

Joint Exhibit 27



January 29, 2014

Jill Bloom
U.S. Environmental Protection Agency
Document Processing Desk (DCI/PRD)
Office of Pesticide Programs (7508P)
2777 South Crystal Drive,
Arlington, VA 22202

Re: DCPA GDCI Data Call In (Order Number: GDCI-0798701-1140)
Chemical # PC Code: 078701 CAS #: 1861-32-1
12 Month Response

Dear Ms. Bloom:

This submission is in response to the Generic Data Call-In (GDCI) Notice dated January 31, 2013. On April 29, 2013, AMVAC included or addressed the appropriate response and support documents requested to fulfill the initial 90 day response requirement. EPA responded to two of the requests on the following dates through email. On August 7, 2013, EPA allowed AMVAC to complete the suggested 28-day Sub-Chronic Inhalation study to fulfill the 90-day Inhalation study (Guideline No. 870.3465). On September 23, 2013, EPA waived the Immunotoxicity requirement (Guideline No. 870.7800). AMVAC is still anticipating a response from EPA regarding several guidelines submitted in Attachments included in the 90 day response. In an effort to track the various guidelines required, the enclosed spreadsheet titled "12 Month Status of DCPA Registration Review" provides the status of each guideline.

In regards to the data AMVAC promised to develop within the 12-month timeline, please find three copies of the following documents enclosed:

Guideline No.	Amvac Study No.	Study Title	Study No.	MRID
870.3465	100-SCH-008	DCPA (Chlorthal Dimethyl): Toxicity Study by Inhalation Administration to Rats for 4 Weeks	BDG0193	
870.6200	100-NEU-001	DCPA (Chlorthal Dimethyl): Neurotoxicity Study by a Single Oral Gavage Administration to Sprague Dawley Rats followed by a 14-Day Observation Period	BDG0194	

Guideline No.	Amvac Study No.	Study Title	Study No.	MRID
870.6200	100-NEU-002	DCPA (Chlorthal Dimethyl): Neurotoxicity Study by Dietary Administration to Sprague-Dawley Rats for 13 Weeks	BDG0195	
850.4500	100-AQU-023	DACTHAL: A 96-HOUR TOXICITY TEST WITH THE MARINE DIATOM (<i>Skeletonema costatum</i>)	246A-103A	
850.1035	100-AQU-022	DACTHAL: A 96-HOUR STATIC ACUTE TOXICITY TEST WITH THE SALTWATER MYSID (<i>Americamysis bahia</i>)	246A-115	
850.4150	100-NON-020	DACTHAL: A TOXICITY TEST TO DETERMINE THE EFFECTS OF THE TEST SUBSTANCE ON VEGETATIVE VIGOR OF TEN SPECIES OF PLANTS	246P-106	
850.4550	100-AQU-019	DACTHAL: A 96-HOUR TOXICITY TEST WITH THE FRESHWATER ALGA (<i>Anabaena flos-aquae</i>)	246P-101	
850.4500	100-AQU-021	DACTHAL: A 96-HOUR TOXICITY TEST WITH THE FRESHWATER DIATOM (<i>Navicula pelliculosa</i>)	246P-102	
850.4400	100-AQU-020	DACTHAL: A 7-DAY STATIC-RENEWAL TOXICITY TEST WITH DUCKWEED (<i>Lemna gibba</i> G3)	246P-104	
850.1300	100-AQU-017	Dacthal – Full Life-Cycle Toxicity Test with Water Fleas, <i>Daphnia magna</i> , Under Static Renewal Conditions	11857.6114	
850.1075	100-AQU-016	Dacthal - Acute Toxicity of Sheepshead Minnow (<i>Cyprinodon variegatus</i>) Under Static-Renewal Conditions	11857.6109	
850.1350	100-AQU-025	DACTHAL: A FLOW-THROUGH LIFE-CYCLE TOXICITY TEST WITH THE SALTWATER MYSID (<i>Americamysis bahia</i>)	246A-116A	

Guideline No.	Amvac Study No.	Study Title	Study No.	MRID
850.4100	100-NON-021	DACTHAL: A TOXICITY TEST TO DETERMINE THE EFFECTS OF THE TEST SUBSTANCE ON SEEDLING EMERGENCE OF TEN SPECIES OF PLANTS	246P-105	
850.1010	100-AQU-018	Dacthal - Acute Toxicity to Water Fleas, Daphnia magna, Under Static Conditions, Following OCSP Guideline 850.1010	11857.6107	

In regards to the promised existing data, please find three copies of the following documents enclosed:

Guideline No.	Amvac Study No.	Study Title	Study No.	MRID
835.4300	100-MET-010	An Aerobic Aquatic Soil Metabolism Study with 14C Dacthal	699-3EF-84-0073-001	
835.4100	100-MET-011	(14C)-TPA, a metabolite of DCPA: Degradation in three soil	1708/016-D2149	
835.1230	100-MET-012	(14C)-TPA, a metabolite of DCPA: Adsorption/Desorption in soil	1708/017-D2149	
850.1075	100-ACT-108	Tetrachloroterephthalic Acid (TPA): Acute toxicity on Oncorhynchus mykiss	1708/020	
850.1010	100-ACT-109	Tetrachloroterephthalic Acid (TPA): Acute toxicity to Daphnia magna	1708/021	
850.1400	100-TOX-057	Chlorthal-dimethyl (DCPA): Prolonged toxicity test to juveniles Oncorhynchus mykiss under semi-static conditions	1708/034	

In regards to the upgradable studies, AMVAC is providing the following justification:

835.1230: Adsorption/Desorption

AMVAC is requesting to upgrade the cited study, “Adsorption and Desorption of Dimethyl Tetrachloroterephthalate to Soils”, by Koresch, B.H. (MRID 41648805), by submitting existing data (AMVAC No. 100-MET-012) enclosed that will meet this regulatory requirement.

860.1380: Storage Stability

EPA has cited 14 MRID residue chemistry submissions for which the Agency is seeking associated storage stability data. We have identified studies related to the crop rotational study requirement for which we have responded separately in this document. We have also identified certain studies related to animal commodities for which we have proposed changes to our label that would eliminate the need for this data. However, for the remaining MRIDs cited by the EPA, we are having difficulty quickly obtaining these submissions due to the fact that AMVAC was not the original submitter. However, to help EPA with their review, we would highlight the fact that the Agency has a GLP storage stability data for five diverse crops that were stored frozen for a 4-year period (MRID 43938901; “Residues of DCPA (dimethyl tetrachloroterephthalate, SDS-893), Its manufacturing Impurity HCB and Its Degradation Products in Crops from a Stability Study (Laboratory Spikes) Final Report” by C.A. Rose, conducted by Ricerca, issued on November 27, 1995). The study was performed on frozen samples associated with six diverse crop matrices, which demonstrates that the parent compound DCPA and SDS-954 (TPA) residues are stable for a 4-year period. A summary of the data is provided in a table within this document associated with AMVAC’s response for the crop rotational study.

This data should be useful as it should validate that most of the cited data was associated with residue samples that were viable because typically residue study samples are not stored for a period beyond this scope. We believe that the assessment of viability of samples associated with EPA’s cited MRID list can be greatly simplified. By determining the time interval between protocol (or initiation of the field trials) and report date (or analytical date), it should be straightforward to substantiate that most if not all of the work was conducted in less than a 4-year period.

860.1900: Field Accumulation in Rotational Crops

Data concerning the storage interval of crops associated with the “Donalsonville, GA” crop rotational study (MRID 41255504) is provided in the final report (Appendix VI, starting with report page 357). Sampling intervals were determined based on the number of days between sampling and sample extraction, which was the initiation of the analytical procedure. The maximum interval for all commodities was 407 days. The storage intervals for each representative commodity is provided in one of the tables below.

Data concerning the storage interval of crops associated with the “Rosa, LA” crop rotational study (MRID 42298303) is provided in the final report (Appendix VII , starting with report page 344). Sampling intervals were determined based on the number of days between sampling and sample extraction, which was the initiation of the analytical procedure. The maximum interval for all commodities was 423 days. The storage intervals for each representative commodity is provided in one of the tables that below.

Support that the samples were viable upon analysis is validated by a 4-year storage stability report titled, “Residues of DCPA (dimethyl tetrachloroterephthalate, SDS-893, Its manufacturing Impurity HCB and Its Degradation Products in Crops from a Stability Study (Laboratory Spikes) Final Report” by C.A. Rose, conducted by Ricerca, issued on November 27, 1995 (MRID 43938901). The study was performed on frozen samples associated with six diverse crop matrices, which demonstrates that the parent compound DCPA and SDS-954 (TPA) residues are stable for a 4-year period.

All summary tables are provided below:

4-Year Crop Matrix		
Storage Stability Study (MRID# 43938901)		
Sample Matrix	DCPA % Recovery	TPA % Recovery
broccoli	92	96
onion	96	104
celery	100	92
snap beans	90	88
bell peppers	92	92
sweet potatoes	88	80

“Donalsonville, GA”	
Crop Rotational Study	
(MRID 41255504)	
Sample Matrix	Longest Interval between Sampling and Extraction (days)
leaves, mustard	322
leaves, lettuce	333
leaves, carrots	352
leaves, radishes	337
roots, carrots	366
roots, radishes	342
seed, corn	249
seed, sorghum	210
seed, oats	140
fodder, corn	254
fodder, sorghum	238
straw, oats	237
silage, corn	407
forage, oat	103

“Rosa, LA”	
Crop Rotational Study	
(MRID 42298303)	
Sample Matrix	Longest Interval between Sampling and Extraction (days)
leaves, mustard	253
leaves, lettuce	252
leaves, carrots	241
leaves, turnip	204
roots, carrots	309
roots, turnip	332
seed, corn	295
seed, sorghum	133
seed, oats	116
fodder, corn	423
fodder, sorghum	128
straw, oats	286
silage, corn	323
forage, oat	365

850.1075: Acute Tox, Freshwater Fish

A new acute marine fish study on Sheepshead Minnow (*Cyprinodon variegatus*) is being submitted at this time. This study demonstrates that the no observed effect concentration (NOEC) for DCPA is associated with the highest concentration tested. This dose level was established to represent the solubility limit of the active ingredient (i.e., 0.5 mg/L). This data is at minimum consistent with previous freshwater fish study findings of very limited toxicity.

The fact that levels of DCPA exceeding solubility limits were tested previously on rainbow trout (*Oncorhynchus mykiss*) and bluegill (*Lepomis macrochirus*) does not preclude study use for fulfilling the requirement. The effects of the insoluble material would likely be limited to ensuring that the solubility limit of test substance was maintained and could overcome potential adsorption to materials in the test system. The fact that the reported LC50s exceed the solubility limit of DCPA in these studies establishes the fact that DCPA is essentially non-toxic to freshwater fish. Overall, we interpret the findings to mean that the LC50 of DCPA to both freshwater and marine fish is greater than the reported solubility limit of 0.5 mg/L.

It is my understanding this submission addresses the requirements due at this time. Please feel free to contact me at 949-221-6104 or email juliep@amvac-chemical.com if you have any questions or need further information.

Best regards,



Julie Porter
Regulatory Product Manager