



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DATE: April 5, 2001
SUBJECT: RD Risk Assessment for Clethodim to Support Request for New Uses of Clethodim on Root Vegetables.
PC Code 121011
D274023
TO: Joanne Miller, Dan Kenny, PM Team 23, Registration Division (7505C)
FROM: Lisa Jones, RD ARIA Team
THRU: Stephen Dapson, Senior Scientist, RAB3
Jane-Scott Smith, RD ARIA Team Leader

Handwritten signatures and dates: Stephen C. Dapson 04/18/2001, Jane-Scott Smith 4/18/2001

1.1 Introduction

This risk assessment amendment evaluates the currently proposed use on root vegetables (except sugar beets) crop subgroup in order to support the decision to replace the recent clethodim tolerance for carrots, radishes and radish greens and replace it with a tolerance for the root vegetable group, which includes carrot and radish products as well as other root vegetables such as turnip and salsify.

The March 14, 2001 Federal Register (66 FR 14829) issued clethodim tolerances for radish root and carrot at 0.50 ppm and radish tops at 0.70 ppm, as well as other agricultural commodities. The registrant had originally petitioned for a tolerance for the entire root vegetable group rather than simply carrots and radishes. HED's original review of the residue chemistry data suggested that the use patterns proposed for Clethodim on carrots and radishes were so different that these two crops should not be treated as equivalent use sites. However, a second review of the residue chemistry data supported the original root vegetable

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tolerance. Section 4.2 describes HED's decisionmaking in detail

Background information used to develop this risk assessment came from the following reference documents.

- Reference A: Attachment #1: HED Risk Assessment: Human Health Risk Assessment for Clethodim to Support Request for New Uses of Clethodim on the Crop Groups Tuberos and Corm Vegetables, Fruiting Vegetables Crop Group, Root Vegetables, Leaves of Root and Tuber Vegetables, and Leaf Petioles, and the Crops Melons, Squash/Cucumbers, Sugar Beets, Sunflower, Canola, Cranberry, Strawberry, and Clover. 30 November 2000, Mary Rust, Manying Xue and Meta Bonner, Registration Action Branch 3, Health Effects Division. Submission#: S556745; Chemical #: 121011; DP Barcode:D254018, D240302; PRAT Case#: Petition # 7F04873, OE06097
- Reference B: Attachment #2: Minutes of 1/17/01 ChemSAC Meeting, February 8, 2001
- Reference C: Attachment #3: Chronic Dietary Exposure Analyses for Clethodim in/on Various Crops, PC Code 121011, DP Barcode: D269821, 27 October 2000
- Reference D: Attachment #4: PP# OE06097. Clethodim (ANSI) in/on Root Vegetables (except Sugar Beet) Crop Subgroup 1b, Leaves of Root and Tuber Vegetables (except Sugar Beet) Crop Group 2, Leaf Petioles Crop Subgroup 4b, Melon Crop Subgroup 9a, Squash/cucumber Crop Subgroup 9b, Cranberry, Strawberry, and Clover. Evaluation of Analytical Method and Magnitude of the Residue Data. 25 October 2000, Manying Xue and Stephen Dapson. Registration Action Branch 3, Health Effects Division. Submission#: S531616 & S556745; Chemical #: 121011; DP Barcode: D263055 PRAT Case No#: Petition # 7F04873, OE06097

1.2 Conclusions and Recommendations

RD's ARIA team and HED recommend for the establishment of tolerances for the residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones as follows:

Root Vegetables 1.0 ppm

As a result the following tolerances set in the March 14, 2001 Federal Register should be deleted:

Radish, roots	0.50 ppm
Radish, tops	0.70 ppm
Carrot	0.50 ppm

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION The Physical/Chemical Properties Characterization is unchanged from Reference A.

3.0 HAZARD CHARACTERIZATION / ASSESSMENT The Hazard Characterization / Assessment, which includes the Dose-Response Assessment, the Hazard Profile, FQPA Considerations, and Endocrine Disruption discussions, is unchanged from Reference A.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Proposed Uses - The Summary of Proposed Uses is unchanged from Reference A except that the set of proposed uses has expanded from radish and carrots to the entire Root Vegetables subgroup.

4.2 Dietary Exposure

4.2.1 Residue Profile The only change from Reference A, the human health risk assessment document involves the establishment of tolerances on the root vegetable subgroup at 1.0 ppm versus the individual tolerances for carrot at 0.50 ppm, radish at 0.50 ppm, and radish top at 0.70 ppm proposed in Reference A. Section 4.2.2 explains how this change occurred.

4.2.2 Magnitude of the Residue in Root Vegetables

The original review of the residue chemistry data, summarized in reference D, concluded the following. "The submitted carrot and radish field trial data and geographic representation are adequate to satisfy the requirements described in OPPTS 860.1500 for tolerances for carrots and radish roots; they are not adequate for a tolerance for the root vegetables (except sugar beets) crop subgroup 1b." The proposed use pattern called for one application per season for radishes and two per season for carrots which suggested that carrots might receive substantially more cletrodin than radishes to the point where the two uses could not be considered comparable.

However, after re-evaluating the residue data and application rates for radishes and carrots generated in support of the proposed tolerance for root vegetables the ChemSAC concluded at its January 17, 2001 meeting, documented in Reference B that the use patterns for these two crops are similar enough to justify establishing a crop subgroup tolerance for root vegetables other than sugar beets. The similarity of the residue levels in carrots and radishes supported this conclusion.

Specifically, the proposed use pattern called for one application per season for radishes and two per season for carrots. These use patterns resulted in residues of 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 in carrots were found at levels between <0.25 ppm and <0.39 ppm after one application and at levels below 0.45 ppm for radishes after two applications, 15 days apart, each equal in amount applied to the single application used on carrots. A 15-day pre-harvest interval (PHI) applied to radishes and a 30-day PHI applied to carrots; radishes are typically harvested 30 days after seeding while carrots are harvested 60 to 90 days after seeding and are thus vulnerable to weed damage for a longer period of time, requiring the second Clethodim application.

The January 17, 2001 ChemSAC concluded that the extra application for carrots relative to radishes was not a significant difference in use pattern, considering the much longer planting-to-harvest interval for carrots. The fact that these residue level differences between carrots and radishes fell within the 5X variation allowed by 40 CFR 180.40(g) for individual crops sampled as representative commodities and because the 30-day PHI is expected to allow any additional residue in carrots to dissipate, supported the ChemSAC conclusion that carrot and radish use patterns are equivalent.

Based on the January 17, 2001 ChemSAC conclusions, the ARIA Team and HED recommend the establishment of tolerances for the residues of clethodim as follows:

Root Vegetables	1.0 ppm
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deleting the following tolerances set in the March 14, 2001 Federal Register:

Radish, roots	0.50 ppm
Radish, tops	0.70 ppm
Carrot	0.50 ppm

The DEEMs conducted and cited in Reference A was conducted using the Root Vegetables at 1.0 ppm. Therefore, the Dietary risk (both water and food) remain

unchanged from the original risk assessment conducted for Reference A.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

The Aggregate Risk Assessments and Risk Characterization section is unchanged from Reference A. The following table is provided for the reader's convenience.

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
US Population (total)	0.01	29	24.2	0.49	250
All Infants (< 1 year)	0.01	43	24.2	0.49	57
Children 1-6 years	0.01	60	24.2	0.49	40
Children 7-12 years	0.01	42	24.2	0.49	58
Females 13-50 years	0.01	22	24.2	0.49	230

This risk assessment used conservative assumptions, e.g. tolerance level residues, therefore the actual risks involved are lower than the risks calculated here. When cPAD levels fall below 100% and surface and groundwater EEC's fall below the chronic DWLOC level, the dietary intake of clethodim has been shown to fall below the level of concern. Reference A, Section 3.3, Dose-Response Assessment, Dietary Endpoint Selection, Chronic discusses this in more detail.

6.0 CUMULATIVE RISK

The Cumulative Risk section is unchanged from Reference A.

7.0 OCCUPATIONAL EXPOSURE

The Occupational Exposure section is unchanged from Reference A.

8.0 DATA NEEDS/LABEL REQUIREMENTS

The Data Needs/Label Requirements section is unchanged from Reference A.

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