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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

9/7/2000

MEMORANDUM

SUBJECT: PP# 7F04873. Clethodim (ANSI) in/on Tuberous and Corm Vegetables (1C Crop Subgroup), Sugar Beets, Sunflower Seed, Canola and Their Processed Commodities. Evaluation of Analytical Method and Magnitude of the Residue Data.

DP Barcodes: D240302 & D254018 PRAT Case Nos:
Submission Nos: S531616 & S556745
PC Code: 121011 Caswell#: 721F
Trade Name: Select® Herbicide EPA Reg#: 59639-78
Select® 2EC Herbicide EPA Reg#: 59639-3
Class: Herbicide 40 CFR: §180.458
MRID Nos: 44323401, 44323402, 44393301 and 44753206

FROM: Manying Xue, Chemist Manying Xue
Registration Action Branch 3
Health Effects Division (7509C)

THRU: Stephen Dapson, Branch Senior Scientist Stephen Q. Dapson 09/11/2000
Registration Action Branch 3
Health Effects Division (7509C)

TO: Joanne Miller, PM Team # 23
Registration Division (7505C)

INTRODUCTION

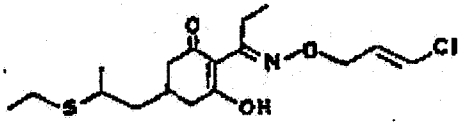
Valent U.S.A. Corporation has submitted residue data for clethodim in/on potatoes, sugar beets, sunflower seed, canola/rapeseed and their processed commodities in support of their request of label amendments and permanent tolerances for residues of the herbicide clethodim (Select® Herbicide 0.94EC (also called Prism) and Select® 2EC Herbicide (EPA Reg. Nos 59639-78 and 59639-3)). The proposed tolerances for the combined residues of clethodim [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones for the raw agriculture commodities are as follows:

Tuberous and Corm Vegetables	1.0 ppm (in tubers)
Potato granules/flakes	2.0 ppm
Sunflower seed	5.0 ppm
Sunflower meal	10.0 ppm
Canola seed	0.50 ppm
Canola meal	1.5 ppm
Sugar beet, tops	1.0 ppm

Clethodim is a member of the cyclohexenone class of herbicides. Tolerances for various plant and animal commodities for the combined residues of clethodim[(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing 2-cyclohexen-1-one moiety or the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones have been established (40 CFR §180.458). The established tolerances are at 1.0 ppm for cottonseed, 2.0 ppm for cottonseed meal, 0.2 ppm for livestock fat, livestock meat by-products, livestock meat, and poultry fat, meat or by products, 1.0 ppm for eggs, 0.5 ppm for potatoes, 1.0 ppm for potato flakes/granules, 0.05 ppm for milk, 10.0 ppm for soybeans, 15.0 ppm for soybean soapstock, 0.2 ppm for dry bulb onions and sugar beet roots, 0.50 ppm for sugar beet tops, and 2.0 ppm for sugar beet molasses. Time-limited tolerances (expiration date 4/30/2001) are 6.0 ppm for alfalfa forage, 10 ppm for alfalfa hay, 2 ppm for dry beans, 3 ppm for peanuts and peanut hay, 5 ppm peanut meal, 1.0 ppm for tomatoes, 3 ppm for tomato paste, and 2 ppm for tomato puree.

The review was performed by the Oak Ridge National Laboratory, Oak Ridge, TN. The data assessment has undergone secondary review within RAB3 and has been revised to reflect current HED and OPP policies.

The chemical structure for clethodim is given below:



[(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one]

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. The product chemistry data for clethodim were previously submitted. The manufacturing process of technical grade active ingredient (TGAI) and the formulations were reviewed

(PP#9F3743, M. Nelson, 3/12/90). No deficiencies and no toxicological concerns for any clethodim impurities were cited.

OPPTS GLN 860.1200: Proposed Uses

2a. A revised Section B/label must be submitted which specifies a maximum of 2 applications at a minimum retreatment interval of 14 days for potatoes, sugar beets, and sunflower.

OPPTS GLN 860.1300: Nature of the Residue - Plants

3a. No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton were reviewed (PP#9F3743, MRIDs 41030137 & 41030138, M. Nelson, 3/12/90). The qualitative nature of the clethodim residue in plants is adequately understood for root crops and oil seed crops. HED prevously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the residues of concern are now described as clethodim and metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones in order to harmonize with the Codex MRL (PP#4F4340, D203378, J. Morales, 1/31/95).

3b. For future petitions on crops other than root crops and oil seed crops, additional metabolism data may be required.

OPPTS GLN 860.1300: Nature of the Residue - Animals

4. Metabolism studies of [propyl-1-^{14}C]-clethodim in a lactating goat and laying hens were reviewed (PP#9F3743, MRID# 41030139 & 41030140, M. Nelson, 3/12/90). The nature of the residue in ruminants and poultry is adequately understood for the purposes of the subject petition. HED prevously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-one moiety.

OPPTS GLN 860.1340: Analytical Methods - Plants

5a. The method RM-26B-3 (a modification of RM-26B-2) was validated for potatoes, processed potato commodities, sugar beets and sunflowers at fortification levels of 0.2 ppm, 0.5 ppm, 1.0 ppm, 2.0 ppm and 5.0 ppm, etc. Average recoveries for most potatoes, sugar beets, sunflowers and their processed commodities were within the acceptable range at all fortification levels tested. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites in potatoes, sugar beets, sunflowers and their processed commodities is acceptable for data collection and enforcement purposes.

5b. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites is similar to the common moiety method RM-26B-2. The method RM-26B-2 has previously undergone a successful Petition Method Validation by the Agency (PP#9F3734, MRID 41389901, M. Nelson, 5/4/90), and a confirmatory method, EPA-RM-26D-2 is also available. Both methods (RM-26B-2 & RM26D-2) have been forwarded to

FDA as ecforcement methods for inclusion in PAM II.

5c. The analyses of canola seeds and its processed commodities by RM-26-A1 were not successfully validated. Recoveries for canola seeds and its processed commodities were higher than the Agency acceptable range. Therefore, HED requires a new or revised analytical method for the analyses of canola seeds and its processed commodities.

OPPTS GLN 860.1340: Analytical Methods - Animals

6. Adequate analytical methodology are available to enforce tolerances for residues of clethodim in animal commodities. The Agency has concluded that the compound specific method, EPA-RM-26D-2, is suitable for enforcement of tolerances for the total clethodim residue in crops and animal tissues, and it has been forwarded to FDA for publication in the Pesticide Analytical Manual, Volume II (PAM II).

OPPTS GLN 860.1360: Multiresidue Method

7. The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim sulfone under FDA's multiresidue protocols. Specific tests using the protocols were previously submitted and forwarded to FDA for review.

OPPTS GLN 860.1380: Storage Stability Data - Plants

8. The existing storage stability data are adequate to support potatoes, sugar beets, sunflower seeds, canola seeds and and their processed commodities. However, storage stability data are not available to support canola meal and canola oil. For future submissions, the petitioner should provide storage stability data for canola meal and canola oil.

OPPTS GLN 860.1500: Crop Field Trials

9a. **The submitted field trial data and geographic representation for potatoes are not adequate to satisfy the data requirement described in OPPTS 860.1500.** The OPPTS guideline indicates that sixteen potato field trials are required and the field trials should be conducted in Regions I (2), II (1), III (1), V (4), IX (1), X (1) and IX (6). Only twelve potato field trials were conducted in Regions I (1), II (1), III (1), V (3), X (1), and XI (5). All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X). The first application was 44 days preharvest, the second application was 30 days prior to harvest. The spray volume for the trials was between 16.6 and 21.7 gallons per acre (GPA). The spray included a tank-mixed crop oil concentrate at 1% v/v of the final spray. The combined residues of DME and DME-OH ranged from <0.2 ppm (the LOD) to 0.80 ppm which support the proposed tolerance at 1.0 ppm for potatoes or Tuberous and Corm Vegetables (1C Crop Subgroup). However, **four additional field trials which need to be conducted in Regions I (1), V (1), IX (1) and XI (1) must be submitted.**

9b. Provided a revised Section B/label is submitted, **the submitted field trial data and geographic representation for sugar beets are adequate to satisfy the data requirement**

described in OPPTS 860.1500. Twelve sugar beet field trials were conducted in Regions V (5), VII (1), VIII (1), X (2), IX (1), and XI (2). The crops in each trial were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X) and all used a tank-mixed crop oil adjuvant at 1% v/v to the final volume. The first application was approximately 54 days preharvest and the second was 14 ± 1days following the first. Harvest occurred 39-42 days after the last application. Clethodim residues were measured as DME or DME-OH. The combined residues of Clethodim were below the limit of detection (<0.2 ppm) in all sugar beet root trials. The residues in sugar beet top samples ranged from <0.2 ppm to 0.88 ppm. The proposed tolerance of 1.0 ppm for sugar beet tops is adequate. However, **a revised Section F must be submitted proposing *a tolerance at 0.2 ppm for sugar beet roots.***

9c. Provided a revised Section B/label is submitted, **the submitted field trial data and geographic representation for sunflower seeds are adequate to satisfy the data requirement described in OPPTS 860.1500.** Eight sunflower field trials were conducted in Regions V (4), VII (3) and VIII (1). Crops in each trial were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was 70-86 days preharvest (30-40 days after emergence) and the second application was 56-72 days prior to harvest. The spray volume for the trials was between 18.8 and 20.8 GPA and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. All clethodim residues were measured as DME or DME-OH. Clethodim residues ranged from 0.46 ppm to 4.4 ppm which supports the proposed tolerance of 5.0 ppm for sunflower seeds.

9d. **The submitted field trial data and geographic representation for canola are inadequate to satisfy the data requirement described in OPPTS 860.1500.** The petitioner has submitted canola/rapeseed field trial data which were conducted in Canada, France and Great Britain. Only six field trials from Canada are acceptable. The submitted field trial data from France and Great Britain are not acceptable. **The analytical method RM-26A-1, which was used to analyze canola seeds and its processed commodities in this petition was not successfully validated; therefore, HED requires new canola field trials. According to OPPTS 860.1500, eight canola field trials should be conducted in Regions II (1), V (2), VII (2) XI (3); and the field trial data should reflect the proposed use including the PHI.**

OPPTS GLN 860.1520: Processed Food/Feed

10a. **The submitted potato processing data are adequate to satisfy the data requirement described in OPPTS 860.1520.** The potato processing data indicate that residues of clethodim were not concentrated in/on potato wet peel and chips. However, residues of clethodim concentrated 2.5x in flakes. The HAFT residue from the current potato field trials reflecting the maximum proposed use pattern is 0.78 ppm. The expected residues in granules/flakes should be 1.95 ppm. The proposed tolerance of 2.0 ppm for granules/flakes is adequate. **The current tolerance of 1.0 ppm on potato granules/flakes should be removed from CFR 180.458.**

10b. **The submitted sugar beet processing data are adequate to satisfy the data**

requirement described in OPPTS 860.1520. The processing study for sugar beets were reviewed (PP# 4F4340, D203378, MRID# 431664-05, J. Morales, 2/8/95); a tolerance of 2.0 ppm for sugar beet molasses was determined. However, the processing study for sugar beets are reevaluated with this petition. In the processing study, two applications of clethodim were made at the rate of 1.25 lbs. ai/A for a total of 2.50 lb ai/A/season (5X). Clethodim residues were <0.10 ppm in sugar beets, dehydrated pulp, refined sugar, and 0.29 ppm in molasses at 5X. The HAFT residue from the current sugar beet field trials reflecting the maximum proposed use pattern is 0.1 ppm. The residues in dehydrated pulp and refined sugar were not concentrated. Assuming a concentration of 0.1 ppm in sugar beet and the residues were concentrated 5.8X in molasses, the expected residues in molasses should be 0.6 ppm. Therefore, **a revised Section F must be submitted amending the tolerance of sugar beet molasses from 2.0 ppm to 1.0 ppm.**

10c. **The submitted sunflower seed processing data are adequate to satisfy the data requirement described in OPPTS 860.1520.** The sunflowers were treated with 2.5 lb ai/A per season (5X). Sunflower hulls are not a required processing commodity for sunflower. The residues in sunflower oil were not concentrated. However, the residues were concentrated 2.1X in sunflower meal. The HAFT from the current sunflower field trials reflecting the maximum proposed use pattern is 4.2 ppm. The expected residues should be 8.82 ppm in sunflower meal. Therefore, the proposed tolerance of 10 ppm for sunflower meal is adequate.

10d. The canola was treated at the rate of 0.19 - 0.21 lb ai/A (2.3-2.6 X) with a 67-75 day PHI. The residues in canola oil did not concentrated. The residues concentrated 2.6X in canola meal. **However, the analytical method RM-26A-1 which was used to analyze canola seeds and its processed commodities in this petition was not successfully validated; therefore, HED requires a new canola processing study.**

OPPTS GLN 860.1480: Magnitude of the Residue in Meat/Milk/Poultry/Eggs

11a. **The current established tolerances on meat and milk are adequate to cover the proposed uses.** According to Table 1 of OPPTS 860.1000 and the recommended and established tolerances for clethodim, the maximum theoretical residues in the diets of beef cattle and dairy cattle were calculated; and the theoretical maximum dietary burdens were determined to be 18.6 ppm for beef and 17.7 ppm for dairy cattle. Based on the previous feeding studies, secondary residues in meat and milk will not exceed the established tolerances.

11b. **The current established tolerances on poultry and eggs are adequate to cover the proposed use.** According to Table 1 of OPPTS 860.1000 and the recommended and established tolerances for clethodim, the maximum theoretical residues in the diet of poultry were calculated and the current theoretical maximum dietary burden was determined to be 7.4 ppm for poultry. Based on the previous poultry feeding studies, secondary residues in poultry and eggs will not exceed the established tolerances.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

12. A confined rotational crop study of [ring-4,6-^{14}C]-clethodim with carrots, lettuce, and wheat (MRID 41030211) was conducted. The study was reviwed by E. B. Conerly (EFGWB Science Chapter for Clethodim, 06/26/1990). Results indicated that there is no need for field rotational crop trials. A 1- month plantback interval for crops rotated with alfalfa was specified (D 236382, M. Collantes, et. al, 2/10/98). The use directions submitted with the current petition do not specifically address rotational crops. The directions for use on fallow or nonproducing agricultural land do not plant any crop for 30 days after application unless clethodim is registered for use on that crop. A revised Section B/label must be submitted which includes a 1-month plantback restriction for all rotated crops without a registered clethodim uses.

International Harmonization of Tolerances

13. Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on sugar beets (0.1 ppm), potatoes (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and sunflower seed oils (0.05 ppm). Some of these proposed tolerances have been recommended for withdrawal or reflect recent changes. Harmonization could be an issue for Codex MRLs for potato/tuberous vegetables (0.2 ppm vs. 1.0 U.S.), sunflower seed (0.5 ppm vs 5.0 ppm) and sunflower oils (0.05 ppm vs.5.0 ppm U.S.). If a separate tolerance for refined sunflower oil was established at 0.1 ppm based on the submitted data, there would still be a Codex harmonization issue for both crude and refined sunflower oil. There could be a harmonization issue with the Canadian MRLs for potatoes (0.5 ppm vs. 1.0 ppm U.S.), sunflowers (0.2 ppm vs. 5.0 ppm U.S.), and rape/canola (0.05 ppm vs. 0.5 ppm U.S.). There are also current Codex harmonization concerns for clethodim residues in chicken meat, eggs, milk, sugar beets (roots), cottonseed, cottonseed oil, and dry bulb onions. There are no harmonization concerns for Mexican MRLs. An International Residue Limit Status Sheet is attached (Attachment 2).

RECOMMENDATIONS

Pending submission of a revised Section B/label as specified in Conclusion 2a, there are no residue chemistry data requirements that would preclude the establishment of permanent tolerances for residues of clethodim in sunflower seeds and their processed commodities.

Pending submission of a revised Section B/label and review of four additionalfield trials (Conclusions 2a & 9a), registration of potato (Tuberous and Corm Vegetable, 1C Crop Subgroup) should be made conditional.

Provided that a revised Section B/labels is submitted as specified in Conclusion 2a and a revised Section F (Conclusion 9b &10b), HED concludes that there are no residue chemistry data requirements that would preclude the establishment of permanent tolerances for residues of clethodim in sugar beets.

HED recommends that the tolerance levels for the combined residues of clethodim [(E)-(±)-2-[1-

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[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones should be established as follows:

Tuberous and Corm Vegetables (Crop Subgroup 1-C)	1.0 ppm
Potato, granules/flakes	2.0 ppm
Sugar beet, tops	1.0 ppm
Sugar beet, roots	0.20 ppm
Sugar beet, molasses	1.0 ppm
Sunflower, seed	5.0 ppm
Sunflower, meal	10.0 ppm

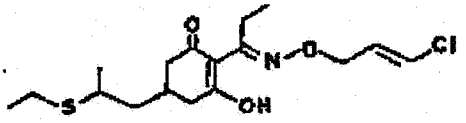
Upon submission of the required data, these tolerances will be reevaluated. HED will now initiate a Human Health Risk Assessment for this use.

HED does not recommend for permanent tolerances on canola seed and its processed commodities because of the deficiencies concerning the residue data and analytical method RM-26A-1, which was used for canola analyses (Conclusion 5c & 9d).

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

The chemical structure for clethodim is given below:



[(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one]

The product chemistry data for clethodim were previously submitted. The manufacturing process of technical grade active ingredient (TGAI) and the formulations were reviewed (PP#9F3743, M. Nelson, 3/12/90). No deficiencies and no toxicological concerns for any clethodim impurities were cited.

OPPTS GLN 860.1200: Proposed Uses

Formulations:

Two registered formulations of clethodim are proposed for use: (1) Select® 2 EC Herbicide (EPA

Reg. No. 59639-3) is an emulsifiable concentrate containing 25% active ingredient (ai) and 75% inerts. This formulation contains 2 pounds ai per gallon.

(2) Select® 0.94EC (EPA Reg. No. 59639-78) is an emulsifiable concentrate containing 12.6% active ingredient (ai) and 87.4% inerts. The formulation contains 0.94 pounds of ai per gallon.

Potatoes

Select® is intended to selectively provide post-emergence control of annual and perennial grasses. Apply Select® 0.94EC at the dose rate of 0.06-0.25 lb ai/A (8-34 fl oz/A)/treatment with no more than 0.5 lb ai/A/season (68 fl oz/A/season). Apply Select® 2EC at the dose rate of 0.06-0.25 lb ai/A (4-16 fl. oz/A)/treatment with no more than 0.5 lb ai/A/season (32 fl oz/A/season). The PHI is 30 days for potato. The spray interval is not specific but is dependent on the rate of kill (7-14 days), rate of emergence of new growth (application 2-3 weeks after emergence or to specific height), irrigation patterns, cultivation patterns, use of other herbicides, and degree of stress induced by adverse conditions. Section B provides general use directions specifying reapplication in 2-3 weeks. A crop oil concentrate containing at least 15% emulsifier at 1% v/v to finished spray volume is to be used as an adjuvant with either formulation. The minimum application volume is 3 gal/A by air and 5 gal/A by ground for either formulation. Maximum spray volumes are 10 gal/A by air and 40 gal/A by ground with nozzle pressure between 30-60 psi. The products are not to be applied by any irrigation system. There are no specific plant-back intervals or directions for rotational crops except that when Select®0.94 EC or Select® 2 EC is used on fallow ground only clethodim registered use crops may be planted within 30 days of application.

Sugar Beets

Select® is intended to selectively provide post-emergence control of annual and perennial grasses. Apply select® 0.94EC at the annual grass dose rate of 0.08 lb ai/A (11 fl oz/A)/treatment with no more than 0.5 lb ai/A/season (68 fl oz/A); apply at the dose rate for perennial grasses of 0.095-0.25 lb ai/A (13-34 fl oz/A) per treatment with a total of 0.5 lb ai/A. Apply Select® 2EC at the annual dose rate is 0.08 lb ai/A (5 fl oz/A)/treatment with no more than 0.5 lb ai/A/season (32 fl oz/A/season); apply for perennial grasses of 0.095-0.25 lb ai/A (6-16 fl oz) per treatment with a total of 0.5 lb ai/A/season. The current PHI is 100 days for sugar beets with a proposal to change the PHI to 40 days. The spray interval is not specific but is dependent on the rate of kill (7-14 days), grass population, rate of emergence of new growth (application 2-3 weeks after emergence or to specific height), irrigation patterns, cultivation patterns, use of other herbicides, and degree of stress induced by adverse conditions. Section B provides general use directions specifying reapplication in 2-3 weeks. A crop oil concentrate containing at least 15% emulsifier at 1% v/v to finished spray volume is to be used as an adjuvant with either formulation. Select® may be tank-mixed with Stinger, Betamix, or Betanex herbicides for use on sugar beets but no crop oil concentrate should be used. The minimum application volume is 3 gal/A by air and 5 gal/A by ground for either formulation. Maximum spray volumes are 10 gal/A by air and 40 gal/A by ground with nozzle pressure between 30-60 psi. The products are not to be applied by any irrigation system. There are no specific plant-back intervals or directions for rotational crops except that when Select® 0.94EC or Select® 2 EC is used on fallow ground only clethodim registered use crops may be planted within 30 days of application. The label use rate for Select® 0.94EC on annual grass control in sugar beets was originally 10 fl. oz./treatment and has been revised in the submitted label to 11 fl. oz./treatment.

There are no grazing restrictions for sugar beets.

Sunflowers

Select® is intended to selectively provide post-emergence control of annual and perennial grasses. Apply Select® 0.94EC at the dose rate of 0.06-0.25 lb ai/A (8-34 fl. oz./A)/treatment with no more than 0.5 lb ai/A/season (68 fl oz/A/season). Apply Select® 2 EC at the dose rate of 0.06-0.25 lb ai/A (4-16 fl oz/A)/treatment with no more than 0.5 lb ai/A/season (32 fl oz/A/season). The PHI is 70 days for sunflowers. The spray interval is not specific but is dependent on the rate of kill (7-14 days), rate of emergence of new growth (application 2-3 weeks after emergence or to specific height), irrigation patterns, cultivation patterns, use of other herbicides, and degree of stress induced by adverse conditions. Section B provides general use directions specifying reapplication in 2-3 weeks but this is not explicitly stated on the labels. A crop oil concentrate containing at least 15% emulsifier at 1% v/v to finished spray volume is to be used as an adjuvant with either formulation. The minimum application volume is 3 gal/A by air and 5 gal/A by ground for either formulation. Maximum spray volumes are 10 gal/A by air and 40 gal/A by ground with a nozzle pressure of 30-60 psi. The products are not to be applied by any irrigation system. There are no specific plant-back intervals or directions for rotational crops except that when Select® 0.94EC or Select® 2EC is used on fallow ground only registered use crops may be planted within 30 days of application. There are no grazing restrictions for sunflowers but there are grazing restrictions for cotton and soybeans.

Canola

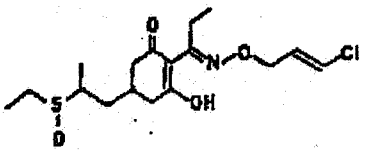
Select® is intended to selectively provide post-emergence control of annual and perennial grasses. Canola is sensitive to Select® herbicides and care must be taken to use reduced rates of treatment. Apply Select® 0.94EC at the dose rate of 0.06-0.08 lb ai/A (8-11 fl oz/A)/treatment with no more than 0.08 lb ai/A/season (11 fl oz/A/season). Apply Select® 2EC at the dose rate of 0.06-0.08 lb ai/A (4-5 fl oz/A)/treatment with no more than 0.08 lb ai/A/season (5 fl oz/A/season). The proposed PHI is 60 days for canola. The spray interval is not specific but is dependent on the rate of kill (7-14 days), rate of emergence of new growth (application 2-3 weeks after emergence or to specific height), irrigation patterns, cultivation patterns, use of other herbicides, and degree of stress induced by adverse conditions. Generally only one application would be made to canola but that is not explicitly stated on the labels. A crop oil concentrate containing at least 15% emulsifier at 1% v/v to finished spray volume is to be used as an adjuvant with either formulation. The minimum application volume is 3 gal/A by air and 5 gal/A by ground for either formulation. Maximum spray volumes are 10 gal/A by air and 40 gal/A by ground with a nozzle pressure of 30-60 psi. The products are not to be applied by any irrigation system. There are no specific plant-back intervals or directions for rotational crops except that when Select® or Select® 2 EC is used on fallow ground only registered use crops may be planted within 30 days of application.

HED Comments/Conclusions:

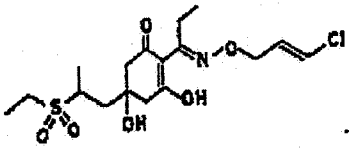
A revised Section B/label must be submitted which specifies a maximum of 2 applications at a minimum retreatment interval of 14 days for potatoes, sugar beets, and sunflowers.

OPPTS GLN 860.1300: Nature of the Residue - Plants

No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton were submitted with PP#9F3743 (MRIDs 41030137 & 41030138) and discussed in the memo of 3/12/90 (M. Nelson). Immature carrots, soybeans, and cotton were treated twice at a 14-day interval with a 50:50 tautomeric mixture of ring [6-^{14}C]-clethodim at a rate equivalent to 0.25 lbs. ai/A as a postemergence foliar spray; grown to maturity in a greenhouse; and harvested with PHI's of 20, 30, and 70 days. The major metabolic pathways of clethodim (C) in plants are initial sulfoxidation to clethodim sulfoxide (CSO, structure shown below) followed by further oxidation to clethodim sulfone (CSO_2), elimination of the chloroallyloxy side chain to give the imine sulfoxide (ISO) and sulfone (ISO_2), and hydroxylation to form the 5-OH sulfoxide (5OH-SO) and sulfone (5OH-SO_2, structure shown below). Clethodim sulfoxide and clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. Data are shown in Table 1. Also present as a minor metabolite was the aromatic sulfone. A study designed to follow the fate of the chloroallyloxy group was done side-by-side with the ^{14}C-ring-labeled clethodim study discussed above. The results showed that the chloroallyloxy moiety cleaved from clethodim underwent extensive metabolism, eliminating the chlorine atom and incorporating the three carbon moieties into natural plant components (with some being evolved as $^{14}CO_2$). Studies have been conducted only in a root crop (carrots) and two oilseeds (soybean and cotton) and it cannot be stated that the nature of the residue is understood in all plants. The residues of concern in Tuberous and Corm Vegetables (Crop Subgroup 1-C), sugar beets, sunflowers, and canola and other root crops and oil seed crops are clethodim and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones.



Clethodim sulfoxide



5-Hydroxy clethodim sulfone

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Table. 1. Characterization of Clethodim Metabolites in Plant Tissues						
	ppm (calculated as clethodim from ^{14}C -labeled clethodim)					
Component	Soybean Bean	Soybean Foliage	Cotton seed	Cotton Foliage	Carrot Root	Carrot Leaves
C	---	---	---	---	0.003	---
CSO	1.24	1.65	0.003	0.55	0.11	3.50
CSO_2	0.178	0.25	0.002	0.054	0.014	0.13
ISO	0.302	3.88	0.004	2.40	0.040	4.93
ISO_2	0.314	2.43	0.002	0.55	0.034	1.32
5OH-SO	0.275	<0.05	<0.001	0.19	0.026	0.36
5OH-SO_2	0.414	0.86	0.001	0.054	0.030	0.42
Arom. SO_2	0.58	0.14	<0.001	0.068	0.006	0.067
Others	0.271[a]	3.63[a]	0.0045[b]	4.22[a]	0.052[a]	2.419[a]
CSO-Conj.	0.329	6.92	<0.001	0.37	0.024	1.90
CSO_2-Conj.	0.050	0.56	<0.001	0.18	0.002	0.11
Other Conj.	0.383[a]	5.11[a]	0.020[c]	4.25[a]	0.041[b]	5.98[a]
Non-extractable	0.058	2.48	0.032	0.62	0.015	1.18
Totals	3.872	27.94	0.069	13.51	0.397	22.32

[a] Composed of ≥9 ^{14}C metabolites
[b] Composed of ≥4 ^{14}C metabolites
[c] Contained too low radioactivity to allow further characterization.
Abbreviations are referenced in the previous text.

HED Comments/Conclusions:

No new plant metabolism study has been submitted with this petition. Metabolism studies for clethodim in/on carrots, soybeans, and cotton were reviewed (PP#9F3743, MRIDs 41030137 & 41030138, M. Nelson, 3/12/90). The qualitative nature of the clethodim residue in plants is adequately understood for root crops and oil seed crops. HED prevously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-one moiety. However, the residues of concern are now described as clethodim and metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones in order to harmonize with the Codex MRL (PP#4F4340, D203378, J. Morales, 1/31/95).

For future petitions on crops other than root crops and oil seed crops, additional metabolism data may be required.

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OPPTS GLN 860.1300: Nature of the Residue - Livestock

A metabolism study has been previously submitted and reviewed: "The in vivo Metabolism of [propyl-1-^{14}C]-Clethodim in a Lactating Goat," 12/29/88, Lab ID# MEF-0038, MRID# 410301-39 (PP#9F3743, M. Nelson, 3-12-90). Metabolites were identified in the urine, as this is where most of the dose was excreted. The major urinary metabolite was clethodim sulfoxide (CSO), varying from 40% of the urinary ^{14}C on day 2 to 67% of the urinary ^{14}C on day 4. The remainder of the urinary ^{14}C was composed of clethodim (3.0-27%), S-methyl sulfoxide (SMSO) (12-18%), S-methyl (SM) (7.0-13%), imine sulfoxide (ISO) (1.5-2.8%), clethodim sulfone (CSO2) (1.5-2.2%), and 5-OH sulfoxide (5OH-SO) (0-3.0%).

The total radioactive residue in milk plateaued at about 0.035 ppm by the evening of day two. The milk was lyophilized for solvent extraction of metabolites. About half the ^{14}C activity was extractable into organic solvents. It was composed of clethodim (≤0.001 ppm), clethodim sulfoxide (0.006-0.013 ppm), and S-methyl sulfoxide (0.001-0.005 ppm). The other half of the ^{14}C activity was water-soluble and was shown by isotopic dilution to be ^{14}C-lactose (0.014-0.017 ppm, as clethodim equivalents) (PP#5F4440/5H5713, DP Code: D210424, D210427, D221693, J. Morales, 6/25/96, MRID#'s 438489-00, 434482-01, 434482-02, 434482-03, 438489-01, 434717-02, 434717-03).

Most (77-95%) of the ^{14}C activity in tissues and blood was extractable into organic solvents, with the acetonitrile and methanol-water fractions containing the highest levels of activity. Those two fractions were pooled for residue characterization, and the metabolic profiles of that extractable activity are given in Table 2.

The dominant metabolic process in the ruminant (goat) is oxidation of clethodim to clethodim sulfoxide and, to a lesser extent, clethodim sulfone. Clethodim can also be converted to the S-methyl derivative, which can be oxidized to S-methyl sulfoxide and S-methyl sulfone derivatives. Cleavage of the oxime N-O bond in clethodim produces the imine, which is rapidly oxidized to imine sulfoxide. In a minor process, clethodim can be hydroxylated to 5-OH, which can be oxidized to 5-OH sulfoxide. Alternately, clethodim sulfoxide may be hydroxylated to 5-OH sulfoxide. The S-methyl derivative is formed only from clethodim; the literature does not support the formation of S-methyl sulfoxide from clethodim sulfoxide. Thus, the S-methyl metabolites have significance only if animals are exposed to clethodim, and this is limited because clethodim is rapidly oxidized to sulfoxides and sulfones in plants (D241704, D. Dotson, 12/19/97) (PP#5F4440/5H5713, D210424, J. Morales, 6/25/96, MRID#'s 438489-00, 434482-01, 434482-02, 434482-03, 438489-01, 434717-02, and 434717-03).

A metabolism study on laying hens was submitted with PP#9F3743 (MRID#410301-40) and discussed in M. Nelson's memo of 3/12/90. Young laying hens were assigned to one of two test groups (8 hens each) or the control group (12 hens). Following a 12-day acclimation period, each hen in the test groups received an oral dose of a 50:50 tautomeric mixture of ring [6-^{14}C]-clethodim:[4-^{14}C]-clethodim (either 2.1 mg/kg/day or 51.3 mg/kg/day) contained in a gelatin gel capsule filled with commercial poultry feed, once daily for 5 consecutive days. Controls received gelatin capsules containing only poultry feed. Clethodim metabolism in hens was not as complex as in goats. The chicken tissues and eggs contained only clethodim (C), clethodim sulfoxide (CSO), and clethodim sulfone (CSO_2). None of the imine analogs, 5-hydroxy analogs, or S-methyl analogs

which were identified in the goat were seen in the chicken.

Table 2. Clethodim metabolite profile (ppm) in goat tissue and blood[a]							
Component	Blood	Liver	Kidney	Heart	Muscle Fqtr.	Muscle Hqtr.	Subcut. Fat
C	0.047	0.114	0.005	0.000	0.000	0.000	0.002
CSO	0.067	0.137	0.139	0.025	0.017	0.014	0.037
CSO_2	0.006	0.013	0.000	0.000	0.000	0.000	0.000
SMSO	0.019	0.025	0.116	0.021	0.009	0.011	0.023
ISO	0.005	0.006	0.016	0.000	0.000	0.000	0.004
5OH-SO_2	0.004	0.000	0.000	0.000	0.000	0.000	0.000
Unknown[b]	0.005	0.016	0.037	0.000	0.000	0.003	0.006

[a] Values reported as 0.000 ppm are below the level of claimed sensitivity, which is <0.001
[b] The unidentified activity was polar in nature and remained at the origin (TLC).

HED Comments/Conclusions:

Metabolism studies of [propyl-1-^{14}C]-clethodim in a lactating goat and laying hens were reviewed (PP#9F3743, MRID# 41030139 & 41030140, M. Nelson, 3/12/90). The nature of the residue in ruminants and poultry is adequately understood for the purposes of the subject petition. HED prevously concluded that the residues of concern are clethodim and its metabolites containing the 2-cyclohexen-1-one moiety.

OPPTS GLN 860.1340: Analytical Methods - Plants

The analytical method previously used to gather the magnitude of the total clethodim residue data on sugar beets, garlic, and onions was Chevron Chemical Method RM-26B-1, "Analytical Method for the Determination of Clethodim Residues". The registrant revised this method at HED's request and designated the revision as Method RM-26B-2 (MRID#413899-01). This revised method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (M. Nelson's memo of 5/4/90). Briefly, the method involves extraction with aqueous methanol, cleanup by alkaline precipitation and acidic back extraction, oxidation to the pentanedioic acid moieties, derivatization to the corresponding dimethyl esters (DME and/or DME-OH), partition of the dimethyl esters in CH_2Cl_2, and determination by GC-FPD-S. The total residue is expressed as clethodim equivalents. The limit of quantitation is 0.10 ppm. The minimum detection limit for residues measured as the dimethyl esters is 0.01 ppm for milk; 0.05 ppm for other animal commodities including eggs; and 0.05 ppm for crops (PP# 4F4340, D203378, J. Morales, 2/8/95).

Method RM-26B-3

Method RM-26B-3 (a modification of RM-26B-2) was used for the analyses of potatoes, sugar beets, sunflower seeds, and canola/ rapeseeds. The analyses were conducted in Valent Technical Center,

Dublin, CA. Method RM-26B-3 measures total residues of clethodim as two common moieties in plant or animal tissues by gas chromatography. The method cannot distinguish between clethodim and sethoxydim. The method involves extraction with methanol and/or water, followed by cleanup with alkaline precipitation and acid back extraction into dichloromethane. An alkaline hydrogen peroxide oxidation converts sulfides and sulfoxides to sulfones and then to dicarboxylic acids. The dicarboxylic acids are derivatized to dimethyl esters which are partitioned into dichloromethane; the measurement of the pentanedioic acid dimethyl esters (DME sulfone and DME-OH sulfone) is by (GC-FID) in the sulfur mode. Quantitation is from a standard curve using DME and DME-OH and the total residue is expressed as clethodim equivalents. For recovery studies the samples may be fortified with clethodim, clethodim sulfoxide, or 5-OH clethodim sulfone, common metabolites of clethodim in plants. Calculations were provided to show the method of conversion of detected DME or DME-OH to clethodim, clethodim sulfoxide, or 5-OH clethodim sulfone. This method modifies RM-26B-2 by updating measurement parameters and calculation procedures and modifying the silica gel cleanup procedure. The fortification levels and recovery data are reported in Tables 3 to 5.

Table 3. Method recovery of clethodim(CS), clethodim sulfoxide (CSO), and 5-OH clethodim sulfone (5-OH CSO_2) from fortified potato samples.

Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries					
		CS (ppm)[a]	CS (%)[b]	CSO (ppm)[a]	CSO (%)[b]	5-OH CSO_2 (ppm)[a]	5-OH CSO_2 (%)[b]
Tubers	0.2 0.5 1.0 2.0	(5) 0.159-0.237 (5) 0.396-0.436 (3) 0.827-0.887 (1) 1.84	80-119 79-87 82-89 92	(2)0.201-0.209	101-105	(7) 0.145-0.205 (6) 0.301-0.420 (3) 0.679-.0870 (1) 1.59	73-102 60-84 68-87 79
Average (%) ± SD[c]		NC	88 ± 10	NC	103	NC	81 ± 11
Wet peel	0.2 0.5	(1) 0.232 (1) 0.434	116 86.8	NA[d]	NA	(1) 0.258 (1) 0.450	88 73.6
Average (%)		NC	101	NA	NA	NC	81
Chips	0.2 1.0	NA	NA	(1) 0.224 (1) 0.851	112 85.1	(1) 0.203 (1) 0.753	102 75.3
Average (%)		NA	NA	NC	99	NC	89
Flakes	0.5	NA	NA	(1) 0 .468	93.6	(1) 0.402	80.4

[a]Uncorrected for untreated control
[b]Corrected for untreated control
[c]Averages calculated by the reviewer from original unrounded data. Average not calculated (NC) for ppm values.
[d] NA= not analyzed

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Sugar beets

Table 4. Method recovery of clethodim(CS) and 5-OH clethodim sulfone (5-OH CSO_2) from fortified sugar beet roots and tops.

Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries			
		CS (ppm)[a]	CS (%)[b]	5-OH CSO_2 (ppm)[a]	5-OH CSO_2 (%)[b]
Roots	0.2 0.5	(10) 0.162-0.197 (2) 0.371-0.401	81-98 74-80	(10) 0.130-0.192 (2) 0.351-0.376	65-96 70-75
Average (%) ± SD[c]		NC	86 ± 7	NC	81 ± 9
Tops	0.2 0.5	(11) 0.190-0.224 (1) 0.317	95-112 63.4	(11) 0.155-0.240 (1) 0.361	78-120 72
Average (%) ± SD		NC	99 ± 13	NC	96 ± 13

[a]Uncorrected for untreated control [b]Corrected for untreated control
[c]Averages calculated by the reviewer from original unrounded data. Average not calculated (NC) for ppm values.

Sunflowers

Table 5. Method recovery of clethodim(CS) and 5-OH clethodim sulfone (5-OH CSO_2) from fortified sunflower samples.

Matrix	Fortification Level (ppm)	(number of analyses) Range of Recoveries			
		CS (ppm)[a]	CS (%)[b]	5-OH CSO_2 (ppm)[a]	5-OH CSO_2 (%)[b]
Seeds	0.2 0.5 1.0 2.0 5.0	(2).231-.236 (1) .431 (3).884-1.05 (1) 1.65 (1) 4.72	116-118 86.2 88.4-95.8 82.7 94.4	(2).212-.214 (1).381 (3).713-.866 (1) 1.52 (1) 4.45	106-107 76.2 71-79 76 89
Average (%) ± SD[c]		NC	97 ± 13	NC	85 ± 14
Hulls	0.5	(1) .535	84.1	(1) .600	120
Meal	0.5	(1) .566	113	(1) .532	107
Crude oil	2.5	(1) 1.69	67.4	(1) 1.71	68.6
Refined oil	0.2	(1) .131	65.3	(1) .146	73.0

[a]Uncorrected for untreated control [b]Corrected for untreated control
[c]Averages calculated by the reviewer from original unrounded data. [d] NA= not analyzed

Canola/Rapeseed

All canola samples were analyzed for clethodim residues using method RM-26A-1 at the limit of quantitation of 0.05 ppm. The analytical method determines combined residues of clethodim and its metabolites containing the 2-cyclohexen-1-one moiety expressed as clethodim. The method involves extraction with methanol and/or water, followed by cleanup with alkaline precipitation and acidic back extraction into methylene chloride. Alkaline hydrogen peroxide oxidation then converts

sulfides and sulfoxides to sulfones, and oxidatively cleaves the cyclohexen-1-one ring to the 3-alkyl and 3-alkyl-3-OH substituted pentanedioic acids, which are derivatized to their corresponding dimethyl esters (DME and DME-OH). The derivatives are quantitated by gas chromatography using a flame photometric detector operated in the sulfur mode (Barcode D241704, Memo, D. Dotson, 12/19/97). For concurrent method validation, canola samples were fortified at levels of 0.05 ppm and 0.20 ppm for mature canola seed, meal and crude oil, and at levels of 0.06 ppm, 0.10 ppm and 0.5 ppm for canola, oilseed and oil. The recovery data for canola seeds and its processed commodities are summarized in Table 6.

Table 6. Recovery of clethodim from canola, rape, and processed products

Trial	Country	Commodity	Fortification Metabolite and (Recovery Analyte)	(Number) Fortification Levels	Recovery DME (%)	Recovery DME-OH (%)
170G	Canada	mature canola seed (milled)	CSO (DME), 5OH-CSO_2 (DME-OH)	(4) 0.05 (5) 0.20	107.7-145.8* 67.6-102.8*	124.3-178.3* 107.3-134.1*
170G	Canada	No recovery data was provided from Mann Laboratories for 1988 trials.				
170E	Canada	mature canola seed (ground)	CSO (DME), 5OH-CSO_2 (DME-OH)	(1) 0.05 (2) 0.20	100* 96.9-125.2*	97* 111.9-124.4*
		Desol. Canola Meal		(1) 0.05 (1) 0.20	285.4* 258.5*	124.8* 97.8*
		Crude Canola Oil		(1) 0.05 (1) 0.20	76.4* 83.7*	78* 94.9*
170F	Canada	Canola Meal (reanalysis of meal from 170E)	CSO (DME), 5OH-CSO_2 (DME-OH)	(1) 0.10	127.4*	131.0
170D	Canada	Canola	clethodim and metabolites (unspecified)	(4) 0.10	66-76 (unspecified metabolites)	
171U	France	Oilseed Rape	clethodim	(1) 0.06 (4) 0.10	120 (as DME &DME-OH) 114-125 (as DME &DME-OH)	
171V	France	Oilseed Rape	clethodim	(7) 0.06 (6) 0.1 (2) 0.5	83.3-110(as DME &DME-OH) 65-97 (as DME &DME-OH) 90-90.6 (as DME &DME-OH)	
		Oil		(1) 0.6 (1) 0.1	101.7 (as DME &DME-OH) 138 (as DME &DME-OH)	
195X	Great Britain	Winter rape seed	not specified/ assume clethodim	not specified	112 (as DME &DME-OH)	

*Data corrected for clethodim recovery in control sample.

HED Comments/Conclusions:

The method RM-26B-3 (a modification of RM-26B-2) was validated for potatoes, processed potato commodities, sugar beets and sunflowers at fortification levels of 0.2 ppm, 0.5 ppm, 1.0 ppm, 2.0 ppm and 5.0 ppm. Average recoveries for most potatoes, sugar beets, sunflowers and their processed commodities were within the acceptable range at all fortification levels tested. The common moiety method (RM-26B-3) for the determination of clethodim and its metabolites in potatoes, sugar beets, sunflowers and their processed commodities is acceptable for data collection and enforcement purposes.

The common moiety method RM-26B-3 for the determination of clethodim and its metabolites is similar to the method RM-26B-2. The method RM-26B-2 has previously undergone a successful Petition Method Validation by the Agency (PP#9F3734, MRID 41389901, M. Nelson, 5/4/90), and A confirmatory method, EPA-RM-26D-2 is also available.

The analyses of canola seeds and its processed commodities by RM-26-A1 were not successfully validated. Recoveries for canola with method RM-26A-1 tended to vary among laboratories with some high recoveries 178.3% for canola seeds and as high as 285.4% for canola meal. Subsequent reanalysis of the desolventized meal had a recovery of 131%. Recoveries for canola seeds and its processed commodities were higher than the Agency's acceptable range. Therefore, HED requires a new or revised analytical method for the analyses of canola seeds and its processed commodities.

OPPTS GLN 860.1340: Analytical Methods - Animals

The analytical method for clethodim tolerances in animal products is the compound specific residue analytical method, EPA-RM-26D-2, "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, and Milk and Eggs" (MRID#429245-02). This method distinguishes clethodim residues from residues of the structurally similar herbicide Poast®, which contains sethoxydim as the active ingredient. The registrant has revised and rewritten this compound specific method as ACB has suggested and has included additional modifications from subsequent method development. This method has successfully completed a Petition Method Validation (PMV) in EPA Laboratories (F. Griffith's memo of 9/29/93). This method has been shown to be suitable to be a quantitative procedure to enforce the total clethodim tolerances in crops and animal tissues and is a qualitative confirmatory method for total clethodim tolerances in milk (F. Griffith's memo of 9/29/93) (PP# 4F4340, D203378, J. Morales, 2/8/95).

HED Comments and Conclusions:

Adequate analytical methodology is available to enforce tolerances for residues of clethodim in animal commodities. The Agency has concluded that the compound specific method, EPA-RM-26D-2, is suitable for enforcement of tolerances for the total clethodim residue in crops and animal tissues, and it has been forwarded to FDA for publication in the Pesticide Analytical Manual, Volume II (PAM II).

OPPTS GLN 860.1360: Multiresidue Method

The petitioner has determined recoveries of clethodim, clethodim sulfoxide, and 5-OH clethodim

sulfone under FDA's multiresidue protocols (PP#9F3743, M. Nelson's memo of 3/12/90). Specific tests of protocols were submitted and forwarded to FDA for review (PP# 4F4340, D203378, J. Morales, 2/8/95).

OPPTS GLN 860.1380: Storage Stability Data -Plants

Potatoes

Adequate storage stability data have been provided for potatoes, potato wet peel, dry peel, flakes and chips. Potato and its processed commodities were stored frozen for up to 6 months before analysis. Storage stability data have been submitted (MRID 43757704), and data showed that potatoes and its processed commodities are stable up to six months under frozen condition (see Table 7).

Table 7. Storage stability of clethodim residues in potatoes and potato processed commodities.

Commodities	Storage Days	% Fresh Recovery (ppm)	
		DME	DME-OH
Potato tubers	0	76.4	68.5
	205	101	81.7
Wet peel	0	77.2	66.6
	180	88.2	82.3
Dry peel	0	83.2	67.6
	180	102	95.2
Flakes	0	86.4	89.4
	189	87.8	75.7
Chips	0	93.8	82.2
	189	92.8	78.7

Data from MRID 43757704

Sugar Beets

Adequate storage stability data have been provided for sugar beets. Freezer storage stability data for sugar beets were reviewed (PP# 4F4340, D211445, F.D. Griffith, 2/13/95). The storage stability data showed total clethodim residues (clethodim, and its sulfoxide and sulfone plus the 5-OH metabolites) are stable at -20°C in sugar beets for 12 months The previously submitted sugar beet tops were stored for 273 days and the roots for 346 days. In the current field trial the longest interval prior to analysis was 118 days for tops or roots. The existing data support the current sugar beet trials. No storage stability data are required for the processed fractions of sugar beets, because the processed fractions were analyzed within 2 weeks of their generation (PP#4F4340, D203378, J.

Morales, 1/31/95).

Sunflowers

Storage stability data are adequate to support magnitude of residue studies in/on sunflower seeds. Sunflower seed samples were stored up to 5 months before analysis. The storage stability of clethodim residues in sunflowers was assessed by reanalysis of field treated samples over time (weathered residues) with correction for fresh fortification and recovery. The initial analysis of the samples occurred on day 57 after harvest and the second analysis occurred on day 154. The sunflower samples in the field trials were extracted 57 to 122 days after harvest. No specific frozen storage temperatures were stated. The stability of clethodim residues in soybeans and cottonseed in frozen storage, also oilseed crops, has been established to be at least 6 months (PP#9F3743, M. Nelson, 5/12/1990). The reanalysis values for the treated sunflower seeds is given in Table 8.

Table 8. Storage stability of weathered clethodim residues in sunflower seeds.

Sample	Storage Days	Residue (ppm)		% Fresh Recovery		% Apparent Recovery /Stored[a]		% Corrected Recovery /Stored[b]	
		DME	DME-OH	DME	DME-OH	DME	DME-OH	DME	DME-OH
B-2	57	2.80	1.18	88.4	78.6	--	--	(3.17)[c]	(1.50)[c]
B-3	57	3.06	1.32			--	--	(3.46)	(1.68)
B-2	154	3.07	1.09	104	73.6	110	92.4	93.1	98.7
B-3	154	2.86	1.07			93.5	81.1	79.5	86.3

[a] 100 X (day 154 ppm found)/(day 57 ppm found)

[b] 100 X (day 154 ppm found corrected for % fresh recovery)/(day 57 ppm found corrected for fresh recovery)

[c] Numbers in () are reported for day 57 samples corrected for fresh recovery.

No storage stability data are required for sunflower oil and meal, because the samples of sunflower oil and meal were analyzed within 2 weeks after sample collection.

Canola

Storage stability data are adequate to support magnitude of residue studies in/on canola seeds and inadequate to support canola meal and oil. Samples of canola seeds, canola meal and canola oil were stored for up to five months. No storage stability data for canola seeds, canola meal, and canola oil were submitted with this petition. However, six month storage stability studies were conducted for soybeans and cottonseeds which indicated that residues of clethodin were stable for up to six months (PP#9F3743, MRID 41030220 & 41030213, M. Nelson, 4/16/1990). The storage stability data of soybeans and cottonseeds can be translated to canola seeds.

HED Comments and Conclusions:

The existing storage stability data are adequate to support potatoes, sugar beets, sunflower seeds, canola seeds and their processed commodities. However, storage stability data are not available to support canola meal and canola oil. For future submissions, the petitioner should provide storage stability data for canola meal and canola oil.

OPPTS GLN 860.1500: Crop Field Trials

Potatoes

Twelve potato field trials were conducted in regions I (1), II (1), III (1), V (3), X (1), and XI (5) [i.e., New York (1), North Carolina (1), Florida (1), Minnesota (1), Wisconsin (1), North Dakota (1), California (1), Idaho (3), Oregon (1), and Washington (1)]. The field trials results are reported in :

> MRID 443234-01. Lai, J.C. (1996) Magnitude of Clethodim Residues in Potatoes, Tubers and Processed Parts (1995). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11123, May 1, 1996. 2 Volumes, Unpublished.

All trials were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X). The first application was 44 days preharvest and the second application was 30 days prior to harvest. The spray volume for the trials was between 16.6 and 21.7 gallons per acre (GPA) and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. Mature tubers were sampled by hand from at least 4 randomly located plants across the plot for a total sample consisting of 16 tubers.

Total clethodim residues were reported as DME and DME-OH and ranged from <0.2 ppm (the LOD) to 0.80 ppm. The highest average field trial value is 0.78 ppm. The residue data for potatoes are summarized in Table 9.

Table 9. Clethodim residues in potato tubers reflecting treatment with Select 0.94EC and a 30 day preharvest intervals.

Test ID	State	lb ai/A per application (includes crop oil concentrate at 1%)	ppm Found converted to Clethodim		
			DME	DME-OH	Total
A	NY	0.25-0.26	0.17, 0.17	0.15, 0.16	0.32, 0.33
B	NC	0.25	0.20, 0.13	0.13, 0.10	0.33, 0.23
C	FL	0.25	0.19, 0.20	<0.10, 0.10	0.24, 0.30
D	WI	0.25	<0.10, <0.10	<0.10, <0.10	<0.20,<0.20
E	MN	0.24-0.25	0.33, 0.31	0.23, 0.18	0.56, 0.49
F	ND	0.25	0.46, 0.50	0.29, 0.30	0.75, 0.80
G*	CA	0.21-0.22	<0.10, <0.10	<0.10, <0.10	<0.2, < 0.2
H	OR	0.25	<0.10, <0.10	<0.10, <0.10	<0.2, <0.2
I	WA	0.25	0.32, 0.38	0.18, 0.21	0.50, 0.59
J	ID	0.25	0.42, 0.33	0.26, 0.24	0.68, 0.57
K	ID	0.25-0.27	0.21, 0.19	0.14, 0.11	0.35, 0.30
M	ID	0.25	0.13, 0.14	<0.10, <0.10	0.18, 0.19

Data from MRID 443234-01, pp. 24-25.
*Trial G had two deviations from the protocol: lower application rates and freezer temperatures that rose above 32°F.

HED Comments/Conclusions:

The submitted field trial data and geographic representation for potatoes are not adequate to satisfy the data requirement described in OPPTS 860.1500. The OPPTS guideline indicates that sixteen potato field trials are required and the field trials should be conducted in Regions I (2), II (1), III (1), V (4), IX (1), X (1) and IX (6). Only twelve potato field trials were conducted in Regions I (1), II (1), III (1), V (3), X (1), and XI (5). All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X). The first application was 44 days preharvest; the second application was 30 days prior to harvest. The spray volume for the trials was between 16.6 and 21.7 gallons per acre (GPA). The spray included a tank-mixed crop oil concentrate at 1% v/v of the final spray. The combined residues of DME and DME-OH ranged from <0.2 ppm (the LOD) to 0.80 ppm which support the proposed tolerance at 1.0 ppm for Tuberous and Corm Vegetables (Crop Subgroup 1-C). However, four additional field trials which need to be conducted in Regions I (1), V (1), IX (1) and XI (1) must be submitted.

Sugar Beets

Twelve field trials for sugar beets were conducted in Regions V (5), VII (1), VIII (1), IX (1), X (2), and XI (2) [i.e., Michigan (1), Minnesota (2), North Dakota (2), Wisconsin (1), Texas (1), Colorado (1), California (2), and Idaho (2)] to support the application to amend the Select® 0.94 EC Herbicide product label for sugar beets. The field trial results are reported in:

> MRID 447532-06. Lai, J.C., (1998) Magnitude of clethodim residues in sugar beet raw agricultural commodities (1977). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11722, April 13, 1998. 4 Volumes, Unpublished.

The distribution and number adequately meet the needs for a nationwide tolerance petition for a change in the PHI for clethodim use on sugar beets. The trials used different varieties of sugar beets, which were all treated two times with Select® 0.94EC by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X). The spray volume for the trials ranged between 11.8-25.2 gal/A and all trials used a tank-mixed crop oil adjuvant at 1% v/v to the final volume. The first application was approximately 54 days preharvest and the second was 14 ± 1 days following the first. Harvest occurred 39-42 days after the last application. The protocol specified a minimum of 14 days between the applications and this is within the label recommendations. Mature sugar beets were sampled by hand from at least 12 random locations across the plot. Tops were removed in the field by cutting through the top 1/4" of beet crown. The samples for analysis consisted of a composite sample from all roots which had been cut in quarters or sixths or a composite of the tops. The protocol stated that the dirt could be knocked off the beets but in trials C, D, E, and F a brush was used to remove dirt from the beet roots. The samples were frozen within 4 hours and sent to the Valent Technical Center, Dublin, CA for analysis.

Clethodim residues were measured as DME or DME-OH in sugar beets. Clethodim residues were below the limit of detection (<0.1 ppm) in all sugar beet root trials. The residues in sugar beet top samples ranged from <0.1 ppm to 0.88 ppm. The highest residue in sugar beet tops was 0.88 ppm. Table 10 contains a summary of the residues in/on sugar beet roots and Table 11 contains a summary of the residues in/on sugar beet tops.

Table 10. Summary of Maximum Residue Data for Clethodim as DME and DME-OH in/on Sugar Beet Roots (ppm), treated 2 x 0.25 lb ai/A with Select® 0.94 EC

Trial/State	PHI (days)	lb ai/A per application	Clethodim as DME (ppm)	Clethodim as DME-OH (ppm)	Clethodim (ppm)
A-WI	41	0.25	<0.1[a]	<0.1	<0.2
B-MI	40	0.25	<0.1	<0.1	<0.2
C-MN	42	0.25	<0.1	<0.1	<0.2
D-MN	42	0.25	<0.1	<0.1	<0.2
E-ND	39	0.25-0.26	<0.1	<0.1	<0.2
F-ND	40	0.25	<0.1	<0.1	<0.2
G-TX	40	0.25-0.26	<0.1	<0.1	<0.2
H-CO	40	0.25-0.26	<0.1	<0.1	<0.2
I-CA	40	0.24-0.25	<0.1	<0.1	<0.2
J-CA	40	0.25	<0.1	<0.1	<0.2
K-ID	40	0.24-0.25	<0.1	<0.1	<0.2
L-ID	40	0.25-0.26	<0.1	<0.1	<0.2

[a] <LOD (<0.1 ppm for all compounds)

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Table 11. Summary of Maximum Residue Data for Clethodim as DME and DME-OH in/on Sugar Beet Tops (ppm), treated 2 x 0.25 lb ai/A with Select® 0.94 EC					
Trial/State	PHI-days	lb ai/A per application	Clethodim as DME (ppm)	Clethodim as DME-OH (ppm)	Total Clethodim (ppm)
A-WI	41	0.25	<0.10[a], <0.10	<0.10, <0.10	<0.2, <0.2
B-MI	40	0.25	0.54, 0.54	0.13, 0.11	0.67, 0.65
C-MN	42	0.25	0.27, 0.37	<0.10, <0.10	0.32, 0.42
D-MN	42	0.25	0.24, 0.35	<0.10, <0.10	0.29, 0.40
E-ND	39	0.25-0.26	0.33, 0.27	<0.10, <0.10	0.38, 0.32
F-ND	40	0.25	0.73, 0.65	0.15, 0.16	0.88, 0.81
G-TX	40	0.25-0.26	0.28, 0.22	<0.10, <0.10	0.33, 0.27
H-CO	40	0.25-0.26	0.23, 0.19	<0.10, <0.10	0.28, 0.24
I-CA	40	0.24-0.25	0.34, 0.37	<0.10, 0.10	0.39, 0.47
J-CA	40	0.25	0.48, 0.41	0.11. 0.12	0.59, 0.53
K-ID	40	0.24-0.25	0.28, 0.41	<0.10, 0.11	0.33, 0.52
L-ID	40	0.25-0.26	<0.10, <0.10	<0.10,<0.10	<0.2, < 0.2

[a] <LOD (<0.10 ppm for all compounds)

HED Comments/Conclusion:

Provided a revised Section B/label is submitted, the submitted field trial data and geographic representation for sugar beets are adequate to satisfy the data requirement described in OPPTS 860.1500. Twelve sugar beet field trials were conducted in regions V (5), VII (1), VIII (1), X (2), IX (1), and XI (2). The crops in each trial were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X) and all used a tank-mixed crop oil adjuvant at 1% v/v to the final volume. The first application was approximately 54 days preharvest and the second was 14 ± 1 days following the first. Harvest occurred 39-42 days after the last application. Clethodim residues were measured as DME or DME-OH. The combined residues were below the limit of detection (<0.2 ppm) in all sugar beet root trials. The residues in sugar beet top samples were ranged from <0.2 ppm to 0.88 ppm. The proposed tolerance of 1.0 ppm for sugar beet tops is adequate. However, a revised Section F must be submitted proposing a tolerance at 0.2 ppm for sugar beet roots.

Sunflowers

Valent U.S.A. Corporation submitted data from 8 sunflower crop field trials conducted in Regions V (4), VII (3) and VIII (1) [i.e., Illinois (1), Minnesota (1), Missouri (1), Nebraska (2), North Dakota (1), Texas (1), and Wyoming (1)] to support their application to amend the Select® 0.94EC and Select® 2EC Herbicide product labels to include uses on sunflowers. The field trials results are reported in:

MRID 443234-02. Lai, J.C. (1996) Magnitude of Clethodim Residues in Sunflowers- Seeds and Processed Parts. Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11186, May 1, 1996. 2 Volumes, Unpublished.

All trials were conducted in 1995 and a total of 5 different varieties of sunflower were used. All crops were treated two times with Select® 0.94 EC (also known as Prism) by ground spray application of 0.25 lb ai/A for a total application of 0.5 lb ai/A/season (1X). Two additional trials were conducted with exaggerated rates of application one using two treatments of 0.48-0.51 lb ai/A (2X) and the second using two treatments of 1.19-1.30 lb ai/A (5X). The first application was 70-86 days preharvest (or 30-40 days after emergence); the second application was 14 days later at 56-72 days prior to harvest. The spray volume for the trials was between 18.8 and 20.8 gallons per acre (GPA) and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. Mature flower heads were sampled by combining at least 12 randomly located plants across the plot for a total sample consisting of at least 2.5 pounds. In several trials the entire plot except the outside edges was harvested and a sample was collected from the entire harvest. The moisture content of the seeds was to be less than 14% according to the protocol but for three trials no actual moisture determination was indicated. For two of the studies the moisture content of sunflowers from nearby fields was taken and found to be acceptable. For the other study the seeds were noted to be small and inferior quality and, therefore, probably had low moisture content. The samples were frozen promptly and sent to the Valent Technical Center in Dublin, CA for analysis. Whole sunflower seeds were macerated in a Hobart mixer prior to analysis.

Total clethodim residues were reported from the analysis of DME and DME-OH. Total detected residues ranged from 0.46 ppm to 4.4 ppm and support the proposed tolerance of 5.0 ppm in sunflower seeds. Concurrent recovery studies from fortified controls validated the methods. Table 12 contains a summary of the residues in/on sunflower seeds. The highest average field trial value is 4.2 ppm for trial B. The results from the trials using exaggerated application rates are shown in Table 13. The results show a proportional response between application rate and residue in/on the sunflower seeds.

Table 12. Clethodim residues in/on sunflower seeds treated twice with Select® 0.94EC at 0.25 lb ai/A/ application.

Test ID	State	PHI (days)	lb ai/A per application (includes crop oil concentrate at 1%)	ppm Found as Clethodim		
				DME	DME-OH	Total
A	IL	56	0.25	0.35, 0.33	0.39, 0.40	0.74, 0.73
B	MN	66	0.24-0.25	2.8, 3.1	1.2, 1.3	4.0, 4.4
C	NE	69	0.24	0.31, 0.37	0.39, 0.48	0.70, 0.85
D	WY	70	0.25-0.26	0.63, 0.74	0.46, 0.68	1.1, 1.4
E	NE	70	0.25	0.68, 0.68	0.43, 0.43	1.1, 1.1
F	TX	70	0.25	0.38, 0.38	0.24, 0.26	0.62, 0.64
G	MO	69	0.25-0.26	0.34, 0.31	0.18, 0.15	0.52, 0.46
H	ND	72	0.24-0.26	2.5, 2.5	1.2, 1.3	3.7, 3.8

Data from MRID 443234-02, pp. 23-24.

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Table 13. Clethodim residues in/on sunflower seeds treated with two applications of Select® 0.94EC using normal and exaggerated application rates.						
Test ID	State	PHI days	lb ai/A per application (includes crop oil concentrate at 1%)	ppm Found as Clethodim		
				DME	DME-OH	Total
G	MO	69	0.25-26	0.34, 0.31	0.18, 0.15	0.52, 0.46
G	MO	69	0.48-51	0.55, 0.74	0.25, 0.26	0.80, 1.0
H	ND	72	0.24-0.26	2.5, 2.5	1.2, 1.3	3.7, 3.8
H	ND	72	1.19-1.30	12.0, 14.0	5.9, 7.8	18.0, 22.0

Data from MRID 443234-02, pp. 23-24.

HED Comments/Conclusion:

Provided a revised Section B/label is submitted, the submitted field trial data and geographic representation for sunflower seeds are adequate to satisfy the data requirement described in OPPTS 860.1500. Eight sunflower field trials were conducted in regions in Regions V (4), VII (3) and VIII (1). Crops in each trial were treated two times with Select® 0.94 EC by ground spray application of 0.25 lb ai/A for a total of 0.5 lb ai/A/season (1X). The first application was 70-86 days preharvest (30-40 days after emergence) and the second application was 56-72 days prior to harvest. The spray volume for the trials was between 18.8 and 20.8 GPA and included a tank-mixed crop oil concentrate at 1% v/v of the final spray. All clethodim residues were measured as DME or DME-OH. Clethodim residues ranged from 0.46 ppm to 4.4 ppm which supports the proposed tolerance of 5.0 ppm for sunflower seeds.

Canola/Rapeseeds

Valent U.S.A. Corporation has submitted data from six reports (containing multiple trials) of clethodim used on canola or rape from Canada, France and Great Britain. Valent has secured and submitted these studies at the request of EPA to propose a U.S. tolerance for canola based on Canadian data. Valent did not oversee or perform the field trials or laboratory analysis of any of these trials and has obtained the data from Tomen Agro, Inc. and Rhone Poulenc. These studies are summarized in

> MRID 443933-01. Bruce, E.D. (1996) Magnitude of Clethodim Residues in Rapeseed (Including Canola), Commodities: Seed, Meal and Oil. Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596. Laboratory ID: EDB.896, August 28, 1996. 3 Volumes, Unpublished.

Report 170-G provides information for four residue trials conducted in Canada in 1989. At each site four rate and adjuvant combinations were tested. The test sites in Canada were in Saskatchewan (2 at same location) and Alberta (2 locations). Trials were conducted using the Select® 2EC formulation. The treatments consisted of a single application of 0.054 lb ai/A (60 g ai/ha) or one application of 0.11 lb ai/A (120 g ai/ha) on the same day with adjuvant CC16255 (0.5% v/v) 70-103 days prior to harvest. The alternate treatments were a single application of 0.094 lb ai/A (105 g

ai/ha) or one application of 0.19 lb ai/A (21 g ai/ha) with a corn oil adjuvant (1% v/v) 70-103 days prior to harvest. The application volumes and methods were not specified and agricultural conditions were not described. Two varieties of canola were used in both provinces. Analyses were performed by Huntingdon Analytical Services, Middleport, NY. The results of the 1989 Canadian trials are given in Table 14.

Table 14. Clethodim residues in/on canola treated with Select 2EC (Canada, 1989)

Trial	Location	PHI days	lb ai/A per application	Adjuvant	ppm Found as Clethodim		
					DME	DME-OH	Total
1	Speers, Saskatchewan	70	0.054	CC16255	<0.05,<0.05	0.108, .098	0.13, 0.12
			0.11		0.072, <0.05	0.247, 0.101	0.32, 0.13
			0.094	Corn Oil	0.050, 0.069	0.157, 0.217	0.21, 0.29
			0.19		<0.05,<0.05	0.10, 0.152	0.13, 0.18
2	Speers, Saskatchewan	70	0.054	CC16255	0.056, 0.124	0.139, 0.192	0.20, 0.31
			0.11		0.104, 0.86	0.250, 0.214	0.35, 0.30
			0.094	Corn Oil	0.051, 0.065	0.104, 0.135	0.16, 0.20
			0.19		0.189,0.145	0.352, 0.322	0.54, 0.47
3	Indus, Alberta	103	0.054	CC16255	<0.05,<0.05	<0.05,<0.05	<0.1,<0.1
			0.11		<0.05,<0.05	<0.05,<0.05	<0.1,<0.1
			0.094	Corn Oil	<0.05,<0.05	<0.05,<0.05	<0.1,<0.1
			0.19		<0.05,<0.05	<0.05,<0.05	<0.1,<0.1
4	Olds, Alberta	86	0.054	CC16255	<0.05, 0.060	<0.05, <0.05	<0.1, 0.09
			0.11		0.064, 0.055	<0.05,<0.05	0.09, 0.08
			0.0994	Corn Oil	0.065, 0.054	<0.05,<0.05	0.09, 0.08
			0.19		<0.05,<0.05	<0.05,<0.05	<0.1,<0.1

Data from MRID 443933-01, pp. 7, 21.

Results are also presented for a 1988 study which used only the 0.094 lb ai/A and 0.19 lb ai/A treatments with 1% corn oil adjuvant and ammonium sulfate (Table 15). The analyses for these trials were performed by Mann Testing Laboratories. These studies were performed in Ontario, Manitoba, Saskatchewan, and Alberta, Canada. The residue levels ranged from <0.05 ppm to 0.14 ppm for both the 0.094 and 0.19 lb ai/A treatments. The individual metabolite values were not reported in this document but the original source citation was provided.

Table 15. Clethodim residues in/on canola treated with Select 2EC with corn oil or corn oil and ammonium sulfate as adjuvants (Canada, 1988)					
Trial	Location	PHI days	Treatment lb ai/A per season	Adjuvant	Clethodim Residue Total ppm
1	Guelph, Ontario	58	0.094	COC	<0.05, 0.07
			0.19	COC	<0.05
			0.094	COC+AS	0.09, 0.09
			0.19	COC+AS	<0.05
2	Birch Hills, Saskatchewan	70	0.094	COC	<0.05,<0.05
			0.19	COC	<0.05, 0.07, 0.14
			0.094	COC+AS	<0.05,<0.05,<0.05,<0.05
			0.19	COC+AS	0.09, <0.05, <0.05
3	Carman, Manitoba	78	0.094	COC	<0.05,<0.05
			0.19	COC	<0.05
			0.094	COC+AS	<0.05,<0.05
			0.19	COC+AS	<0.05
4	Indus, Alberta	87	0.094	COC	<0.05, <0.05, 0.06
			0.19	COC	<0.05,<0.05, 0.13
			0.094	COC+AS	0.14, 0.14, <0.05
			0.19	COC+AS	<0.05

Data from MRID 443933-01, pg. 23.

Report 170D contains the results of three crop field trials conducted in Manitoba, Canada in 1986. The samples were analyzed by Mann Testing Laboratories, Inc. (address unknown). The trials used a single application of Select® 2EC at three different rates 0.08, 0.10 and 0.21 lb ai/A (90, 120, 240 g ai/ha). The spray volume is 125 L/ha. Only the 0.10 and 0.21 lb ai/A treatments were analyzed. The use of adjuvants or crop oils is not discussed and is not noted on the sample submission forms. The samples were noted to have higher moisture content than recommended for commercial harvest. The results are given in Table 16. Total values that were not detected are given as being less than LOD for either metabolite.

Table 16. Clethodim residues in/on canola treated with Select® 2EC (Canada, 1986)							
Trial	Location	PHI days	lb ai/A per application	Adjuvant	ppm Found as Clethodim		
					DME	DME-OH	Total
1	Miami, Manitoba	74	0.10	Not stated	0.06	<0.05	0.09
			0.21		0.05	<0.05	0.1*
2	Mariapolis, Manitoba	86	0.10	Not stated	<0.05	<0.05	<0.1
			0.21		<0.05	<0.05	<0.1
3	Treherne, Manitoba	75	0.10	CC16255	<0.05	<0.05	<0.1
			0.21		<0.05	<0.05	<0.1

Data from MRID 443933-01, pp. 755-775.
*Summary data sheet does not record this as measurable value. Laboratory data sheet does list it as such.

Reports 171U and 171V are the results of field trials in oil seed rape conducted in 1986 and 1987 in France and analyzed at RCC Umweltchemie AG, Itingen, Switzerland. The application rate was 0.16 to 0.86 lb ai/A (180-960 g ai/ha) and no adjuvant is specified. Application volume for most trials was 400 L/ha. The harvest intervals are long because the applications were made in the fall and the harvest occurred the following summer. The analytical method RUE/27/87 was taken from PAM II, Sec.180.412. The results are presented in Table 17. Only the 0.16 lb ai/A application supports the tolerance and label use. The very long PHIs for winter rape are not applicable to canola uses.

Table 17. Total Residue (ppm Clethodim) in Rape Seed from 1986 Trials in France						
Trial	Location	Application Rate (lb ai/A)	PHI (days)	DME	DME-OH	Total Clethodim
TE-2210	Azay-sur-Cher	0.32	98	<0.03, <0.03	0.049, 0.038	0.06, 0.05
TE-2211	Fontaine-Denis	0.16	253	<0.03, <0.03	<0.03, <0.03	<0.06, <0.03
		0.32	253	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
TE-2212	Licy-Clingnon	0.16	126	<0.03, <0.03	<0.03, 0.049	<0.06, 0.06
			305	<0.03, <0.03	0.055, 0.053	0.07, 0.07
TE-2213	Reugny	0.16	248	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32	248	0.030, <0.03	0.054, 0.031	0.07, 0.05
TE-2214	Réveillon	0.16	117	<0.03, <0.03	0.091, 0.064	0.11, 0.08
			299	<0.03, <0.03	0.073, 0.087	0.09, 0.10
TE-2215	Ville Gongis	0.16	253	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32	253	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
TE-2225	Voué (Vué)	0.16	108	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
			283	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06

		.032	283	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.43	108	<0.03, <0.03	0.63, 0.084	0.066, 0.10
			283	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
TE-2226	Levroux	0.16	106	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
			267	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32	106	<0.03, <0.03	0.114, 0.063	0.13, 0.08
			267	<0.03, <0.03	0.032, 0.048	0.05, 0.06
		0.43	106	<0.03, <0.03	0.069, 0.099	0.08, 0.11
			267	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.86	106	0.047, 0.065	0.121, 0.112	0.168, 0.177
TE-2227	Azay-sur-Cher	0.16	107	<0.03, <0.03	<0.03, 0.054	<0.06, 0.07
			268	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32	107	0.038, <0.03	0.070, 0.032	0.108, 0.05
			268	0.052, <0.03	0.076, <0.03	0.128, <0.06
		0.43	107	<0.03, <0.03	0.04, 0.04	0.06, 0.06
			268	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.86	107	0.044, 0.065	<0.03, 0.037	0.06, 0.10
TE-2228	Fontaine-Denis	0.16	288	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32		<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.43		<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
TE-2229	Bléré	0.16	268	<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.32		<0.03, <0.03	<0.03, <0.03	<0.06, <0.06
		0.43		<0.03, <0.03	<0.03, <0.03	<0.06, <0.06

Data from MRID 443933-01, pp. 10, 12, 790-827, 843-892.

Report 195X contains information for three residue trials for winter rape grown in Great Britain from 1987 to 1988. The trials used one application of clethodim at 0.32 or 0.64 lb ai/A (1.5 or 3 L/ha of 240g/L formulation) The adjuvant is not specified. The long PHIs are due to planting and application in the fall and harvest the following spring. Analyses were conducted at RCC-Umwelchemie AG, Switzerland. All residues were not detectable. The data are presented in Table 18. The data are not applicable to canola tolerances or PHIs.

Table 18. Total Residues (ppm Clethodim) in Rape Seed from 1988 trials in Great Britain				
Report No.	Location	Application Rate (lb ai/A)	PHI (days)	Clethodim (ppm)
0428-88	Gt. Green, Thurston, Suffolk	0.32	258	<0.06
0429-88	Humby Hall, Ingoldsby, Lincolnshire	0.32	294	<0.06
0551-88	Humby Hall, Ingoldsby, Lincolnshire	0.64	294	<0.06

Data from MRID443933-01, pp. 14, 894-908

HED Comments/Conclusion:

The submitted field trial data and geographic representation for canola are inadequate to satisfy the data requirement described in OPPTS 860.1500. The petitioner has submitted canola/rapeseed field trial data which were conducted in Canada, France and Great Britain. Only six field trials from Canada are acceptable. The submitted field trial data from France and Great Britain are not acceptable. The analytical method RM-26A-1, which was used to analyze canola seeds and its processed commodities in this petition was not successfully validated; therefore, HED requires new canola field trials. According to OPPTS 860.1500, eight canola field trials should be conducted in Regions II (1), V (2), VII (2) XI (3); and the field trial data should reflect the proposed use including the PHI.

OPPTS GLN 860:1520: Processed Food/Feed

The petitioner has submitted the following data pertaining to the magnitude of celethodim residues in/on potatoes and potato processed commodities. These data are included in this review of the permanent tolerance petition:

> MRID 443234-01. Lai, J.C. (1996) Magnitude of Clethodim Residues in Potatoes, Tubers and Processed Parts (1995). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11123, May 1, 1996. 2 Volumes, Unpublished.

Russet Burbank potatoes were grown in Idaho and treated with two applications of Select® 0.94EC at the rate of 1.25-1.26 lb ai/A per application (5X). This rate is consistent with the recommendation of HED (D2603582, 5/25/94). Clethodim was tank mixed with 1% crop oil. The two treatments were separated by 14 days and harvest occurred 30 days after the last treatment. The potatoes were delivered fresh to William Englar and Associates, Moses Lake, Washington for processing to flakes, chips and wet peel. Processing at William Englar and Associates was conducted using Good Laboratory Practices and commenced within 3 days of receipt of the potatoes.

In the processing of potatoes for chips, the potatoes were washed by hand in a wash tub and a sugar analysis was taken of the potato. The washed potatoes were batch peeled in a mechanical abrasive peeler leaving a small amount of peel on the potato. The peeled potatoes were inspected and

trimmed by hand to remove rot or green tissue. The peeled potatoes were sliced into ~0.16 cm (~1/16") slices using an electric slicer. The sliced potatoes were placed in warm water to remove starch, drained and fried in ~181 °C oil for 90 seconds. The chips were drained and salted by hand. The chips passed through a final inspection and undesirable chips were removed. Samples of the chips were packaged, labeled, and frozen.

For the processing of potato flakes, the potatoes were washed by hand in a wash tub, sorted and inspected. A specific gravity analysis was performed on the potatoes. The potatoes were peeled using a continuous batch steam peeler [5.6-6.0 kg/cm^2 (8-90 psi)] for 45-60 seconds. The peels loosened by the steam peeler were removed using a mechanical peeler fitted with rubber scrubbers for 30 seconds. The peel was hydraulically pressed to increase the solids content. Potatoes were inspected again and trimmed by hand to remove damaged tissue. The potatoes were cut into ~1/2"slabs using a food cutter/slicer and rinsed ~30 seconds in cold water to remove starch from the surface of the slices. The potatoes were precooked for 20 minutes in a batch steam jacketed kettle and cooled by running tap water into the kettle. The precooked slices were cooked at 94-100 °C for ~40 minutes using a free flowing steam batch cooker. The cooked potatoes were mashed using a meat grinder without the grinding attachment. The mashed potatoes were placed in a commercial mixer and typical commercial additives such as antioxidants were added with mixing. The potato mash was fed into a drum dryer where the mash was dried into a thin sheet followed by fluid bed drying if necessary to dry to flakes to less than 9% moisture. The sheets of potato were broken and fed into a hammermill to create uniform sized flakes. Samples of the flakes were packaged, labeled and frozen. Commercial waste flakes and defective flakes may be used for animal feed.

All analyses were conducted by Valent Technical Center, Dublin, California using method RM-26-B3. The method was validated by adequate recovery studies. The results for the processing study for potatoes are given in Table 19.

Table 19. Clethodim residues (ppm) in potato tubers and processed fractions after treatment with a total of 2.5 lb ai/A of Select 0.94EC.

Potato Fraction	Clethodim Total	Concentration Factor
Tubers (Unwashed sample collected at processing plant)	2.5	--
Wet Peel	1.4	0.56X
Granules/flakes	6.2	2.5X
Chips	1.2	0.48X

HED Comments/Conclusions:

The submitted potato processing data are adequate to satisfy the data requirement described in OPPTS 860.1520. The potato processing data indicate that residues of clethodim were not concentrated in potato wet peel and chips. However, residues of clethodim concentrated 2.5x in flakes. The HAFT residue from the current potato field trials reflecting the maximum proposed use pattern is 0.78 ppm. The expected residues in granules/flakes should be 1.95 ppm. The proposed tolerance of 2.0 ppm for potato granules/flakes is adequate.

Sugar Beets

No sugar beet processing studies were submitted with this petition. The petitioner previously submitted a report of residues resulting from the processing of sugar beets (PP# 4F4340, D203378, MRID# 431664-05, J. Morales, 2/8/95). The processing study for sugar beets has been reevaluated with this petition. The sugar beet field trial was conducted during 1990 in ND. Two applications of clethodim were made at the rate of 1.25 lbs. ai/A (5X). Sugar beets were processed into sliced roots, dehydrated pulp, molasses, and refined sugar. The petitioner stated that processed fractions were analyzed within 2 weeks of their generation. The results are in the Table 20.

Table 20. Clethodim Residues Found in Processed Fractions of Sugar Beets

Commodity	DME (ppm)[1]	DME-OH (ppm)[2]	Total (ppm)	Concentration Factor
Sugar Beet	<0.10	<0.10	<0.10	
Sliced Beets	<0.10	<0.10	<0.10	
Dehydrated Pulp	<0.10	<0.10	<0.10	
Refined Sugar	<0.10	<0.10	<0.10	
Molasses	0.24	<0.10	0.29	5.8X

1 and 2 - acronyms for the dimethyl esters of 3-[2-(ethylsulfonyl) propyl]pentanedioic acid and 3-[2-(ethylsulfonyl)propyl]-3-hydroxypentanedioic acid, respectively.

HED Comments/Conclusions:

The submitted sugar beet processing data are adequate to satisfy the data requirement described in OPPTS 860.1520. The processing study for sugar beets were reviewed (PP# 4F4340, D203378, MRID# 431664-05, J. Morales, 2/8/95); a tolerance of 2.0 ppm for sugar beet molasses was determined. However, the processing study for sugar beets are reevaluated with this petition. In the processing study, two applications of clethodim were made at the rate of 1.25 lbs. ai/A for a total of 2.50 lb ai/A/season (5X). Clethodim residues were <0.10 ppm in sugar beets, dehydrated pulp, refined sugar, and 0.29 ppm in molasses at 5X. The HAFT residue from the current sugar beet field trials reflecting the maximum proposed use pattern is 0.1 ppm. The residues in dehydrated pulp and refined sugar were not concentrated. Assuming a concentration of 0.1 ppm in sugar beet and the residues were concentrated 5.8X in molasses, the expected residues in molasses should be 0.6 ppm. Therefore, a revised Section F must be submitted amending the tolerance of sugar beet molasses from 2.0 ppm to 1.0 ppm.

Sunflowers

Processing studies were conducted for products from sunflowers grown near New Rockford, North Dakota in 1995. The results of the processing study are reported in:

> MRID 443234-02. Lai, J.C. (1996) Magnitude of Clethodim Residues in Sunflowers- Seed and Processed Parts. Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11186, May 1, 1996. 2 Volumes, Unpublished.

The sunflowers were mechanically harvested from plots that were treated at the 5x rate of 2.5 lb ai/A per season (i.e., 2 X 1.19-1.30 lb ai/A) with a 72 day PHI. The entire plot was harvested and the sunflower seed samples were collected from the combine bin. Sunflower seeds were shipped frozen to Texas A&M Food Protein Research and Development Center, Highway 21 West, Building 7180, Bryan, TX for processing to fractions that simulate commercial methods. The processing was conducted using GLP. In addition to samples of the unprocessed seeds, hull material, kernel, solvent extracted presscake (meal), crude oil, refined oil, and soapstock fraction were produced. Only seeds, hulls, meal, crude oil and refined oil were analyzed for clethodim residues. The processing methods varied from commercial methods in that small batches were used instead of continuous processes. Whole sunflower seeds were initially dried to between 7-10% moisture in a 130-160°F oven. The light debris was separated by aspiration and the sample was screen cleaned in a two-screen cleaner. The whole sunflower seed was fed into a disc mill to crack the hull and liberate the kernel. After hulling, the material was again aspirated to separate the hull and kernel. The kernel material was then conditioned to 12% moisture, heated to 190-220°F, and pressed in an expeller to liberate part of the crude oil. After pressing, the presscake is flaked in a flaking roll, placed in extractors and submerged in 120-140°F hexane. After 30 minutes of extraction, the hexane is drained and fresh hexane is added two more times. After the final removal of hexane, warm air is forced through the presscake to remove residual hexane. The hexane crude oil mixture is passed through a recovery unit to separate hexane and crude oil by heating to 163-194°F. Crude oil from the expeller and extraction is combined and refined (heated and mixed with NaOH), settled and separated to yield refined oil and soapstock. The processed samples were frozen and shipped to Valent Dublin Laboratories, Dublin, California (Valent Technical Center). The samples were analyzed within one week of receipt at the laboratory. The residues in sunflower processed products are presented in Table 21. The recoveries of clethodim and metabolites from sunflower seeds was acceptable and the recoveries from hulls, meal, crude oil, and refined oil ranged from 65.3 to 120%. There was only one recovery sample per processed fraction but they were generally acceptable.

Table 21. Clethodim and metabolite residues (ppm) in processed sunflower products treated at 5 X with 2.5 lbs ai/A (2 X 1.25 lb ai/A) and 72 day PHI .

Fraction	DME-as Clethodim	DME-OH as Clethodim	Total Clethodim	Concentration Factor
Sunflower seeds (field sample)	12, 14	5.9, 7.8	18, 22	--
Sunflower seeds (processing sample)	12, 10	5.9, 4.3	18, 14	--
Sunflower hulls	16, 12	7.6, 5.8	24, 18	1.3X
Sunflower meal	23, 23	10, 9.9	33, 33	2.1X
Crude sunflower oil	3.1, 2.8	0.38, 0.40	3.5, 3.2	--
Refined sunflower oil	<0.1, <0.1	<0.1, <0.1	<0.1, <0.1	--

Data from MRID ,pp. 426, 480-484

HED Comments/Conclusions:

The submitted sunflower seed processing data are adequate to satisfy the data requirement described

in OPPTS 860.1520. The sunflowers were treated with 2.5 lb ai/A per season (5X). Sunflower hulls are not a required processing commodity for sunflower. The residues in sunflower oil were not concentrated. However, the residues were concentrated 2.1X in sunflower meal. The HAFT from the current sunflower field trials reflecting the maximum proposed use pattern is 4.2 ppm. The expected residues should be 8.82 ppm in sunflower meal. Therefore, the proposed tolerance of 10 ppm for sunflower meal is adequate.

Canola/Rape Seeds

Processing studies were conducted for products from canola and rape seeds and results of the processing studies are reported in:

> MRID 443933-01. Bruce, E.D. (1996) Magnitude of Clethodim Residues in Rapeseed (Including Canola) Commodities :Seed, Meal and Oil. Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596. Laboratory ID: EDB.896, August 28, 1996. 3 Volumes, Unpublished.

These processing studies used canola or rape seeds that were grown in Canada or France. Reports 170E and 170F of the referenced MRID describe the field trials in Speers, Saskatchewan or Poplar Point, Manitoba. The fields were treated with 2.3-2.6 X the suggested label rate (0.19-0.21 lb ai/A) with a 67-75 day PHI. The harvest details were not provided but the samples were sent to Huntingdon Analytical Services, Middleport, New York for analysis prior to processing. The Saskatchewan sample had the highest residue so only frozen canola from that site was sent to the POS Pilot Plant Corp. in Saskatoon, Saskatchewan approximately 90 days after harvest. Of the twenty one fractions collected, only desolventized meal, crude canola oil, hydrogenated oil, deodorized hydrogenated oil, desolventized oil and spent clay were sent to the laboratory and only crude oil and desolventized meal results were reported. The results of the clethodim analysis for canola processed commodities is reported in Table 22.

Table 22. Clethodim and metabolite residues (ppm) in processed canola products treated at 2.6X the label rate with one treatment of .208 lbs ai/A and a 67 day PHI (Saskatchewan, Canada, 1989)

Fraction	DME-as Clethodim	DME-OH as Clethodim	Total Clethodim	Concentration Factor
Canola seed (preprocess sample)	0.077, 0.099, 0.067[a]	0.205, 0.230, 0.224	0.30	--
Desolventized canola meal	0.091, 0.103, 0.124[b]	0.355, 0.621, 1.008	0.77	2.5
Crude canola oil	<0.05	<0.05	<0.05	

[a] Data from triplicate samples
[b] Data from triplicate analysis of one sample.

HED Comments/Conclusions:

The canola was treated at the rate of 0.19 - 0.21 lb ai/A (2.3-2.6 X) with a 67-75 day PHI. The residues in canola oil did not concentrated. The residues concentrated 2.6X in canola meal. However, the analytical method RM-26A-1 which were used to analyze canola seeds and its

processed commodities in this petition was not successfully validated; therefore, HED requires a new canola processing study.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

No feeding studies were submitted with this petition. Feeding studies were previously submitted and reviewed (PP#9F3743, MRIDs 41030221 & 41030222, M. Nelson, 05/12/1990). Permanent tolerances for livestock and poultry have been established for the combined residues of clethodim[(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-[2-(ethylthio)propyl]cyclohexene-3-one and 5-[2-(ethylthio)propyl]-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones (40 CFR §180.458).

Dairy Cattle

The petitioner conducted a feeding study with lactating dairy cows (MRID 41030222). Fourteen Holstein cows were used for the study (randomly divided into one control group of two cows and three test groups of four cows each). Following an acclimation period of 7 days, each cow in the test groups was given an oral dose of a 5:95 mixture of clethodim:clethodim sulfoxide contained in a gelatin capsule, once daily for 28 consecutive days. The dosing levels were 10 ppm, 30 ppm, and 100 ppm equivalency in the diet for the three test groups based on the highest daily food consumption, determined during the acclimation period: 85 lbs/cow/day. These dosing levels would be equivalent to 0.5x, 2x and 5x the theoretical maxium dietary burden for beef cattle, and 0.6x, 2x and 6x the theoretical maxium dietary burden for dairy cattle (based on the current theoretical maximum daily dosage levels).

Three cows from each dose level and one control cow were sacrificed on test day 29, within 24 hours of the last dose; and the remaining cow in each group on day 31, after 2 days withdrawal. Samples of liver, kidney, composite muscle, and composite fat (peritoneal and subcutaneous) were collected from each carcass for residue analysis.

Milk samples, consisting of equal parts of morning and evening milkings for a given day, were collected from each cow on days -1, 1, 2, 4, 7, 12, 16, 20, 24, 28, 29, 30, and 31.

All tissue and milk samples were maintained under frozen storage (-20°C) until analysis for total clethodim residues (measured as DME, DME-OH, and S-DME expressed as clethodim equivalents) by a modified version of RM-26A (adapted for milk and bovine tissues). The results of residue analysis of bovine tissues and milk are summarized in Table 23.

Table 23. Clethodim Residues in Dairy Cows						
Feeding Levels	Chemicals	Milk	Liver	Kidney	Muscle	Fat
10 ppm	DME	ND	0.06	0.05	ND	ND
	DME-OH	ND	ND	ND	ND	ND
	S-MEDME	ND	ND	ND	ND	ND
30 ppm	DME	0.03	0.12	0.17	ND	0.05
	DME-OH	ND	ND	ND	ND	ND
	S-MEDME	ND	ND	ND	ND	ND
100 ppm	DME	0.08	0.45	0.54	0.07	0.15
	DME-OH	ND	ND	ND	ND	ND
	S-MEDME	0.03	0.09	0.08	ND	ND

ND = Not Detected (<O.0125 ppm for milk and <0.05 ppm for tissues)

DME residues were found in liver and kidney at all feeding levels; in milk and fat, at the 30 and 100 ppm feeding levels; and, in muscle, at the 100 ppm level only. S-DME was found in milk, liver, and kidney at the 100 ppm level. DME-OH was not found in milk or any tissue at any feeding level. Residues in milk plateaued on test days 1 or 2.

No detectable residues of DME, DME-OH, or S-DME were reported in any control milk (<O.0125 ppm) or bovine tissue (<O.05 ppm) samples.

Composite whole milk samples collected on test days 25, 26, and 27 from the control group and the 100 ppm dose level group were processed to obtain skim milk (nonfat solids), cream (fat solids), pasteurized milk, and acid whey (lactose). Analysis for total clethodim residues (DME + DME-OH + S-DME) was performed on these processing fractions. Based on the recommended tolerances in this submission and established tolerances, the maximum theoretical residues in diets of beef and dairy cattle were calculated and the current theoretical maximum daily dosage levels were determined (see Table 24).

Table 24. Theoretical dietary burden of clethodim from various feed commodities for beef and dairy cattle						
Feed Commodity	Tolerance or **Proposed Tolerance** (ppm)	% Dry Matter	Beef Cattle		Dairy Cattle	
			% of Diet	Burden (ppm)	% of Diet	Burden (ppm)
Sugar Beet Tops	1.0	23			10	0.43
Soybeans	10.0	48	40	8.3	50	10.4
Alfalfa forage	6	35	60	10.3	40	6.9
Total			100	18.6	100	17.7

HED Comments/Conclusions:

The established tolerances on meat and milk are adequate to cover the proposed used. According to Table 1 of OPPTS 860.1000 and the recommended and established tolerances for clethodim, the maximum theoretical residues in the diets of beef cattle and dairy cattle were calculated; and the theoretical maximum dietary burdens were determined to be 18.6 ppm for beef and 17.7 ppm for dairy cattle. Based on the previous feeding studies, the secondary residues in meat and milk will not exceed the established tolerances.

Poultry

The petitioner conducted a feeding study with laying hens (MRID 41030221). Young laying hens were randomly assigned (20 hens each) to one of three test groups or the control group. Following an acclimation period of 35 days, each hen in the test groups received an oral dose of a 5:95 mixture of clethodim:clethodim sulfoxide (purity, >98.5%) contained in a gelatin capsule, once daily for 28 consecutive days. Controls received gelatin capsules containing only the carrier (corn oil and evaporated acetone). Hens received poultry mash and water *ad libitum* throughout the dosing period.

The dose levels for the three test groups were 10 ppm, 30 ppm, and 100 ppm equivalency in the diet based on the highest daily food consumption, determined during the 35 day acclimation period: 151.3 grams/hen/day. These dosing levels would be equivalent to 1.4x, 4x and 14x the theoretical maxium dietary burden for poultry (based on the current theoretical maximum daily dosage levels).

Egg samples were retained and pooled by dose group for days -1, 1, 2, 4, 7, 14, 21, 28, 29, and 30. On day 29, ten hens from each group were randomly selected for sacrifice; all remaining hens were sacrificed on day 31. Thigh and breast muscle, liver, gizzard, and subcutaneous and abdominal fat were collected for residue analysis from each hen, pooled by tissue and test group, and 2-3 subportions of each were taken for analysis by method RM-26A (adapted for eggs and chicken tissues). The results of the residue analysis are summarized in Table 25.

Table 25. Clethodim Residues in Laying Hens

Feeding Levels	Chemicals	Eggs	Fat	Gizzard	Liver	Muscle
10 ppm	DME [a]	NDc	ND	ND	ND	ND
	DME-OH [b]	ND	ND	ND	ND	ND
	S-MEDME [c]	ND	ND	ND	ND	ND
30 ppm	DME	0.05-0.09	ND	ND	ND	ND
	DME-OH	ND	ND	ND	ND	ND
	S-MEDME	ND	ND	ND	ND	ND
100 ppm	DME	0.14-0.24	ND	ND	0.06	ND
	DME-OH	ND	ND	ND	ND	ND
	S-MEDME	ND	ND	ND	ND	ND

[a] Expressed as clethodim (C)

[b] Expressed as 5-OH clethodim sulfoxide (5-0H-SO_2)
[c] Expressed as S-methyl clethodim sulfone (SMSO)
.ND = no detectable residue (<O.05 ppm)

No detectable residues (0.05 ppm) of DME, DME-OH, or S-MEDME were found in any control samples of eggs or poultry tissues. No residues were detected (<O.05 ppm) in any of the fat, gizzard, or muscle samples, even at the 100 ppm dose level.

Clethodim (DME) of 0.06 ppm was found in only one liver sample (day 29), which was from the 100 ppm dose level. No DME-OH and S-MEDME were detected (<O.05 ppm) in any of the liver samples.

No detectable residues (<O.05 ppm) of DME, DME-OH, or S-MEDME were reported in any control egg or poultry tissue samples. No detectable residues (<O.05 ppm) of clethodim were found in eggs from the 10 ppm dose level. Clethodim residues were found in eggs from both the 30 ppm (0.05-0.09 ppm) and 100 ppm (0.14- 0.24 ppm) dose levels; these residues declined to <0.05 ppm by day 29. No DME-OH and S-MEDME were detected (<O.05 ppm) in any of the egg samples.

Based on the recommended tolerances in this submission and the established tolerances, the maximum theoretical residues in poultry were calculated and the current theoretical maximum daily dosage levels were determined (see Table 26).

Table 26. Theoretical dietary burden of clethodim from various feed commodities for poultry.

Feed Commodity	Tolerance or Proposed Tolerance (ppm)	Poultry	
		% of Diet	Burden (ppm)
Soybean meal	10.0	40	4.0
Sunflower meal	10.0	30	3.0
Canola meal	1.5	15	0.2
Rape seed meal	1.5	15	0.2
Total		100	7.4

HED Comments/Conclusion:

The current established tolerances on poultry and eggs are adequate to cover the proposed use. According to Table 1 of OPPTS 860.1000 and the recommended and established tolerances for clethodim, the maximum theoretical residues in the diet of poultry were calculated and the current theoretical maximum dietary burden was determined to be 7.4 ppm for poultry. Based on the previous poultry feeding studies, secondary residues in poultry and eggs will not exceed the established tolerances.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

A confined rotational crop study for [ring-4,6-^{14}C]-clethodim with carrots, lettuce, and wheat (MRID 41030211) was conducted. The study was reviwed by E. B. Conerly (EFGWB Science Chapter for Clethodim, 06/26/1990). Results indicated that there is no need for field rotational crop trials. A 1 month plantback interval for crops rotated with alfalfa was specified (D 236382, M. Collantes, et. al, 2/10/98). The use directions submitted with the current petition do not specifically address rotational crops. The directions for use on fallow or nonproducing agricultural land is to not plant any crop for 30 days after application unless clethodim is registered for use on that crop. A revised Section B/label must be submitted which includes a 1 month plantback restriction for all rotated crops without a registed use.

International Harmonization of Tolerances

Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on sugar beets (0.1 ppm), potatoes (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and sunflower seed oils (0.05 ppm). Some of these proposed tolerances have been recommended for withdrawal or reflect recent changes. Harmonization could be an issue for Codex MRLs for potato/tuberous vegetables (0.2 ppm vs. 1.0 U.S.), sunflower seed (0.5 ppm vs 5.0 ppm) and sunflower oils (0.05 ppm vs.5.0 ppm U.S.). If a separate tolerance for refined sunflower oil was established at 0.1 ppm based on the submitted data, there would still be a Codex harmonization issue for both crude and refined sunflower oil. There could be a harmonization issue with the Canadian MRLs for potatoes (0.5 ppm vs. 1.0 ppm U.S.), sunflowers (0.2 ppm vs. 5.0 ppm U.S.), and rape/canola (0.05 ppm vs. 0.5 ppm U.S.). There are also current Codex harmonization concerns for clethodim residues in chicken meat, eggs, milk, sugar beets (roots), cottonseed, cottonseed oil, and dry bulb onions. There are no harmonization concerns for Mexican MRLs. An International Residue Limit Status Sheet is attached.

cc: RF, PP# 7F4849, MXue, MRust
RDI: ChemTeam:08/24/2000 :Sdapson 8/29/2000
7509C: RAB3, MXue :CM-2: RM 810F: 703 305-6198:8 /29/2000

CITATIONS

MRID 443234-01. Lai, J.C. (1996) Magnitude of Clethodim Residues in Potatoes, Tubers and Processed Parts (1995). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA94568. Laboratory ID. V-11123, May 1, 1996. 2 Volumes, Unpublished.

MRID 447532-06. Lai, J.C., (1998) Magnitude of Clethodim Residues in Sugar Beet Raw Agricultural Commodities (1977). Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA 94568. Laboratory ID. V-11722, April 13, 1998. 4 Volumes, Unpublished.

MRID 443234-02. Lai, J.C. (1996) Magnitude of Clethodim Residues in Sunflowers- Seed and Processed Parts. Valent U.S.A. Corporation, Valent Technical Center, 6560 Trinity Court, Dublin, CA94568. Laboratory ID. V-11186, May 1, 1996. 2 Volumes, Unpublished.

MRID 443933-01. Bruce, E.D. (1996) Magnitude of Clethodim Residues in Rapeseed (Including Canola), Commodities: Seed, Meal and Oil. Valent U.S.A. Corporation, 1333 N. California Blvd., Suite 600, Walnut Creek, CA 94596. Laboratory ID: EDB.896, August 28, 1996. 3 Volumes, Unpublished.

INTERNATIONAL RESIDUE LIMIT STATUS

[(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one]	Common Name: clethodim	x Proposed tolerance □ Reevaluated tolerance □ Other	Date: 09/19/2000

Codex Status (Maximum Residue Limits)	U. S. Tolerances
Codex proposal step 6 or above Codex proposal step 6 or above for the crops requested (see below)	Petition Number: 9F6037 DP Barcode: D240302 Other Identifier: EPA Reg. No. 59639-3, 59639-78
Residue definition (step 8/CXL): [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones expressed as clethodim	Reviewer/Branch: Manying Xue/ RAB 3
	Residue definition: [(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones expressed as clethodim per 40 CFR 180.458

Crop (s)[1]	MRL (mg/kg)	Crop(s)	Proposed Tolerance (ppm)
Fodder beet (stage 3)	0.1	Beets, sugar tops	1.0
Sugar beet (stage 6)	0.1		
Potato (stage 6)	0.2	Tuberous and corm vegetables (in tubers)	1.0
Sunflower seed (stage 6)	0.5	Potato flakes/granules	2.0
Sunflower oil-crude (stage 6, recommended for withdrawal)	0.05	Sunflower seed (includes sunflower oil)	5.0
Sunflower oil-edible (stage 6, recommended for withdrawal)	0.05	Sunflower meal	10.0
Rape seed (stage 6)	0.5	Canola/rape seed	0.5
Rape seed oil crude (stage 6, previously 0.05)	0.5	Canola meal (includes canola oils)	1.5

Rape seed oil edible (*stage 6, previously 0.05*)	0.5		

Limits for Canada	Limits for Mexico
X No Limits X No limits for the crops requested	X No Limits XNo Limits for the crops requested
Residue definition: Clethodim and metabolites containing the 2-cyclohex-1-enone moiety	Residue definition: Clethodim

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
soybeans	10	Soya (soybean)	10
lentils	0.5		
peas (dry)	0.5		
potatoes	0.5		
mustard seed	0.4		
flax seed	0.3		
sunflower seed	0.2		
rape seed (canola)	0.05		

Notes/Special Instructions:
Updated S. Funk 04/19/00.
[1] For Codex, included only products related to current petition, additional MRLs are proposed or available.