

# **Joint Exhibit 85**



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

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** October 23, 2013

**SUBJECT:** DCPA (Dacthal): HED Response to Comments on the Residue Chemistry Requirements of the Generic Data Call In (GDCI-0798701-1140).

**PC Code:** 078701

**DP Barcodes:** D413176, D413177, D413195,  
D413202, D413218

**Decision Nos.:** 480912, 480882, 480883, 480915,  
480920

**Registration No.:** NA

**Petition No.:** NA

**Regulatory Action:** Response to comments

**Risk Assessment Type:** NA


**Case No.:** NA


**TXR No.:** NA

**CAS No.:** 1861-32-1

**MRID No.:** 49115401

**40 CFR:** 180.185

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Amvac Chemical Corporation has submitted their 90-day comments to a DCPA (Dacthal) Generic Data Call-In (GDCI) notice (GDCI-0798701-1140, dated 1/31/13) in a document titled *Dacthal DCI Residue, Environmental Fate, and Ecotoxicology Response for Non-Terrestrial Animals* (4/13/13; MRID 49115401). In the current memorandum, each residue chemistry deficiency is briefly summarized, followed by Amvac's comments, and the current HED response.

## Residue Chemistry Deficiency

### **1) Nature of the Residue –Poultry (860.1300):**

There is a requirement for a poultry metabolism study for DCPA since a poultry feeding study (MRID 00058378) indicates the potential for accumulation of residues in egg yolk and fat. HED has previously used the poultry feeding results for exposure and risk assessment based on the tentative assumption that the residues of concern in poultry tissues and eggs are the same as those delineated in meat and milk from the acceptable ruminant metabolism study. The poultry metabolism study will confirm if the residues of concern are indeed the same for both ruminant and poultry. In addition, a decision as to the need for a new poultry feeding study will be made on submission of an acceptable poultry metabolism study; the utility of this original poultry feeding study is questionable due to the limited nature of supporting information provided, variability in residue determinations both in controls and treated samples, and the unexpected result with the contaminant hexachlorobenzene (HCB) i.e. no accumulation was apparent in fat.

**Amvac:** Amvac is proposing to remove the alfalfa use of DCPA in order to eliminate the treated feedstocks for poultry and thus the need for a poultry metabolism study.

**HED:** There are no DCPA end-use products (EUPs) registered for use on alfalfa, nor are there any tolerances established for DCPA on alfalfa. [Note: It is not clear why, but alfalfa is listed on the technical formulation label (EPA Reg. 5481-495) along with several other crops, many for which there are no registered direct uses, but for which tolerances are established for *indirect or inadvertent residues* caused by soil drift (40 CFR 180.185(d)).] There are currently no direct uses of DCPA on any poultry feedstuff. However, there are current tolerances for indirect or inadvertent residues of DCPA on the major poultry feedstuffs of corn grain and soybean; corn grain and soybean seed may be fed to poultry at up to 75% and 20% in the diet, respectively (Table 1 Feedstuffs (June 2008)). In addition to indirect residues from the drifting of treated soil onto non-target crops, there is also the possibility of residues accumulating in rotated crops that have been planted after harvest of the treated crop. Limited data indicate that rotated crops, such as corn and soybeans, may contain measurable DCPA residues and revised tolerances based on rotational crop data may be necessary (see section 860.1900 below). Once the DCPA residues in corn and soybean as rotated crops have been determined in conjunction with possible soil drift contributions, a dietary burden can be estimated for poultry. If the dietary burden results in sufficiently low anticipated secondary residues in poultry tissue and eggs then it may not be necessary to perform a poultry metabolism study.

### **2) Residue Analytical Method-Livestock (860.1340)**

A GC/EC analytical method, similar to those for plants, is available for determining DCPA, MTP, and TPA (the residues of concern for both tolerance consideration and risk assessment) in milk and beef fat. Recoveries of each compound using 12 samples each of milk and beef fat fortified at 0.01-5 ppm were acceptable. The level of detection (LOD) is 0.01 ppm. This method is suitable for Agency validation and inclusion in PAM, Vol. II pending a successful independent laboratory validation (ILV). HED is requiring that the registrant submit independent laboratory

validation and radiovalidation data for enforcement method(s) for animal commodities and submit the method(s) for Agency validation and inclusion in PAM, Vol. II.

**Amvac:** Amvac is proposing to remove the use of DCPA on alfalfa, white potatoes and peas in order to eliminate the treated feedstocks for ruminants and thus the need for a residue analytical method for livestock.

**HED:** There are currently no direct uses of DCPA on any livestock feedstuff. There are no DCPA EUPs registered for use on alfalfa, white potatoes or peas (although they are listed on the technical formulation label (EPA Reg. 5481-495)). There are no tolerances for DCPA on alfalfa. However, there are tolerances for indirect residues of DCPA on potato and on pea, blackeyed, seed. There are also tolerances for indirect or inadvertent residues of DCPA on the major livestock feedstuffs corn and soybean. Once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed (see section 860.1900 below), a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then a livestock residue analytical method would not be necessary.

### **3) Storage Stability Data (860.1380)**

The final report for a 4-year storage stability study (MRID 43938901) on DCPA support the conclusion that residues of DCPA, MTP, TPA and HCB are stable in frozen samples of broccoli, onion bulbs, celery, snap beans, bell peppers, and sweet potatoes stored for 4 years. However, the registrant must submit storage intervals and conditions for field trial samples analyzed in MRIDs 00017975, 00018299, 00033087, 00038919, 00058377, 00058378, 00072099, 00090259, 00114643, 00114678, 00114679, 00114680, 00114681, 00121864, and 00130562. If it can be confirmed that samples from these earlier field trials had been stored frozen and for durations not significantly longer than 4 years, all field trial data will be considered to be fully validated by the 4-year storage stability study.

**Amvac:** Amvac has responded that they intend to meet this requirement by providing EPA with the additional information regarding sample storage stability intervals and conditions for the aforementioned field trial studies.

**HED:** HED acknowledges Amvac's intention to submit the requested information and will evaluate that information upon receipt.

### **4) Meat/Milk/Poultry/Eggs (Ruminant Feeding Study) (860.1480)**

A new ruminant feeding study is required to determine whether tolerances are needed (and if so, the appropriate tolerance levels) for milk and meat. The requested ruminant feeding 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. A ruminant feeding study conducted in 1963 (MRID 00114643) is of limited usefulness because most edible tissues were not analyzed and data for milk and fat are inconsistent with the results of a goat metabolism study.



**Amvac:** Amvac is proposing to remove the use of DCPA on alfalfa, white potatoes and peas in order to eliminate the treated feedstocks for ruminants and thus the need for a ruminant feeding study.

**HED:** There are currently no DCPA EUPs registered for use on alfalfa, white potatoes or peas (although they are listed on the technical formulation label (EPA Reg. 5481-495)). There are no tolerances for DCPA on alfalfa. There are tolerances for indirect residues of DCPA on potato and on pea, blackeyed, seed. There are no direct uses of DCPA on any livestock feedstuff, but there are tolerances for indirect or inadvertent residues of DCPA on the major livestock feed crops of corn and soybean. Once the tolerances for DCPA residues in corn and soybean as rotated crops have been reassessed (see section 860.1900 below), a dietary burden can be estimated for ruminants. If the dietary burden results in sufficiently low anticipated secondary residues in ruminant tissue and milk, then a ruminant feeding study would not be necessary.

### **5) Field Accumulation in Rotated Crops (860.1900)**

The agency is requiring additional field rotational crop data for DCPA and its metabolites.

**Amvac:** Amvac cites two previously submitted limited rotational crop studies (MRID 42155504 and MRID 42298303) and proposes that the outstanding data requirement for rotational crops may be fulfilled once sample integrity is established for these two studies.

**HED:** HED previously reviewed these studies and did not find them scientifically deficient in regard to sample integrity or any other study aspect (W. Smith, D211773, 10/23/95). These limited study results did, however, indicate that since there are measurable residues on rotated crops (residues on some crops were evident up to a 1-year plantback interval (PBI)) rotational crop tolerances are likely needed and that plantback restrictions are required on DCPA labels. The appropriate tolerance levels for rotated crops cannot be assessed until data are submitted showing the residues levels at the specific PBIs that the registrant desires. The registrant has not yet submitted the additional rotational crop data nor proposed any label restrictions that would obviate the need for rotational crop tolerances.

The submitted studies (MRID 42155504 and MRID 42298303), which were conducted in soil that had been treated at the current maximum label rate (10.5 lbs a.i./A), show that significant levels of DCPA and metabolite residues can occur in rotated crops at plantback intervals of 30 to 220 days. At a PBI of 30 days, combined residues of DCPA, MTP, and TPA ranged from <LOQ (0.01 ppm for each analyte) in corn grain to as high as 2.7 ppm in lettuce. At a PBI of about 200 days, combined residues of concern were as high as 0.15 ppm (in carrot roots). Carrot roots and tops, corn fodder and silage, oat forage, and turnip tops from plants sowed at a 1-year PBI in soil treated at 10.5 lb a.i./A bore quantifiable residues in one or more samples. These data indicate that tolerances are likely needed for residues of DCPA and metabolites in some crops if they are rotated to fields that have been treated at the maximum label rate.

Extensive rotational crop field trials are required to determine the appropriate tolerance levels for rotated crop commodities (860.1900). The scope of the required tests is dependent upon the registrant's intent with respect to 1) the crops to be allowed in rotation and 2) the desired PBIs

for these crops. The registrant must specify their intentions as to which crops are to be allowed in rotation with the crops on the label(s) and the desired PBIs for rotated crops.

The requirements for field trials for purposes of rotational crop tolerances are the same as those to establish primary tolerances on crops or crop groups; these requirements are covered in EPA Guideline 860.1500. 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, the standard number of trials needed to support direct crop treatment tolerances are typically required, e.g., 20 trials for wheat.