12/011

18 September 1989

NOTE TO EEB CLETHODIM FILE

SUBJECT: Meeting with registrant re: freshwater invertebrate study and plant protection data requirements.

FROM: Dave Warburton, EEB

Doug Urban, Dave Warburton, and Charles Lewis of EEB met with representatives from Valent and Chevron Environmental Health Center, as well as Joanne Miller (RD), 14 September 1989 to discuss the EEB review of the freshwater invertebrate study "Invalid" classification (Record No. 238236) and the Agency's phytotoxicity data requirements for clethodim. The registrant presented arguments as for why the study should be classified as "Core" (see attached). The main issue was that the solubility, and therefore the actual concentrations under testing conditions, of the test substance was not adequately documented, as discussed in the DER. It was decided that the registrant will conduct solubility tests of the technical material in acetone and in DMF solvents, analyzing both the solute and the precipitate fractions for levels of clethodim. These data will be presented to EEB for consideration via RD. Charles Lewis also provided an explanation for the basis of the Agency's phytotoxicity data requirements for EUP and Section 3 registrations of clethodim; no further issues were raised.

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P.O. Box 8025
Walnut Creek, CA 94596-8025
(415) 256-2700

VALENT.

August 14, 1989

SELECT HERBICIDE
(FILE SYMBOL 59639-G)
SELECT HERBICIDE
(EXPERIMENTAL USE PERMIT
NO. 59639-EUP-1)
CLETHODIM TECHNICAL
(FILE SYMBOL 59639-E)
CHEVRON CLETHODIM TECHNICAL
(FILE SYMBOL 239-EANG)
PESTICIDE PET. NO. 9F3743
MEETING REQUEST

Ms. Joanne I. Miller
U.S. Environmental Protection Agency
Product Manager, Team 23
Fungicides-Herbicides Branch
Registration Division (H7505C)
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Miller:

I will be taking over responsibility for Valent's communications with EPA on activities relating to registration of herbicides containing the active ingredient clethodim, including SELECT Herbicide.

I am writing to request meetings with yourself and representatives of the Toxicology, Ecological Effects, and Dietary Exposure Branches, to discuss issues relating to SELECT. I would propose three meetings, as follows:

1. EPA ATTENDEES: J. Miller, PM Team 23; appropriate scientists from Toxicology Branch.

   VALENT/CHEVRON ATTENDEES: D. Fay, Valent; J. Finegan, Valent; D. Krass, Chevron Chemical; K. Dougherty, Chevron Environmental Health Center.

   SUBJECT:

   A. SELECT Herbicide EUP label signal word - In the EUP Toxicology review, #07222, dated May 31, 1989, Valent was

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advised to change the signal word on the EUP label to "Danger" based on results of the acute eye irritation study conducted with the 2EC (MRID 409745-15). Valent agreed for the purpose of EUP approval, however we believe that the data still supports the originally proposed "Warning" signal word. We intend to submit arguments supporting our position to you by August 28. Please arrange for distribution of this document to the appropriate scientists who will attend this meeting.

B. Acute Inhalation Study with SELECT 2EC (MRID 409745-13) - On May 25, 1989, Ms. Michele Radcliffe submitted to Mr. Schnaubelt Valent's position regarding EPA's review (#07222, May 31, 1989) of the above study (copy attached). However, the classification of this study has not been upgraded. We would like to further discuss the information submitted which we believe supports upgrade of the study.

2. EPA ATTENDEES: J. Miller, PM Team 23; appropriate scientists from Ecological Effects Branch.

VALENT/CHEVRON ATTENDEES: D. Fay, Valent; J. Finegan, Valent; D. Krass, Chevron Chemical; K. Dougherty, Chevron Environmental Health Center.

SUBJECTS:

A. Acute toxicity of RE-45601 (clethodim) Technical to Daphnia magna (MRID 409745-30) - EPA classified this study as "invalid" due to "absence of a verifiable LC50 value" (Review Record No. 238236). We dispute this conclusion, and we will submit arguments supporting our position to you by August 28. Please arrange for distribution of this document to the appropriate scientists who will attend this meeting.

B. Plant Protection data requirements - In the same review cited above, the reviewer concluded that studies to address the following Plant Protection guideline requirements would be required "as a minimum" for registration: 122-1 (Seed germination/Seedling emergence, Vegetative vigor), 123-1 (Seed germination/Seedling emergence, Vegetative vigor), 123-2 (Aquatic plant growth).

We do not understand the Agency's rationale for requiring these studies, as the rulemaking required to establish such requirements for terrestrial food crops has not been conducted. We would like to understand EPA's technical and procedural justification for requiring these studies.

3. EPA ATTENDEES: J. Miller, PM Team 23; appropriate scientists from Dietary Exposure Branch.

VALENT/CHEVRON ATTENDEES: D. Fay, Valent; J. Finegan, Valent; D. Krass, Chevron Chemical; B. Ho, Chevron Chemical.

SUBJECT: Residue analytical method - The method submitted to EPA for measuring residues of clethodim and its significant metabolites in plant and animal tissues (MRID 410301-41) is the same method used to analyze residues associated with the registered active ingredient sethoxydim. Known as the "common moiety" method, it is incapable of distinguishing residues resulting from application of sethoxydim from those associated with clethodim. We propose to present technical arguments supporting EPA's use of the common moiety method for enforcement purposes, using a compound-specific method (currently under development) for confirmatory analyses only.

If possible, we would like to schedule all three meetings for Thursday, September 14. If any of the meetings cannot be scheduled that day, please consider September 13 as an alternate. As soon as you can confirm the meeting times, or if you have any questions, please contact John Finegan at our Washington D.C. office (202) 872-4682.

Sincerely yours,

Daniel P. Fay

Daniel P. Fay
Senior Project Manager

DPF/154.DPF

Attachment

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VALENT

Dave –
Information for the "Select" Meeting of 9/14/89
11-12 AM, Rm 913.
J. Miller
Acting PM-23

August 28, 1989

SELECT HERBICIDE
(FILE SYMBOL 59639-G)
SELECT HERBICIDE
(EXPERIMENTAL USE PERMIT NO. 59639-EUP-1)
CLETHODIM TECHNICAL
(FILE SYMBOL 59639-E)
CHEVRON CLETHODIM TECHNICAL
(FILE SYMBOL 62499-GL)
PESTICIDE PET. NO. 9F3743

RESPONSE TO DATA EVALUATION RECORDS FOR STUDIES ON DAPHNIA ACUTE TOXICITY, ACUTE INHALATION ON SELECT 2EC, AND ACUTE EYE IRRITATION ON SELECT 2EC

Ms. Joanne I. Miller
Product Manager, Team 23
Fungicides-Herbicides Branch
Registration Division (H7505C)
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Miller:

As promised in our letter of August 14, we are sending attached our responses to Data Evaluation Records contained in Ecological Effects and Toxicology reviews of the Experimental Use Permit submission for SELECT® Herbicide. We are offering our comments to EPA reviews of the following studies:

1. Freshwater Acute Toxicity of CHEVRON RE-45601 Technical to Daphnia magna in a Static Test System. MRID No. 409745-30.

2. The Acute Inhalation Toxicity of SELECT 2.0 EC (CC-14900) (SX-1721) in Rats. MRID No. 409745-13.

3. The Acute Eye Irritation Potential of SELECT 2.0 EC (CC-14900) (SX-1721). MRID No. 409745-15.

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In summary, we believe the studies submitted are valid and fully meet the subject data guideline requirements. In addition, we believe that SELECT Herbicide should be placed in Toxicity Category II, with a WARNING signal word, based on the above eye irritation study.

We look forward to meeting with you and representatives of the Ecological Effects and Toxicology Branches on September 14 to discuss these issues further. If you have any questions on the attached information, please contact me at (415) 256-2770, or Mr. John Finegan at our Washington D.C. office (202) 872-4682.

For your information, please note also that the pending registration application for CHEVRON Clethodim Technical has been transferred to a new company number belonging to Chevron Chemical Company, Agricultural Chemicals Division. The old registration number, 239-EANG, has been changed to 62499-GL.

Sincerely yours,

Daniel P. Fay

Daniel P. Fay
Senior Project Manager

DPF/159.DPF

Attachment

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RESPONSE TO DATA EVALUATION RECORD FOR RE-45601 (CLETHODIM): Freshwater Invertebrate Acute Toxicity of CHEVRON RE-45601 Technical to Daphnia magna in a Static Test System.

MRID No.: 409745-30

Our comments on the data evaluation record for the above captioned study are as follows:

The stock solution was prepared by mixing the RE-45601 Technical with acetone and diluting an aliquot of this preparation to a final volume of 2-liters with daphnia culture water. The preparation of the stock solution was corrected for the purity of the technical material (83.3%) and had a calculated nominal concentration of 100 mg/l RE-45601. The stock solution was mixed for approximately 21 hours. The fact that an aliquot taken from the high concentration of 100 mg/l, prepared directly from this stock solution, contained an average of 104 mg RE-45601/l when analyzed at the beginning and at the end of the exposure period supports our conclusion that the nominal concentration of 100 mg/l was achieved at the high concentration. Further evidence for dissolution of the RE-45601 is supported by the fact that analysis for RE-45601 in the mid and low concentrations, prepared by diluting the stock solution, accurately reflect their calculated nominal concentrations. This would not have occurred had RE-45601 not been in a uniform solution. We hypothesize that "Test material ... visible on the bottom and surface area of the test solution" were the undissolved impurities in the technical test material.

INCONSISTENT WITH STUDY REPORT METHODS

DOCUMENT IF FILTERED AND ANALYZED BOTH FILTERED AND SOLUTION.

Both DMF and acetone are acceptable solvents for aquatic toxicity studies and since a solvent control was used in this study, it should not make a difference which solvent was used. We believe that the reason the solvent system was different for the invertebrate compared with the fish studies is that the laboratory performing the studies is divided into vertebrate and invertebrate departments with different Study Directors for these studies.

Finally, we disagree with the reviewer's conclusion that the LC50 requirements were not met. We feel the requirements of a limit test were sufficiently met with the complete survival at 48 hours of all twenty organisms exposed to the high concentration, which had an average analyzed concentration of 104 mg RE-45601/l.

Consequently we believe that this study satisfies the requirements for Core Minimum classification.

DATE OF FISH STUDY? (LINE # INDICATES LATER STUDY)

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