PB-907
TXR-6439

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

006437

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 28, 1985

SUBJECT: EPA File Symbol: 748-EUO
Rez Stain and Wood Preservative Solid Color Oil

FROM: Deloris F. Graham DFG 11/5/85
Technical Support Staff
Fungicide-Herbicide Branch
Registration Division (TS-767C) E 11/7/85

TO: Henry Jacoby
Product Manager (21)
Registration Division (TS-767C)

Applicant: PPG Industries, Inc.
Coatings and Resins
Pittsburgh, PA 15272

Active Ingredients:

Bis(tributyltin) oxide (TBTO)	0.50%
Folpet [n-([trichloromethyl]thio) phthalimide]	0.50%
Inert Ingredients	99.00%

BACKGROUND

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization Studies. Studies conducted by Biotecs Laboratory. All studies, except Dermal Sensitization, are under Accession Number 254916 and Dermal Sensitization is under 255202. Method of support not indicated.

RECOMMENDATIONS

(1) FHB/TSS finds these data acceptable to support conditional registration of this product, however, for future submissions please note, in the Primary Dermal Study individual scores for erythema and edema for all animals at 24 and 72 hours after treatment must be submitted.

(2) Although acute Oral LD50 could not be converted from ml/Kg to mg/Kg to determine appropriate toxicity category, it is unlike however that the category will be greater than III - CAUTION.

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(3) The appropriate signal word is WARNING.

LABEL

Please see enclosed copy for appropriate labeling procedures and format for appropriate placement of precautionary and ingredient statements.

REVIEW

(1) Acute Oral Toxicity Study: Biotecs Laboratory; Report 84-145; June 4, 1984.

PROCEDURE

Two groups consisting of five male and five female rats each received 5.0 ml/kg dose of one of the following materials: test substance or [redacted] Observation made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS

No mortalities reported in either group. Hair loss around uro-anal area noted is [redacted] group. Necropsy of test group indicated endemic hydronephrosis; slight lung congestion with grey focal areas. Necropsy of [redacted] group indicated endemic hydronephrosis; small, pale, rough surface spleen; lung abscesses, yellow area on right kidney, spleen adhered to body wall; pancreas purple and injected. LD_{50} for both groups reported to be greater than 5.0 ml/kg (?).

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Since confidential statement of formula was not available, LD50 could not be converted from ml/kg to mg/kg to determine appropriate category.

(2) Acute Dermal Toxicity Study: Biotecs Laboratory; Report 84-145; June 4, 1984.

PROCEDURE

Four groups consisting of five male and five female rabbits each received one of the following doses: 1.0, 2.0, 3.0 or 4.0 g/kg at abraded skin sites under occlusive wrap for 24-hour exposure period. Observations made for 14 days postdosing. Necropsy performed on all animals. Only females dosed at 4.0 g/kg.

RESULTS

At 1.0 g/kg, 1/5 M and 1/5 F died; at 2.0 g/kg 3/5 M and 3/5 F died; at 3.0 g/kg, 5/5 M and 3/5 F died; at 4.0 g/kg, 5/5 F died. Marked capillary injection, moderate erythema and severe edema noted. Vocalization, languidness, depressed respiration, piloerection, iritis, recu-limb immobility, whole-body tumors, cyanosis, convulsions, mydriasis, anorexia, dehydration, hunched posture were some of the clinical signs noted. Necropsy report indicated moderate congestion and peripheral hemorrhages of lungs; mottled color liver; black spleen; stomach shrunken, corroded; kidneys moderately swollen and hydronephrosis; ventral surface black; dorsal surface purple; small intestines reddened; hemorrhages on cecum and/or white plaque formed along the collecting vessel of the duodenum; enlarged and/or trabeculated thymus gland; pancreas with blood; to name some of the abnormalities at necropsy. LC_{50} for males reported to be 1.62 g/kg with confidence limits between 1.17 and 2.26 g/kg. LD_{50} for females reported to be 1.88 g/kg with confidence limits between 1.29 and 2.75 g/kg. LD_{50} for male and females combined reported to be 1.72 g/kg with confidence limits between 1.35 and 2.19 g/kg.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: III - CAUTION

(3) Acute Inhalation Toxicity Study: Biotecs Laboratory; Report 84-145; June 4, 1984.

PROCEDURE

Five male and five female rats were exposed nose only to a 134.3 mg/m^3 mouse respirable or 338.8 m/m^3 human respirable gravimetric concentrations. Observations made for 14 days postexposure. Necropsy performed on all animals. Two groups consisting of 5 rats per sex per dose were treated in a similar manner as previously stated group except [redacted] or Air Only was used.

RESULTS

No mortalities reported in either of the three groups. Weight loss, thin, hunched appearance, ataxia noted in test group. Slight coordination loss, slight whole body tremors noted in [redacted] Changes in spleen color and size, enlargement of adrenal glands, hydronephrosis noted in all three groups at necropsy. In addition, minor pleural adhesions noted in [redacted] group at necropsy.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: ~~III~~ - CAUTION

(4) Primary Dermal Irritation Study: Biotecs Laboratory; Report 84-145; June 4, 1984.

PROCEDURE

Six New Zealand rabbits received 0.5 ml of the test material at two abraded and two intact skin sites per rabbit for 24-hour exposure period. Observations made according to procedures in §163.81-5, p. 37360, of the Federal Register for August 22, 1978 and J.H. Draize (1959) technique.

RESULTS

At 24 and 72 hours, severe erythema, eschar and moderate to severe edema on intact and abraded skin sites. Irritation reported to have subsided by day 12.

STUDY CLASSIFICATION

Core Minimum Data. Individual score erythema and edema for each animal at 24 and 72 hours must be submitted.

TOXICITY CATEGORY: II - WARNING

(5) Eye Irritation Study: Biotecs Laboratory; Report 84-145; June 4, 1984.

PROCEDURE

Nine New Zealand rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with lukewarm tap water 20 to 30 seconds after treatment. Observations made according to the Federal Register, August 22, 1978, part II, pg. 37360, §163.81-4 and J.H. Draize technique (1959).

RESULTS

No irritation reported in any of the animals tested.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: IV - CAUTION

(6) Dermal Sensitization Study: Biotecs Laboratory; Report 84-445; October 11, 1984.

PROCEDURE

Twenty guinea pigs received 0.1 ml of the test material to an intact skin site, then wrapped in 1-inch square gauze and a second 0.1 ml applied to gauze for 6-hour exposure. Applications during the induction phase were applied three times a week for three weeks totaling nine dose applications. Two weeks after ninth dose, challenge dose was applied. Observations made at 6, 24 and 48 hours after treatment.

RESULTS

At 6 hours posttreatment during induction phase 8/20 pigs had slight reactions; at 24 hours, 1/20 had slight reactions; at 48 hours, 4/20 slight reaction. At 6 hours during challenge phase, 8/20 slight reaction; at 24 hours, 1/20 slight reaction; at 48 hours, 4/20 slight reaction. It was therefore concluded that this product is a skin sensitizer.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Sensitizer

TBTO Scientific Reviews

Page _____ is not included in this copy.

Pages 6 through 8 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

X A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
