



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

7-13-93

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. # 59639-TI; Select Herbicide

To: Joanne Miller/Daniel Kenny PM # 23
Herbicide/Fungicide Branch
Registration Division (H7505C)

From: David L. Ritter, Toxicologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

DLR 7-8-93

Thru: Thomas C. Ellwanger, Jr. Head,
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

E 7/13/93

Registrant: Valent USA Corporation
1333 N. California Blvd.
Suite 600 PO Box 8025
Walnut Creek CA 94596-8025

Formulation From Label:

	<u>% by Wt.</u>
<u>Active Ingredient(s)</u>	
*Clethodim	12.6
<u>Inert Ingredient(s)</u>	87.4
Total	100.0

*(E)-2[1-[[3-chloro-2-propenyl)oxy[limino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one

Action Requested:

Review Primary Eye Irritation study (§81-4) and comment on precautionary labeling.



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Background:

The 5/28/92 Memorandum of W. Woodrow included reviews of Acute Oral, Acute Dermal and Dermal Irritation studies submitted in support of this application. The studies were performed using Select 0.94 EC Herbicide. In addition, studies were cited which used Select 2EC (Reg. # 59639-3), a similar formulation. These included Acute Inhalation, Eye Irritation and Dermal Sensitization studies. The studies are summarized here:

Acute Toxicology Data Requirements (40 CFR §158.340).
Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human And Domestic Animals (1982; revised 1984).

<u>Data Required</u>	<u>MRID #</u>	<u>Toxicity Category</u>	<u>Classification</u>
Acute Oral (§81-1) ¹	422865-02	III	G
Acute Dermal (§81-2) ¹	" -03	IV	G
Acute Inhalation (§81-3) ²	----	IV	M
Eye Irritation (§81-4) ²	----	II	M
Dermal Irritation (§81-5) ¹	422865-02	II	G
Dermal Sens. (§81-6) ²	----	N.S.	M

¹ From W.S. Woodrow 5/28/92 Memorandum; studies used Select 0.94 EC.

² Cited in the W.S. Woodrow Memorandum; used Select 2EC.

PRS Data Review:

The submitted Eye Irritation study was performed using Select 0.94EC. It is placed in TOX Category II and is classified CORE Guideline.

Discussion:

Select 0.94 EC Herbicide contains 12.6% AI. Select 2EC Herbicide contains 26.6% AI. For the purpose of this registration they are considered to be toxicologically equivalent (see the Woodrow Memo).

The new study did not alter the previous TOX Category II for eye irritation assigned by Woodrow.

Precaution Labeling Review:

The new study using Select 0.94 EC Herbicide did not change the TOX category II classification for eye irritation; therefore, the Precautionary Labeling proposed by Woodrow will stand as is.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING §81-4

Product Manager : Joanne Miller/Dan Kenny PM # 23

Submitted for EPA Reg. No.: 59639-TI

Reviewer: David L. Ritter, Toxicologist DLK 7-8-93

MRID No.: 425468-01

Testing Laboratory: Ricerca, Inc.
7528 Auburn Road
Painesville OH 44077

Title of Report: Primary Eye Irritation in Albino Rabbits with
Select Herbicide (0.94 EC).

Date of Report: 8/31/92

Laboratory Identification No.: 92-0071

Author(s): Steven Shults, BA; Ann W. Brock, MS; James Laveglia,
Ph.D.

Species: New Zealand White rabbit

Sex: 3M + 3F

Wt.: 2008 - 2225 Gm.

Test Material: Select Herbicide (0.94 EC) undiluted.

Dosage: 0.1 ml undiluted

Quality Assurance 940 CFR 160.12): Acceptable

Summary: PII = 37.2

Toxicity Category: II

Classification: Guideline

Procedure (note any serious deviation from §81-4):

Standard laboratory animal GLP and husbandry.

0.1 ml undiluted Test Material instilled into right lower conjunctivae. Observations for ocular effects were made at 1, 24, 48 and 72 hours and on days 4, 7, 10, 14 and 21. Fluorescein exams were made at 72 hours and on days 7, 14 and 21. Severity of the lesions were graded according to Draize (1965). Observations for mortality and moribundity were made twice daily for the duration of the study. Animals were not autopsied.

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Results:

All animals survived the experiment.

Corneal opacity and vascularization were reported. Minimal conjunctival redness, chemosis and discharge, including purulent discharge were also reported. All effects had disappeared between days 14 and 21.

Effects on Eyes	Observations Eyes affected/Eyes tested							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/6	4/6	5/6	6/6	6/6	4/6	1/6	0/6
Iris	0/6	3/6	4/6	3/6	3/6	1/6	0/6	0/6
Conjunctivae								
Redness	6/6	6/6	6/6	6/6	6/6	5/6	1/6	0/6
Chemosis	6/6	6/6	6/6	6/6	6/6	0/6	0/6	0/6
Discharge	6/6	6/6	6/6	6/6	6/6	0/6	0/6	0/6

PII = 37.2 (calculated by laboratory).

ACUTE TOX ONE-LINER

1. PC CODE: 121011 Clethodim
2. CURRENT DATE: 6/30/93
3. TEST MATERIAL: Select Herbicide (0.94EC)
4. EPA Reg. #: 59639-TI

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Eye Irr./Rabbit/ Ricera/92-0071/ 31-92	425468-01	PII = 37.2 Corneal & Conjunctival effects gone between day 14 & 21.	II	G

D 627-8-93

Core Grade Key:

- G = Guideline
- M = Minimum
- S = Supplementary