

Joint Exhibit 59



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 6, 2022

PC Code: 078701

MEMORANDUM

DP Barcodes: 420820, 420822, 420823, 420868, 420869, 420871, 420873, 420874, 420906, 423300, 424913, 432679, 432681, 460199, & 461050

SUBJECT: Dimethyl 2,3,5,6-tetrachloroterephthalate, (Dacthal or DCPA) and its degradate Tetrachlorophthalic Acid (TPA): Transmittal of Data Evaluation Records (DERs) for 23 Ecotoxicity Studies

FROM: Christina Wendel, Biologist
Environmental Risk Branch 2
Environmental Fate and Effect Division

Digitally signed by CHRISTINA WENDEL
Date: 2022.01.21 11:33:00 -05'00'

THROUGH: Michael Wagman, Senior Scientist
Karen Milians, Ph.D., Risk Assessment Process Leader
Amy Blankinship, Branch Chief
Environmental Risk Branch 2
Environmental Fate and Effects Division

MICHAEL
WAGMAN

Digitally signed by MICHAEL
WAGMAN
Date: 2022.01.21 14:26:03 -05'00'

AMY
BLANKINSHIP

Digitally signed by AMY
BLANKINSHIP
Date: 2022.01.24 17:28:04
-05'00'

Digitally signed by Karen
Milians
Date: 2022.01.24
12:06:35 -05'00'

TO: James Douglass, Chemical Review Manager
Jill Bloom, Team Leader
Cathryn Britton, Branch Chief
Risk Management and Implementation Branch 5
Pesticide Re-evaluation Division

The Environmental Fate and Effects Division (EFED) has reviewed 23 ecotoxicity studies to support the Registration Review of the herbicide dimethyl 2,3,5,6-tetrachloroterephthalate, also known as dacthal and/or DCPA (PC Code 078701) and its degradate Tetrachlorophthalic Acid (TPA).

Please refer to the attached DERs for additional details. A summary of the study classifications can be found in **Table 1** and the full DERs are attached.

Table 1. Summary of Evaluations of Ecotoxicity Data for Dacthal (DCPA) and Tetrachlorophthalic Acid (TPA) Submitted to the Agency

MRID	OCSP Guideline	Study Type	Study Classification	CETIS Flag ^A	Comments	Additional Data Recommended (Y/N)
49307504	850.4500	Acute Toxicity of DCPA Technical to Marine Diatom, (<i>Skeletonema costatum</i>)	Supplemental, may be used for risk characterization	CO	There are uncertainties due to high variability in the endpoints for the negative control (CVs up to 29% in yield and area under the curve) and potential solvent interaction (growth promotion). The study utilized the initial-measured concentrations to estimate the endpoints, although there is potential that this may overestimate actual exposure conditions.	N
49307505	850.1035	96-hour Static Acute Toxicity of DCPA Technical to the Saltwater Mysid (<i>Americamysis bahia</i>)	Supplemental, may be used for risk characterization	CO	Dissolved oxygen (DO) was ≤60% saturation in the controls and numerous treatment levels; mortalities were ≤10% in the controls and treatment groups.	N
49307506	850.4150	Terrestrial Plant Toxicity of DCPA formulation, Vegetative Vigor of Ten Species of Plants	Acceptable	AT*	None	N
49307507	850.4550	Acute Toxicity of DCPA Technical to Freshwater Blue-Green Alga, (<i>Anabaena flos-aquae</i>)	Supplemental, results for the growth rate may be used to calculate risk quotients, while the results for the yield and area under the curve may be used for risk characterization.	CO	Although there are uncertainties due to high variability in the cell density and AUC endpoints for the negative control (CVs up to 52%; CV <15% for growth rate), there were no effects at the solubility limit. The study utilized the initial-measured concentrations to estimate the endpoints, although there is potential that this may overestimate actual exposure conditions.	N
49307508	850.4500	Acute Toxicity of DCPA Technical to Freshwater Diatom, (<i>Navicula pelliculosa</i>)	Supplemental, and may be used to calculate risk quotients	CO	All endpoints were significantly affected in the highest test level, but no effects reached 50%. The study utilized the initial-measured concentrations to estimate the endpoints, although there is potential that this may overestimate actual exposure conditions.	N
49307509	850.4400	Acute Toxicity of DCPA Technical to Aquatic Vascular Plants, (<i>Lemna gibba</i>)	Acceptable	CO	None	N
49307510	850.1300	Chronic Toxicity DCPA Technical to the Water Flea, (<i>Daphnia magna</i>)	Acceptable	AT*	None	N
49307511	850.1075	96-hour Static-Renewal Acute Toxicity of DCPA Technical to the Sheepshead Minnow, (<i>Cyprinodon variegatus</i>)	Acceptable	CO	None	N

MRID	OCSP Guideline	Study Type	Study Classification	CETIS Flag ^A	Comments	Additional Data Recommended (Y/N)
49307512	850.1300	Chronic Toxicity DCPA Technical to the Saltwater Mysid, (<i>A. bahia</i>)	Supplemental, may be used for risk characterization	AT*	A definitive NOAEC could not be established in the study as dose-responsive effects on male weight and length were observed at all doses. Additional data that includes lower concentrations is recommended to reach a definitive NOAEC value. It is also recommended that any new test consider using a different solvent, as there may be an interaction between the test substance and the solvent. There was a statistically significant promotion in the solvent control, compared to the negative control in the number of offspring per surviving female endpoint (-159% ↑; p= 0.04). See DER for additional details.	Y
49307513	850.4100	Terrestrial Plant Toxicity of DCPA formulation, Seedling Emergence of Ten Species of Plants	Acceptable for all species <u>except</u> ryegrass and lettuce.	AT*	For ryegrass, the study is considered supplemental and may be used to calculate risk quotients (for endpoints with survival as most sensitive endpoint) and for lettuce, the study is considered supplemental and may be used for risk characterization only. Additional data is recommended for lettuce (only) as registered application rates result in higher estimated exposure concentrations than the concentrations tested in this study. For lettuce: 1) Survival does not meet the OCSP 850.4100 test validity element of at least 90% survival at test termination (73%, based on number planted) in the negative control; 2) there was high variability in the study; and 3) lack of dose-response, even with inhibitions >25% observed in some concentrations during the test, and the IC25 is considered above the highest test concentration for all lettuce endpoints. See DER for additional details.	Y, for lettuce (only).
49307514	850.1010	48-hour Static Acute Toxicity of DCPA Technical to the Water Flea, (<i>D. magna</i>)	Acceptable	CO	None	N
49307518	850.1075	96-hour Static Acute Toxicity of TPA, metabolite of DCPA to the Rainbow Trout, (<i>Oncorhynchus mykiss</i>)	Acceptable	CO	None	N
49307519	850.1010	48-hour Static Acute Toxicity of TPA, metabolite of DCPA to the Water Flea, (<i>D. magna</i>)	Acceptable	CO	None	N

MRID	OCSPP Guideline	Study Type	Study Classification	CETIS Flag ^A	Comments	Additional Data Recommended (Y/N)
49477601	850.2100	Acute Oral Toxicity of DCPA Technical to the Zebra Finch, (<i>Taeniopygia guttata</i>)	Supplemental, and may be used to calculate risk quotients	CO	There were no apparent treatment-related effects on food consumption or on body weight at any dosage level tested. However, per OCSPP 850.2100 guideline, the study should have tested up to the maximum expected environmental concentration on food items. The estimated residues based on current registered products are >2x levels where no effects were observed for any avian species (e.g., zebra finch and bobwhite quail) that has been tested (2000 mg/kg-bw), resulting in uncertainty as to whether lethal effects could still occur at expected concentrations.	Y**
49500701	850.1025	96-hour Flow-through Acute Toxicity Test with the Eastern Oyster, (<i>Crassostrea virginica</i>)	Supplemental, may be used for risk characterization	AT	Dissolved oxygen (DO) was ≤60% saturation in the controls and numerous treatment levels. Growth results were highly variable (using the standard deviations, the confidence intervals for the mean individual measurements for all test concentrations would overlap), and only visual comparisons of toxicity could be made due to the lack of replication.	N
49865801	Non-guideline	Chronic (42-day) Sediment Toxicity of DCPA Technical to Freshwater Amphipods, (<i>Hyalella azteca</i>)	Acceptable	AT*	None	N
49865802	Non-guideline	Chronic (60-day) Sediment Toxicity of DCPA Technical to Freshwater Midge, (<i>Chironomus dilutus</i>)	Supplemental, may be used for risk characterization	AT*	It was determined that there was a potential solvent interaction, as noted by the significant differences that were observed between the solvent and negative control for several endpoints. It was determined that the statistically significant inhibitions observed for treatments compared to the negative control were likely the effect of the solvent and not actually an effect of the test substance. See DER for additional details.	Y
51235101	850.1300	Chronic Toxicity of TPA, metabolite of DCPA to the Water Flea, (<i>D. magna</i>)	Acceptable	CO	None	N
51235102	850.4100	Terrestrial Plant Toxicity of TPA, metabolite of DCPA, Seedling Emergence of Ten Species of Plants	Supplemental overall	CO	Individual species are classified as follows: Acceptable for all species <u>except</u> soybean, sugarbeet, onion, sunflower, and ryegrass. For soybean, sugarbeet, onion and sunflower, the study is considered supplemental and may be used to calculate risk quotients (for endpoints with survival as most sensitive endpoint) and for ryegrass, the study is considered supplemental and may be used for risk characterization only. See DER for additional details.	N

MRID	OCSPP Guideline	Study Type	Study Classification	CETIS Flag ^A	Comments	Additional Data Recommended (Y/N)
51398104	850.1300	Chronic Toxicity of DCPA Technical to the Water Flea, (<i>D. magna</i>)	Supplemental, may be used for risk characterization	CO	Solubility and stability concerns were present in this study. The analytical measurements indicate that test organisms in the two lowest concentrations may not have been exposed to any bioavailable DCPA during part of the study, and the third concentration is the LOAEC (13 µg/L) which exhibited reproductive effects and also had analytical recovery issues below the Level of Detection (LOD) during part of the study and no Level of Quantification (LOQ) was reported. Therefore, a NOAEC could not be determined, and there is considerable uncertainty as to the actual doses the test organisms were exposed to for the three lowest test concentrations (including the LOAEC). Additional data is not requested at this time, as an acceptable chronic daphnid study (MRID 49307510; see above) has been submitted. EFED notes that study has a valid NOAEC as well as a LOAEC (270 µg/L) that is an order of magnitude higher than this study. Therefore, EFED will estimate risk using endpoints from MRID 49307510, but may characterize potential risks as being greater given the data in MRID 51398104.	N
51398105	850.1075	96-hour Static Acute Toxicity of Dacthal W-75 (formulation of DCPA) to the Rainbow Trout, (<i>O. mykiss</i>)	Supplemental, may be used for risk characterization	CO	Test material was both unstable and insoluble in all treatment levels. No mortality was observed in the control or any treatment group.	N
51499401	850.4500	Acute Toxicity of TPA, metabolite of DCPA to Freshwater Green Algae, <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i>)	Supplemental, may be used for risk characterization	CO	All endpoints in this study were significantly affected in the two highest test levels. Issues with pH across the treatment groups resulted in reduced confidence in results.	N
51499402	850.4500	Acute Toxicity of Dacthal W-75 (formulation of DCPA) to Freshwater Green Algae, <i>P. subcapitata</i> (formerly <i>S. capricornutum</i>)	Supplemental, may be used for risk characterization	CO	Issues with pH and solubility (poor chemical recovery) resulted in reduced confidence in test results.	N

TGAI=Technical Grade Active Ingredient; TEP= typical end-use product

^A CETIS flags include the following codes followed by the number of CETIS records (i.e., test codes) for each flag and the total number of potential CETIS records for the study (e.g., "AT (2 of 3)");

"CO" – the contractor's CETIS records were not altered.

"AT" – a CETIS database file is attached to the logout email because the contractor's CETIS records were updated or new CETIS records were created.

"**" – Indicates for "CO" and "AT" flags that at least one regulatory endpoint in the DER differs from that concluded in the CETIS statistical output.

** A dose-based study may not be feasible due to the high dose levels that need to be tested, up to 5045 mg/kg-bw (calculated Upper-bound Kenaga Maximum EEC), in accordance with the OCSPP guideline; therefore, testing may need to switch to the dietary-based test paradigm. EFED recommends the registrant consult with the Agency prior to initiating dietary-based testing of a passerine species.