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RECORD NO.

129009-7
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 11/7/89 OUT JAN 19 1990

FILE OR REG. NO 15

PETITION OR EXP. NO

DATE OF SUBMISSION: 10/16/89

DATE RECEIVED BY EFED: 10/31/89

RD REQUESTED COMPLETION DATE: 1/27/90

EEB ESTIMATED COMPLETION DATE: 1/27/90

RD ACTION CODE/ TYPE OF REVIEW: 117

TYPE PRODUCT(S): Herbicide

ACCESSION NUMBER(S):

PRODUCT MANAGER: J. Miller (23)

PRODUCT NAME(S): SELECT Herbicide

COMPANY NAME: Valent

PURPOSE OF SUBMISSION: Registrant response concerning 9/14/89 meeting with Agency.

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	%A.I.
	Clethodim	

1/6 39

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

JAN 19 1990

SUBJECT: clethodim (SELECT Herbicide) freshwater invertebrate data requirement.

FROM: James Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Joanne Miller, PM 23
Fungicides-Herbicides Branch
Registration Division (H7505C)

EEB has reviewed the attached correspondence from Valent U.S.A. Corporation and notes the proposal to repeat the freshwater invertebrate acute toxicity study of clethodim using the end-use product is consistent with that recommended by EEB in both the initial review of the study (MRID No. 409745-30) and the referenced meeting of 14 September 1989.

Returned to Sec.
Routed 10-27-89

1333 North California Blvd.
Suite 600
P.O. Box 8025
Walnut Creek, CA 94596-8025
(415) 256-2700

October 16, 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

SEPT. 14 MEETING WITH EEB AND TOXICOLOGY BRANCHES

Ms. Joanne I. Miller
Product Manager, Team 23
Fungicides-Herbicides Branch
Registration Division (TS-767C)
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Miller:

I would like to review our understanding of items discussed at the September 14 meeting regarding SELECT Herbicide. Valent/Chevron attendees were D.K. Krass (Chevron), K.K. Dougherty (Chevron), J.J. Finegan (Valent) and myself. Attending for EPA were J.H. Chen (Tox), Y.M. Ioannou (Tox), D.J. Urban (EEB), D.B. Warburton (EEB), M.C. Matzer and yourself.

SELECT Herbicide EUP label signal word - Eye Irritation (MRID 409745-15).

EPA agrees that the Category I classification was inappropriate based on the eye irritation study using the formulated product. SELECT Herbicide should be classified Category II for eye hazard.

Acute Inhalation Study with SELECT 2EC (MRID 409745-13)

The Data Evaluation Record for this study questioned the particle size used during the dosing period. After further discussion, Dr. Ioannou and Dr. Chen concluded that the particle sizes used do meet the requirements for an acute inhalation study.

39

Also discussed was the apparent discrepancy between the total aerosol concentration and the concentration of the active ingredient. This discrepancy was related to the fact that test animals were dosed with formulated product diluted in water to a concentration equivalent to two times the maximum field application concentration. The Agency reviewers stated that the test should have been conducted with neat formulation, and that the product could not be classified lower than Category I, even though no test animals died during the study. In conclusion, the Agency is willing to upgrade the study to acceptable, but places the product in Category I for inhalation hazard. The views expressed by the reviewers regarding the potential for Category I classification were not contained in the Data Evaluation Record.

We disagree with the reviewers' conclusions. Our position is outlined in an attachment to this letter. In summary, we believe that classification of SELECT Herbicide for inhalation hazard should reflect the most probable route of exposure under conditions of use, and that this interpretation is supported by language in the Agency's guidelines and Standard Evaluation Procedure for such studies. Category I is not the appropriate classification in our opinion. We believe that our comments fully address the issues raised in the review, and that the Agency should lower the classification of SELECT Herbicide for inhalation hazard.

Acute toxicity of RE-45601 (clethodim) Technical to Daphnia magna (MRID 409745-30)

In the Data Evaluation Record for this study, and during our meeting, EEB reviewers expressed concern regarding the solubility of the test material, and questioned the identity of undissolved material in the testing containers. At the meeting, we offered to conduct an analytical study comparing solubility of test material following procedures used in the Daphnia and LC50 studies for trout and bluegill. Upon further consideration of the expense and delay involved in conducting such a study, we would prefer to accept EPA's initial recommendation to repeat the Daphnia study using the end-use product. If EEB has any objection to this approach, we would appreciate your advising us at your earliest convenience.

If you have any questions, please contact me at (415) 256-2770, or John Finegan at our Washington D.C. office (202) 872-4632.

Sincerely yours,

Daniel P. Fay

Daniel P. Fay
Senior Project Manager

DPF/178.DPF

Attachment

The Acute Inhalation Toxicity of Select 2.0 EC (CC-14900, SX-1721) in Rats

MRID No.: 409745-13

Our response to comments on the above captioned study made by EPA representatives at the meeting held on September 14, 1989 follow. At this meeting, EPA questioned the rationale for testing SELECT 2.0 EC as a dilution and indicated that the low level of the active ingredient, RE-45601, in the test chamber would suggest a Category I labeling requirement. We disagree. We have tested many of our end use products at a dilution which is two times stronger than the most concentrated use dilution because that represents the most likely exposure scenario. In addition, agricultural spray equipment produces very little respirable aerosol in contrast to the aerosol tested in this study.

SELECT 2.0 EC is designed to form an emulsion in water. This emulsion is then sprayed on the target area. It is during application of the diluted form that a person would be exposed by inhalation. A person would not be exposed to respirable aerosols of the undiluted product; while a vapor exposure would occur only when the product is being transferred to spray equipment for mixing. A vapor exposure would be to the solvent since the active ingredient, RE-45601, has such a low vapor pressure (less than 10^{-7} Torr at 25 degrees Centrigrade).

Acute inhalation studies are required for both technical and end use products under 40 CFR Part 158 for all general use patterns provided that "...the product consists of, or under conditions of use will result in, an inhalable material (e.g. gas, volatile substance, or aerosol/particulate)." To determine what form of the product to use in this study, we used Section (a)(2)(iii) of the guideline which states that an acute inhalation study is required for an end use product if: "The product under conditions of use will produce inhalable liquid or solid particles (that is, particles of aerodynamic diameter of 15 micrometers or less)." Both 40 CFR and the testing guidelines refer to "conditions of use." The major inhalation exposure to this product "under conditions of use" occurs in the diluted form. The guideline further states in Section (f)(3) that "The chemical composition and physical state of the substance being tested should, if possible, be the same as that which is encountered during the use of the product. ..." Since the end-use product is diluted for use, the dilution should be tested.

In addition, the Standard Evaluation Procedure for Acute Inhalation Studies states in Section III A that " The test substance will vary depending upon form of the pesticide . . . or an end-use dilution", indicating that an end-use dilution is acceptable for testing. It is also stated in this section that " The physical and chemical form of the test material should be similar to that to which man or animals will be exposed." As noted above, the most likely form of inhalation exposure would be in the form of a spray from the diluted material. Table 1 of the SEP under #4 Test Substances states: "Technical, manufacturing, formulation products, and/or use dilutions; test same physical and chemical form as expected exposure; must be respirable for test animal." The most likely form of exposure is to the diluted material,

consequently the diluted form was tested.

This study was conducted in accordance with the guidance outlines in 40 CFR, Testing Guideline 81-3, and the SEP for inhalation studies. We believe that this study meets guideline requirements and should be acceptable to the Agency based on the Agency's own guidelines.

It is our opinion that placing SELECT 2.0 EC in Category I for inhalation based on this study is incorrect - no animals have died from inhalation exposure to clethodim technical or SELECT 2.0 EC. Pesticides classified in Category I have LC50s $\geq$0.2 mg/l and require a "Fatal if Inhaled" label warning statement. This would be an inappropriate and misleading classification based on data from the technical material and from this study.

[redacted]

312