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

MAY 26 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID# 059639-00002. Clethodim in/on Potatoes. Cursory Review [SCREEN] of Canadian Data to Identify Data Gaps.

DPCode: **D203582** CBTS#: 13748 MRID#: N/A

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THRU: Esther C. Saito, Chief
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TO: Lindsay Moose
Immediate Office, OPP (7501C)

and

Dan Kenny, PM Team 23
Registration Division (7505C)

BACKGROUND. The cc mail message from Lindsay Moose, 5/3/94, to CBTS directs: "...do a quick review of the data to determine what if any would be acceptable, what obvious gaps exist, what general problems exist (e.g., formatting, GLPs, actual requirements, etc.). ...get a feel for what is there."

The "data" consists of Rhône-Poulence Canada Inc. residue studies for clethodim/potatoes, Canada, 1991 (field and analytical portions), ID# 92-001.DC (no MRID). Accompanying this are what appear to be reviews from Canada of (1) these 1991 field trials as well as those conducted in 1990 on potatoes; and, (2) the adjuvant CC16255. Also provided is a 7/93 Status Report on Clethodim from Health and Welfare Canada.

CBTS notes these data were submitted under the Canada-US Trade Agreement Pesticides Technical Working Group MRL Harmonization Pilot Project.

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CBTS SCREEN.

A. Administrative

Chemical:	Clethodim (ANSI)
Class:	Herbicide
Chemical#:	121011
Chemical Name:	(E)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino] propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one
PP#:	Data package is not submitted as a petition. If a tolerance is to be pursued, it should be.
Petitioner:	Not stated; possibly the data would be incorporated into a forthcoming Valent (USA) petition.
Commodity:	Potatoes
Proposal:	To establish a tolerance for the combined residues of clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in/on potatoes at X ppm. X = 0.2 or 0.5 ppm, both are mentioned.
40 CFR:	§180.458
Formulation:	Select® 2EC

Packaging: Data should be organized into a petition (per 40 CFR 180.7) and formatted per PR Notice 86-5. An explanatory letter naming a contact person should accompany it.

Confidentiality: The data (1991 field trials) are stamped "Trade Secret/Proprietary Data of Rhône-Poulenc Canada Inc./Confidential". Petition data, with the exception of certain product chemistry information, should be submitted under a signed "Statement of No Confidentiality Claims".

GLP Compliance Statement: The petition should include an overall statement whether GLPs were followed. In this data package, the GLC portion of the '91 trials was conducted in compliance with EPA's GLPs. No information was provided re the field phase.

Quality Assurance Statement: The petition should include an overall statement whether the data were subjected to a Quality Assurance examination. In this data package, the GLC portion of the '91 trials was QA'd. No information was provided re the field phase.

B. Scientific

Product Chemistry. No data are provided. Assuming USA registration is involved and Valent will be the registrant, we may have adequate product chemistry data on file (ref. PP#9F3743); we would need to make sure the manufacturing process hasn't changed and that we have current Confidential Statements of Formula for the TGAI and EP.

Formulation. Information is provided that Select 2EC (clethodim, ai) was used in the '91 potato field trials in combination with the adjuvant CC-16255. The identity of CC16255 (CC16255B) is provided. USA field trials should use adjuvants cleared under §180.1001.

Directions for Use. The proposed use pattern is sketchily mentioned in the text. It should be formalized into a Section B and described in detail.

Plant Metabolism. The Status Report submitted summarizes metabolism studies in cotton, soybeans, and carrots. CBTS reviewed the metabolism of clethodim in cotton, soybeans, and carrots in re PP#9F3743. The nature of the residue is adequately delineated. Assuming these Valent studies could be referenced, we could translate the findings to cover potatoes.

Animal Metabolism. The Status Report submitted summarizes metabolism studies in rats, goats, and chickens. CBTS reviewed the metabolism of clethodim in goats and chickens in re PP#9F3743. The nature of the residue is adequately delineated. Assuming these Valent studies could be referenced, no new studies would be needed.

Analytical Methods. GLC/FPD(S) Method RM-26A-1 (with minor modifications) was used for analysis of the '91 field trials samples. The performing lab was Huntingdon Analytical Services, Middleport, NY. Method RM-26A-1 is adequate for generating residue data.

PP#9F3743 discusses methods extensively and needed PMVs have been conducted. CBTS has recommended that analytical method RM-26D-2 (Valent's compound-specific method) serve as the primary tolerance enforcement procedure for crops (cottonseed, soybeans) and animal tissues except milk; the common moiety method, RM-26B-2, is the enforcement method for milk.

The additional clethodim/potatoes field trials (USA) needed to support a tolerance should use method RM-26D-2 for analysis of residues; procedural recovery data should be provided. This will validate the primary enforcement method for use with potatoes.

Confirmatory Methods. For confirmation of total clethodim residues in crops (cottonseed, soybeans) and animal tissues except milk CBTS has recommended the common moiety method, RM-26B-2; for confirmation of total clethodim residues in milk, compound-specific method RM-26-D-2 would be used.

Methods Recovery Data. Procedural recovery data for RM-26A-1 were provided in re the '91 potato trials. Procedural recovery data for method RM-26D-2 use with potatoes and potato processed commodities should be part of the additional field/processing trials (USA) data package.

Independent Lab Validation. Already provided as part of PP#9F3743. No additional independent validation is required.

Petition Method Validation. Already conducted as part of PP#9F3743. Procedural recovery data for MR-26D-2, as part of the additional field/processing trials (USA) data on potatoes and potato processed commodities, are all the additional validation needed.

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Analytical Reference Standards. All necessary clethodim standards are available from the Pesticides Repository, RTP, NC. (Repository code nos. 03965, 03961, 03960, and 03959.)

Multiresidue Methods Testing. Done in re PP#9F3743. No additional testing needed.

Frozen Storage Stability Data. None provided. Samples from the '91 potato field trials were frozen stored from 1 week to 3 months prior to extraction for residue analysis.

Storage data are provided in PP#9F3743 for clethodim and metabolites in soybeans, cotton, processing fractions, and animal commodities. However, these data are not sufficiently representative of a broad spectrum of crops for us to waive data specifically for potatoes.

Frozen storage stability data are needed for clethodim and metabolites in potatoes. The duration of the study should reflect the longest storage interval prior to analysis of (the '90 field trials samples, if these are submitted), the '91 field trials samples, and the additional field trials studies (US) samples.

Additionally, if potato processed commodities are frozen stored prior to analysis, storage stability data for these commodities will also be needed.

Residue Data. Full data are provided for 8 potato field trials conducted in Canada in 1991 using Select 2EC. Those data could be counted in support of a tolerance with US registration, provided the proposed use pattern for the tolerance remains the same. The data provide geographical representation across Canada, 1X and 2X rates, and PHIs at (60 days) or less than (ca 45 days) the proposed use.

Summary data are also provided for 4 trials conducted in 1990. If full data are provided these trials could also be used to support a tolerance/US registration, again provided the proposed use pattern for the tolerance remains the same.

In addition to the Canadian data, to support a tolerance with US registration some field trials conducted in the USA are needed. The recommendation in our Field Trials guidance document (April 1994 draft) is for 16 trials for potatoes by the proposed use pattern. In this specific instance, CBTS considers the Canadian trials plus 8 domestic (USA) trials would suffice.

The domestic field trials should be geographically diverse. We recommend the 8 potato trials be conducted in the following areas: Northeast (1), mid-Atlantic (1), Florida (1), Lower Midwest (1), Southwest (1), California (1), Northwest (2). These trials should precisely reflect the intended use (e.g., maximum rate, minimum PHI, formulation).

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Processing Study Data. No data are provided. Residue data from a potato processing trial are needed for: wet potato peel, dry potato peel, potato granules, potato flakes, and potato chips. Since it is desirable to process potatoes containing appreciable residues, we recommend the field trial to provide potatoes for processing be conducted at an exaggerated rate (up to 5X, phytotoxicity considerations permitting).

Animal Feeding Studies. The Status Report submitted summarizes feeding studies in the lactating cow and laying hens. CBTS reviewed cow and hen feeding studies in re PP#9F3743. Up to 100 ppm in the diet was fed. Assuming those Valent studies can be referenced, no additional feeding studies are needed. Meat, milk, poultry, and egg tolerances are pending in re PP#9F3743; CBTS has recommended in favor of the establishment of those tolerances. We'd need to be sure meat/milk tolerances are in place before or concurrent with establishing a tolerance on potatoes. Higher tolerance levels for animal commodities probably won't be needed.

Rotational Crops. No information was provided. Appropriate rotational crop studies will be needed to provide information as to whether crop rotation restrictions will be needed.

IRL Harmonization. No information was provided. CBTS will check into this once a petition is submitted and, if applicable, attempt to harmonize to the extent possible.

C. Other Considerations

TOX/HED should be consulted to ascertain if TOX considerations would be an impediment to the establishment of a potato tolerance, were one to be proposed. OREB and EFED should also be queried.

The question might arise whether a potato tolerance with (1) full US registration, or (2) a regional registration (Northern states only), could be established with no supporting domestic field trials data. CBTS recognizes this is a policy decision, but would counsel against setting such a precedent. If scenario (2) is seriously considered, BEAD should be consulted re the advisability of this; potatoes are grown throughout the USA, on approximately 1.3 million acres.

cc: M. Nelson, RF, Circ., Clethodim Subject File.

7509C:CBTS:MJN:mjn:CM#2:Rm804U:305-7585:**CLETPOT.CAN**:5/17/94.
RDI:SecHd:RSQuick:5/19/94:BrSrSci:RALoranger:5/24/94:BrChf:ECSaito:5/25/94.

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