



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 25, 1996

MEMORANDUM

Subject: Review of Acute Toxicity Data for Precautionary Labeling
EPA ID No.: 59639-IG; Select® 37% M.U.P.

DP Barcode: D223282
Active Ingredient: 121011; Clethodim

Sponsor: Valent U.S.A. Corporation
P.O. Box 8025
Walnut Creek, CA 94596-8025

From: S. Oonnithan
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)
[Handwritten signature and date: 03/25/96]

To: Rob Forrest, PM 23
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FORMULATION FROM LABEL

Table with 2 columns: Ingredient(s) and % by wt.
Rows: Clethodim (37.0), Inerts (63.0), Total (100.0)

BACKGROUND

Valent U.S.A. Corporation has requested in a letter to the Agency (dated 12/21/95), reclassification of a previously reviewed acute oral toxicity study from supplementary to acceptable (Memorandum dated 06/01/95; S. Oonnithan). The subject study was a limit test performed at 5000 mg/kg (MRID 428654-02) for Select® herbicide using Sample No.

Handwritten mark: 1/4

2  
PRS Review (contd.); EPA File Symbol: 59639-IG; Valent U.S.A. Corp.

SX-1860 (Basic Formula). The Agency recommended either a multiple dose study or a limit test at 2000 mg/kg to better define the acute oral toxicity category, because 2/5 test animals in each sex group died at the test concentration.

#### BASIS FOR RECLASSIFICATION

The registrant submitted acute oral toxicity profile of Clethodim product formulations to support the reclassification request. The submitted data are summarized below:

EPA Reg. No., Name, and (AI)	Rat A. Oral LD <sub>50</sub> (mg/kg)		Toxicity Category
	Males	Females	
59639-2; Technical (91.2%)	1630	1360	III <sup>a</sup>
59639-IG; Select® M.U.P. (37.0%)	≈ 5000	≈ 5000	? <sup>b</sup>
59639-3; Select® 2 EC (26.4%)	3610	2920	III <sup>a</sup>
59639-78; Select® (12.6%)	> 5000	4800	III <sup>a</sup>

Notes:

<sup>a</sup> = Registrant's letter dated 12/21/95

<sup>b</sup> = EPA Memorandum dated 06/01/95

#### RECOMMENDATION

The rat acute oral toxicity data summarized above indicate that the LD<sub>50</sub> of formulations containing active ingredient levels ranging from 12.6 to 91.2% fall into 1300 to 4800 mg/kg or Category III toxicity. Female rats appear to be more susceptible to Clethodim than males. The registrant reported that the inert ingredients in these formulations are substantially similar, thus ruling out any significant synergism to the systemic oral toxicity. Based on the above data, the acute oral toxicity of the subject formulation is estimated to be between 2000 to 2500 mg/kg, assigning a toxicity Category III.

The acute oral LD<sub>50</sub> toxicity categories of the Clethodim formulations (more severe category of the two samples tested; Nos. SX-1860 and SX-1861; Basic and Alternate Formulas) are given below:

Guide Line No. and Study Type	Tox. Category & Core Grade <sup>a</sup>
81-1: Acute Oral	III; A
81-2: Acute Dermal	III; A <sup>b</sup>
81-3: Acute Inhalation	IV; A <sup>b</sup>
81-4: Primary Eye Irritation	III; A <sup>b</sup>
81-5: Primary Dermal Irritation	II; A <sup>b</sup>
81-6: Dermal Sensitization	Positive; V <sup>b</sup>

Notes:

<sup>a</sup> A = Acceptable; V = Self Validated;

<sup>b</sup> Memorandum dated 06/01/95.

**LABELING**

**SIGNAL WORD: WARNING**

**PRECAUTIONARY STATEMENTS**

Causes skin irritation and moderate eye irritation. Harmful if swallowed or absorbed through skin. Do not get on skin or on clothing. Avoid contact with eyes. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**STATEMENT OF PRACTICAL TREATMENT**

**IF SWALLOWED:** Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF IN EYES:** Flush eyes with plenty of water. Call a physician if irritation persists.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pneumonia hazard due to petroleum distillates in the product.

7: . . .  
PRS Review (contd.); EPA File Symbol: 59639-IG; Valent U.S.A. Corp.

**ACUTE TOXICITY ONE-LINER**

**EPA ID No.:** 59639-IG; Select® 37% M.U.P.

**DP Barcode:** D223282

**Chemical:** 121011; Clethodim

**Applicant:** Valent U.S.A. Corporation

**Test Material:** Sample No. SX-1860

**Date:** March 25, 1996

G.L. #; Animal; Test Laboratory; Study #; Date	MRID No.	Results	Tox. Cat.	Core Grade <sup>a</sup>
81-1; Rat; Hilltop Biolabs; 91-8140-21(A); 01/16/92	428654-02	LD <sub>50</sub> : 2000 - 2500 mg/kg (Estimate)	III	A

<sup>a</sup> A = Acceptable