

Exhibit 5



April 29, 2013

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
90-Day Response

Dear Ms. Bloom:

This submission is in response to the Generic Data Call-In (GDCI) Notice dated 1/31/2013. Amvac has included or addressed the appropriate response and support documents requested to fulfill the initial 90 day response requirement. The Generic Data Call-In Response and the Requirements Status and Registrant's Response forms are provided in **Attachment 1 and 2**.

In support of the responses provided in these forms, Amvac is providing the following justification documents to explain the position of our decision:

- Residue, Environmental Fate, and Ecotoxicology for non-terrestrial animals. This includes several guidelines regarding the parent (TGAI), followed by the major degradate (TPA) requested. (**Attachment 3**)
- Avian Reproduction guideline (850.2300 Avian Reproduction Test) providing justification to cite existing studies. With this, AMVAC requests EPA reconsider its initial evaluation of these studies in light of additional information that has been provided by the original testing laboratory (Wildlife International Ltd). (**Attachment 4**)
- Immunotoxicity Waiver (Guideline No. 870.7800) (**Attachment 5**)
- Avian Acute Inhalation Waiver (Special Study No. SS-1075) (**Attachment 6**)

In regards to the 90-day Inhalation study (Guideline No. 870.3465), AMVAC is proposing to conduct a 28-day rat inhalation study to satisfy this requirement. Our 28-day study (supported by a 7-day prelim) will include all the endpoints that are specified in the 90-day guideline requirement. This approach of conducting a foreshortened 28-day study has been approved previously by EPA on several occasions and is now thought to be considered the EPA standard for such a requested study. This can be confirmed from our recent experience conducting other active ingredient DCI testing, within AMVAC's product portfolio. This study will begin when authorization of this revision has been received from the Agency.

In addition to the response forms and supporting documents, Amvac has included the following protocols required in the GDCI response:

- Avian Acute Oral Toxicity (Guideline No. 850.2100) (**Attachment 7**)
 - This protocol was requested by Margaret Hathaway via phone conversation on 3/27/2013)
- Comparative Thyroid Toxicity (Special Study No. SS-thyroid tox.) (**Attachment 8**)
- Chronic Sediment – Hyalella Azteca (Special Study SS-1066) (**Attachment 9**)
- Chronic Sediment – Chironomus dilutes (Special Study SS -1069) (**Attachment 10**)
- Chronic Sediment – Leptocheirus plumulosus (Special Study SS -1072) (**Attachment 11**)

Lastly, in response to the Nature of Residue – poultry (Guideline No. 860.1300), Residue Analytical Method (Guideline No. 860.1340), and Meat/Milk/Poultry/Eggs – Ruminants (Guideline No. 860.1480), Amvac has requested to delete uses as the basis to waive these requirements. Upon receipt of EPA's agreement, Amvac will submit the label amendments needed to begin the process to remove these uses from the DCPA registrations.

It is my understanding this submission addresses the requirements due at this time and I look forward to working with you to complete a successful Registration Review process. 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

Attachment 1

Generic Data Call-In Response

United States Environmental Protection Agency
 Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address AMVAC CHEMICAL CORPORATION 4695 MACARTHUR COURT, SUITE 1200 NEWPORT BEACH, CA 926601706	2. Case # and Name 0270 - DCPA (or chlothal-dimethyl?) Chemical # and Name: 078701 DCPA (or chlothal-dimethyl?)	3. Date and Type of DCI and Number 31-Jan-2013 GENERIC ID # GDCI-078701-1140
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4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
5481-495	-	-	YES	N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative Regulatory Product Manager	9. Date 29-APR-2013
10. Name of Company Amvac Chemical Corporation	11. Phone Number 949-221-6104

Attachment 2

Generic Requirements Status and Registrant's Response

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address AMVAC CHEMICAL CORPORATION 4695 MACARTHUR COURT, SUITE 1200 NEWPORT BEACH, CA 926601706	2. Case # and Name 0270 - DCPA (or chlorthal-dimethyl?) Chemical # and Name: 078701 DCPA (or chlorthal-dimethyl?)	3. Date and Type of DCI and Number 31-Jan-2013 GENERIC ID # GDCl-078701-1140
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Environmental Fate Data Requirements (Conventional Chemical)								
835.1230	Sediment and soil absorption/desorption for parent and degradates (3)	N				U,A,II,K,C,B	DEGR	12	4, 5
835.1240	Soil column leaching (3)	N				U,A,II,K,C,B	DEGR	12	6
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C (3)	N				U,A,II,K,C,B	DEGR	12	6
835.4100	Aerobic soil metabolism (3)	N				U,A,II,K,C,B	DEGR	24	1, 4
835.4200	Anaerobic soil metabolism (3)	N				U,A,II,K,C,B	DEGR	24	6
835.4300	Aerobic aquatic metabolism (2)	N				U,A,II,K,C,B	COMMENT	24	4, 9 (Note 3)
835.4400	Anaerobic aquatic metabolism (3)	N				U,A,II,K,C,B	DEGR	24	9
835.6100	Terrestrial field dissipation (2)	N				U,A,II,K,C,B	COMMENT	24	6

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.	11. Date 29-APR-2013
Signature and Title of Company's Authorized Representative Regulatory Product Manager	
12. Name of Company Amvac Chemical Corporation	13. Phone Number 949-221-6104

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Washington, D.C. 20460
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4100	Terrestrial Plant Toxicity (Seedling Emergence) (2) (20, 25)	N				U,A,II,K,C,B	TEP COMMENT	12	1, 9 (Note 1)
850.4150	Terrestrial plant toxicity, Tier 1 (vegetative vigor) (X) 20, 25)	N				U,A,II,K,C,B	COMMENT TGAI	12	1
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II (2, 22, 24)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
850.5400	Algal toxicity, Tiers 1 and II (2, 21, 24)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
Residue Chemistry Data Requirements for Food Uses (Conventional Chemical)									
860.1300	Nature of the residue - plants, livestock (18)	N				U,A,II,K,C,B	PAIRA	24	7
860.1340	Residue analytical method (7)	N				U,A,II,K,C,B	Residue of Concern	24	7
860.1380	Storage stability data (11)	N				U,A,II,K,C,B	TEP; res of concern	24	5
860.1480	Meat/milk/poultry/eggs (23)	N				U,A,II,K,C,B	TGAI; plant metab	24	7

Note 1 - TGAI (1), TPA (9).

Note 2 - TGAI marine (1), TGAI two freshwater (5), TPA freshwater (4) marine (9).

Note 3 - TGAI (4), TPA (9).

Note 4 - Propose 28 day inhalation toxicity test instead of 90 day toxicity test.

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.1010	Aquatic invertebrate acute toxicity, test, freshw ater daphnids (2)	N				U,A,II,K,C,B	COMMENT	12	4
850.1025	Oyster acute toxicity test (shell deposition) (2, 15)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
850.1035	Mysid acute toxicity test (2, 13)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
850.1075	Fish acute toxicity test, freshw ater and marine (2, 16)	N				U,A,II,K,C,B	COMMENT	12	1, 5, 4, 9 (Note 2)
850.1300	Daphnid chronic toxicity test (2, 14)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
850.1350	Mysid chronic toxicity test (2, 13)	N				U,A,II,K,C,B	COMMENT	12	1, 9 (Note 1)
850.1400	Fish early-life stage toxicity test (2, 16)	N				U,A,II,K,C,B	COMMENT	12	4, 9 (Note 3)
850.2100	Avian acute oral toxicity test (12)	N				U,A,II,K,C,B	TGAI	12	1
850.2300	Avian reproduction test (17)	NY				U,A,II,K,C,B	TGAI	24	6

Note 1 - TGAI (1), TPA (9).
 Note 2 - TGAI marine (1), TGAI two freshwater (5), TPA freshwater (4) marine (9).
 Note 3 - TGAI (4), TPA (9).
 Note 4 - Propose 28 day inhalation toxicity test instead of 90 day toxicity test.

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1. Company Name and Address		2. Case # and Name			3. Date and Type of DCI and Number				
AMVAC CHEMICAL CORPORATION 4695 MACARTHUR COURT, SUITE 1200 NEWPORT BEACH, CA 926601706		0270 - DCPA (or chlorthal-dimethyl?) Chemical # and Name: 078701 DCPA (or chlorthal-dimethyl?)			31-Jan-2013 GENERIC ID # GDCl-078701-1140				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
850.1730	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical), Environmental Fate Data Requirements (Conventional Chemical) Fish BCF (3)	N				U,A,I,K,C,B	DEGR	12	9
870.3465	90-day inhalation toxicity	N				U,A,I,K,C,B	TGAI	24	1 (Note 4)
870.6200	Neurotoxicity screening battery	N				U,A,I,K,C,B	TGAI	12	1
870.7800	Immunotoxicity	N				U,A,I,K,C,B	TGAI	12	9
860.1900	Field accumulation in rotational crops (1)	N				U,A,I,K,C,B	TEP	36	5
SS-1066	Chronic Sediment - Hyalella Azteca (6, 8)	Y				U,A,I,K,C,B	TGAI	24	1
SS-1069	Chronic Sediment - Chironomus dilutus (5, 9)	Y				U,A,I,K,C,B	TGAI	24	1
Note 1 - TGAI (1), TPA (9). Note 2 - TGAI marine (1), TGAI two freshwater (5), TPA freshwater (4) marine (9). Note 3 - TGAI (4), TPA (9). Note 4 - Propose 28 day inhalation toxicity test instead of 90 day toxicity test.									

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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
SS-1072	Chronic Sediment - <i>Leptocheirus plumulosus</i> (9, 19)	Y				U,A,II,K,C,B	TGAI	24	1
SS-1075	Avian Acute Inhalation (4)	Y				U,A,II,K,C,B	TGAI	9	9
SS-thyroid tox.	comparative thyroid toxicity study (10)	Y				U,A,II,K,C,B	TGAI	24	1

Note 1 - TGAI (1), TPA (9).
 Note 2 - TGAI marine (1), TGAI two freshwater (5), TPA freshwater (4) marine (9).
 Note 3 - TGAI (4), TPA (9).
 Note 4 - Propose 28 day inhalation toxicity test instead of 90 day toxicity test.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0270 - DCPA (or chlorthal-dimethyl?)

DCI Number: GDCI-078701-1140

Key: Residue of Concern = Residue of Concern; TEP = Typical End Use Product [TEP]; TGA I = Technical Grade Active Ingredient [TGA I]; TGA I/PAIRA = Technical Grade of the Active Ingredient or Pure Active Ingredient, Radio Labelled; TGA I, TEP = Technical Grade of the Active Ingredient or Technical End-Use Product; TGA I/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

A - Terrestrial food crop

B - Terrestrial feed crop

C - Terrestrial nonfood crop

K - Residential

U - Residential and public access premises

II - Residential Use Conventional Chemical

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

- 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.
- 2 Tests to be conducted with DCPA parent and TPA degradate.
- 3 Test to be conducted with TPA degradate only.
- 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.
- 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
- 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
- 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.
- 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.
- 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
- 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.
- 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.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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DCI Number: GDCI-078701-1140

Key: Residue of Concern = Residue of Concern; TEP = Typical End Use Product [TEP]; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI/PAIRA = Technical Grade of the Active Ingredient or Pure Active Ingredient, Radio Labelled; TGAI, TEP = Technical Grade of the Active Ingredient or Technical End-Use Product; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

- 12 Preferred test species is redwing blackbird, *Agelaius phoeniceus*.
- 13 Preferred test species is *Mysidopsis bahia*, mysid shrimp.
- 14 Preferred test species is *Daphnia magna*.
- 15 Preferred test species is *Crassostrea virginica*, Eastern oyster.
- 16 Preferred test species are rainbow trout, *Oncorhynchus mykiss* and bluegill sunfish, *Lepomis macrochirus* (freshwater); and sheepshead minnow, *Cyprinodon variegatus* (estuarine/marine).
- 17 Preferred test species are mallard duck and Northern bobwhite quail.
- 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.
- 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
- 20 Data are required for six species of dicots from at least four families, one species of which is soybean (*Glycine max*). Data are required for four species of monocots from at least two families, one species of which is corn (*Zea mays*). At least one of either the monocot or dicot species must be a root crop.
- 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).
- 22 Data are required for a duckweed species.
- 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.
- 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.
- 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.

Attachment 3

Residue, Environmental Fate, and
Ecotoxicology Response
For Non-Terrestrial Animals

Residue, Environmental Fate, and Ecotoxicology Response

For Non-Terrestrial Animals

D. Freedlander 04/11/2013

I. DCPA Residue Chemistry Study Requirements

The current product labels for Dacthal® have uses that yield important feedstock commodities for poultry and ruminants. Amvac is proposing changes in its label that would eliminate treatment of significant feedstocks. Specifically, Amvac intends to remove alfalfa, which is the only registered crop that is fed to poultry.

Amvac proposes the following:

Guideline	Description	Registrant Response
860.1300	DCPA: Nature of the residue: Plants, livestock (poultry)	7 - Deleting Uses
860.1340	DCPA: Residue analytical method	7 - Deleting Uses
860.1380	DCPA: Storage stability data	5 - Upgrading a Study
860.1480	DCPA: Meat/milk/ poultry/eggs (ruminant)	7 - Deleting Uses
860.1900	DCPA: Field accumulation in rotational crops	5 - Upgrading a Study

1. **860.1300:** Nature of the residue – plants, livestock (poultry): Amvac intends to remove its use for alfalfa, which would eliminate treated feedstocks for **poultry**. On that basis, Amvac seeks a waiver from this requirement. Amvac will provide label amendment upon EPA’s agreement that elimination of the use would satisfy this data requirement.

2. **860.1340:** Residue analytical method: Amvac seeks a waiver from the need to provide an enforcement method for ruminant commodities. Amvac will provide label amendment upon EPA’s agreement that elimination of the use would satisfy this data requirement.

3. **860.1380:** Storage stability data: Amvac intends to meet this requirement by providing EPA with additional information concerning sample storage stability intervals and conditions. The studies to be addressed have the following MRIDs: 00017975, 00018299, 00033087, 00038919, 00058377, 00072099, 0009059, 00114643, 00114678, 00114679, 00114680, 00114681, 00121864 and 00130562. Further justification provided below.

4. **860.1480:** Meat/milk/poultry/eggs (ruminant): Amvac intends to remove its uses for alfalfa, white potatoes, and peas from the label, which would eliminate treated feedstocks for ruminants. On that basis, Amvac seeks a waiver from this requirement. Amvac will provide label amendment upon EPA's agreement that elimination of these uses would satisfy this data requirement.
5. **860.1900:** Field accumulation in rotational crops: Amvac proposes that the requirement be considered completely fulfilled once sample integrity is established for the two studies. Further justification provided below.

Further Justification for DCPA Residue Study Requirements Proposal:

Within a preliminary review of the storage stability requirement, Amvac has noted that the storage stability study for DCPA, the mono-carboxylate metabolite, and TPA 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 Rose, C. A. (MRID 43938901). This study provides data that illustrates the stability of all compounds in wide a variety of frozen crops (i.e., broccoli, onions, celery, snap beans, bell peppers and sweet potatoes) for a 4 year period. Analytical recoveries are all at or above 80%. It may be possible to determine that samples from all studies were analyzed within this period on the basis of the study initiation and completion dates.

With respect to the crop rotational study requirement, Amvac has reviewed the studies titled, "Determination of Residues of DCPA (Dimethyltetrachlorophthalate), SDS-893, Its Degradation Products and HCB on Crops and Soil from a Crop Rotation Study Near Donalsonville, GA – 1989, 1990" by Fowanik, J. B. (MRID 42155504) and "Determination of Residues of DCPA (Dimethyltetrachlorophthalate), SDS-893, Its Degradation Products and HCB on Crops and Soil from a Crop Rotation Study Near Rosa, LA – 1989, 1990" by Fowanik, J. B. (MRID 42298303).

On November 16, 1993, A letter was written by Lois Rossi/EPA to Elizabeth Owens/ISK. Attached to this letter was a document written on September 13, 1993 from Akiva Abromovitch/EPA to Walter Waldrop/ Eric Feris/ EPA that provides a review of the studies. For the Rosa, LA study (MRID 42298303), three deficiencies were noted: 1. The soil within the test plot was not characterized with respect to sand, silt, and clay content. 2. The sampling methods for crop samples, crop size, and number of crops in samples describing the size and methods. 3. Storage stability data was not provided.

For the Donalsonville, GA study (MRID 42155504), two deficiencies were noted: 1. The sampling methods for crop samples were not described (the size and number of the samples and methods were not reported. 2. Storage stability data were not provided for plant and soil substrates.

Within its review, EPA commented following review of the GA study as follows: "Because this study, and the preceding one demonstrate unambiguously that accumulation occurs, EFGWB will not require additional studies at this time". Apparently, there was no response from ISK at the time as the crop rotational requirement was fulfilled. It is not clear why EPA has now determined that new studies are required.

Amvac has evaluated the studies and EPA’s review comments. We believe that the studies should be upgradeable as the key deficiency in our view is the establishment of sample storage stability. Further, if the Agency believes that there is a critical need for characterizing the soil associated with the GA study. Amvac believes that this information can be retrieved. In Amvac’s view, we do not find that the other deficiencies are of a magnitude that would relegate the studies as not fulfilling the guideline requirement.

Based on the results of the crop rotational studies, Amvac recognizes that certain revisions of established tolerances may be appropriate in order to accommodate a label that provides for a 30-day rotational interval, which is Amvac’s intention. Amvac has determined that it has tolerances already established for all potentially rotated crops that it intends to associate with this interval. We would propose further rotational timing restrictions for the remaining crops on the basis that these crops when rotated at intervals longer than 30 days do not contain residues.

II. DCPA Environmental Fate Study Requirements

Amvac proposes the following:

Guideline	Description	Registrant Response
835.4300	DCPA: Aerobic Aquatic metabolism	4 - Submitting Existing Data
835.6100	DCPA: Terrestrial field dissipation	6 - Citing Existing Study

1. **835.4300:** Aerobic aquatic metabolism: Amvac developed data that will meet this regulatory requirement. This has not been submitted previously to the EPA.
2. **835.6100:** Terrestrial field dissipation: Amvac proposed to rely upon previously submitted 2003 study, “DCPA (Dacthal® Small-Scale Ground-Water Monitoring Study”, by Cooper, S.C. (MRID 44082601). Amvac has reviewed the study and believes that it should be considered sufficient for addressing the current guideline requirement. A request for the DER has been made to the Agency and further justification is provided below.

Further Justification for DCPA Environmental Fate Study Requirements Proposal:

A brief review of the two dissipation studies associated with MRID 44082601 follows:

One study was conducted near Porterville, CA within the years 1992-1993. The site received 2 applications. The first application was applied at a rate of 7.6 lb ai/A and ca. 2-months later, a second application was applied at a rate of 10.6 lb ai/A. The half-life of DCPA in soil subsequent to the second and final application was 56.4 days. In general, the metabolite monomethyl tetrachloroterephthalate was confined to the upper soil horizon and were not detectable by the 6-month interval. The highest soil residue level was 0.10 ppm. The metabolite tetrachloroterephthalic acid demonstrated mobility through the soil profile. The highest soil residue level was 0.96 ppm.

A second study was conducted near Clifton-Park, NY within the years 1992-1993. The site was turf based and received 3 applications. The first application was applied at a rate of 14.3 lb ai/A, and ca. 9-months later, a second application was applied at a rate of 9.6 lb ai/A, followed by a third application ca. 2-months later at an application rate of 6.5 lb ai/A. The half-life of DCPA in soil subsequent to the third and final application was 2.7 days. In general, the metabolite monomethyl tetrachloroterephthalate was confined to the upper soil horizon and were barely detectable by the 6-month interval. The highest soil residue level was 0.07 ppm. The metabolite tetrachloroterephthalic acid demonstrated mobility through the soil profile. The highest soil residue level was 1.23 ppm.

III. DCPA Ecotoxicology Study Requirements

Amvac proposes the following:

Guideline	Description	Registrant Response
850.1010	DCPA: Aquatic invertebrate acute toxicity, test, freshwater daphnid	4 - Submitting Existing Data
850.1025	DCPA: Oyster acute toxicity test (shell deposition)	1 - Developing Data
850.1035	DCPA: Mysid acute toxicity test	1 - Developing Data
850.1075	DCPA: Fish acute toxicity test, freshwater and marine	1 - Developing Data (marine) 5 - Upgrading a Study (freshwater x 2)
850.1300	DCPA: Daphnid chronic toxicity test	1 - Developing Data
850.1350	DCPA: Mysid chronic toxicity test	1 - Developing Data
850.1400	DCPA: Fish early life-stage toxicity test	4 - Submitting Existing Data
ss-1066	DCPA: Chronic Sediment - Hyalella Azteca	1 - Developing Data
ss-1069	DCPA: Chronic Sediment - Chironomus dilutus	1 - Developing Data
ss-1072	DCPA: Chronic Sediment - Leptocheirus plumulosus	1 - Developing Data
850.4100	DCPA: Tier I Plant toxicity – (Seedling Emergence)	1 - Developing Data
850.4150	DCPA: Tier I Plant toxicity – (Vegetative Vigor)	1 - Developing Data
850.4400	DCPA: Tier I/II Plant toxicity (Lemna spp.)	1 - Developing Data
850.5400	DCPA: Algal toxicity test, Tier I/II	1 - Developing Data

1. **850.1010:** Aquatic invertebrate acute toxicity test, freshwater daphnids: Amvac developed data that will meet this regulatory requirement. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA.

2. **850.1025:** Oyster acute toxicity test (shell deposition): Amvac will provide a new study.

3. **850.1035:** Mysid acute toxicity test: Amvac will provide a new study.
4. **850.1075:** Fish acute toxicity test, freshwater and marine: Amvac will provide a new sheepshead minnow (*Cyprinodon variegatus*) study. In addition, Amvac proposes that the acceptability of the previously submitted acute rainbow trout (*Oncorhynchus mykiss*) and bluegill sunfish (*Lepomis macrochirus*) be reconsidered for reasons provided below.
5. **850.1300:** Daphnid chronic toxicity test: Amvac will provide a new study.
6. **850.1350:** Mysid chronic toxicity test: Amvac will provide a new study.
7. **850.1400:** Fish early life-stage toxicity test: Amvac developed data that will meet this regulatory requirement. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA.
8. **SS-1066:** Chronic sediment – *Hyalella Azteca*: Amvac will provide a new study. A protocol is being provided to EPA for review prior to initiation of the study.
9. **SS-1069:** Chronic sediment – Chironomous dilutus: Amvac will provide a new study. A protocol is being provided to EPA for review prior to initiation of the study.
10. **SS-1072:** Chronic sediment – *Leptocheirus plumulosus*: Amvac will provide a new study. A protocol is being provided to EPA for review prior to initiation of the study.
11. **850.4100:** Terrestrial plant toxicity (seedling emergence): Amvac will provide a new study. On 3/27/2013, Margaret Hathaway notified Amvac that the test substance to be used in this study should be the TGAI. As a result, Amvac added EPA footnote (2) by this guideline on the Requirements Status and Registrant's Response document attached. However, before initiating this study, Amvac is seeking clarification as to why the TGAI is to be used as the test substance, when typically the EPA requires the use of the typical end-use product (TEP).
12. **850.4150:** Terrestrial plant toxicity, Tier 1 (vegetative vigor): Amvac will provide a new study. However, before initiating this study, Amvac is seeking clarification as to why the TGAI is to be used as the test substance, when typically the EPA requires the use of the typical end-use product (TEP).
13. **850.4400:** Aquatic plant toxicity test using *Lemna* spp. Tiers I and II: Amvac will provide a new study.
14. **850.5400:** Algal toxicity, Tiers I and II: Amvac will provide a new study.

Further Justification for DCPA Ecotoxicology Study Requirements Proposal:

Amvac proposes that the requirements for both freshwater fish species be considered fulfilled on the basis of reconsidering the studies titled, “Static, Acute Toxicity (LC₅₀) Study in Bluegill with technical DCPA (Dimethyl 2,3,5,6-Tetrachlorophthalate)” by Shults, S. K. (MRID 41054827) and “Static Acute Toxicity (LC₅₀) Study in Rainbow Trout Technical DCPA” by Shults, S.K. and Wilson, N.H. (MRID 41054826). Amvac proposes that the study results only be used to substantiate that toxicity to these species does not occur at the solubility limit of DCPA. Therefore, the LC₅₀ would be >0.5 mg/L. The fact that both fish species were also exposed to insoluble material should not have reduced the inherent toxicity of the solubilized material. This conclusion can be better substantiated once the new acute marine fish study is performed, assuming that the results are similar in the absence of any suspended test substance.

IV. TPA Environmental Fate Study Requirements

Amvac seeks to propose a more limited and tiered testing strategy for the degradate TPA. Such a proposal is in keeping with the Agency’s remarks within its May 31, 2011 Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA). Specifically, the Agency states the following:

“**TPA:** No data have been submitted on the major degradate, TPA. TPA forms at high levels relative to parent chemical, it is expected to be more mobile than DCPA, and is expected to be somewhat persistent. Therefore, availability of a relatively comprehensive dataset on the toxicity and environmental fate of TPA is needed. However, a more limited testing strategy will be considered *in lieu* of a comprehensive data submission if one is proposed”.

Environmental fate data being sought by EPA in the DCI can be reliably deduced from studies associated with the parent compound. Certain physicochemical and biological assumptions made by EPA within the Agency’s February 19, 2009 document, “Risks of DCPA Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*) Pesticide Effects Determination” can be relied upon as modeling input parameters for determination of estimated environmental concentrations (EECs). Amvac does intend to submit an aerobic soil metabolism study and an adsorption/desorption study for TPA.

Amvac proposes the following:

Guideline	Description	Registrant Response
835.1230	TPA: Adsorption/Desorption	5 - Upgrading a Study 4 - Submitting Existing Data
835.1240	TPA: Leaching	6 - Citing Existing Study
835.2120	TPA: Hydrolysis	6 - Citing Existing Study
835.4100	TPA: Aerobic soil metabolism	4 - Submitting Existing Data
835.4200	TPA: Anaerobic soil metabolism	6 - Citing Existing Study
835.4300	TPA: Aerobic aquatic metabolism	9 - Waiver
835.4400	TPA: Anaerobic aquatic metabolism	9 - Waiver
835.6100	TPA: Terrestrial field dissipation	6 - Citing Existing Study

1. **835.1230:** Sediment and soil adsorption/desorption for parent and degradates: Amvac is requesting to upgrade the cited study by submitting existing data that will meet this regulatory requirement. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA. Further justification provided below.
2. **835.1240:** Soil column leaching: Amvac proposes to rely upon previously submitted study, “DCPA (Dacthal® Small-Scale Ground-Water Monitoring Study”, by Cooper, S.C. (MRID 44082601). Amvac has reviewed the study and believes that it fully meets the current guideline requirement. A request for the DER has been made to the Agency and further justification is provided below.
3. **835.2120:** Hydrolysis of parent and degradates as a function of pH at 25 C: Amvac proposes to rely upon previously submitted study, “The Effect of Light, Temperature, and pH on the Hydrolysis of Dacthal”, by Szalkowski, M. B. (MRID 114648). Further justification provided below.
4. **835.4100:** Aerobic soil metabolism: Amvac developed data that will meet this regulatory requirement. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA. Further justification provided below.
5. **835.4200:** Anaerobic soil metabolism: Amvac proposes to rely upon previously submitted study, “Anaerobic Soil Metabolism of Dacthal”, Duane, W. C. (MRID 114651). Further justification provided below.
6. **835.4300:** Aerobic aquatic metabolism: Amvac proposes to defer this requirement until the review of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
7. **835.4400:** Anaerobic aquatic metabolism: In the same manner that EPA has concluded that the anaerobic aquatic metabolism requirement has been fulfilled for the parent compound by relying upon the EFED “Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides” dated February 28, 2002, Amvac proposes to meet this requirement for TPA.
8. **835.6100:** Terrestrial field dissipation: Amvac proposes to rely upon previously submitted study, “DCPA (Dacthal® Small-Scale Ground-Water Monitoring Study”, by Cooper, S.C. (MRID 44082601). Amvac has reviewed the study and believes that it fully meets the current guideline requirement. A request for the DER has been made to the Agency.

Further Justification for TPA Environmental Fate Study Requirements Proposal:

Concerning the adsorption/desorption study requirement for TPA, Amvac has previously submitted a 1988 study, “Adsorption and Desorption of Dimethyl Tetrachloroterephthalate to Soils”, by Koresch, B.

H. (MRID 41648805) that the Agency has relied upon within EPA's February 19, 2009 document, "Risks of DCPA Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*) Pesticide Effects Determination." Although EPA commented that within this study, the supernatant was incompletely removed, it is relevant to note that the overall chemical equilibrium is highly shifted to the water phase; thus refining the data would be of little consequence. This study demonstrated a Koc (L/kg) range from 4 – 90, and is in agreement with findings in a more recent European study on a single soil that yielded a Koc (L/kg) value of 4.

The rationale for not conducting the remaining battery of environmental fate studies relates to the fact that much can be inferred about TPA based on an assessment of the parent compound and studies that have been conducted with the parent compound. For hydrolysis, the DCPA hydrolysis study demonstrates that the ester functionality of the parent molecule is not very susceptible to chemical hydrolysis. As the degradate TPA has the ester functionality removed, there are no new chemical features associated with the molecule that would make it susceptible to chemical hydrolysis in a manner different than the parent compound. A similar conclusion can be drawn concerning the photolysis of TPA in that it contains the same chromophore as the parent compound, which has been shown not to be susceptible to photolysis.

Also, in terms of microbial degradation, there is clear evidence within the parent aerobic soil and anaerobic soil metabolism studies that TPA is quite stable over the duration of the guideline studies. Although there is evidence in the literature that microorganism induced reductive dechlorination and decarboxylation reactions can occur, these reactions seem to require an induction period that is longer than that observed in the laboratory tests. Within EPA's February 19, 2009 document, "Risks of DCPA Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*) Pesticide Effects Determination", the Agency designated TPA as stable to both aerobic and anaerobic soil metabolism. Amvac intends to provide new study data to verify this finding for the aerobic soil metabolism of TPA; but proposes to utilize the findings of the DCPA anaerobic soil metabolism study for fulfilling the requirement for TPA.

The potential for TPA to adsorb to soil has been studied and data is available that is reasonably accurate and that clearly demonstrates that this degradate is susceptible to leaching. With the very low Kocs associated with TPA, Amvac believes that there is satisfactory information for assigning a value to the Kow.

Overall, there is data to demonstrate that TPA is relatively persistent and can leach into groundwater. The mitigating risk factor at this point appears to be the low toxicity associated with this chemical species. In fact, two ecotoxicology studies have been conducted that support this premise. These existing studies will be submitted. The first study is an acute study on rainbow trout (*Oncorhynchus mykiss*) for which the 96 hour LC50 was determined to be higher than the highest tested dose of 100 mg/L. Similarly, an acute study on *Daphnia magna* was conducted for which the 48 hour EC50 was determined to be higher than the highest tested dose of 100 mg/L.

V. TPA Ecotoxicology Study Requirements

Amvac proposes that the remaining ecotoxicology studies be deferred until the ecotoxicology studies for DCPA associated with this DCI are complete. Ecological risk assessments would be conducted utilizing the toxicological endpoints associated with the parent compound and if there were any untoward risks then the appropriate ecotoxicology studies would be conducted for the metabolite.

Amvac proposes the following:

Guideline	Description	Registrant Response
850.1010	TPA: Aquatic invertebrate acute toxicity, test, freshwater daphnids	4 - Submitting Existing Data
850.1025	TPA: Oyster acute toxicity test (shell deposition)	9 - Waiver
850.1035	TPA: Mysid acute toxicity test	9 - Waiver
850.1075	TPA: Fish acute toxicity test, freshwater and marine	4 - Submitting Existing Data (freshwater) 9 - Waiver (freshwater and marine)
850.1300	TPA: Daphnid chronic toxicity test	9 - Waiver
850.1350	TPA: Mysid chronic toxicity test	9 - Waiver
850.1400	TPA: Fish early life-stage toxicity test	9 - Waiver
850.1730	TPA: Fish Bioconcentration	9 - Waiver
850.4100	TPA: Terrestrial plant toxicity, Tier 1 (seedling emergence)	9 - Waiver
850.4150	TPA: Terrestrial plant toxicity, Tier 1 (vegetative vigor)	Not required.
850.4400	TPA: Aquatic vascular plant growth - Lemna spp. Tiers I/II	9 - Waiver
850.5400	TPA: Algal toxicity test, Tier I/II	9 - Waiver

1. **850.1010:** Aquatic invertebrate acute toxicity, test, freshwater daphnids: Amvac developed data that will meet this regulatory requirement. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA.
2. **850.1025:** Oyster acute toxicity test (shell deposition): Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current

DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.

3. **850.1035:** Mysid acute toxicity test: Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
4. **850.1075:** Fish acute toxicity test, freshwater and marine: Amvac developed data that will meet one of the two required species for freshwater. This was initially generated for regulatory requirements outside of the US, and has not been submitted previously to the EPA. In addition, Amvac proposes to defer the remainder of this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
5. **850.1300:** Daphnid chronic toxicity test: Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
6. **850.1350:** Mysid chronic toxicity test: Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
7. **850.1400:** Fish early life-stage toxicity test: Amvac proposes to defer this requirement until the review of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
8. **850.1730:** Fish BCF: Amvac seeks a waiver on this study on the basis of EPA's Ecological Effects Test Guidelines OPPTS 850.1730 testing criteria. Further justification provided below.
9. **850.4100:** Terrestrial plant toxicity, Tier 1 (seedling emergence): On 3/27/2013, Margaret Hathaway notified Amvac that the TPA requirement needs to be added to this guideline on the DCI. As a result, Amvac added EPA footnote (2) by this guideline on the Requirements Status and Registrant's Response document attached. Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.

10. **850.4150:** Terrestrial plant toxicity, Tier 1 (vegetative vigor): On 3/27/2013, Margaret Hathaway notified Amvac that the TPA requirement was inadvertently requested on the DCI. As a result, Amvac removed EPA footnote (2) listed by this guideline on the Requirements Status and Registrant's Response document attached and will not be conducting this study.
11. **850.4400:** Aquatic plant toxicity test using *Lemna spp.* Tiers I and II: Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.
12. **850.5400:** Algal toxicity, Tiers I and II: Amvac proposes to defer this requirement until the completion of this study requirement for DCPA as required by the current DCI and then to perform an ecological risk assessment of the metabolite TPA using the endpoint determined for DCPA. Further justification provided below.

Further Justification for TPA Ecotoxicology Study Requirements Proposal:

Within EPA's May 31, 2011 document titled, "Registration Review – Preliminary Problem Formulation for the Ecological risk Assessment of Dimethyl 2,3,5,6-Tetrachlorophthalate (DCPA)", the Agency provides the opportunity for Amvac to propose a more limited testing strategy for TPA. Specifically, the Agency states the following:

“TPA: No data have been submitted on the major degradate, TPA. TPA forms at high levels relative to parent chemical, it is expected to be more mobile than DCPA, and is expected to be somewhat persistent. Therefore, availability of a relatively comprehensive dataset on the toxicity and environmental fate of TPA is needed. However, a more limited testing strategy will be considered *in lieu* of a comprehensive data submission if one is proposed”.

Also, within this document, the Agency describes an ecological risk assessment procedure that would be used in the absence of ecotoxicity data for TPA. EPA has indicated that it would use the highly conservative assumptions in assessing the ecological risk of the metabolite. Amvac believes this can be accomplished by using the ecotoxicity endpoints associated with DCPA for TPA. The practice of using surrogate data from the parent compound for a metabolite is a practice that has been used by EPA in the past. Specifically, the Agency states the following:

“The major degradates of DCPA are tetrachloroterephthalic acid (TPA) and monomethyl tetrachloroterephthalic acid (MTP). The toxicity data for these chemicals are limited to mammals. The available data indicate that the adverse effects associated with TPA are much milder than those for the parent and tend to occur at doses that are lower by approximately an order of magnitude (U.S. EPA, 2008a). However, DCPA and TPA are among the most commonly found pesticides/degradates in water samples (U.S. EPA, 2008a), DCPA is slightly mobile and TPA is very mobile, respectively, and both are persistent. There is no aquatic toxicity data available for the degradate TPA. In past risk assessments for DCPA (i.e., the CRLF ESA, U.S. EPA 2009), EFED bridged the data gap using structurally similar benzoic acid herbicides (i.e., dicamba). However, for future assessments, in the absence of toxicity data

for the degradate TPA, EFED will make highly conservative assumptions when evaluating the toxicity of TPA”.

Concerning the specific requirement for a bioaccumulation study for TPA, EPA’s Ecological Effects test Guidelines OPPTS 850.1730 testing criteria state the following:

“(2) **Criteria for performing test.** The test is most commonly required for chemicals that are relatively persistent (stable) in water and have a relatively high potential for bioaccumulation as indicated by log Pow (log of the octanol/water partition coefficient) values less than or equal to 1.0”.

Although TPA meets the first criteria concerning its persistence in water, it is a highly water soluble compound and would be expected to predominantly partition into a water phase and demonstrate a log Pow value significantly greater than 1.0. Evidence for this partitioning behavior is evident in the adsorption/desorption studies where TPA significantly fractionates into the water phase for soils with high organic matter content.

Attachments 4 - 11 have been omitted