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

JAN 9 1992

MEMORANDUM:

Subject: EPA Registration Number: 50534-188
Bravo 720

From: Mary L Waller, Biologist Mary Waller 1/9/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Cynthia Giles-Parker, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)
E 1/10/92

Applicant: ISK Biotech Corporation
5966 Heisley Road
P.O. Box 8000
Mentor, OH 44061-8000

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Chlorothalonil	54%
Inert Ingredient(s):	46%
Total:	100%

1-24

BACKGROUND: This review responds to two submissions. The first submission involves the applicant contesting an Agency request for addition of a statement of practical treatment for oral exposure. The registrant claims that the acute oral toxicity category is IV based on results of an acute oral study (MRID NO. 00038920) and that a statement of practical treatment for oral exposure is unnecessary since statements of practical treatment are not required for category IV classifications.

The second submission involves the referral to PRS of a letter from Frank L. Davido to PM 21 concerning a pesticide exposure involving this product in which a pesticide applicator suffered corneal opacification which eventually cleared. Mr. Davido has requested that the precautionary labeling be reviewed to determine if labeling changes are needed.

The registration jacket for this product contains a 7/30/86 HFB/TSS review of primary eye irritation data which was classified as category II and acute dermal toxicity data which was classified as category III. RSB/PRS files contain a dermal sensitization data review that indicates that this product is a sensitizer.

RECOMMENDATION: RSB/PRS findings are as follows:

1. The acute oral study cited to support the registrant's claim that the product is in toxicity category IV is unacceptable and classified as supplementary. Therefore, the registrant cannot remove the statement of practical treatment for oral exposure. The registrant must conduct another study or cite acceptable data on this product to satisfy the acute oral toxicity data requirement. The acute oral study was classified as deficient for the following reasons: insufficient number of animals tested, no females tested, toxic symptoms were not recorded and gross necropsy was not performed.

2. The registrant should submit an acute inhalation toxicity study and a primary skin irritation study if these data requirements have not been fulfilled.

3. A review of the precautionary labeling in reference to the eye exposure does indicate that the labeling is insufficient and needs clarification. See requested changes in labeling section.

4. The signal word is "WARNING" based on the primary eye irritation data. However, as pointed out in the 7/30/86 HFB/TSS review, RSB/PRS cannot be certain of the accuracy of the signal word until all acute toxicity data requirements are fulfilled.

LABELING:

1. The following precautionary labeling includes oral and inhalation precautionary statements as a means of providing some protection to pesticide users until acceptable acute oral and acute inhalation toxicity data are submitted. However, upon submission of these data, the precautionary labeling statements will be reviewed and may be revised based on the data. Revise the precautionary statements as follows:

   "Causes substantial but temporary eye injury. Wear goggles or safety glasses. Harmful if swallowed, inhaled or absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

2. The "Note to User" under the Directions for Use section which reiterates the personal protective clothing required while mixing, loading, and applying this product must be revised to include the requirement for goggles or safety glasses. When a registrant chooses to repeat the personal protective clothing and equipment requirements under the Directions for Use section, all required personal protective clothing and equipment must be listed.

3. The statement of practical treatment should read as follows:

   "IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

   IF SWALLOWED: Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, large quantities of water. Avoid alcohol.

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

009344

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1)

Product Manager: 22
MRID No.: 2400-506-01
Testing Facility: International Research & Development Corporation
Author(s): Francis X. Wazeter, Ph.D
Species: Albino rats, (Carworth CFE)
Age: Not Specified
Weight: 200-231 g.
Source: Not Specified
Test Material: Bravo 6-F (thick gray liquid)
Quality Assurance (40 CFR §160.12): Study conducted prior to GLP's

Reviewer: M. Waller
Report Date: 10/29/71
Report No. 293-005

Conclusion:

1. LD_{50} (mg/kg): **Males =**
   Females =
   Combined =
2. **The estimated LD_{50} is**
3. **Tox. Category:** **Classification:** Supplementary

Procedure (Deviations from §81-1): Study conducted using only males; Toxic symptoms were not recorded; Gross necropsy not performed;

Results:

Dosage	(Number Killed/Number Tested)		
	Males	Females	Combined
5000 mg/kg	0/5		
7500 mg/kg	0/5		
10,000 mg/kg	4/5		

Symptoms & Gross Necropsy Findings: Not conducted.

4