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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: September 4, 1985

SUBJECT: EPA File Symbol 2829-REL
Vinyzene BP-55 DIDP

FROM: Mary L. Waller MW 9/16/85 CJ 9/17/85
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

Applicant: Morton Thiokol
Ventron Division
150 Andover Street
Danvers, MA 01923

ACTIVE INGREDIENT:
10,10'-oxybisphenoxarsine..... 5%
INERT INGREDIENT..... 95%

Background:

The applicant has submitted an acute oral, acute dermal, primary dermal irritation and a primary eye irritation study. The studies were conducted by Food & Drug Research Laboratories, Inc., and the data Accession Number is 254794. The type of support was not indicated.

Recommendation:

FHB/TSS finds the studies acceptable to support registration only of the formulation tested. First, the applicant must identify which formulation was tested since there are five formulations, [redacted] Second, the applicant must submit an acute inhalation study on the formulation tested or data to support a waiver. Third, the applicant must submit a dermal sensitization study on either the

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED

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formulation tested or the technical. Fourth, the applicant must submit a complete battery of acute toxicology studies on the other four product formulations.

Based on the data provided. The signal word is DANGER.

Labeling:

The labeling must be revised as follows:

1. The following practical treatment statements for category I products must appear on the front panel of the label grouped with the signal word and child hazard warning.

PRACTICAL TREATMENT

If in eyes: Flush with plenty of water.
Call a physician.
If on skin: Wash with plenty of soap and water.
Get medical attention.
If swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water.
Get medical attention.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

2. Delete heading "First Aid" and the paragraph immediately following from side panel.

3. Revise precautionary statements as follows:

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

4. Additional labeling comments may be necessary upon submission of acceptable inhalation and dermal sensitization data.

Review:

1. Acute Oral Toxicity Study: Food & Drug Research Laboratories, Inc.; FDRL Study No. 7923; February 10, 1984.

Procedure:

Five groups each consisting of five male and five female fasted rats received one of the following doses of test material orally: 500 mg/kg, 810 mg/kg, 1320 mg/kg, 2150 mg/kg, 3500 mg/kg. Animals were weighed prior to testing, on days 8 and 15 or at death. Animals were observed frequently on the day of dosing and twice daily thereafter. All toxic effects were recorded, and all animals were subjected to gross necropsy.

Results:

At 500 mg/kg, no mortalities occurred. At 810 mg/kg, 2/5 M and 4/5 F died. At 1320 mg/kg, 2150 mg/kg and 3500 mg/kg, 5/5 M and 5/5 F died. The LD_{50} for males was reported to be 930 mg/kg with a 95 percent confidence interval of 340 to 1510 mg/kg. The LD_{50} for females was reported to be 790 mg/kg with a 95 percent confidence interval of 230 mg/kg to 1350 mg/kg. The combined LD_{50} is 860 mg/kg with a 95 percent confidence interval of 460 mg/kg to 1260 mg/kg.

The following toxic effects were observed: diarrhea, decreased activity, ataxia, salivation, wet abdomen, labored breathing, hair loss on abdomen, dark material around nose, dried blood around eyes, anorexia and an increased rate of respiration.

Observations noted at necropsy are as follows: small white raised areas on spleen, stomach and kidney adhered to abdominal wall, bloodlike viscose liquid in intestines, abdominal organs adhered together and clear or bloodlike liquid in abdominal and thoracic cavity.

Study Classification: Core Guideline Data

Toxicity Category: Category III - Caution

2. Acute Dermal Toxicity Tests: Food & Drug Research Laboratories; February 1, 1984; FDRL Study No. 7923A

Procedure:

Five male and five female New Zealand White rabbits were clipped the day before, and each received 2000 mg/kg of test material applied to a test site which was kept under occlusive wrap for 24 hours. After 24 hours, the binders were removed, and the exposure sites were wiped with clean gauze to remove all residual test material.

All animals were observed frequently on day of dosing and twice daily thereafter for the remainder of the study. All toxic effects were noted and body weights were recorded prior to the study and on days 8 and 15. Gross necropsy was performed on all animals.

Results:

No deaths occurred. Toxic effects noted included moderate to severe eschar formation at test site, diarrhea, decreased activity, anorexia, nasal discharge and soft stools. No abnormalities were noted at gross necropsy.

Study Classification: Core Guideline Data

Toxicity Category: Category III - Caution

3. Primary Dermal Irritation Study: Food & Drug Research Laboratories, Inc.; FDRL Study No. 7923A; January 16, 1984.

Procedure:

Six New Zealand White rabbits each received 0.5 ml of test material applied to two intact test sites which were clipped the day before. The test sites were kept under occlusive wrap for 4 hours after which the wrap was removed, and the test site was wiped with clean gauze to remove any remaining test material.

Observations to note skin reactions were conducted at 1/2 hours after unwrapping, at 28, 52, and 72 hours, and at day 4, 7, 10 and 14.

Results:

At 30 minutes after exposure, 6/6 animals exhibited well-defined erythema and moderate edema. At 28 hours, 5/6 animals exhibited severe erythema with slight eschar formation and slight edema. At 52 and 72 hours, 6/6 animals exhibited severe erythema with slight to severe eschar formation and slight edema. At 4, 7, 10, and 14 days, 6/6 animals exhibited severe erythema with moderate to severe eschar formation and very slight to well-defined edema.

Study Classification: Core Guideline Data

Toxicity Category: Category I - Danger

4. Primary Eye Irritaton Study: Food & Drug Research Laboratories, Inc.; FDRL Study No. 7923A; February 1, 1984.

Procedure:

Nine New Zealand White rabbits were examined with sodium fluorescein solution one day prior to treatment with 0.1 ml of test material applied to one eye of each animal. The animals' eyelids were held shut for one second, and 3/9 animals' eyes were washed with physiological saline solution 30 seconds after instillation of the test material. The untreated eye served as a control.

Observations to note eye irritation were conducted at 1, 24, 48 and 72 hours and at 4, 7, 10, 13, 16, 19 and 21 days. Test animals were weighed at the beginning and end of the study.

Results:

The animals with unwashed eyes exhibited the following effects: At 24 hours, corneal opacity (2/6 = 10, 4/6 = 5), iris irritation (6/6 = 1), conjunctiva redness (6/6 = 3), chemosis (6/6 = 4), and discharge (6/6 = 3); at 7 days, corneal opacity (1/6 = 10, 1/6 = 30), iris irritation (6/6 = 1), conjunctiva redness (1/6 = 3, 3/6 = 2, 2/6 = 1), chemosis (1/6 = 3, 5/6 = 2), and discharge (2/6 = 2, 4/6 = 4); at 16 days, corneal opacity (1/6 = 20, 1/6 = 5), iris irritation (2/6 = 1), conjunctiva redness (1/6 = 1), chemosis (1/6 = 2, 1/6 = 1), and discharge (1/6 = 1), and at 21 days, corneal opacity (1/6 = 20, 1/6 = 5), iris irritation (1/6 = 1), conjunctiva redness (1/6 = 1), chemosis (1/6 = 1) and discharge (1/6 = 1).

The animals with washed eyes exhibited the following effects: At 24 hours, corneal opacity (3/3 = 5), iris irritation (3/3 = 1), conjunctiva redness (3/3 = 3), chemosis (3/3 = 4), and discharge (1/3 = 3, 2/3 = 2); at 7 days, iris irritation (3/3 = 1), conjunctiva redness (3/3 = 1), chemosis (1/3 = 3, 2/3 = 2) and discharge (3/3 = 1); and at 13 days, all irritation had cleared.

Study Classification: Core Guideline Data

Toxicity Category: Category I - Danger