



44686501

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

08/FEB/1999

MEMORANDUM

Subject: EPA Reg. No.: 59639-03 Select 2 EC Herbicide  
DP Barcode: D251587  
Case No: 193924  
PC Code: 121011

From: Eugenia McAndrew, Biologist *Em*  
Technical Review Branch *JCR*  
Registration Division (7505C)

To: Daniel Kenny, PM Team 23  
Herbicide Branch  
Registration Division (7505C)

Applicant: Valent U.S.A. Corporation  
1333 North Carolina Blvd.  
P.O. Box 8025  
Walnut Creek, CA 94596-8025

FORMULATION FROM LABEL:

|                              |                 |
|------------------------------|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| 121011 Clethodim             | 26.4            |
| <u>Inert Ingredient(s):</u>  | <u>73.6</u>     |
| Total:                       | 100.0%          |

**ACTION REQUESTED:** "I am forwarding the dermal sensitization study (MRID 446865-01) and proposed labeling for your review."

**BACKGROUND:** Valent U.S.A. Corporation conducted a dermal sensitization study (MRID 44686501) with Select 2 EC Herbicide, EPA Reg. No. 59639-3, and concluded that the product exhibits a potential to produce dermal sensitization in guinea pigs. Along with the study, Valent has submitted revised copies of the label for this product.

**RECOMMENDATIONS:** The dermal sensitization study has been reviewed and is classified as acceptable. TRB has been unable to locate the toxicity profile for this product and therefore cannot determine the complete list of precautionary and first aid statements required according to the Label Review System. The proposed label does contain the appropriate sentence regarding prolonged or frequent skin contact.

**LABELING:** The following statements pertain only to the fact that Select 2 EC is a sensitizer and it contains >10% petroleum distillates. All of the required statements cannot be determined since the complete toxicity profile is not available.

#### LABEL REVIEW SYSTEM

ID #: 059639-00003 SELECT 2 EC HERBICIDE

#### INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD: CAUTION

#### PRECAUTIONARY STATEMENTS:

Wear long-sleeved shirt and long pants, socks and shoes. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

#### STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.

The proposed label should contain the following guidance:

Note to Physician: This product may pose an aspiration pneumonia hazard. Contains petroleum distillate.

## DATA REVIEW FOR DERMAL SENSITIZATION TESTING ( 870.2600)

**Product Manager:** 23  
**MRID No.:** 44686501

**Reviewer:** Eugenia McAndrew  
**Study Completion Date:** October 9, 1998  
**Study No.:** 98-1814

**Testing Facility:** Huntingdon Life Sciences, East Millstone, New Jersey  
**Author:** Donna L. Blaszak, B.S., AALAS LATG

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Select 2 EC; Lot No. 10340396320C; Batch No. VIB-007EC-7; 26.1% active ingredient; amber liquid

**Positive Control Material:** Dinitrochlorobenzene (DNCB)

**Species:** Guinea pig; albino; Dunkin Hartley

**Age:** 5 to 6 weeks old

**Weight:** Males: 360 to 467 g; Females: 317 to 382 g

**Source:** Covance, Inc., Denver, Pennsylvania

**Method:** Buehler

### Conclusion:

1. **This product is a dermal sensitizer.**
2. **Classification:** Acceptable

**Procedure (Deviations from 870.2600):** None

**Procedure:** For the induction phase, 0.3 mL of the undiluted test material was applied under occlusion to 20 test animals for six hours. This was performed once per week for three weeks for a total of three induction exposures. Fourteen days after the last induction exposure, a naive site on each of the animals was challenged with the test substance and appropriate amount of saline to produce a 75% concentration applied in the same manner as in the induction phase. A naive control group of 10 animals was treated with the 75% concentration at challenge only. The report states that the results of the challenge were "equivocal" so the challenge procedure was repeated at a 50% concentration. Reactions were scored 24 and 48 hours after each exposure.

**Results:** All test animals showed a positive reaction during the three induction phases with scores of 0.5 to 3. Four of the 20 test animals challenged had clear dermal responses with scores of 2. Because 8/10 control animals also showed some irritation with scores of 0.5 and 1, a re-challenge was performed at a lower, less irritating concentration of 50%. In the re-challenge results, 7/20 of the test animals exhibited clear dermal responses with scores of 1 or greater while none of the control animals scored 1 or greater. The conclusion under conditions of this study is that Select 2 EC has the potential to produce dermal sensitization in guinea pigs.

Appendix D of the study report contains the results of the positive control DNCB test which was conducted in February to March 1998. The results were appropriate.

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# ACUTE TOX ONE-LINERS

1. DP BARCODE: D251587
2. PC CODE: 121011
3. CURRENT DATE: 08/FEB/1999
4. TEST MATERIAL: Select 2 EC; Lot No. 10340396320C; Batch No. VIB-007EC-7; 26.1% active ingredient; amber liquid

| Study/Species/Lab<br>Study #/Date  | MRID     | Results    | Tox.<br>Cat. | Core<br>Grade |
|--|----------|------------|--------------|---------------|
| Dermal sensitization<br>guinea pig/Huntingdon Life<br>Sciences/98-1814/10-9-98 | 44686501 | Sensitizer | -            | A             |
|  |          |            |              |               |
|  |          |            |              |               |
|  |          |            |              |               |
|  |          |            |              |               |
|  |          |            |              |               |

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated