

PD-606
12-7-77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002896 ✓

DATE: December 7, 1977

SUBJECT: EPA Reg. No. 1839-31. BTC-8358. Addition of Teratology Study to Files. *duplicate*

FROM: Edwin R. Budd/Toxicology Branch/RD/OPP WH-567

TO: Joseph Tavano/FM #31/RD/OPP WH-567

Caswell No. 16E

Formulation

BTC-8358 (Onyx Chemical Co.). EPA Reg. No. 1839-31. Active ingredients: n-Alkyl (C₁₂, 40%; C₁₆, 50%; C₁₈, 10%) dimethyl benzyl ammonium chlorides--80%; ethyl alcohol--10%. Concentrated Disinfectant for Manufacturing Use Only.

Action Requested

Review submitted teratology study for addition to files.

Summary and Recommendations

BTC-8358 did not induce terata in experimental animals in this study. The NEL $\geq$ 50 mg/kg/day (highest level tested). The study is categorized as Core Study-Minimum Data. RPAR criteria were not exceeded. Add study to files as requested.

BEST AVAILABLE COPY

Study Identification

Teratologic Evaluation of BTC-8358 in Rats, Food and Drug Research Laboratories, Inc., Laboratory No. 5443-B, August 30, 1977. (Accession No. 232093).

Test Material

BTC-8358, Notebook #1607, Activity 80%, 676-12/L.

Protocol

Daily oral administrations of BTC-8358 (in aqueous solution) to groups of adult female, Sprague Dawley albino rats during days 6-15 of gestation at dosage levels of 0 (negative control), 5, 15 and 50 mg/kg/day. The number of pregnant females in each group was 32, 21, 20 and 20 for 0, 5, 15 and 50 mg/kg/day respectively. An additional positive control group containing 32 pregnant females was given 250 mg/kg/day of aspirin in a similar manner. Daily observations for appearance and behavior. Body weights on days 0, 6, 11, 15 and 20. Caesarean sections on day 20. Uterine contents examined; number of implantation sites recorded; number of live fetuses, dead fetuses and resorption sites determined; number of corpora lutea recorded; and urogenital tract examined. Body weights and sex of live fetuses recorded. One-third of fetuses in each litter (including all fetuses showing any gross external abnormalities) fixed in Bouin's solution and then

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examined for soft tissue abnormalities using the Wilson free-hand slicing technique. Remaining pups stained with Alizarin-Red S and examined under magnification for skeletal abnormalities.

Results

No apparent adverse effects due to the test material in the following parameters: body weights of dams during pregnancy, number of pregnancies carried to 20 days, number of live fetuses/dam, number of implantation sites/dam, number of dead fetuses/dam, number of resorptions/dam, male/female ratios of fetuses, average body weights of fetuses, results of examinations for skeletal and soft tissue abnormalities. A slight increase in rudimentary 14th ribs in high dose (50 mg/kg/day) animals was observed. Toxicology Branch considers this increase to be a normal, spontaneous variant (probably due to stress) and not a teratologic effect. Positive control animals (aspirin, 250 mg/kg/day) had low body weights of fetuses, increased numbers of resorptions and increased numbers of skeletal and soft tissue abnormalities.

Conclusions

The test material did not induce terata at dosage levels of up to 50 mg/kg/day (highest level tested).

NEL $\geq$ 50 mg/kg/day
Core Study-Minimum Data

Colleen R. Biedel 12/7/77

ONYX



BTC-8358 is a cationic germicide.

BTC-8358 in recommended use dilutions is non-corrosive to inanimate surfaces.

FISH & WILDLIFE PRECAUTIONS.

This product is toxic to fish. Keep out of lakes, streams or ponds.

Do not contaminate water by cleaning of equipment or disposal of waste.

Do not reuse empty drum. Return to drum reconditioner or destroy by perforating or crushing and burying in a safe place.

DO NOT MIX WITH SOAP OR ANIONIC MATERIALS.

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BTC-8358

CONCENTRATED GERMICIDE FOR MANUFACTURING USE ONLY

Active Ingredients:

n-Alkyl (C ₁₂ 40%, C ₁₄ 50%, C ₁₆ 10%) Dimethyl Benzyl	
Ammonium Chlorides	80%
Ethyl Alcohol	10%
Inert ingredients	10%
TOTAL	100%

Net Contents:

EPA Reg. No. 1839-31

ONYX CHEMICAL COMPANY

Division of Millmaster Onyx Corporation
190 WARREN STREET

Jersey City, New Jersey 07302

DANGER

Keep Out of Reach of Children. See right panel for additional precautionary statements.

DANGER

Keep Out of Reach of Children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

FIRST AID

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For yes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock as well as oxygen and measures to support breathing manually or mechanically may be needed. If persistent, convulsions may be controlled by the cautious intravenous injection of a short-acting barbiturate drug.

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