Joint Exhibit 38

EPA OALJ Docket No. FIFRA-HQ-2022-0002



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: February 17, 2015

SUBJECT: DCPA (Dacthal): HED Response to Comments on the Residue Chemistry Requirement 860.1900 (Field Accumulation in Rotational Crops) of the Generic Data Call In (GDCI-0798701-1140).

PC Code: 078701 Decision Nos.: 496485 Petition No.: NA Risk Assessment Type: NA TXR No.: NA MRID No.: NA DP Barcodes: D423450 Registration No.: NA Regulatory Action: Response to comments Case No.: NA CAS No.: 1861-32-1 40 CFR: 180.185

FROM: Danette Drew, Chemist Risk Assessment Branch V Health Effects Division (HED) (7509P)

THROUGH: Michael Metzger, Branch Chief Risk Assessment Branch V/VII Health Effects Division (7509P)

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Amvac Chemical Corporation (Amvac) has submitted a response (8/11/2014; No MRID) to Guideline 860.1900 Field Accumulation in Rotational Crop data requirements from a DCPA (Dacthal) Generic Data Call-In (GDCI) notice (GDCI-0798701-1140, dated 1/31/13).

HED had previously responded to Amvac's 90-day and 12-month comments on the residue chemistry aspects of the GDCI [D. Drew, 10/23/2013, D413176, and D. Drew, 7/7/2014, D420907]. More details pertaining to the GDCI 860 guideline data requirements can be found in those documents. In this memorandum, HED is only responding to the residue chemistry justifications presented in the 8/11/2014 Amvac letter for the 860.1900 data requirement.

TO:

860.1900 Field Accumulation in Rotational Crops

Amvac cites two previously submitted limited rotational crop studies (MRID 42155504 and MRID 42298303). These studies have been reviewed by the Agency and have been determined to be scientifically acceptable (W. Smith, D211773, 10/23/95). The study results indicate that since there are measurable residues on rotated crops (residues on some crops were evident up to a 1-year plant back interval (PBI)), rotational crop tolerances are likely needed and that plant back restrictions are required on DCPA labels.

In the current submission (8/11/2014 letter), Amvac has proposed to maintain the current label PBI restriction of 8 months that is in place to prevent crop injury and intends to permit replanting of only those crops that are listed on the label for treatment and for which current tolerances exist. The following wording appears on one label, EPA Reg. No. 481-490:

Replanting crops other than those included on this label in DACTHAL W-75 treated soil within 8 months of application may result in crop injury. If replanting is required because of an early crop failure, the planting of onions, seeded cucurbits, potatoes, tomatoes, eggplants or peppers at this time may result in crop injury. However, all crops on this label may be planted following harvest of a DACTHAL W-75 treated crop.

Based on the available rotational crop data (MRIDs 42155501 and 42298303; see Appendix A for a summary), the currently established tolerances (see Appendix B), and in light of the 8 month requirement for crop injury, HED has determined that the following rotational crop restrictions are appropriate: Rotation to a crop with an established tolerance for residues of DCPA (40 CFR 180.185) is permitted with a minimum plant back interval of 8 months; rotation to any other crop is not permitted.

All labels for DCPA use on agricultural crops should be modified to reflect the appropriate rotational crop restrictions. The specific crops and permissible plant back interval are listed in Table 1 below. Provided that the correct label modifications are made, additional field rotational crop data are not needed and the 860.1900 data requirement will be considered fulfilled for DCPA. If rotation to crops without current tolerances for DCPA is desired, full rotational crop studies may be performed at the desired plant back intervals for those crops so that appropriate tolerance levels may be determined.

ROTATIONAL CROP PLANT BACK REST	RICTIONS
Minimum 8 Month Plant Back (allowed on the following individual crops with tolerances for DCPA)	Plant Back Not Permitted
-Root and Tuber Vegetables: Celeriac, chicory, ginseng, horseradish, potato, oriental radish, radish, rutabaga, sweet potato, turnip, yam.	Rotation to all other crops not specifically listed in column to the left is prohibited.
-Bulb Vegetables: Chive, bulb onion, green onion, garlic.	
-Leafy Vegetables (except Brassica): Lettuce, radicchio.	
-Leafy Brassica Vegetables (Crop Group 5): All Brassica vegetables (Broccoli; broccoli, Chinese (gai lon); broccoli raab (rapini); Brussels sprouts; cabbage; cabbage, Chinese (bok choy); cabbage, Chinese (napa); cabbage, Chinese mustard(gai choy); cauliflower; cavalo broccolo; collards; kale; kohlrabi; mizuna; mustard greens; mustard spinach; rape greens). -Legume Vegetables: Blackeyed pea, dry bean, mung bean,	
snap bean, soybean.	
-Fruiting Vegetables: Eggplant, pepper, pimento, tomato.	
-Cucurbits: cantaloupe, cucumber, muskmelon, summer squash, watermelon, winter squash.	
-Berry and Small Fruit: Strawberry.	
-Cereal Grains: Field corn, popcorn, sweet corn.	
-Herbs: Basil, coriander, dill, marjoram, parsley.	
-Oilseed: Cottonseed.	

Table 1. DCPA Rotational Crop Plant Back Restrictions

Crop Grouping/					Residues Found (ppm) ^e			
Representative Rotational Crop	MRID (Location)	Commodity	PBI ^a (days)	PTI ^b (days)	DCPA	МТР	TCP (TPA)	НСВ
Root and Tuber Vegetables	42155504 (GA)	Roots	30	128	0.33 (0.33) ^d	ND ^c (ND)	0.57 (0.56)	0.0012 (0.0014)
Carrot			220	342	0.027 (0.030)	ND (ND)	0.11 0.13	ND (ND)
			365	458	0.012 (0.012)	ND (ND)	ND ND	0.0005 (0.0006)
	42298303 (LA)	Roots	29	112	1.03 (0.87, 0.96)	ND (0.011)	0,13 (0,15)	0.0015 (0.0016)
		See 4	103	242	ND (ND)	ND (ND)	0.31 (0.26)	ND (ND)
			355	449	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Radish 42155504 (GA)	Roots	30	59	0.24 (0.25)	0.020 (0.021)	0.054 (0.052)	ND ND	
			220	248	ND (ND)	ND (ND)	ND (ND)	ND ND
		365	414	ND (ND)	ND (ND)	ND (ND)	ND 0.0006	
Turnip 42298303 (LA)	Roots	29	89	0.041 (0.045)	ND (ND)	ND (ND)	ND (ND)	
			90	130	0.042 (0.045)	ND (ND)	0.13 (0.14)	ND (ND)
			355	428	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Leaves of Root and Tuber Vegetables	42155504 (GA)	Leaves	30	128	0.25 (0.25)	0.014 (0.019)	2.30 (2.13)	0.0009 (0.0008)
Carrot			220	342	0.014 (ND)	ND (ND)	ND (ND)	ND (ND)
	10.00	365	458	0.012 (0.013)	ND (ND)	ND (ND)	ND (0.0006)	
42298303 (LA)	Leaves	29	112	0.17 (0.19)	ND (ND)	0.15 (0.15)	0.0005 (0.0005)	
	1000		103	204	0.012 (ND)	ND (ND)	0.090 (0.11)	ND (ND)
			355	449	ND (ND)	ND (ND)	ND (ND)	ND (ND, 0.0008, 0.0006)

Appendix A. Residues of DCPA, MTP, and TPA in/on rotational crops following a single application to soil of the 75% WP at 10.5 lb ai/A (1x to the primary crop).

Crop Grouping/						Residues	Found (ppm)	e
Representative Rotational Crop	MRID (Location)	Commodity	PBI ^a (days)	PTI ^b (days)	DCPA	MTP	TCP (TPA)	HCB
Radish	42155504 (GA)	Leaves	30	59	0.67 (0.74)	0.13 (0.13)	0.28 (0.27)	ND (ND)
			220	248	ND (ND)	ND (ND)	ND (ND)	ND (ND)
			365	414	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Turnip	42298303 (LA)	Leaves	29	89	0.070 (0.071)	ND (ND)	0.030 (0.026)	ND (ND)
			90	130	0.020 (0.018)	ND (ND)	0,16 (0.10)	0.0007 (ND)
			355	428	ND (ND)	ND (ND)	0.013 (ND)	ND (ND)
Leafy Vegetables (Except Brassica)	42155504 (GA)	Leaves	30	80	0.53 (0.47)	0.47 (0.48)	1.60 (1.73)	ND (ND)
Lettuce			220	380	ND (ND)	ND (ND)	ND (ND)	ND (ND)
			365	437	ND (ND)	ND (ND)	ND (ND)	ND (ND)
42298: (LA	42298303 (LA)	Leaves	29	81	1.32 (1.28)	0.058 (0.057)	0.038 (0.047)	0.0005
			103	162	0.021 (0.025)	ND	0.65	ND (ND)
			355	396	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Brassica Leafy 421 Vegetables (42155504 (GA)	Leaves	30	73	0.19 (0.21)	0.18 (0.18)	0.38 (0.34)	ND (ND)
Mustard			220	248	ND (ND)	ND (ND)	ND (ND)	ND (ND)
			365	414	ND (ND)	ND (ND)	ND (ND)	ND (ND)
422 ()	42298303 (LA)	Leaves	29	80	0.17 (0.17)	0.012 (0.014)	0.027 (0.027)	ND (ND)
			103	141	0.013 (0.014)	ND (ND)	0.080 (0.067)	ND (ND)
			355	410	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Cereal Grains Field Corn	42155504 (GA)	Grain	30	152	ND (ND)	ND (ND)	ND (ND)	ND (ND)
			91	205	ND (ND)	ND (ND)	ND 0.010	ND (ND)
			365	512	ND (ND)	ND (ND)	ND (ND)	ND (ND)
		Grain	29	167	ND	ND	ND	ND

Crop Grouping/				PTI ^b (days)	Residues Found (ppm) ^e			
Representative Rotational Crop	MRID (Location)	Commodity	PBI ^a (days)		DCPA	МТР	TCP (TPA)	НСВ
	42298303 (LA)				(ND)	(ND)	(ND)	(ND)
			90	201	ND (ND)	ND (ND)	ND (0.011)	ND (ND)
			374	533	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Oats	42155504 (GA)	Grain	213	437	ND (ND)	ND (ND)	ND (ND)	ND (ND)
	42298303 (LA)	Grain	375	473	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Sorghum	42155504 (GA)	Grain	91	192	ND (ND)	ND (ND)	0.012 (0.014)	ND (ND)
			365	510	ND (ND)	ND (ND)	ND (ND)	ND (ND)
	42298303 (LA)	Grain	103	201	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Forage, Fodder, and Straw of Cereal Grains Field Corn	42155504 (GA)	Fodder	30	152	ND (ND)	ND (ND)	ND (ND)	0.0006 (0.0009)
	1.00		91	205	ND (ND)	ND (ND)	0.033 (0.035)	ND (ND)
			365	512	ND (ND)	ND (0.010)	ND (ND)	ND (ND)
	s	Silage	30	128	ND (ND)	ND (ND)	0.10 (0.10)	ND (ND)
			365	463	ND (ND)	ND (ND)	0.017 (ND)	ND (ND)
	42298303 (LA)	Fodder	29	167	ND (ND)	ND (ND)	0.053 (0.058)	ND (ND)
	Contraction of the second seco		90	201	ND (ND)	0.010 (0.010)	0.11 (0.094)	0.0008
			374	564	ND (ND)	ND (ND)	ND (ND)	ND (ND)
		Silage	29	116	ND (ND)	ND (ND)	0.046 (0.044)	ND (ND)
			90	167	ND (ND)	ND (ND)	0.11 (0.10)	ND (ND)
			374	481	ND (ND)	ND (0.012)	ND (ND)	ND (ND)
Oats	42155504 (GA)	Forage	213	364	ND (ND)	0.015 (0.020)	ND (ND)	ND (ND)
	(204)	Straw	213	437	ND (ND)	ND (ND)	ND (ND)	ND (ND)
	42298303 (LA)	Forage	29	74	0.095 (0.095)	0.010 (ND)	0.43 (0.39)	ND (ND)

Crop Grouping/			PBI ^a (days)	PTI ^b (days)	Residues Found (ppm) ^e			
Representative Rotational Crop MRID (Location	MRID (Location)	Commodity			DCPA	MTP	TCP (TPA)	HCB
			375	410	ND (ND)	ND (ND)	0.079 (ND, ND, ND)	ND (ND)
		Straw	29	106	0.18 (0.16)	0.015 (0.010)	1.20 (0.82)	ND (ND)
			375	473	ND (ND)	ND (ND)	ND (ND)	ND (ND)
Sorghum	42155504 (GA)	Fodder	91	192	ND (ND)	ND (ND)	0.14 (0.16)	ND (ND)
			365	510	ND (ND)	ND (ND)	ND (ND)	ND (ND)
42289303 (LA)	Fodder	103	201	ND (ND)	ND (ND)	0.036 (0.046)	ND (ND)	

* PBI=plant back interval.

^b PTI=post treatment interval.
^c ND=below the limit of detection (<0.0005 ppm for HCB; <0.01 ppm for each DCPA, MTP, and TPA).
^d Numbers listed parenthetically represent duplicate extraction and analysis of a single field sample.
^e DCPA, MTP, and TCP are the only residues of concern. HCB is not a residue of concern.

Appendix B

ELECTRONIC CODE OF FEDERAL REGULATIONS e-CFR Data is current as of January 28, 2015

Title 40 \rightarrow Chapter I \rightarrow Subchapter E \rightarrow Part 180 \rightarrow Subpart C \rightarrow §180.185

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Title 40: Protection of Environment PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD Subpart C—Specific Tolerances

§180.185 DCPA; tolerances for residues.

(a) General. Tolerances for the combined residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyltetrachloroterephthalate (MTP) and tetrachloroterephthalic acid (TCP) (calculated as dimethyl tetrachloroterephthalate) are established in or on the following food commodities:

Commodity	Parts per million		
Cantaloupe	1.0		
Garlic	1.0		
Ginseng	2.0		
Horseradish	2.0		
Muskmelon	1.0		
Onion, bulb	1.0		
Onion, green	1.0		
Strawberry	2.0		
Tomato	1.0		
Vegetable, brassica, leafy, group 5	5.0		
Watermelon	1.0		

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. Tolerances with regional registration, as defined in §180.1(I), are established for the combined inadvertent residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyl tetrachloroterephthalate acid (MTP) and terachlorophthalic acid (TCP) (calculated as DCPA) in or on the following food commodities:

Commodity	Parts per million
Radish, roots	2.0
Radish, tops	15.0

(d) Indirect or inadvertent residues. Tolerances are established for the combined indirect or inadvertent residues of the herbicide dimethyl tetrachloroterephthalate (DCPA) and its metabolites monomethyl tetrachloroterephthalate acid (MTP) and terachlorophthalic acid (TCP) (calculated as DCPA) in or on the following food commodities:

Commodity	Parts per million
Basil, dried leaves	20.0
Basil, fresh leaves	5.0
Bean, dry	2.0
Bean, mung, seed	2.0
Bean, snap, succulent	2.0
Celeriac	2.0
Chicory, roots	2.0
Chicory, tops	5.0
Chive	5.0
Coriander, leaves	5.0
Corn, field, forage	0.4
Corn, field, grain	0.05
Corn, field, stover	0.4
Corn, pop, forage	0.4
Corn, pop, grain	0.05
Corn, pop, stover	0.4
Corn, sweet, forage	0.4
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.4
Cotton, undelinted seed	0.2
Cucumber	1.0
Dill	5.0
Eggplant	1.0
Lettuce	2.0
Marjoram	5.0
Parsley, dried leaves	20.0

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Parsley, leaves	5.0
Pea, blackeyed, seed	2.0
Pepper	2.0
Pimento	2.0
Potato	2.0
Radicchio	5.0
Radish, oriental, roots	2.0
Radish, oriental, tops	2.0
Rutabaga	2.0
Soybean	2.0
Squash, summer	1.0
Squash, winter	1.0
Sweet potato	2.0
Turnip, roots	2.0
Turnip, tops	5.0
Yam, true, tuber	2.0