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

003719

3/30/84

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: P3-Oxonia Active - EPA File Symbol No. 887-UA.
CASWELL Nos. 642 F and 486 AAA

TO: Arturo E. Castillo, PM #32
Disinfectant Branch
Registration Division (TS-767)

THRU: David Ritter, Acting Section Head DGR 3-26-84
Review Section #1
Toxicology Branch/HED (TS-769)

FROM: Carlos A. Rodriguez CAR 3/30/84
Review Section #1
Toxicology Branch/HED (TS-769)

Applicant:

Bonewitz Chemical Services
P.O. Box 927
1731 North Roosvelt
Burlington, Iowa 52601

Requested Action:

Registration as an acid liquid sanitizer for food processing equipment.

Recommendations:

Under "Precautionary Statements" precede the word "Corrosive" with "Danger".

Under "Eye First Aid" add "Get medical attention".

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Add under "If Swallowed":
Note To Physicians:

Probable mucosal damage may contraindicate the use of gastric lavage.

Hydrogen Peroxide is GRAS under 21 CFR 182.1366 as a bleaching agent in foods. There are also direct food additive clearnaces; e.g., 21 CFR 172.892 (Modified Food Starch) and 21 CFR 240.1051. (Treatment of wine).

Peracetic Acid is cleared under 21 CFR 172.892 (Modified Food Starch) and 172.560 (Modified Hop exhoct). We understand that FDA sets limits for levels of Souitzers in wash waters.

A. Formulation of P3 Oxonia Active

Active Ingredients:

Peracetic Acid----------4.00%
Hydrogen Peroxide----------25.00%

Inert Ingredients:

[redacted] Total 100.00%

Uses:

P3 oxonia active Sanitizers is recommended for use on internal surfaces of closed systems such as pipes, tanks, fillers, evaporators and pasteurizers in dairies, breweries, wineries and beverage plants.

Toxicology Data Submitted in Support of this Action

1. Acute Oral Toxicity of P3 Oxonia Active, (F-FE/ALAB TOXIKOLOGIE, Dr. Kastner, Report No. 210, March 25, 1977).

5 male and 5 female Wistar rats with a mean body weight of 197.4 and 157.5 g were used per dose level in this study. The product was administered once as an 20 ml/kg of body weight per application. The animals were observed for eight days after treatment for toxic symptoms. Eight days after treatment the surviving rats were sacrificed and dissected. Also all rats that died during the study were dissected. Procedure of Litchfield and Wilcoxon was used to calculate the LD50.

2.

Results:

LD50 (male rats) = 2.43 (2.04 - 2.88) g/kg

LD50 (female rats) = 2.10 (1.92 - 2.30) g/kg

Toxic symptoms observed

Ruffed fur, reduced motility, gasping, cramps and diarrhea.

Gross Pathological Findings

Mucous membrane of the stomach corroded, white discoloration of the liver. Stomach heavily filled with gas. Acute gastritis, acute enteritis and peritonitis.

Inflammations found in the abdominal cavity: hepatitis, lienitis, cystitis, pancreatitis and colitis.

TOX Category: III

Classification: Core-Minimum Study.
(1) The different dosages tested were not reported.

2. Acute Oral Toxicity of Hydrogen Peroxide (35%) in Rats, (FMC Tox. Lab., Study No. 183-745, 8/19/83).

Groups of 10 male and 10 female young adult Sprague-Dawley CD strain rats were fasted overnigth prior to dosage by oral intubation of the test material. Male body weights ranged from 204 to 286 g and female weights ranged between 200 to 242 grams. Male rats were dosed at 2000, 1588, 1260, 1000, 794 and 630 mg/kg, female rats were dosed at 1588, 1260, 1000 and 794 mg/kg. The rats were observed frequently for mortality and clinical signs on the day of dosage and twice daily thereafter for 13 days and on day 14 they were observed once. Body weights were taken on day 0, 7 and 14 of the study. Gross necropsies were performed on all animals which died during the study. Survivors were sacrificed on day 14 and submitted for gross necropsy.

Results: (Laboratory Report)

LD50 (male rats) = 1193 mg/kg.

LD50 (female rats) = 1270 mg/kg.

Mortality:

All males died in the highest dose groups 2000 mg/kg and six died in the 1588 dose group. Eight females died in the 1588 dose group indicating that the material is slightly more toxic orally to female rats.

Signs of Toxicity:

In the 1588 mg/kg dose group a high incidence of decreased locomotion was observed in the male rats and continued until day 3 of the study. In the 1260 mg/kg dose group the decreased locmotion subsided by day 1 of the study. Most of the surviving rats returned to normal.

Body Weigths:

All the surviving females gained weight by the 14th day observation period. Of the four surviving males in the 1588 mg/kg dose group, two of them lost weight. All surviving males in all of the other groups gained weight.

Necropsy: (male rats)

In the 2000 and 1588 mg/kg groups gross internal abnormalities observed in most animals included blood in the intestines, stomach white and hemorrhagic, white tongues, blood filled bladders, white foci in livers, blood in the stomach. These findings appeared less common in the lower dose group levels. In the 630 mg/kg dose group one rat showed hemorrhagic cystitis and urinary bladder filled with blood.

Necropsy: (female rats)

In the 1588 and 1260 mg/kg dose groups female internal abnormalities observed were similar as those observed for male rats. Few instances of internal abnormalities such as blood in the intestines, stomach and intestines lining red appeared in the lower dose groups.

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3. 8-Week Subchronic Oral Toxicity of Peracetic Acid by Veger et al., Cz. Hyg., Vol. 22, pp. 59-63, 1977.

Summary

72 male rats of the Wistar strain weighing an average of 217 grams were used in this study. The rats were divided into 6 groups of 12 animals each. Three groups received distilled water containing Persteril in concentrations of 0.0001%, 0.001% and 0.005% CH_3 COOOH. The first two dosages considered for practical disinfection (1-10 mg/l) and the latter in a dosage (5-50 times) higher than the practical disinfection. Two other control groups were used. The first control group received pure distilled water. The second control group was divided into two subgroups; the rats received chlorinated water in two concentrations (1 mg and 10 mg of free residual chlorine per liter). Calcium chloride was used as the source of active chlorine. The rats were weighed twice a day.

Results:

(Statistically using t-test).

Macroscopic Examination:

Control and test rats comparable throughout the experiment.

Weight:

No significant difference between individual groups.

Hematology:

The number of erythrocytes (red cells) were not statiscally significant between the control and test groups. Hemoglobin was significantly increased in the rats given Persteril (0.0001%) as compared with the rats in the control group. Increased blood pigment values, as compared with the initial values, were also noted with the higher concentration of Persteril (0.001% and 0.005%). In the rats that received the chlorinated drinking water a decreased in the amount of hemoglobin occurred, which was significantly different from that of the controls.

The number of leukocytes and the differential blood count also remained unaffected.

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Organ Weights

The average weight of the spleen in the test animals which received Persteril at all concentrations in their drinking water and chlorinated water in the lower concentration was significantly higher when compared to controls. No weight changes relative to controls were found in the lungs, heart, liver, kidneys, adrenals and the stomach.

Histologic Examination

The organs investigated histologically from the rats which drank Persteril treated and chlorinated water at concentrations of (0.0001% and 0.001%) exhibited no essential differences from the controls. The liver, spleen, and kidneys also exhibited no essential findings from the group of animals that received Persteril at 0.0001%. Concentration (0.001%) of both subtances tested, cloudy swellin of the plasma, cloudy swelling of the white pulp in the spleen, and congestion of the medulla in the kidneys appeared in the majority of the rats. An increase of hemosiderin in the red pulp of the spleen was also noted in the rats that received Persteril at 0.0001% and 0.001%.

Water Intake

Persteril treated rats had significantly lower water intake than water with chlorine or pure distilled water treated rats.

Conclusion

a) A NOEL has not been determined. The Persteril treated animals at the lower concentration tested (0.0001%) experienced a significant increased of hemoglobin when compared with the control group. In addition, there was an increase in hemosiderin in the red pulp of the spleen. The average weight of the spleen was significantly higher than that of the controls.

b) Male rats only were tested. Equal numbers of animals by each sex should be used.

Classification: ~~Supplementary~~ Study.
Core Minimum 3/30/84
Cat.

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4. Acute Inhalation LC50 of P3 Oxonia Active and 5% Aqueous Preparation of P3 Oxonia Active, (F-FE/ALAB TOXIKOLOGIE, Report No. 210, 3-25-1977).

20 male and 20 female Wistar rats weighing between 151 to 178 g were used in this study. The 5% aqueous preparation as well as the undiluted product were tested on 10 male and 10 female rats. The rats were placed into an air-tight and closed inhalation vessel with a volume of 120 liters. Male and female rats were kept separately. The material was introduced into the inhalation vessel in the form of mist by a fogging nozzle. The rats were sprayed for four hours with 38.2 g of the 5% solution and 28.8 g of the undiluted product which corresponds to 851 and 13429 mg/m^3 concentration in the air.

Results:

LC50 = > 13439 mg/m^3 (13 mg/L)

Toxic Signs:

The rats exposed to the 5% P3 oxonia concentration did not exhibit any toxic symptoms after or throughout the experiment.

The rats exposed to the P3 oxonia active showed sneezing, wet fur and hunched back. These symptoms disappered within one hour after termination of the test.

Mortality:

All rats exposed to P3 oxonia active or the 5% P3 oxonia active concentration survived.

Body Weight:

All rats exposed to P3 oxonia active or the 5% P3 oxonia active concentration showed an increase in body weight at the completion of the test.

Pathological Findings:

None observed in the male rats. Slight enteritis observed in six females treated with 5% P3 oxonia active concentration. This observation was seen in one female only in the P3 oxonia active treated rats.

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