- Coberly

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Teratologic evaluation of three quaternary compounds (Bardac 22, Bardac 20, Bardac LF) For inclusion into product file. Caswell No. 331A, 613A, 392H. DATE: 8/17/77

FROM: Toxicology Branch R/D
C. Frick C. Frick B for OEP 8/16/77

TO: Mr. H. Jacoby, PM#24

Product: Bardac LF EPA Reg. No. 6836-40

Submission By: Lonza Inc., Fairlawn, N.J.

Study By: Food & Drug Research Labs., Inc. 3/4/77 Lab#5155

Materials Tested:

a) Bardac-22 Lot #B3683

Didecyl Dimethyl ammonium chloride 50%

[redacted]

EPA Reg. #6836-18

b) Bardac-20 Lot #B35307

octyl decyl dimethyl ammonium chloride 25%
dietyl dimethyl ammonium chloride 12.5%
didecyl dimethyl ammonium chloride 12.5%

[redacted]

EPA # 6836-19

c) Bardac LF Lot #B3414

Diectyl Dimethyl ammonium chloride 50%

[redacted]

EPA # 6836-40

EPA Form 1320-6 (Rev. 6-72)

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Animals Used: Virgin, adult female albino rats (wistar derived stock)

Experimental Design:

| Group | No. of Animals Bred (Females) | Test Material | Dose Level (mg/kg) |
|---|---|---|---|
| A | 51 | Water | - |
| B | 52 | Aspirin | 250 |
| C | 25 | Bardac-22 | 10 |
| D | 24 | | 25 |
| E | 24 | | 50 |
| F | 23 | Bardac-20 | 10 |
| G | 25 | | 25 |
| H | 23 | | 50 |
| I | 26 | Bardac LF | 10 |
| J | 23 | | 25 |
| K | 16 | | 50 |

Parameters Measured:

I Pregancies
- Total Number
- Wastage to 19 days

II Implant sites
- Total Number
- Avg per dam

III Live Fetuses
- Total Number
- Avg per dam
- Male/Female ratio
- Avg Fetus wt

IV Resorptions
- Total Number & Number of Dams involved

V Dead Fetuses
Total no and number of dams involved

VI Body wt. on days 0, 6, 11, 15, 20

VII Skeletal and soft tissue abnormalities

Comments:

The test compounds had no deleterious effect on gestation but all Bardac compounds did cause more dams to resorb one or more fetuses at the high (50 mg/kg) dose level. Possible fetotoxicity effect. The control fetuses were smaller ($P < .05$) than all but 3 of the Bardac treatment groups -10 & 25 mg/kg Bardac 20 and 25 mg/kg Bardac 22. No such elevation of weight occurred in the dams so the biological significance of this finding is not known. The skeletal and soft tissue findings indicated no significant difference between tested compounds and control. No maternal toxicity was noted. In summary, no teratological findings could be ascribed to the Bardac compounds tested in this study at doses up to 50 mg/kg.

Validation Category-Core Minimum Data