

Joint Exhibit 19



April 04, 2019

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 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, submitted in support of Registration Review of DCPA (aka Dacthal; chlorthal dimethyl):

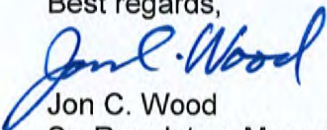
- DCPA: Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl (DCPA) in Rat Plasma (K2EDTA) using Liquid Chromatography with Tandem Mass Spectrometric Detection (LCMS/MS) – [Envigo Study No. DC87NT].
- DCPA: Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl (DCPA) in Rat Milk using Liquid Chromatography with Tandem Mass Spectrometric Detection (LC-MS/MS) – [Envigo Study No. CH09GN].

All the method development in both milk and plasma are completed and fully reported now.

Please provide us with EPA's review of the DRF study (JW36WK study plan): 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. We submitted this protocol for EPA's review in 2018. We are now waiting to receive the Agency's acceptance before we can schedule and start the DRF study at the testing lab.

Note that the reports submitted herein are 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

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
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Regulatory Actions:

Submission of report in support of Registration Review of DCPA (chlorthal dimethyl).

Transmittal Date: April 05, 2019

List of Submitted Studies:

Vol.#	Contents	Guideline No.	Study Report Title	MRID No.
1	Validation of Method for DCPA in Rat Plasma	SS-comparative thyroid toxicity	110-AMN-045- 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 (LCMS/MS) [non-GL, Report ID <u>DC87NT</u>].	50827702
2	Validation of Method for DCPA in Rat Milk	SS-comparative thyroid toxicity	110-AMN-044 DCPA: Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl (DCPA) in Rat Milk using Liquid Chromatography with Tandem Mass Spectrometric Detection (LCMS/MS) [non-GL, Report ID <u>CH09GN</u>].	50827701



Report

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 Number:	CH09GN
Sponsor Name:	AMVAC Chemical Corporation
Version ID:	Final
Issue date:	04 April 2019
Study Director:	Stephen Mustchin
Testing Facility:	Envigo CRS Limited Woolley Road Alconbury Huntingdon Cambridgeshire PE28 4HS UK



Report

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 Number:	DC87NT
Sponsor Name:	AMVAC Chemical Corporation
Version ID:	Final
Issue date:	20 March 2019
Study Director:	Stephen Mustchin
Testing Facility:	Envigo CRS Limited Woolley Road Alconbury Huntingdon Cambridgeshire PE28 4HS 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_2019_000247
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DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
20190404 DCPA Thyroid Validation Reports_cover Letter signed.pdf	Submission Cover Letter	N.A.	Y	04/05/2019
20190405 DCPA Reg Review_CTA Validation reports_Transmittal doc.pdf	Transmittal Document	N.A.	N.A.	04/05/2019

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. 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 GDCL_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. 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 GDCL_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. 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 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
100-ANM-044 Validation of a Bioanalytical Method for the Determination of Chlorthal Dimethyl.pdf	Study	50827701	No CBI	04/05/2019
100-ANM-045 Validation of Bioanalytical Method for the Determination of Chlorthal Dimethyl.pdf	Study	50827702	No CBI	04/05/2019
Submitter Information				
Submitter	Eileen Rodriguez			
Submitted Date	04/08/2019			
I certify, under penalty of law that the information provided in this document is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.				

From: helpdesk@epacdx.net
To: [Rodriguez, Eileen](#)
Subject: CDX DCI Data Submission Transmitted to OPP
Date: Monday, April 8, 2019 8:04:42 AM

Your Data Submission (GDCI-078701-1140) has been successfully transmitted to OPP and is awaiting processing. Your tracking number is CDX_DCI_2019_000247.

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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