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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

FEB 15 1996

MEMORANDUM

SUBJECT: **Dimethoate Reregistration.** Wheat, potato, field corn, cottonseed, orange, and tomato processing data. Includes 6(a)(2) issues.
CBRS Nos.: 14023, 14250, 14224, and 15267
DP Barcode Nos.: D205591, D206804, D206555, and D213099
MRID Nos.: 43288201, 43288202, 43293701, 43318401, 43308701, and 43554401
Chemical No.: 035001
Reregistration Case No.: 0088

Bonnie Cropp-Kohlligian

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division [7509C]

THRU: Susan V. Hummel, Acting Section Head
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division [7509C]

Susan V. Hummel

TO: Larry Schnaubelt/Susan Jennings [PM-72]
Reregistration Branch
Special Review and Reregistration Division [7508W]

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., has submitted new wheat grain (MRID 43288201), potato (MRID 43288202), field corn (MRID 43293701), cottonseed (MRID 43318401), orange (MRID 43308701), and tomato

(MRID 43554401) processing studies. These data submissions are summarized in the attached Data Evaluation Records (DERs) produced by Dynamac Corporation under contract to the Agency and are reviewed herein for their adequacy to fulfill reregistration data requirements.

CBRS notes that the subject cottonseed and orange processing data were submitted to the Agency under 6(a)(2). Preliminary results for these studies (MRID 43235301) were previously submitted to the Agency under 6(a)(2) and screened by the 6(a)(2) SWAT Team. CBRS was informed by SRRD of the data screening but was not required to review the preliminary results of the cottonseed and orange processing studies.

CONCLUSIONS

Magnitude of the Residue in Wheat Processed Commodities (MRID 43288201)

1. The submitted wheat grain processing study is deemed adequate to satisfy reregistration requirements. Food/feed additive tolerances for residues of dimethoate and omethoate in wheat bran, flour, middlings, and shorts are not needed. Residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.02 ppm total) in bran, flour, middlings, and shorts processed from wheat grain bearing residues below the LOQ following treatment with dimethoate at 5x the maximum single application rate. [Note: CBRS has previously recommended in favor of a waiver from the need for dimethoate residue data concerning aspirated grain fractions (CBRS No. 12575, DP Barcode D195313, B. Cropp-Kohlligian, 10/13/93).]

2. As a result of changes in the Livestock Feeds Table (TABLE II (September 1995)), magnitude of the residue data are currently required by the Agency for wheat germ. This new data requirement should be imposed at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document but should not impinge on the reregistration eligibility decision for dimethoate.

Magnitude of the Residue in Potato Processed Commodities (MRID 43288202)

3. The submitted potato processing study is deemed adequate to satisfy reregistration requirements. Food/feed additive tolerances for residues of dimethoate and omethoate in potato granules/flakes, chips, and wet peel are not needed. Residues of dimethoate and omethoate did not concentrate in granules, chips, or wet peel processed from potato tubers treated with dimethoate at 5x the maximum single application rate.

Magnitude of the Residue in Field Corn Processed Commodities (MRID 43293701)

4. The submitted field corn processing study is deemed adequate to satisfy reregistration requirements. Food/feed additive tolerances for residues of dimethoate and omethoate in processed field corn commodities are not needed. The submitted data indicate that the

combined residues of dimethoate and omethoate do not concentrate in grits, meal, flour, starch, wet-milled crude oil, wet-milled refined oil, dry-milled crude oil, or dry-milled refined oil processed from field corn grain treated at 5x the maximum single application rate. Although, residues of omethoate *per se* did concentrate in two samples of dry-milled crude oil (greater than 4x), the Agency has determined that tolerances will not be established on crude oil processed from corn at this time (Livestock Feeds Table (TABLE II (September 1995)). [Note: CBRS has previously recommended in favor of a waiver from the need for dimethoate residue data concerning aspirated grain fractions (CBRS No. 12575, DP Barcode D195313, B. Cropp-Kohlligian, 10/13/93).]

Magnitude of the Residue in Cottonseed Processed Commodities (MRID 43318401)

5. The submitted cottonseed processing study is deemed adequate to satisfy reregistration requirements. Food/feed additive tolerances for residues of dimethoate and omethoate in cottonseed processed commodities are not needed. Residues of dimethoate and omethoate did not concentrate in crude oil, refined oil, or bleached/deodorized oil processed from cottonseed bearing detectable residues. Based on the submitted cottonseed processing data, residues of dimethoate and omethoate are not expected to concentrate in cottonseed meal (1.3x) to a significant degree. Although the study indicates that the combined residues of dimethoate and its oxygen analog omethoate do concentrate in cottonseed hulls (2.7x) processed from cottonseed treated with dimethoate at 5x the maximum single application rate, adjusting these results for the exaggerated application rate used in the study (5x the maximum single application rate), dimethoate residues of concern in cottonseed hulls would be less than the currently established RAC tolerance set at the LOQ (0.1 ppm). Therefore, a feed additive tolerance for residues of dimethoate and its oxygen analog omethoate in cottonseed hulls is not needed.

6. As a result of changes in the Livestock Feeds Table (TABLE II (September 1995)), magnitude of the residue data are currently required by the Agency for cotton gin byproducts. A minimum of six (6) field trials for cotton gin byproducts (three on picker and three on stripper cotton) are required. This new data requirement should be imposed at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document but should not impinge on the reregistration eligibility decision for dimethoate.

7. Although the subject dimethoate cottonseed processing study was submitted to the Agency under 6(a)(2), CBRS has determined that, in this case, over-tolerance residues of dimethoate in/on any cottonseed processed product are not indicated and there is no evidence of unreasonable adverse effects.

Magnitude of the Residue in Orange Processed Commodities (MRID 43308701)

8a. The submitted orange processing study is deemed adequate to satisfy reregistration requirements. **[NOTE: Decisions made herein by the Agency concerning citrus processed commodities are based solely on the subject orange processing study and**

supersede previous conclusions/decisions reached/made by the Agency concerning this subject.]

8b. The study indicates that the combined residues of dimethoate and its oxygen analog omethoate do not concentrate in orange juice and oil but do concentrate in dried pulp (2x). The Agency does not consider citrus molasses a processed commodity of citrus (Livestock Feeds Table (TABLE II (September 1995))).

8c. Based on the highest average orange field trial (HAFT) data (2 ppm) reflecting the currently registered maximum use rate by ground equipment permitted on citrus and the concentration factor for dried citrus pulp (2x) determined in the subject processing study, residues of dimethoate and its oxygen analog omethoate in dried citrus pulp should not exceed 4 ppm. Since citrus dried pulp is not considered "ready-to-eat" (RTE) and has a dilution factor of 3 (memo by M. Metzger, dated 9/13/95), a feed additive tolerance (Section 409) for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp is not needed; however, a maximum residue limit (Section 701) should be established.

8d. CBRS recommends that at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document, the currently established feed additive tolerance (Section 409) for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp [40 CFR §186.2100] should be revoked concomitant with the establishment of a maximum residue limit (Section 701) for these same residues in citrus dried pulp. Available data indicate that a 4 ppm maximum residue limit for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp would be appropriate.

9. The subject orange processing study, which was conducted using ground equipment, may be used to support the currently registered maximum use rate of dimethoate on citrus using aerial equipment. The subject data indicate that the combined residues of dimethoate and its oxygen analog omethoate in/on citrus resulting from two foliar applications per growing season to oranges at 1.0-2.0 lb ai/A with a 15-day preharvest interval (PHI) will not exceed the currently established tolerance for dimethoate residues of concern in/on citrus fruits (2 ppm).

10. Although the subject dimethoate orange processing study was submitted to the Agency under 6(a)(2), CBRS has determined that, in this case, over-tolerance residues of dimethoate in/on any citrus processed product are not indicated and there is no evidence of unreasonable adverse effects.

Magnitude of the Residue in Tomato Processed Commodities (MRID 43554401)

11a. The subject tomato processing study is acceptable and may be used to satisfy reregistration requirements. Food additive tolerances for residues of dimethoate and its oxygen analog omethoate are not required for tomato puree and tomato paste. The study indicates that the combined residues of dimethoate and its oxygen analog omethoate do concentrated in tomato puree (1.5x) and tomato paste (2.6x) processed from whole tomatoes bearing detectable residues. However, tomato puree and tomato paste are not ready to eat (RTE) and the dilution factors for tomato puree and tomato paste are 1.5x and 2.5x, respectively, based on the recipe files in USDA's Survey System/Food Consumption Laboratory of the Beltsville Human Nutrition Center (memo by J. Morales dated 2/8/96). Hence, no food additive tolerances are needed for tomato puree or paste.

11b. Maximum Residue Limits (MRLs) for residues of dimethoate and its oxygen analog omethoate are not required for tomato puree and tomato paste. The subject processing data indicate that the combined residues of dimethoate and its oxygen analog omethoate in tomato puree (0.36 ppm average) and tomato paste (0.62 ppm average) processed from whole tomatoes treated with dimethoate at 5x the currently registered maximum single application rate will not exceed the currently established tolerance in/on tomatoes (2 ppm). Available tomato field trial data (MRID 000775500) do support the assertion that residues of dimethoate *per se* will not exceed 0.18 ppm in/on tomatoes resulting from treatment with dimethoate at the currently registered maximum use rate. [Note: The reviewer has determined the aforementioned based on a single tomato sample (mature, green) analyzed by a chlorodinitrobenzene colorimetric method. Omethoate residue levels were not determined in/on this sample. Available tomato field trial data are not deemed sufficient to permit CBRS to recommendation lowering the currently established 2 ppm tolerance for dimethoate residues in/on tomatoes.]

Storage Stability Data to Support the Subject Processing Studies

12. The subject wheat, potato, field corn, and cottonseed processing studies are adequately supported by available raw agricultural commodity (RAC) storage stability data. Storage stability data are not required to support the subject orange and tomato processing studies in consideration of the relatively short frozen storage interval of test samples.

RECOMMENDATIONS

The submitted wheat, potato, field corn, cottonseed, orange, and tomato processing studies are deemed adequate to satisfy reregistration data requirements. These data do not indicate the need to establish food/feed additive tolerances (Section 409) or maximum residue levels (Section 701) for the combined residues of dimethoate and omethoate in the processed commodities of wheat grain, potato, field corn, cottonseed, citrus, and tomato with the exception of citrus dried pulp. At the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document, the currently established feed additive tolerance (Section 409) for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp [40 CFR §186.2100] should be revoked concomitant with the establishment of a maximum residue limit (Section 701) for these same residues in citrus dried pulp. Available data indicate that a 4 ppm maximum residue limit for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp would be appropriate.

As a result of changes in the Livestock Feeds Table (TABLE II (September 1995)), magnitude of the residue data are currently required by the Agency for wheat germ and cotton gin byproducts. A minimum of six (6) field trials for cotton gin byproducts (three on picker and three on stripper cotton) are required. These new data requirements should be imposed at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document but should not impinge on the reregistration eligibility decision for dimethoate.

Although the subject dimethoate cottonseed and orange processing studies were submitted to the Agency under 6(a)(2), CBRS has determined that, over-tolerance residues of dimethoate in/on any processed cottonseed or citrus processed product is not indicated and that there is no evidence of unreasonable adverse effects.

Note to PM:

In the course of this review, CBRS found that at least one product label (EPA Reg. No. 34704-207) permits aerial applications of dimethoate to crops (i.e., wheat, potatoes, field corn, cotton, and tomatoes) in minimum spray volumes less than 2 gallons/A and to tree crops (i.e., oranges) in minimum spray volumes less than 10 gallons/A. The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre (or 10 gallons per acre in the case of tree crops).

Also the end-use product label for the 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400) must be revised to specify use rate information for apples, pears, and citrus fruits in terms of dosage per acre.

Attachment 1: Dimethoate, CBRS No. 14023, DP Barcode No. D205591
Data Evaluation Record: Magnitude of the Residue in Wheat Processed Commodities [GLN 171-4(l)], 5 pages.

Attachment 2: Dimethoate, CBRS No. 14023, DP Barcode No. D205591
Data Evaluation Record: Magnitude of the Residue in Potato Processed Commodities [GLN 171-4(l)], 6 pages.

Attachment 3: Dimethoate, CBRS No. 14023, DP Barcode No. D205591
Data Evaluation Record: Magnitude of the Residue in Field Corn Processed Commodities [GLN 171-4(l)], 6 pages.

Attachment 4: Dimethoate, CBRS No. 14250, DP Barcode No. D206804
Data Evaluation Record: Magnitude of the Residue in Cottonseed Processed Commodities [GLN 171-4(l)], 6 pages.

Attachment 5: Dimethoate, CBRS No. 14224, DP Barcode No. D206555
Data Evaluation Record: Magnitude of the Residue in Orange Processed Commodities [GLN 171-4(l)], 7 pages.

Attachment 6: Dimethoate, CBRS No. 15267, DP Barcode No. D213099
Data Evaluation Record: Magnitude of the Residue in Tomato Processed Commodities [GLN 171-4(l)], 7 pages.

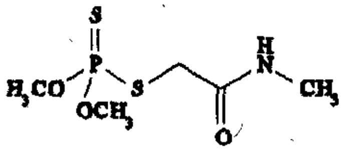
cc: BLCKohlligian (CBRS), Deborah Hartman - PSPS (7501C), Dimethoate Reg. Std. File, Dimethoate SF, RF, Circulate.

RDI: SHummel:2/12/96 RPerfetti:2/15/96 EZager:2/15/96

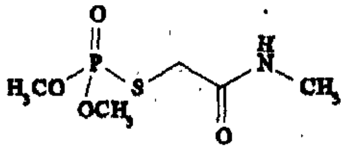
7509C:CBRS:BLCKohlligian:CM#2:Rm 805B:703-305-7462:7/5/95.

DATA EVALUATION RECORD

DP BARCODE(S):	D205591
CBRS NO.:	14023
STUDY TYPES:	Magnitude of the Residue in Wheat Processed Commodities [Guideline Reference No. 171-4(l)].
STUDY SPONSOR:	Cheminova Agro A/S (Lemvig, Denmark).
MRID NO.:	43288201 F. Rice, J. Beckerman, and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Wheat Grain and Its Processed Commodities. ABC Laboratory Project Identification 40895. Study Completed on 6/10/94.
PERFORMING LABORATORIES:	<u>Field and Analytical</u>: ABC Laboratories (Columbia, MO); <u>Processing</u>: Engineering Biosciences Research Center, Texas A&M University (College Station, TX).
TEST MATERIAL APPLIED TO CROP:	Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).
EPA REG. NO.:	34704-207 (Clean Crop® Dimethoate 400).
RESIDUES MEASURED:	Dimethoate



Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate]



DETAILED CONSIDERATIONS

Magnitude of the Residue in Wheat Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1994; MRID 43288201) from a processing study conducted in 1993 depicting the residues of dimethoate and its oxygen analog omethoate in the processed commodities of wheat grown in KS. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 0.04 ppm has been established for total residues of dimethoate including its oxygen analog omethoate in/on wheat grain [40 CFR §180.204]. No tolerance has been established for dimethoate residues of concern in any wheat processed commodity.

Use patterns registered to Cheminova: A REFS search conducted 8/17/94 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate 267 E.C. Systemic Insecticide), which was suspended for failure to comply with DCI requirements.

Other registered use patterns: The submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for a maximum of two foliar applications to wheat per season at 0.17-0.375 lb ai/A/application using ground, chemigation, or aerial equipment. No retreatment interval is specified. A 60-day preharvest interval (PHI) and a 14-day pregrazing interval (PGI) have been established. Applications may be made in a minimum of 5 gal/A using ground equipment or a minimum of 1 gal/A using aerial equipment (5 gal/A in CA).

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre.

Discussion of the data: Wheat grain grown in KS was harvested 37 days after a single application of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207) at 1.9 lb ai/A/application (2.5x the maximum seasonal application rate, 5x the maximum single application rate) in 19 gal/A using ground equipment (CO_2-powered sprayer). An additional field trial was conducted in which the 4 lb/gal EC formulation was applied at 0.38 lb ai/A/application (0.5x the maximum seasonal application rate, 1x the maximum single application rate); however, samples from this trial were not analyzed.

Wheat grain samples were harvested using a self-propelled combine, placed in plastic-lined cloth bags, and stored in a portable freezer until frozen at the facility. The harvested treated and untreated wheat grain samples were stored frozen (-27 to -14 C) at the field facilities. Samples were shipped frozen via a freezer truck (-29 to -1 C) to Engineering Biosciences Research Center, Texas A&M University (College Station, TX) where they were stored frozen (-23 to -7 C) until processing. At the processing facility, treated and untreated wheat grain samples were processed into bran, middlings, shorts, low-grade flour, and patent flour using a small scale processing procedure which simulated normal commercial processing conditions.

Briefly, the wheat samples were cleaned and the light impurities were collected by aspiration. Cleaned grain was moisture adjusted, broken into small pieces in a corrugated roller mill, and sieved to separate the bran and middlings. The middlings were reduced to flour in a smooth roller mill and sieved to separate into shorts, low-grade flour, and patent flour. Aspirated grain fractions (grain dust) were also collected but not analyzed because data requirements concerning grain dust have been waived (CBRS No. 12575, DP Barcode D195313, B. Cropp-Kohlligian, 10/13/93).

Following processing, the samples were shipped to the analytical facility (ABC, Columbia, MO), where they were stored frozen (-23 to -18 C) until analyzed. The intervals between harvest and residue analysis were 62-126 days (~2-4 months). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues of dimethoate and omethoate in/on treated and untreated wheat grain and its processed commodities were determined using an adequate data collection method. Residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on two samples of treated wheat grain and two samples each of bran, middlings, shorts, low-grade flour, and patent flour processed from treated wheat grain. Apparent residues of dimethoate and omethoate were below the LOQ (<0.01 ppm each) in/on one sample of untreated wheat grain, and one sample each of bran, middlings, shorts, low-grade flour, and patent flour processed from untreated wheat grain.

Study summary:

Residues of dimethoate and omethoate were below the LOQ (<0.01 ppm each) in bran, middlings, shorts, and flour processed from wheat grain bearing nondetectable residues following treatment with dimethoate at an exaggerated rate (5x the maximum single application rate). Hence, food/feed additive tolerances for residues of dimethoate and omethoate in wheat bran, middlings, shorts, flour, and milled byproducts are not needed.

As a result of changes in the Livestock Feeds Table (TABLE II (September 1995)), magnitude of the residue data are currently required by the Agency for wheat germ. This new data requirement should be imposed at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document but should not impinge on the reregistration eligibility decision for dimethoate.

Residue Analytical Methods

The raw agricultural commodities from the submitted field trials were analyzed for residues of dimethoate and its oxygen analog omethoate using a gas chromatography/ flame photometric detection (GC/FPD) method with a LOQ of 0.01 ppm for each compound. This method uses an Rtx-5 capillary column and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. The method included in this submission is entitled "Determination of Dimethoate and Omethoate Residues in Wheat Grain and Its Processed Commodities by Gas Chromatography".

In this method, samples of wheat grain were homogenized in dry ice; samples of bran, middlings, shorts, low-grade flour, and patent flour were extracted as received. Samples were extracted with acetone:water (3:1, v:v) and filtered. A subsample was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated twice. The combined organic phases were dried, concentrated by rotary evaporation, and cleaned on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v). The eluate was then concentrated and analyzed by GC/FPD. An alternate GC column (DB-17) was required to resolve chromatographic interferences in bran samples.

Concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Samples of untreated commodities from the wheat processing study were fortified with dimethoate and omethoate at 0.01-0.50 ppm. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 1. These data indicate that the GC/FPD method is adequate for collecting data on residues of dimethoate and omethoate in wheat processed commodities.

Table 1. Concurrent method recoveries of dimethoate and omethoate from samples of untreated wheat grain and its processed commodities separately fortified with each analyte and analyzed by GC/FPD.

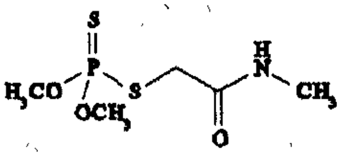
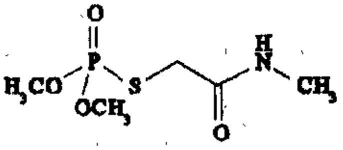
Matrix Residue of Concern	Fortification Level (ppm)	Percent Recovery (Number of Samples) ᵃ
Wheat grain		
dimethoate	0.01-0.50	90-96 (7)
omethoate	0.01-0.50	103-120 (7)
Bran		
dimethoate	0.01-0.50	86-96 (9)
omethoate	0.01-0.50	88-109 (9)
Middlings		
dimethoate	0.01-0.50	80-99 (7)
omethoate	0.01-0.50	91-100 (7)
Shorts		
dimethoate	0.01-0.50	90-102 (7)
omethoate	0.01-0.50	92-120 (7)
Flour		
dimethoate	0.01-0.50	70-100 (6); 140 (1)
omethoate	0.01-0.50	73-100 (6); 124 (1)

ᵃ Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

All samples from the submitted processing study were stored frozen (~-20 C) prior to residue analysis. The maximum storage interval between harvest and residue analysis was 126 days. Although no data are available depicting the frozen storage stability of dimethoate and its oxygen analog omethoate in/on wheat grain and/or wheat processed commodities, available storage stability data (MRID 43348801; CBRS No. 14333, DP Barcode No. D207004, B. Cropp- Kohlligian, 8/17/95) demonstrate that residues of dimethoate and omethoate are stable in/on cottonseed, orange, potato, sorghum forage, and sorghum grain matrices for a longer storage period (up to six months) when stored frozen. Available dimethoate storage stability data adequately support the subject wheat processing data.

DATA EVALUATION RECORD

DP BARCODE(S):	D205591
CBRS NO.:	14023
STUDY TYPES:	Magnitude of the Residue in Potato Processed Commodities [Guideline Reference No. 171-4(l)].
STUDY SPONSOR:	Cheminova Agro A/S (Lemvig, Denmark).
MRID NO.:	43288202 F. Rice, J. Beckerman, and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural and Processed Commodities of White Potatoes. ABC Laboratory Project Identification 40899. Study Completed on 6/10/94.
PERFORMING LABORATORIES:	Field and Analytical: ABC Laboratories (Columbia, MO); Processing: Wm J. Englar and Associates (Moses Lake, WA)
TEST MATERIAL APPLIED TO CROP:	Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).
EPA REG. NO.:	34704-207 (Clean Crop® Dimethoate 400)
RESIDUES MEASURED:	Dimethoate  Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate] 

DETAILED CONSIDERATIONS

Magnitude of the Residue in Potato Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1994; MRID 43288202) from a processing study conducted in 1993 depicting the residues of dimethoate and its oxygen analog omethoate in the processed commodities of potatoes grown in WA. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 0.2 ppm has been established for total residues of dimethoate and its oxygen analog omethoate in/on potatoes [40 CFR §180.204]. No tolerance has been established for any potato processed commodity.

Use patterns registered to Cheminova: A REFS search conducted 8/17/94 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate 267 E.C. Systemic Insecticide), which was suspended for failure to comply with DCI requirements.

Other registered use patterns: The submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for application to potatoes at 0.25-0.50 lb ai/A using ground, chemigation, or aerial equipment. A 0-day preharvest interval (PHI) has been established. No maximum number of applications per season or maximum seasonal rate has been established. Applications may be made in a minimum of 5 gal/A using ground equipment or a minimum of 1 gal/A using aerial equipment (5 gal/A in CA).

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre.

Discussion of the data: Potato tubers grown in WA were harvested on the day of the last of three applications of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207) at 2.5 lb ai/A/application (5x the maximum single application rate) in 20 gal/A using ground equipment (CO_2-powered sprayer). The applications were made at 7-day intervals. An additional field trial was conducted in which the 4 lb/gal EC was applied at 0.5 lb ai/A/application (1x the maximum single application rate); however, samples from this trial were not analyzed.

Potato tubers were harvested using a potato fork and tractor-drawn potato digger, placed in plastic-lined cloth bags, and stored in a cooler until frozen at the facility. The harvested treated and untreated potato tuber samples were stored frozen (-30 to -15 C) at the field facilities. Samples were shipped to Wm. J. Englar and Associates Processing Facility (Moses Lake, WA) where they were stored frozen (-24 to 2 C) until processing. At the processing facility, potato tubers were processed into granules, chips, wet peel, and dry peel using a procedure which simulated normal commercial processing conditions. Potatoes were washed and steam peeled; an abrasive scrubber was used to remove the loosened peel. Potatoes were then inspected and trimmed to remove any rot or green or damaged portions. The peel was pressed and then combined with any collected trim waste to form the wet peel fraction. The wet peel was then dried using an air dryer to form dry peel. A portion of the peeled potatoes was sliced, fried in oil, drained, and salted to form potato chips. A second portion of the peeled potatoes was sliced into slabs, washed, precooked (71-74 C), cooled, steam cooked (~100 C), mashed, dried (38-45 C then 80-91 C), and then screened to isolate potato granules.

Following processing, the samples were shipped to the analytical facility (ABC, Columbia, MO), where they were stored frozen (-21 to -18 C) until analyzed. The intervals between harvest and residue analysis were 49-68 days (~2 months). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues of dimethoate and omethoate in/on treated and untreated potato tubers and potato processed commodities were determined using an adequate data collection method. The results of the potato processing study are presented in Table 1. Apparent residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on one sample of untreated potato tubers, and one sample each of granules, chips, wet peel, and dry peel processed from untreated potato tubers.

Table 1. Residues of dimethoate and its oxygen analog omethoate in the processed commodities of potatoes harvested on the day of the last of three foliar applications at 5x the maximum single application rate.

Substrate	Uncorrected Residues (ppm) [a]			Concentration/Reduction Factor[b]		
	Dimethoate	Omethoate	Combined	Dimethoate	Omethoate	Combined
potato tubers	0.06, 0.08	<0.01 (2)	<0.07, <0.09	--	--	--
granules	0.01 (2)	<0.01 (2)	<0.02 (2)	0.14	--	0.25x
chips	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.14x	--	0.25x
wet peel	0.02 (2)	<0.01 (2)	<0.03 (2)	0.3x	--	0.4x
dry peel	0.06 (2)	<0.01 (2)	<0.07 (2)	0.9x	--	0.9x

[a] Each residue value represents a single sample unless otherwise noted in parentheses.
[b] Calculations based on average residues.

Study summary:

The submitted data indicate that the combined residues of dimethoate and omethoate do not concentrate in granules, chips, or wet peel processed from potato tubers treated with dimethoate.

Residue Analytical Methods

The raw agricultural commodities from the submitted field trials were analyzed for residues of dimethoate and its oxygen analog omethoate using a gas chromatography/ flame photometric detection (GC/FPD) method with a LOQ of 0.01 ppm for each compound. This method uses an Rtx-5 capillary column and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. The method included in this submission is entitled "Determination of Dimethoate and Omethoate Residues in Potatoes and Processed Commodities by Gas Chromatography".

In this method, samples of potato tubers were homogenized in dry ice; samples of granules, wet peel, and dry peel were analyzed as received. Acetone was added to samples with a moisture content of >45%, and acetone:water (2:1, v:v) was added to samples with a moisture content <45%. The samples were extracted and filtered. A subsample was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated twice. The combined organic phases were dried, concentrated by rotary evaporation, and cleaned on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v). The eluate was concentrated and analyzed by GC/FPD.

Chip samples were crushed by hand and extracted with ethyl acetate in the presence of sodium sulfate. The sample was filtered, concentrated, dissolved in methylene chloride:cyclohexane (15:85, v:v), and cleaned up using GPC; residues were eluted with methylene chloride:cyclohexane (15:85, v:v). The eluate was concentrated and analyzed by GC/FPD.

Concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Untreated samples from the potato processing study were fortified with dimethoate and omethoate at 0.01-0.50 ppm for potato tubers, chips, and dry peel, and 0.01-1.00 ppm for granules and wet peel. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 2 and indicate that the GC/FPD method is adequate for collecting data on residues of dimethoate and omethoate in potato processed commodities.

Table 2. Concurrent method recoveries of dimethoate and omethoate from samples of untreated potato tubers and potato processed commodities fortified with each analyte and analyzed by GC/FPD.

Matrix Residue of Concern	Fortification Level (ppm)	Percent Recovery (Number of Samples) [a]
Potato tubers		
dimethoate	0.01-0.50	90-100 (8)
omethoate	0.01-0.50	80-119 (7); 130 (1)
Granules		
dimethoate	0.01-1.00	90-106 (9)
omethoate	0.01-1.00	101-120 (8); 130 (1)
Chips		
dimethoate	0.01-0.50	91-120 (7)
omethoate	0.01-0.50	77-120 (6); 130 (1)
Wet peel		
dimethoate	0.01-1.00	80-97 (9)
omethoate	0.01-1.00	80-120 (9)
Dry peel		
dimethoate	0.01-0.50	80-93 (7)
omethoate	0.01-0.50	76-100 (7)

[a] Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

All samples from the submitted processing study were stored frozen (~-20 C) prior to residue analysis. The maximum storage interval between harvest and residue analysis was 68 days. Although, no data are available depicting the frozen storage stability of dimethoate and its oxygen analog omethoate in/on potato processed commodities, available storage stability data (MRID 43348801; CBRS No. 14333, DP Barcode No. D207004, B. Cropp- Kohlligian, 8/17/95) demonstrate that residues of dimethoate and omethoate are stable in/on potato as well as cottonseed, orange, sorghum forage, and sorghum grain matrices for a longer storage period (up to six months) when stored frozen. Available dimethoate storage stability data adequately support the subject potato processing data.

DATA EVALUATION RECORD

DP BARCODE(S): D205591

CBRS NO.: 14023

STUDY TYPES: Magnitude of the Residue in Field Corn Processed Commodities [Guideline Reference No. 171-4(l)].

STUDY SPONSOR: Cheminova Agro A/S (Lemvig, Denmark).

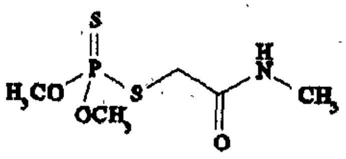
MRID NO.: 43293701 F. Rice, J. Beckerman, and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Corn Grain and Its Processed Commodities. ABC Laboratory Project Identification 40896. Study Completed on 6/28/94.

PERFORMING LABORATORIES: Field and Analytical: ABC Laboratories (Columbia, MO); Processing: Engineering Biosciences Research Center, Texas A&M University (College Station, TX).

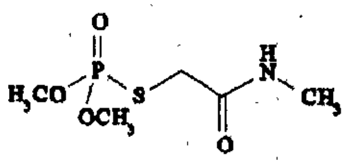
TEST MATERIAL APPLIED TO CROP: Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).

EPA REG. NO.: 34704-207 (Clean Crop® Dimethoate 400)

RESIDUES MEASURED: Dimethoate



Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate]



DETAILED CONSIDERATIONS

Magnitude of the Residue in Field Corn Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1994; MRID 43293701) from a processing study conducted in 1993 depicting the residues of dimethoate and its oxygen analog omethoate in the processed commodities of field corn grown in IA. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 0.1 ppm has been established for total residues of dimethoate including its oxygen analog omethoate in/on corn grain [40 CFR §180.204]. No food/feed additive tolerance has been established for dimethoate residues of concern in any field corn processed commodity.

Use patterns registered to Cheminova: A REFS search conducted 8/17/94 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate 267 E.C. Systemic Insecticide), which was suspended for failure to comply with DCI requirements.

Other registered use patterns: The submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for a maximum of three foliar applications to field corn per season at 0.33-0.5 lb ai/A/application using ground, chemigation, or aerial equipment. No retreatment interval is specified. A 14-day preharvest interval (PHI) and a 14-day pregrazing interval (PGI) have been established. Application during pollen-shed periods is prohibited. Applications may be made in a minimum of 5 gal/A using ground equipment or 1 gal/A using aerial equipment (5 gal/A in CA).

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre.

Discussion of the data: Field corn grain grown in IA was harvested 14 days after the last of 3 applications of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207), at 7-day intervals, at 2.5 lb ai/A/application (5x the maximum single application rate) in 20 gal/A using ground equipment (CO_2-powered sprayer). An additional field trial was conducted in which the 4 lb/gal EC formulation was applied at 0.5 lb ai/A/application (1x the maximum single application rate); however, samples from this trial were not analyzed.

Field corn grain samples were harvested using a self-propelled combine and placed in plastic-lined cloth bags at ambient temperatures until frozen at the facility (within ~1.5 hours). The harvested treated and untreated field corn grain samples were stored frozen (-22 to -18 C) at the field facilities. Samples were shipped frozen via a freezer truck (-29 to -13 C) to Engineering Biosciences Research Center, Texas A&M University (College Station, TX) where they were stored frozen (-26 to -18 C) until processing. At the processing facility, field corn grain samples were processed into grits, meal, flour, starch, and crude, refined, and bleached oil from wet and dry milling using a small scale processing procedure which simulated normal commercial processing conditions.

The dry-milling procedure began with the drying and cleaning of the harvested field corn by aspiration and screening. The clean corn was moisture adjusted and milled to produce hull, grits, meal, flour, and germ. The germ was heat-conditioned and pressed in an expeller for the purpose of liberating the majority of the crude oil. The residual crude oil remaining in the solid material (presscake) exiting the expeller was later extracted with hexane. The solvent-extracted presscake was desolventized. The crude oil recovered from the expeller and solvent extraction was combined, sampled, and refined. The wet-milling procedure began with the drying and cleaning of the harvested field corn by aspiration and screening. The cleaned corn was steeped in water and then milled to recover germ, hull, coarse gluten-starch, gluten, and starch. After drying, the germ was heat conditioned and the process continued as previously described for the dry-milling procedure for crude and refined oil. Aspirated grain fractions (grain dust) were also obtained but not analyzed because data requirements concerning grain dust have been waived (CBRS No. 12575, DP Barcode D195313, B. Cropp-Kohlligian, 10/13/93).

Following processing, the samples were shipped to the analytical facility (ABC, Columbia, MO), where they were stored frozen (-21 to -18 C) until analyzed. The intervals between harvest and residue analysis were 86-113 days (~3-4 months). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues of dimethoate and omethoate in/on treated and untreated field corn grain and its processed commodities were determined using an adequate data collection method. The results of the field corn processing study are presented in Table 1. Apparent residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on one sample of untreated field corn grain and one sample each of grits, meal, flour, starch, wet-milled crude oil, wet-milled refined oil, wet-milled bleached oil, dry-milled crude oil, dry-milled refined oil, and dry-milled bleached oil *processed from untreated field corn grain.*

Table 1. Residues of dimethoate and its oxygen analog omethoate in the processed commodities of field corn treated at 5x the maximum single application rate.

Substrate	Uncorrected Residues (ppm) [a]			Concentration/Reduction Factor[b]		
	Dimethoate	Omethoate	Combined	Dimethoate	Omethoate	Combined
grain	0.06, 0.07	<0.01 (2)	<0.07, <0.08	--	--	--
grits	0.02 (2)	<0.01 (2)	<0.03 (2)	0.3x	--	0.4x
meal	0.02 (2)	<0.01 (2)	<0.03 (2)	0.3x	--	0.4x
flour	0.02 (2)	<0.01 (2)	<0.03 (2)	0.3x	--	0.4x
starch	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x
wet milled crude oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x
wet milled refined oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x
wet milled bleached oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x
dry milled crude oil	0.02 (2)	0.01, 0.04	0.03, 0.06	0.3x	>4x [c]	0.7x
dry milled refined oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x
dry milled bleached oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.2x	--	0.3x

[a] Each residue value represents one sample unless otherwise indicated in parentheses.

[b] Calculations based on average residues.

[c] Minimum concentration factor calculated using the limit of quantitation.

Study summary: The submitted data indicate that the combined residues of dimethoate and omethoate do not concentrate in grits, meal, flour, starch, wet-milled crude oil, wet-milled refined oil, dry-milled crude oil, or dry-milled refined oil processed from field corn grain treated at 5x the maximum seasonal rate. Residues of omethoate *per se* did concentrate in two samples of dry-milled crude oil (greater than 1x and greater than 4x).

Residue Analytical Methods

The raw agricultural commodities from the submitted field trials were analyzed for residues of dimethoate and its oxygen analog omethoate using a gas chromatography/ flame photometric detection (CG/FPD) method with a LOQ of 0.01 ppm for each compound. This method uses an Rtx-5 capillary column (or DB-17 for confirmation) and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. The method included in this submission is entitled "Determination of Dimethoate and Omethoate Residues in Corn Grain and Its Processed Commodities by Gas Chromatography".

In this method, samples of field corn grain, grits, meal, flour, and starch were homogenized in dry ice. The samples were extracted with acetone:water (2:1, v:v) and filtered. A subsample was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated twice. The combined organic phases were dried, concentrated by rotary evaporation, and cleaned on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v); the eluate was then concentrated and analyzed by GC/FPD.

Residues in corn oil samples were extracted with methylene chloride:cyclohexane (15:85, v:v); the sample was centrifuged following extraction, if necessary. The extract was cleaned by GPC, using methylene chloride:cyclohexane (15:85, v:v) to elute the residues. The eluate was then concentrated by evaporation and analyzed by GC/FPD.

Concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Untreated samples from the field corn processing study were fortified with dimethoate and omethoate at 0.01- 0.50 ppm. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 2. These data indicate that the GC/FPD method is adequate for collecting data on residues of dimethoate and omethoate in field corn processed commodities.

Table 2. Concurrent method recoveries of dimethoate and omethoate from samples of untreated field corn grain and its processed commodities separately fortified with each analyte and analyzed by GC/FPD.

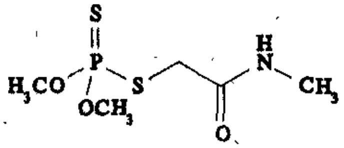
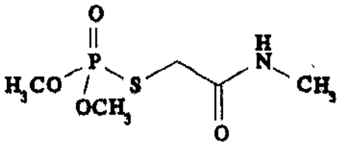
Matrix Residue of Concern	Fortification Level (ppm)	Percent Recovery (Number of Samples) [a]
Grain		
dimethoate	0.01-0.50	80-92 (7)
omethoate	0.01-0.50	78-100 (7)
Grits		
dimethoate	0.01-0.50	87-94 (7)
omethoate	0.01-0.50	83-110 (7)
Meal		
dimethoate	0.01-0.50	76-100 (7)
omethoate	0.01-0.50	74-100 (7)
Flour		
dimethoate	0.01-0.50	91-100 (7)
omethoate	0.01-0.50	82-120 (7)
Starch		
dimethoate	0.01-0.50	80-90 (7)
omethoate	0.01-0.50	80-100 (7)
Wet-milled crude oil		
dimethoate	0.01-0.50	78-91 (7)
omethoate	0.01-0.50	66, 69 (2); 70-100 (4)
Dry-milled crude oil		
dimethoate	0.01, 0.02	90-120 (2)
omethoate	0.01, 0.02	70-90 (2)

[a] Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

All samples from the submitted processing study were stored frozen (~-20 C) prior to residue analysis. The maximum storage interval between harvest and residue analysis was 113 days. Although, no data are available depicting the frozen storage stability of dimethoate and its oxygen analog omethoate in/on field corn grain and its processed commodities, available storage stability data (MRID 43348801; CBRS No. 14333, DP Barcode No. D207004, B. Cropp- Kohlligian, 8/17/95) demonstrate that residues of dimethoate and omethoate are stable in/on cottonseed, orange, potato, sorghum forage, and sorghum grain matrices for a longer storage period (up to six months) when stored frozen. Available dimethoate storage stability data adequately support the subject corn grain processing data.

DATA EVALUATION RECORD

DP BARCODE:	D206804
CBRS NO.:	14250
STUDY TYPES:	Magnitude of the Residue in Cottonseed Processed Commodities [Guideline Reference No. 171-4(l)].
STUDY SPONSOR:	Cheminova Agro A/S (Lemvig, Denmark).
MRID NO.:	43318401 F. Rice, J. Beckerman, and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Cottonseed and Its Processed Commodities. ABC Laboratory Project Identification 40897. Study Completed on 7/20/94.
PERFORMING LABORATORIES:	<u>Field and Analytical</u>: ABC Laboratories (Columbia, MO); <u>Processing</u>: Engineering Biosciences Research Center of Texas A&M University (Bryan, TX)
TEST MATERIAL APPLIED TO CROP:	Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).
EPA REG. NO.:	34704-207 (Clean Crop® Dimethoate 400)
RESIDUES MEASURED:	Dimethoate  Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate] 

DETAILED CONSIDERATIONS

Magnitude of the Residue in Cottonseed Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1994; MRID 43318401) from a processing study depicting the magnitude of the residues of dimethoate and its oxygen analog omethoate in the processed commodities of cottonseed. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 0.1 ppm has been established for total residues of dimethoate and its oxygen analog omethoate in/on cottonseed [40 CFR §180.204]. No food/feed additive tolerance has been established for any cottonseed processed commodity.

Use patterns registered to Cheminova: A REFS search conducted 4/27/95 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate® 267 E.C. Systemic Insecticide), which was suspended (4/91) for failure to comply the requirements of a Label Data Call-In Notice dated 10/89.

Other registered use patterns: The submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for a maximum of two foliar applications per growing season to cotton grown in AZ and CA at 0.25-0.50 lb ai/A and for an unspecified number of foliar applications to cotton grown in other states at 0.125-0.25 lb ai/A. A 14-day preharvest interval (PHI) and a 14-day retreatment interval have been established. The feeding of treated forage or grazing of livestock on treated fields is prohibited. Applications may be made using ground, chemigation, or aerial equipment in a minimum of 5 gal/A using ground equipment or a minimum of 1 gal/A using aerial equipment (5 gal/A in CA).

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre.

Discussion of the data: Cottonseed grown in TX was harvested 14 days following the last of two applications, made at 13-day intervals, of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207) at 2.5 lb ai/A/application (5x the maximum single application rate) in 15 gal/A using ground equipment (CO_2-powered sprayer). An additional field trial was conducted in which the 4 lb/gal EC was applied at 0.5 lb ai/A/application (1x the maximum single application rate); however, samples from this trial were not processed or analyzed.

Cottonseed RAC samples were harvested by hand and immediately ginned after collection. Cottonseed samples for processing were harvested using a self-propelled cotton picker. All samples were placed in plastic bags and stored at ambient temperatures for a maximum of 2 hours until transferred to frozen storage (-27 to -1 C) at the facility. Some cottonseed samples were shipped directly to the analytical facility (ABC Laboratories, Columbia, MO). Other cottonseed samples were shipped to Texas A&M University Food Protein Research and Development Center (Bryan, TX) where they were stored frozen (-18 to -7 C) until processing. At the processing facility, cottonseed samples were ginned and processed into delinted cottonseed, meal, hulls, oil (crude, refined, and bleached/deodorized), and soapstock using procedures which simulated normal commercial processing conditions. The harvested cotton was ginned at the processing center. The ginned cottonseed was delinted, hulled, and separated into kernels and hulls. The kernel material with some hull material was heated, flaked, expanded to form "collets", and extracted with hexane. Warm air was passed through the extracted collets for desolventization and a sample of cottonseed meal was taken from the desolventized collets. The hexane extract was evaporated to remove the hexane, yielding crude cottonseed oil. The crude oil was then mixed with sodium hydroxide and heated resulting in refined oil and soapstock. The refined oil was further bleached and deodorized.

Following processing, the samples were shipped to the analytical facility (ABC Laboratories, Columbia, MO), where they were stored frozen (-24 to -10 C) until analysis. The interval between harvest and residue analysis was 55-112 days (1.8-3.7 months). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues of dimethoate and omethoate in/on treated and untreated cottonseed (delinted) and cottonseed processed commodities were determined using an adequate data collection method. The results of the cottonseed processing study are presented in Table 1. Apparent residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on one sample of untreated cottonseed, and one sample each of hulls, meal, crude oil, refined oil, and bleached/deodorized oil processed from untreated cottonseed. Apparent residues of dimethoate and omethoate were below the LOQ of the analytical method (<0.02 ppm each) in one sample of soapstock processed from untreated cottonseed (delinted).

Table 1. Residues of dimethoate and its oxygen analog omethoate in the processed commodities of cottonseed harvested 14 days following the last of two foliar applications at 5x the maximum single application rate.

Substrate	Uncorrected Residues (ppm) [a]			Concentration/Reduction Factor[b]		
	Dimethoate	Omethoate	Combined	Dimethoate	Omethoate	Combined
cottonseed (delinted)	0.02 0.03	<0.01 (2)	<0.03 <0.04	--	--	--
meal	0.04 0.03	<0.01 (2)	<0.05 <0.04	1.4x	--	1.3x
hulls	0.08 0.09	<0.01 (2)	<0.09 <0.10	3.4x	--	2.7x
crude oil	0.02 (2)	<0.01 (2)	<0.03 (2)	0.8x	--	0.9x
refined oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.4x	--	0.6x
bleached/deodorized oil	<0.01 (2)	<0.01 (2)	<0.02 (2)	<0.4x	--	0.6x
soapstock	<0.02 (2)	-- [c]	<0.02 (2)	<0.8x	--	0.6x

[a] Each residue value represents a single sample unless otherwise noted in parentheses.
[b] Calculations based on average residue.
[c] *No omethoate residues are expected in this substrate due to the strongly basic nature of soapstock.*

Study summary: The subject cottonseed processing study is acceptable and may be used to satisfy reregistration requirements. The study indicates that the combined residues of dimethoate and its oxygen analog omethoate do not concentrate in crude oil, refined oil, bleached/deodorized oil, or soapstock processed from cottonseed bearing detectable residues and that concentration of dimethoate residues of concern in cottonseed meal is not significant (1.3x). Although the study indicates that the combined residues of dimethoate and its oxygen analog omethoate do concentrate in cottonseed hulls (2.7x) processed from cottonseed treated with dimethoate at 5x the maximum single application rate, adjusting these results for the exaggerated application rate used in the study (5x the maximum single application rate), dimethoate residues of concern in cottonseed hulls would be less than the currently established RAC tolerance set at the LOQ (0.1 ppm). Therefore, a feed additive tolerance for residues of dimethoate and its oxygen analog omethoate in cottonseed hulls is not needed. [Note: The Agency currently recognizes undelinted cottonseed as the raw agricultural commodity (RAC) of cotton (Livestock Feeds Table (TABLE II (September 1995)). Although the subject study was conducted using delinted cottonseed, CBRS does not expect that, in this case, cottonseed processing study results reflecting residues of concern in/on undelinted cottonseeds would have been significantly different from those obtain in the subject processing study.]

Residue Analytical Methods

The registrant provided descriptions of and method validation data for a gas chromatography/flame photometric detection (GC/FPD) method that was used to determine residues of dimethoate and its oxygen analog omethoate in/on cottonseed and its processed fractions from the current study. The method, entitled "Determination of Dimethoate and Omethoate Residues in Cottonseed and Its Processed Commodities by Gas Chromatography", has a detection limit of 0.01 ppm for each compound (except for soapstock for which the detection limit was 0.02 ppm for each compound). The method uses an Rtx-5 capillary column and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. Briefly, samples were homogenized in dry ice. Samples of cottonseed meal and hulls (moisture content <45%) were extracted with acetone:water (2:1, v:v) and filtered. A subsample was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated twice. The combined organic phases were dried by rotary evaporation. The residues were redissolved in hexane:acetone (1:1, v:v) and cleaned up on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v). The eluate was concentrated and analyzed by GC/FPD.

Cottonseed samples were Soxhlet extracted using ethyl acetate. The ethyl acetate was rotary evaporated until only oil remained and the oil was dissolved in methylene chloride:cyclohexane (15:85, v:v) and cleaned up using GPC. Cottonseed oil samples were dissolved in methylene chloride:cyclohexane (15:85, v:v) and cleaned up using GPC. Soapstock samples were acidified with glacial acetic acid and then treated like oil samples. Residues were eluted with methylene chloride:cyclohexane (15:85, v:v), concentrated by rotary evaporation, and analyzed by GC/FPD.

Method validation and concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Untreated samples from the cotton processing study were fortified with dimethoate and omethoate at 0.01-0.50 ppm for cottonseed, meal, hulls, and crude oil, and 0.02-0.05 ppm for soapstock. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data for dimethoate, presented in Table 2, are for the most part within the acceptable 70-120% recovery range. The recovery data for omethoate are also mostly within the acceptable 70-120% recovery range for meal, hulls, crude oil; however, recoveries below 50% were obtained for cottonseed and soapstock.

Table 2. Method validation and concurrent method recoveries of dimethoate and omethoate from samples of untreated cottonseed and its processed commodities fortified with each analyte and analyzed by GC/FPD.

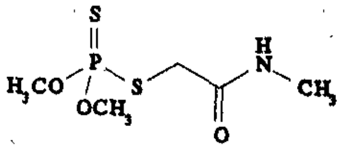
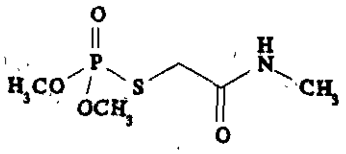
Matrix Residue of Concern	Fortification Level (ppm)	Percent Recovery (Number of Samples) [a]
Cottonseed		
dimethoate	0.01-0.50	90-110 (6)
omethoate	0.01-0.50	49; 56; 60; 80 (3)
Meal		
dimethoate	0.01-0.50	78-90 (7)
omethoate	0.01-0.50	66; 80-90 (6)
Hulls		
dimethoate	0.01-0.50	83-90 (7)
omethoate	0.01-0.50	81-100 (7)
Crude Oil		
dimethoate	0.01-0.50	90-120 (7)
omethoate	0.01-0.50	99-120 (6); 140 (2)
Soapstock		
dimethoate	0.02-0.05	70-82 (4)
omethoate	0.02-0.05	24; 28; 30; 40

[a] Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

All samples from the submitted processing study were stored frozen (-27 to -1 C) prior to residue analysis. The maximum storage interval between harvest and residue analysis was 112 days (3.7 months). Although, no data are available depicting the frozen storage stability of dimethoate and its oxygen analog omethoate in/on processed cottonseed commodities, available storage stability data (MRID 43348801; CBRS No. 14333, DP Barcode No. D207004, B. Cropp-Kohlligian, 8/17/95) demonstrate that residues of dimethoate and omethoate are stable in/on cottonseed, orange, potato, sorghum forage, and sorghum grain matrices for a longer storage period (up to six months) when stored frozen. Available dimethoate storage stability data adequately support the subject cottonseed processing data.

DATA EVALUATION RECORD

DP BARCODE:	D206555
CBRS NO.:	14224
STUDY TYPES:	Magnitude of the Residue in Orange Processed Commodities [Guideline Reference No. 171-4(l)].
STUDY SPONSOR:	Cheminova Agro A/S (Lemvig, Denmark).
MRID NO.:	43308701 F. Rice, J. Beckerman, and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Oranges and Its Processed Commodities. ABC Laboratory Project Identification 40898. Study Completed on 7/14/94.
PERFORMING LABORATORIES:	<u>Field and Analytical</u>: ABC Laboratories (Columbia, MO); <u>Processing</u>: Citrus Research and Education Center of University of Florida (Lake Alfred, FL)
TEST MATERIAL APPLIED TO CROP:	Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).
EPA REG. NO.:	34704-207 (Clean Crop® Dimethoate 400)
RESIDUES MEASURED:	Dimethoate  Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate] 

DETAILED CONSIDERATIONS

Magnitude of the Residue in Orange Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1994; MRID 43308701) from a processing study depicting the magnitude of the residues of dimethoate and its oxygen analog omethoate in the processed commodities of oranges. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 2 ppm has been established for total residues of dimethoate and its oxygen analog omethoate in/on oranges [40 CFR §180.204]. A feed additive tolerance of 5 ppm has been established for the same residues in dried citrus pulp for cattle feed [CFR §186.2100]. No food additive tolerances have been established for dimethoate residues of concern in orange processed fractions.

Use patterns registered to Cheminova: A REFS search conducted 4/27/95 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate® 267 E.C. Systemic Insecticide), which was suspended (4/91) for failure to comply with the requirements of a Label Data Call-In Notice dated 10/89.

Other registered use patterns: The subject submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for a maximum of two foliar applications per growing season to oranges at 0.25-0.75 lb ai/100 gal using ground equipment or 1.0-2.0 lb ai/A using aerial equipment in a spray volume of 5-20 gal/A. A 45-day preharvest interval (PHI) has been established for foliar broadcast applications at 0.5-0.75 lb ai/100 gal using ground equipment and a 15-day preharvest interval (PHI) is specified for foliar broadcast applications at 0.25-0.5 lb ai/100 gal using ground equipment or 1.0-2.0 lb ai/A using aerial equipment. No retreatment interval is specified. The grazing of livestock on cover crops in treated orchards is prohibited. The 4 lb/gal EC formulation is also registered for use limited to AZ and CA on nonbearing citrus and citrus nursery stock as a foliar spray at 0.5 lb ai/100 gal/application or as a soil drench at 2 lb ai/A/application.

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or

10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 10 gallons per acre.

Discussion of the data: Oranges grown in FL were harvested 14 days following the last of two foliar applications, made at 14-day intervals, of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207) at 3.75 lb ai/100 gal/application (5x the maximum ground application rate; 1.9x the maximum aerial application rate) in 203 gal/A using ground equipment (air-blast orchard sprayer). An additional field trial was conducted in which the 4 lb/gal EC formulation was applied at 0.75 lb ai/100 gal/application (1x the maximum ground application rate; 0.4x the maximum aerial application rate); however, samples from this trial were not processed or analyzed.

Two sets of treated and untreated orange samples were collected. The first set, designated as orange RAC, were collected for RAC analysis. The orange RACs were harvested by hand, placed in plastic-lined cloth bags, stored in a cooler prior to transfer to freezer storage (-24 to -7 C) within 3 hours of harvest, and then shipped frozen directly to the analytical facility (ABC Laboratories, Columbia, MO).

The second set of samples were used for processing. These samples were harvested by hand, transferred to cardboard boxes, transported by a refrigerator truck to the research facility, and then shipped to the Citrus Research and Education Center, University of Florida (Lake Alfred, FL) where they were stored frozen (-27 to -22 C) until processing. At the processing facility, orange samples were processed into juice, dried pulp, molasses, and oil using procedures which simulate normal commercial processing conditions. Briefly, the harvested oranges were washed and rinsed. The juice was extracted from the washed oranges using a Commercial FMC 391B In-Line-Juice Extractor. Excess pulp was removed and finished juice was collected. The oil/water/peel-fruit emulsion from the FMC extractor was passed through a finisher equipped with a 0.02-inch screen, and peel frits and the oil/water emulsion were collected. The oil was centrifuged and frozen to remove water and to produce cold-pressed oil. The peel residue (peel-membrane-seed) from the FMC extractor was transferred to a hopper and chopped to a uniform size. After addition of a liquid lime slurry, the wet pulp was passed through a continuous press which separated the wet pulp into press cake and press liquor. The press cake was dried to produce dried citrus pulp. The press liquor was heated to boiling under vacuum and concentrated to produce molasses.

Following processing, the samples were shipped to the analytical facility (ABC Laboratories, Columbia, MO), where they were stored frozen (-21 to -11 C) until analyzed. The interval between harvest and residue analysis was 27-34 days (~1 month). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues in/on treated and untreated oranges and orange processed commodities were determined using an adequate data collection method. The results of the orange processing study are presented in Table 1. Apparent residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on one sample each of untreated unwashed and washed whole oranges, and one sample each of juice, dried pulp, molasses, and oil processed from untreated oranges.

Table 1. Residues of dimethoate and its oxygen analog omethoate in the processed commodities of oranges harvested 14 days following the last of two foliar applications at 5x the maximum ground application rate (1.9x the maximum aerial application rate).

Substrate	Uncorrected Residues (ppm) [a]			Concentration/Reduction Factor[b]		
	Dimethoate	Omethoate	Combined	Dimethoate	Omethoate	Combined
whole orange, unwashed	1.07 1.82	0.12 0.17	1.19 1.99	--	--	--
whole orange, washed	1.98 1.03	0.20 0.12	2.18 1.15	1x	1x	1x
juice	0.20 0.21	0.03 (2)	0.23 0.24	0.2x	0.2x	0.2x
dried pulp	3.18 2.92	0.24 (2)	3.42 3.16	2x	1.6x	2x
molasses	8.14 8.73	0.71 1.06	8.85 9.79	6x	6x	6x
oil	0.28 0.29	<0.01 (2)	<0.29 <0.30	0.2x	<0.1x	<0.2x

[a] Each residue value represents a single sample unless otherwise noted in parentheses.
[b] Calculations based on average residues.

Study summary: The subject orange processing study is acceptable and may be used to satisfy reregistration requirements. The study indicates that the combined residues of dimethoate and its oxygen analog omethoate do not concentrate in orange juice and oil but do concentrate in dried pulp (2x). The Agency does not consider citrus molasses a processed commodity of citrus (TABLE II (September 1995)).

The highest average field trial (HAFT) data (MRID 00073441) indicate that the combined residues of dimethoate and its oxygen analog omethoate in/on treated oranges resulting from the maximum registered use of dimethoate on citrus by ground equipment (two foliar applications per growing season to oranges at 0.5-0.75 lb ai/100 gal using ground equipment and a 15- to 45-day preharvest interval (PHI)) will be 2 ppm, which is equivalent to the currently established tolerance for residues of dimethoate and its oxygen analog omethoate in/on oranges. Therefore, CBRS expects that based on the HAFT residue level (2 ppm) and the concentration factor for dried citrus pulp (2x), residues of dimethoate and its oxygen analog omethoate in dried citrus pulp should not exceed 4 ppm resulting from the currently registered maximum use rate of dimethoate on citrus using ground equipment. Since the Agency has determined that citrus dried pulp is not "ready-to-eat" (RTE) and has a dilution factor of 3 (memo by M. Metzger, dated 9/13/95), a feed additive tolerance (Section 409) for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp is not needed; however, a maximum residue limit (Section 701) must be established. CBRS recommends that at the issuance of the Dimethoate Reregistration Eligibility Decision (RED) document, the currently established feed additive tolerance (Section 409) for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp residues for cattle feed [CFR §186.2100] should be revoked concomitant with the establishment of a maximum residue limit (Section 701) for these same residues in citrus dried pulp. The available data indicate that a 4 ppm maximum residue limit for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp would be appropriate.

CBRS further notes that the subject orange processing study which was conducted using ground equipment may be used to support the currently registered maximum use rate of dimethoate on citrus using aerial equipment. The subject data indicate that the combined residues of dimethoate and its oxygen analog omethoate in/on citrus resulting two foliar applications per growing season to oranges at 1.0-2.0 lb ai/A with a 15-day preharvest interval (PHI)) will not exceed the currently established tolerance for dimethoate residues of concern in/on citrus fruits (2 ppm).

Residue Analytical Methods

The registrant provided descriptions of and method validation data for a gas chromatography/flame photometric detection (GC/FPD) method that was used to determine residues of dimethoate and its oxygen analog omethoate in/on citrus fruits and citrus processed fractions from the current study. The method, entitled "Determination of Dimethoate and Omethoate Residues in Oranges and Its Processed Commodities by Gas Chromatography", has a detection limit of 0.01 ppm for each compound. The method uses an Rtx-5 capillary column and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. Briefly, samples of whole oranges, juice, and molasses (moisture content >45%) were homogenized with acetone whereas samples of dry pulp (moisture content <45%) were homogenized with acetone:water (2:1, v:v) and filtered. Although the moisture content of molasses was >45%, additional water was required to thin the sample to prevent it from adhering to the sides of the blender cup. A subsample of the filtrate was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated two more times. The combined organic phases were dried by rotary evaporation, and cleaned up on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v). The eluate was concentrated and analyzed by GC/FPD.

Residues in orange oil samples were extracted with methylene chloride:cyclohexane (15:85, v:v); the sample was centrifuged or filtered following extraction, if necessary. The extract was cleaned up by GPC, using methylene chloride:cyclohexane (15:85, v:v) to elute the residues. The eluate was then concentrated by rotary evaporation and analyzed by GC/FPD.

Method validation and concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Untreated control samples from the orange processing study were fortified with dimethoate and omethoate at 0.01-0.50 ppm for whole oranges, juice, dried pulp, molasses, and oil. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data, presented in Table 2, are for the most part within the acceptable 70-120% recovery range. The subject GC/FPD method is adequate for collecting data on residues of dimethoate and omethoate in orange processed commodities.

Table 2. Method validation and concurrent method recovery of dimethoate and omethoate from samples of untreated orange commodities fortified with each analyte and analyzed by GC/FPD.

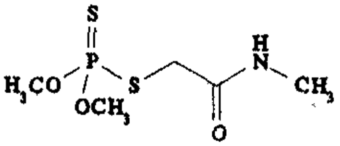
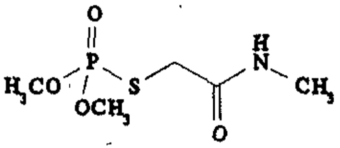
Matrix Analyte	Method Validation		Concurrent Method Recovery	
	Fortification Level (ppm)	Percent Recovery (Number of Samples) [a]	Fortification Level (ppm)	Percent Recovery (Number of Samples)
Whole oranges				
dimethoate	0.01-0.50	95-110 (8)	0.01, 2.0	90, 97
omethoate	0.01-0.50	82-120 (8)	0.01, 2.0	90, 101
Juice				
dimethoate	0.01-0.50	102-110 (7)	--	--
omethoate	0.01-0.50	90-107 (7)	--	--
Dried pulp				
dimethoate	0.01-0.50	69; 77-84 (6)	5.0	73
omethoate	0.01-0.50	63; 68; 70-80 (5)	5.0	57
Molasses				
dimethoate	0.01-0.50	70-100 (7)	14.0	90
omethoate	0.01-0.50	66; 86-101 (6)	14.0	78
Oil				
dimethoate	0.01-0.50	80-100 (7)	--	--
omethoate	0.01-0.50	65; 68 (2); 72-120 (3)	--	--

[a] Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

The maximum storage interval between RAC harvest and residue analysis of processed fractions was 34 days (~1 month). All samples from the submitted processing study were stored frozen (-21 to -7 C) prior to residue analysis. In consideration of the relatively short frozen storage interval of samples from the current study, storage stability is not at issue. No storage stability data for citrus processed fractions are required to validate the results this citrus processing study.

DATA EVALUATION RECORD

DP BARCODE:	D213099
CBRS NO.:	15267
STUDY TYPES:	Magnitude of the Residue in Tomato Processed Commodities [Guideline Reference No. 171-4(l)].
STUDY SPONSOR:	Cheminova Agro A/S (Lemvig, Denmark).
MRID NO.:	43554401 F. Rice and B. Williams Magnitude of the Residues of Dimethoate and Its Oxygen Analog, Omethoate, in or on Raw Agricultural and Processed Commodities of Tomatoes. ABC Laboratory Project Identification 41489. Study Completed on 1/18/95.
PERFORMING LABORATORIES:	Field and Analytical: ABC Laboratories (Columbia, MO); Processing: The National Food Laboratory, Inc. (Dublin, CA)
TEST MATERIAL APPLIED TO CROP:	Dimethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate] (CAS No. 60-51-5).
EPA REG. NO.:	34704-207 (Clean Crop® Dimethoate 400)
RESIDUES MEASURED:	Dimethoate  Omethoate [O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate] 

DETAILED CONSIDERATIONS

Magnitude of the Residue in Tomato Processed Commodities

Cheminova Agro A/S, through its authorized representatives Jellinek, Schwartz, and Connolly, Inc., submitted data (1995; MRID 43554401) from a processing study depicting the magnitude of the residues of dimethoate and its oxygen analog omethoate in the processed commodities of tomatoes. Data from this submission are described and presented in this Data Evaluation Record.

Established tolerance: A tolerance of 2 ppm has been established for total residues of dimethoate and its oxygen analog omethoate in/on tomatoes [40 CFR §180.204]. No food/feed additive tolerance has been established for dimethoate residues of concern in any tomato processed commodity.

Use patterns registered to Cheminova: A REFS search conducted 4/27/95 identified one Cheminova dimethoate end-use product, a 30.5% or 2.67 lb/gal EC formulation (EPA Reg. No. 4787-9; Chemathoate® 267 E.C. Systemic Insecticide), which was suspended (4/91) for failure to comply with the requirements of a Label Data Call-In Notice dated 10/89.

Other registered use patterns: The submission included a specimen label for a 43.5% or 4 lb/gal EC formulation registered to Platte Chemical Co., Inc. (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400); this product was the test substance used in the processing study. The 4 lb/gal EC formulation is registered for foliar application to tomatoes at 0.25-0.50 lb ai/A using ground, chemigation, or aerial equipment. A 7-day PHI has been established. No maximum number of applications per growing season or maximum seasonal rate has been established. Applications may be made in a minimum of 5 gal/A using ground equipment or a minimum of 1 gal/A using aerial equipment (5 gal/A in CA).

The registrant has previously stated that no field trials using aerial applications will be conducted (CBRS No. 12258, DP Barcode No. D193232, 12/30/93, B. Cropp-Kohlligian) and no data reflecting aerial applications were provided in the subject submission. The Agency has determined that crop field trial data reflecting aerial application are not required provided that: (i) there are adequate field trial data from ground equipment reflecting the same application rate, number of applications, and preharvest interval, (ii) product labels specify that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), and (iii) aerial applications do not permit diluents other than water. Therefore, the registrant(s) must either (i) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre.

Discussion of the data: Tomatoes grown in CA were harvested 7 days following the last of four foliar applications, made at 7-day intervals, of the 4 lb/gal EC formulation (EPA Reg. No. 34704-207) at 2.5 lb ai/A/application (5x the maximum single application rate) in 20 gal/A using ground equipment (backpack sprayer with hand-held boom). Two additional field trials were conducted in which the 4 lb/gal EC was applied at 0.5 lb ai/A/application (1x the maximum single application rate) and 1.0 lb ai/A/application (2x the maximum single application rate); however, samples from these trials were not processed or analyzed.

Tomato RAC samples were harvested by hand, placed in plastic-lined cloth bags, and stored in a cooler until frozen at the facility. Tomato samples for processing were harvested by hand, placed in cardboard boxes, and then transported by truck to the processing facility. The harvested treated and untreated tomato RAC samples were stored frozen (-32 to -10 C) at the field facilities within 3 hours of harvest and then shipped to the analytical facility (ABC Laboratories, Columbia, MO). At the analytical laboratory samples were stored frozen (-19 to -16 C). Tomato samples for processing were shipped to the National Food Laboratory (Dublin, CA) where they were stored in a temperature controlled room (14 to 16 C) until processing; samples were processed within 4 hours of receipt. At the processing facility, tomato samples were processed into juice, wet pomace, dry pomace, puree, paste, and catsup using procedures which simulate normal commercial processing conditions. Briefly, the harvested tomatoes were washed and then crushed through a disintegrator; subsamples of unwashed tomatoes were separately kept and analyzed for residue concentration determination. The crushed tomatoes were heated to 91 C and then filtered; the resulting juice was canned. The remaining material was broken up to generate wet pomace. A portion of the wet pomace fraction was dried at 66 C for 30 hours to generate dry pomace. A portion of the tomato juice was concentrated under slight vacuum and then heated to 89 C to generate tomato puree; the puree was canned. A portion of tomato puree was concentrated under slight vacuum and then heated to 88 C to generate tomato paste; the paste was canned. A portion of the paste and other unspecified ingredients were mixed together and then heated to 95 C to generate catsup; the catsup was also canned.

Following processing, the samples were frozen (-23 to -22 F) and shipped to the analytical facility (ABC Laboratories, Columbia, MO), where they were stored frozen (-19 to -16 C) until analysis. The storage interval between harvest and residue analysis was 19-33 days (~1 month). Adequate raw data pertaining to field trial information, application of the test substance, sample handling, and processing procedures (including material balance) were provided.

Residues in/on treated and untreated tomatoes and tomato processed commodities were determined using a GC/FPD method. The results of the tomato processing study are presented in Table 1. Apparent residues of dimethoate and omethoate were below the limit of quantitation (LOQ) of the analytical method (<0.01 ppm each) in/on one sample of untreated whole tomatoes, and one sample each of juice, wet pomace, dry pomace, puree, paste, and catsup processed from untreated tomatoes.

Table 1. Residues of dimethoate and its oxygen analog omethoate in the processed commodities of tomatoes harvested 7 days following the last of four foliar applications at 5x the maximum single application rate.

Substrate	Uncorrected Residues (ppm) [a]			Concentration/Reduction Factor		
	Dimethoate	Omethoate	Combined	Dimethoate	Omethoate	Combined
whole tomatoes	0.13 0.15 0.18 0.24 (0.18)	-- 0.05 -- 0.07 (0.06) [b]	0.19 [c] 0.20 0.24 [c] 0.31 (0.24)	--	--	--
juice	0.02 0.02 (0.02)	<0.01 <0.01 (<0.01)	<0.03 <0.03 (<0.03)	0.1x	<0.2x	<0.1x
wet pomace	0.10 0.12 (0.11)	0.01 0.02 (0.02)	0.11 0.14 (0.13)	0.6x	0.3x	0.5x
dry pomace	0.09 0.11 (0.10)	<0.01 0.01 (<0.01)	<0.10 0.12 (<0.11)	0.6x	<0.2x	<0.5x
puree	0.29 0.31 (0.30)	0.06 0.06 (0.06)	0.35 0.37 (0.36)	1.7x	1x	1.5x
paste	0.50 0.56 (0.53)	0.08 0.09 (0.09)	0.58 0.65 (0.62)	2.9x	1.5x	2.6x
catsup	0.31 0.34 (0.33)	0.05 0.06 (0.06)	0.36 0.40 (0.38)	1.8x	1x	1.6x

[a] Each residue value represents a single sample; the average total residue value used in calculating concentration/reduction factor is noted in parentheses.

[b] Only two samples were quantitated for omethoate.

[c] The combined residue values were derived by adding the residue value for dimethoate and the average residue value for omethoate.

Study summary:

The subject tomato processing study is acceptable and may be used to satisfy reregistration requirements.

Food/feed additive tolerances for residues of dimethoate and its oxygen analog omethoate are not required for tomato puree and tomato paste. The study indicates that the combined residues of dimethoate and its oxygen analog omethoate do concentrated in tomato puree (1.5x) and tomato paste (2.6x) processed from whole tomatoes bearing detectable residues. Tomato puree and tomato paste are not ready to eat (RTE) and the dilution factors for tomato puree and tomato paste are 1.5x and 2.5x, respectively, based on the recipe files of USDA's Survey System/Food Consumption Laboratory of the Beltsville Human Nutrition Center (memo by J. Morales dated 2/8/96). Hence, no food additive tolerances are needed for tomato puree or paste.

Maximum Residue Limits (MRLs) for residues of dimethoate and its oxygen analog omethoate are not required for tomato puree and tomato paste. The subject processing data indicate that the combined residues of dimethoate and its oxygen analog omethoate in tomato puree (0.36 ppm average) and tomato paste (0.62 ppm average) processed from whole tomatoes treated with dimethoate at 5x the currently registered maximum single application rate will not exceed the currently established tolerance in/on tomatoes (2 ppm). Available tomato field trial data (MRID 000775500) do support the assertion that residues of dimethoate *per se* will not exceed 0.18 ppm in/on tomatoes resulting from treatment with dimethoate at the currently registered maximum use rate. [Note: The reviewer has determined the aforementioned based on a single tomato sample (mature, green) analyzed by a chlorodinitrobenzene colorimetric method. Omethoate residue levels were not determined in/on this sample. Available tomato field trial data are not deemed sufficient to permit CBRS to recommendation lowering the currently established 2 ppm tolerance for dimethoate residues in/on tomatoes.]

No concentration of residues was observed in tomato juice, wet pomace, or dry pomace and although concentration of residues was observed in catsup (1.6x), the Agency does not considers catsup a processed commodity of tomatoes (TABLE II (September 1995)).

Residue Analytical Methods

The registrant provided descriptions of and method validation data for a gas chromatography/ flame photometric detection (GC/FPD) method that was used to determine residues of dimethoate and its oxygen analog omethoate in/on tomatoes and tomato processed fractions from the current study. The method, entitled "Determination of Dimethoate and Omethoate Residues in Tomatoes and Its Processed Commodities by Gas Chromatography", has a detection limit of 0.01 ppm for each compound. The method uses an Rtx-5 capillary column and flame photometric detection in the phosphorus mode and is similar to Method C in PAM Vol. II. Briefly, samples with a moisture content $>45\%$ including whole tomatoes, juice, wet pomace, puree, paste, and catsup were homogenized with acetone and samples with a moisture content $<45\%$ including dry pomace were homogenized with acetone:water (2:1, v:v) and filtered. A subsample was partitioned with methylene chloride in the presence of sodium chloride, and the organic layer was drained through sodium sulfate. The partitioning/draining process was repeated two more times. The combined organic phases were dried by rotary evaporation, and cleaned up on a Celite:charcoal:sodium sulfate column; residues were eluted with hexane:acetone (1:1, v:v). The eluate was concentrated and analyzed by GC/FPD.

Method validation and concurrent method recoveries were conducted by ABC Laboratories (Columbia, MO) to determine the suitability of this method for data collection purposes. Untreated control samples from the tomato processing study were fortified with dimethoate and omethoate at 0.01-0.50 ppm for whole tomatoes, juice, wet pomace, dry pomace, puree, paste, and catsup. Representative chromatograms, sample calculations, and standard curves were provided. The recovery data are presented in Table 2 and indicate that the GC/FPD method is adequate for collecting data on residues of dimethoate and omethoate in tomato processed commodities.

Table 2. Method validation and concurrent method recovery of dimethoate and omethoate from samples of untreated tomato commodities fortified with each analyte and analyzed by GC/FPD.

Matrix Analyte	Method Validation		Concurrent Method Recovery	
	Fortification Level (ppm)	Percent Recovery [a] (Number of Samples)[b]	Fortification Level (ppm)	Percent Recovery [a] (Number of Samples)[b]
Whole tomatoes (unwashed)				
dimethoate	0.01-0.50	80-96 (7)	0.01-0.50	90, 93
omethoate	0.01-0.50	100-116 (7)	--	--
Juice				
dimethoate	--	--	0.01-0.50	97, 100
omethoate	--	--	0.01-0.50	104, 110
Wet pomace				
dimethoate	--	--	0.01-0.50	83, 90
omethoate	--	--	0.01-0.50	85, 100
Dry pomace				
dimethoate	0.01-0.50	70-104 (7)	--	--
omethoate	0.01-0.50	70-114 (7)	--	--
Puree				
dimethoate	--	--	0.01-0.50	80, 97
omethoate	--	--	0.01-0.50	80, 114
Paste				
dimethoate	0.01-5.0	90-110 (7)	--	--
omethoate	0.01-5.0	60; 70-107 (6)	--	--
Catsup				
dimethoate	--	--	0.01-0.50	90, 101
omethoate	--	--	0.01-0.50	60, 106

[a] Corrected for recovery in respective control.

[b] Recovery values outside the 70-120% range are listed separately.

Storage Stability Data

All samples from the submitted processing study were stored frozen (-33 to -10 C) prior to residue analysis. The maximum storage interval between harvest and residue analysis was 19-33 days (~1 month). Processed samples were analyzed within 32 days of processing. No data are available depicting the frozen storage stability of dimethoate and its oxygen analog omethoate in/on tomatoes and tomato processed commodities. However, no storage stability data are needed because frozen samples were stored ~30 days.