8-8-77

16E
16C
19

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 003622

DATE: August 8, 1977

SUBJECT: EPA Reg. No. 6836-2; 6836-25; 6836-26; 6836-36. BARQUAT MB-50; BARQUAT 4250; BARQUAT 4250-Z; BARQUAT MX-50. Lonza, Inc., Fair Lawn, New Jersey. Teratologic Evaluation.

FROM: Toxicology Branch

TO: Mr. Joseph Tavano, Product Manager # 31

BARQUAT MB-50. Active ingredients: n-alkyl (C_{14}, 50%; C_{12}, 40%; C_{16}, 10%) dimethyl benzyl ammonium chloride - 50%; Ethanol 10%.
BARQUAT 4250. Active ingredients: n-alkyl dimethyl benzyl ammonium chlorides 25%; n-alkyl dimethyl ethylbenzyl ammonium chlorides, 25%.
BARQUAT 4250-Z. Active ingredients: n-alkyl dimethyl benzyl ammonium chlorides 25%; n-alkyl dimethyl ethylbenzyl ammonium chlorides, 25%.
BARQUAT MX-50. n-alkyl (C_{14}, 60%; C_{16}, 30%; C_{12}, 5%; C_{18}, 5%) dimethyl benzyl ammonium chloride, 50%; isopropanol, 5%.

Teratology data were submitted for subject quaternary disinfectants. The study was conducted by Food and Drug Research Laboratories and is dated February 11, 1977.

45 female rats were assigned to the control (water) group, 45 females to the aspirin positive control group at a dose of 250 mg/kg/day from day 6 through day 15 of gestation, and 25 females for each dose level (10, 25, & 50 mg/kg/da of each quaternary from day 6 through day 15 of gestation.

Indices of reproductive performance such as conception, live pups per dam, resorptions per dam, and dead fetuses per dam did not differ significantly between groups.

There was no dose related fetotoxicity as indicated by body weight depression except as expected from dams receiving aspirin treatment, where fetal weights were 80% of control values.

There were no dose related and significant incidences of any skeletal abnormalities attributable to any of the compounds tested.

Soft tissue abnormalities were frequently seen, as expected, in the aspirin treated group but not in the other groups. The incidences of occurrence were not greater between other treated groups and controls.

CONCLUSIONS: Daily oral administration of Barquat MB-50, Barquat MX-50, Barquat 4250, or Barquat 4250-Z to rats at doses of 10, 25, or 50 mg/kg during days 6-15 of pregnancy did not produce any indication of significant fetotoxicity or teratogenicity in these studies.

Roland A. Gessert
Roland A. Gessert, D.V.M.
Toxicology Branch

E for OEP 8/8/77

2

EPA Form 1320-6 (Rev. 3-76)

d 5154 ; 2/11/77 FDA