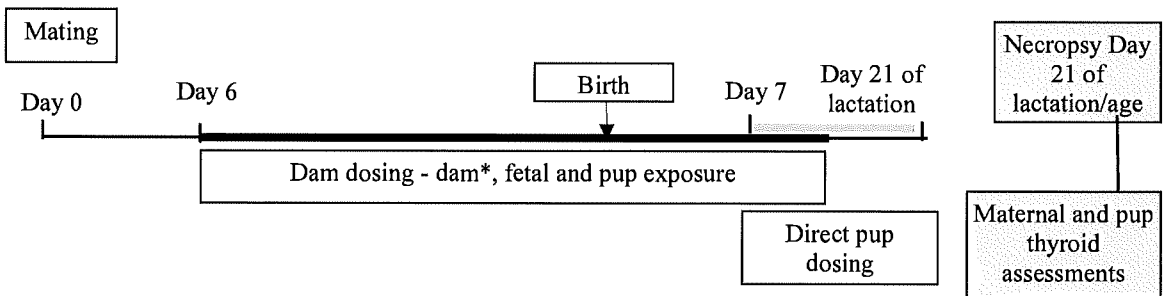


*Groups 1-5: Exposure to DCPA in milk and plasma investigations only

Phase II Treatment arm C: Groups 11-15

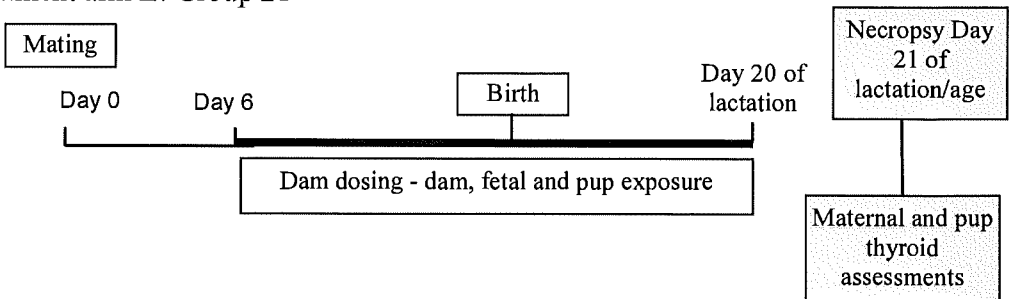


Phase II Treatment arm D: Groups 16-20



*Dams dosed until Day 14 of lactation

Phase II Treatment arm E: Group 21



<p>General assessments</p>	<p>Clinical observations, pre and post-dose signs, body weight, food consumption, macropathology Littering phase: gestation length, clinical observations, offspring survival, sex ratio, body weight</p>
<p>Plasma and milk exposure assessments</p>	<p><u>Phase I – Exposure in plasma and milk investigations</u> Treatment arm A: Groups 1-5 only</p> <p>Milk samples from culled pups on Day 4 of age, and from dams on Days 11, 14 and 21 of lactation, analysed for DCPA concentrations. Plasma samples from dams and up to 1 male and 1 female pup per litter on each of Days 4, 11, 14 and 21 of lactation analysed for DCPA concentrations.</p> <p>The results will be used to confirm that the chosen doses of DCPA are tolerated by lactating females and their offspring and to determine the extent of direct oral gavage dosing of the pups with DCPA formulations required on Phase II of the study.</p>

Thyroid specific assessments	<p>Phase II Treatment arms B to E: Groups 6-21 only (Adults): Thyroid hormones (T₃, T₄, TSH)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;"><u>Animals/occasion</u></th> <th style="text-align: left; padding: 2px;"><u>Time point relative to dose administration</u></th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;"><u>Groups 6-10: all females</u></td> <td style="padding: 2px;"><u>2 hours (± 10 minutes) after last dose administration on Day 21 of lactation (25 samples)</u></td> </tr> <tr> <td style="padding: 2px;"><u>Groups 11-15: all females</u></td> <td style="padding: 2px;"><u>2 hours (± 10 minutes) after last dose administration on Day 7 of lactation (25 samples)</u></td> </tr> <tr> <td style="padding: 2px;"><u>Groups 16-20: all females</u></td> <td style="padding: 2px;"><u>2 (± 10 minutes) after last dose administration on Day 14 of lactation (25 samples)</u></td> </tr> <tr> <td style="padding: 2px;"><u>Group 21: all females</u></td> <td style="padding: 2px;"><u>On the morning of Day 21 of lactation at necropsy (25 samples)</u></td> </tr> </tbody> </table> <p style="padding: 5px;">Thyroid (with parathyroid) and liver from all adults in Groups 1-15 and 21 only, preserved in fixative.</p> <p style="padding: 5px;">Groups 6-21 only (Juveniles): Thyroid hormones (T₃, T₄, TSH)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 2px;"><u>Animals</u></th> <th style="text-align: left; padding: 2px;"><u>Time point relative to dose administration</u></th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Groups 6-21: Up to one male and one female (culls) per litter on Day 4 of age</td> <td style="padding: 2px;">2 hours (± 10 minutes) after maternal dose administration on Day 4 of lactation (150 samples per analyte)</td> </tr> <tr> <td style="padding: 2px;">Groups 6-21: one male and one female pup per litters</td> <td style="padding: 2px;">2 hours (± 10 minutes) after dose administration (dam dosing, pup dosing or dam and pup dosing as applicable to each group) on Day 14 of lactation (150 samples per analyte)</td> </tr> <tr> <td style="padding: 2px;">Groups 6-21: one male and one female pup per litters</td> <td style="padding: 2px;">2 hours (± 10 minutes) after last dose administration on Day 21 of lactation (150 samples per analyte)</td> </tr> <tr> <td style="padding: 2px;">Group 21: Up to one male and one female (culls) per litter on Day 4 of age</td> <td style="padding: 2px;">On the morning of Day 4 of lactation at necropsy (10 samples per analyte)</td> </tr> <tr> <td style="padding: 2px;">Group 21: one male and one female per litter</td> <td style="padding: 2px;">On the morning of Day 21 of lactation at necropsy (10 samples per analyte)</td> </tr> </tbody> </table> <p style="padding: 5px;">Organ weights/fixation</p> <p style="padding: 5px;">Dams: liver and thyroids retained and weighed.</p> <p style="padding: 5px;">Day 4 of age: One male and one female (culls) per litter (where possible); Thyroid (with parathyroid, including section of trachea) and liver retained (1 male and 1 female per litter, where possible), preserved in fixative.</p> <p style="padding: 5px;">Day 21 of age: Thyroid (with parathyroid, including section of trachea) and liver retained (1 male and 1 female per litter (where possible on Day 21 of age), preserved in fixative.</p>	<u>Animals/occasion</u>	<u>Time point relative to dose administration</u>	<u>Groups 6-10: all females</u>	<u>2 hours (± 10 minutes) after last dose administration on Day 21 of lactation (25 samples)</u>	<u>Groups 11-15: all females</u>	<u>2 hours (± 10 minutes) after last dose administration on Day 7 of lactation (25 samples)</u>	<u>Groups 16-20: all females</u>	<u>2 (± 10 minutes) after last dose administration on Day 14 of lactation (25 samples)</u>	<u>Group 21: all females</u>	<u>On the morning of Day 21 of lactation at necropsy (25 samples)</u>	<u>Animals</u>	<u>Time point relative to dose administration</u>	Groups 6-21: Up to one male and one female (culls) per litter on Day 4 of age	2 hours (± 10 minutes) after maternal dose administration on Day 4 of lactation (150 samples per analyte)	Groups 6-21: one male and one female pup per litters	2 hours (± 10 minutes) after dose administration (dam dosing, pup dosing or dam and pup dosing as applicable to each group) on Day 14 of lactation (150 samples per analyte)	Groups 6-21: one male and one female pup per litters	2 hours (± 10 minutes) after last dose administration on Day 21 of lactation (150 samples per analyte)	Group 21: Up to one male and one female (culls) per litter on Day 4 of age	On the morning of Day 4 of lactation at necropsy (10 samples per analyte)	Group 21: one male and one female per litter	On the morning of Day 21 of lactation at necropsy (10 samples per analyte)
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Dose selection	<p>Doses of 0.01, 0.1, 1 or 10 mg/kg/day DCPA were chosen based on results from Phase I of a dose range finding pre and post natal developmental thyroid study (Envigo Study No. BDG0204) where treatment of pregnant females with DCPA was associated with:</p> <p>Male and female fetal serum T3 concentrations were statistically significantly low two hours after maternal treatment at 1 mg/kg/day (82% or 86%, respectively) and were BLQ (<5.00 pg/mL) in both sexes following maternal treatment at 10 or 100 mg/kg/day. T3 concentrations were statistically significantly low in male and female fetuses at 24 hours after maternal treatment at 100 mg/kg/day (36% or 34%, respectively). Fetal T3 concentrations were unaffected at two hours after maternal treatment at 0.1 mg/kg/day. When compared with Control, adult T4 concentrations were statistically significantly low at 10 or 100 mg/kg/day at two hours after treatment on Day 20 of gestation (75% or 50%, respectively) and were statistically significantly low at 100 mg/kg/day at 24 hours after treatment (58%). Adult T4 concentrations were unaffected at 0.1 or 1 mg/kg/day.</p> <p>Male and female fetal serum T4 concentrations were statistically significantly low both sexes at 1, 10 or 100 mg/kg/day at two hours after maternal treatment on Day 20 of gestation (75%, 23% or 12% and 84%, 26% or 12% of Control, respectively) and were statistically significantly low at 100 mg/kg/day at 24 hours after treatment (17% of Control).</p> <p>A dose of 2.0 mg/kg/day PTU was chosen since on a previous positive control validation study (Envigo Study No. XJ05HV) maternal treatment at this dose was associated with the following spectrum of effects on the dams and fetuses/pups including several effects on thyroid hormone levels and the macroscopic and microscopic appearance of the thyroids: low food intake during gestation and lactation and offspring body weight on Day 1 of age and subsequent growth to Day 21 of age were low. Adjusted liver weight was low and thyroid weight was high and the thyroid was enlarged in three females on Day 20 of gestation. Adjusted thyroid weight was markedly high and the thyroid was enlarged at the end of lactation. Reductions in levels of T3 and T4 and an increase in TSH were apparent in adults at Day 20 of gestation. In adults on Day 21 of lactation, T3 and TSH concentrations were increased whilst T4 was decreased. In fetuses on Day 20 of gestation and in pups on Day 4 and Day 21 of age, TSH concentrations were increased. T3 and T4 concentrations were reduced in male and female pups at Day 21 of age. Microscopic examination of the thyroid of the dams revealed follicular cell hyperplasia and hypertrophy and reduced follicular lumina and colloid in the thyroid. Examination of the thyroids of the fetuses revealed follicular cell hyperplasia and hypertrophy that showed relationship to maternal treatment at 0.1 or 2.0 mg/kg/day. Follicular cell hypertrophy was evident in neonates (Day 4 of age) and follicular cell hyperplasia and hypertrophy and reduced follicular lumina and colloid in the follicles was evident in juveniles (Day 21 of age).</p>
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TABLE: Summary of Thyroid Hormone Methods and Control Ranges – Sprague Dawley Rats, Charles River UK

Data collected from 2016 – to present

Analyte	TSH: Plasma	TSH: Serum	T3: Serum	T4: Serum
Methodology	Immunoassay	Immunoassay	LC-MS/MS	LC-MS/MS
Method number	BBC017	BBC017	BM/2016/0632	BM/2016/0632
Validation Study	HLS0980 and SL13SG	SL13SG	FF58YR	FF58YR
Minimum Required Dilution	3	3	Neat	Neat
Limit of Quantitation	123 pg/mL	123 pg/mL	5 pg/mL	70 pg/mL

Age	Study	Control Ranges (pg/mL)			
		TSH: Plasma	TSH: Serum	T3: Serum	T4: Serum
Dams					
Gestational Day 20	BDG0204	884 – 2550 (5)	NT	381 – 560 (5)	12300 – 17400 (5)
Gestational Day 20	XJ05HV	374 – 3110 (5)	NT	NT	NT
Lactation Day 13	XJ05HV	NT	323 – 890 (4)	360 – 498 (5)	31300 – 39000 (5)
Lactation Day 13	XJ05HV	1190 (1)*	1750 (1)*	NT	NT
Lactation Day 21	XJ05HV	209 – 4380 (5)	NT	NT	NT
Lactation Day 28	Extended One Gen Repro-tox Study 1	655 – 1540 (10)	NT	NT	23400 – 50500 (10)
Lactation Day 28	Extended One Gen Repro-tox Study 2	447 – 2650 (10)	NT	NT	NT

Pups					
Male foetus Gestational Day 20	BDG0204	2310 – 6410 (5)	NT	9.9 – 14.3 (5)	2650 – 3940 (5)
Male foetus Gestational Day 20	XJ05HV	1810 – 3330 (5)	NT	NT	NT
Female foetus Gestational Day 20	BDG0204	2760 – 3330 (2)	NT	14.2 – 16.6 (5)	3150 – 3630 (5)
Female foetus Gestational Day 20	XJ05HV	1720 – 4120 (5)	NT	NT	NT
Male Lactation Day 13	XJ05HV	NT	1020 – 3950 (21)	600 – 1020 (22)	32900 – 55000 (22)
Male Lactation Day 13	XJ05HV	476 (1)*	561 (1)*	NT	NT
Female Lactation Day 13	XJ05HV	1230 – 6650 (21)	NT	NT	NT
Female Lactation Day 13	XJ05HV	1310/1770 (1)*	1040/1440 (1)*	NT	NT
Male Lactation Day 21	XJ05HV	417 – 1210 (4)	NT	NT	NT
Female Lactation Day 21	XJ05HV	178 – 690 (5)	NT	NT	NT
Male Lactation Day 22	Study 1	579 – 1810 (10)	NT	NT	37900 – 68700 (10)
Female Lactation Day 22	Study 1	425 – 2630 (10)	NT	NT	39700 – 56900 (10)

(n) = number of animals analysed

NT = not tested

*Contemporaneous samples analysed from the same animal(s)

References

Study Number	Year Performed	Study title
BDG0204	2016-17	DCPA (Chlorthal Dimethyl): Dose Range Finding Pre Natal Thyroid Study in Sprague-Dawley Rats by Oral Administration
XJ05HV	2016	PTU (Propylthiouracil): Positive Control Pre and Post Natal Developmental Thyroid Study in Sprague-Dawley or Han Wistar Rats by Oral Administration or When Untreated
Study 1	2016-17	Extended One Generation Reproductive toxicology study
Study 2	2017	Extended One Generation Reproductive toxicology study

Notes on hormone analysis:

TSH was analysed in plasma until mid-2017, then moved to serum to align with the T3 and T4 LC-MS/MS analyses that are conducted in serum. At present the number of TSH analyses conducted in serum is limited but the available data from analyses conducted in both serum and plasma on the same animal indicate that similar values are obtained.

Inter-animal variation for T4 and T3 within control samples and within age ranges is approximately 2 to 3-fold and should provide adequate sensitivity for detecting compound-induced effects.

The variation within control TSH values is greater, with some control animals having excessively low or high values. However, a low TSH value is usually accompanied by high T4 and T3 values and vice versa. For example see below thyroid hormone values for individual control animals from Study XJ05HV. In this case mean values for TSH are 1770 pg/mL and mean values for T4 are 28.8 pg/mL. An excessively low value for TSH in animal 17 of 209 is accompanied by a high value for T4 of 47.4.

Plasma Thyroid Hormone Concentrations in Group 4 (Control group) Adults on Day 21 of lactation

Animal	T3 (ng/mL)	T4 (ng/mL)	TSH (pg/mL)
16	4.22	NVR	1610
17	8.25	47.4	209
18	3.96	28.6	4380
19	2.32	27.8	1760
20	5.64	11.3	892
Mean	4.88	28.8	1770
SD	2.22	14.8	1590
CV%	45.6	51.3	89.8
N	5	4	5

T3 BLQ - Below limit of quantification (0.391 ng/mL)

T4 BLQ - Below limit of quantification (1.95 ng/mL)

TSH BLQ - Below limit of quantification (123 pg/mL)

NVR No valid result, no sample remaining for reanalysis



Study Data Summary

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)

Test Guidelines	Original Study performed to GLP
Envigo Study Number:	Data from FF58YR
Version ID:	Final
Issue Date:	07 June 2018
Author:	Andrew Peard
Testing Facility:	Envigo CRS Limited Woolley Road Alconbury Huntingdon Cambridgeshire PE28 4HS UK



Study Data Summary

The Validation of a Immunoassay Method for the Measurement of Thyroid- Stimulating Hormone (TSH) in Rat Serum

Test Guidelines	Original Study performed to GLP
Envigo Study Number:	Data taken from study SL13SG
Sponsor Name:	Envigo
Version ID:	Final
Issue Date:	08 June 2018
Author:	Lisa Seavers
Testing Facility:	Envigo CRS Limited Woolley Road Alconbury Huntingdon Cambridgeshire PE28 4HS UK



Report

DCPA (Chlorthal Dimethyl): Dose Range Finding Pre-Natal Developmental Thyroid Study in Sprague-Dawley Rats by Oral Administration

Test Guidelines	Not Applicable
Envigo Study Number:	BDG0204
Sponsor Name:	AMVAC Chemical Corporation
Version ID:	Final Report
Study Completion Date:	29 June 2018
Study Director:	Adam Leggett
Test Facility:	Envigo CRS Limited Eye Suffolk IP23 7PX UK

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, Marquee
Chemical Name	DCPA (or chlorthal-dimethyl?)
Chemical Number	078701

Data Submission Information

Tracking Number	CDX_DCI_2018_000403
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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 GDCl_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	NA.			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCl_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	NA.			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCl_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	NA.			
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. 15. Preferred test species is Crassostrea virginica, Eastern oyster.
Registrant Response	N.A.

Uploaded Documents				
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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				
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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. 13. Preferred test species is Mysidopsis bahia, mysid shrimp.
Registrant Response	N.A.

Uploaded Documents				
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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				
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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. 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				
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File Name	File Type	MRID	CBI	Submitted Date

20180222 DCPA GDCl_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. 14. Preferred test species is Daphnia magna.			
Registrant Response	NA			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCl_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. 13. Preferred test species is Mysidopsis bahia, mysid shrimp.			
Registrant Response	NA			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCl_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. 16. Preferred test species are rainbow trout, <i>Oncorhynchus mykiss</i> and bluegill sunfish, <i>Lepomis macrochirus</i> (freshwater); and sheepshead minnow, <i>Cyprinodon variegatus</i> (estuarine/marine).			
Registrant Response	NA			

Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCL_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	NA			
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, <i>Agelaius phoeniceus</i> .			
Registrant Response	NA			
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	NA			
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)	<p>20. Data are required for six species of dicots from at least four families, one species of which is soybean (<i>Glycine max</i>). Data are required for four species of monocots from at least two families, one species of which is corn (<i>Zea mays</i>). At least one of either the monocot or dicot species must be a root crop.</p> <p>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.</p>			
Registrant Response	NA			
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)	<p>2. Tests to be conducted with DCPA parent and TPA degradate.</p> <p>20. Data are required for six species of dicots from at least four families, one species of which is soybean (<i>Glycine max</i>). Data are required for four species of monocots from at least two families, one species of which is corn (<i>Zea mays</i>). At least one of either the monocot or dicot species must be a root crop.</p> <p>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.</p>			
Registrant Response	NA			
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)	<p>2. Tests to be conducted with DCPA parent and TPA degradate.</p> <p>22. Data are required for a duckweed species.</p> <p>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.</p>			

Registrant Response	N.A.			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCL 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)	<p>2. Tests to be conducted with DCPA parent and TPA degradate.</p> <p>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).</p> <p>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.</p>			
Registrant Response	N.A.			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
20180222 DCPA GDCL 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 concern
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 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

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 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 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-01/020			
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

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.

CDX Homepage
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