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 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

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 19, 1977 MLG 12/27/77

SUBJECT: Lonza Formulation 71-30 - Addition of Data to Files EPA Reg. #6836-34
Caswell #613A, 392H, 331A, 846, 898 Shaughnessy #069165, 069179, 069166, 039107, 076406

FROM: Toxicology Branch
Registration Division

TO: Joseph Tavano
Product Manager #31

Recommendation

The acute dermal LD_{50} study is adequate and has been designated Core-Minimum Data.

*No RPAR criteria have been exceeded.

Review

1. Acute Dermal LD_{50} of Disinfectant Cleaner 71-30 - (Leberco Laboratories, Assay #73136, 3/8/77, submitted by Lonza on 4/5/77, Acc.#232263)

   4 female rabbits had 10% of their hair removed from their backs with an electric clipper. The test material was applied at 5 ml/kg, which was the largest amount that could be applied. The test sites were occluded for 24 hours, afterwhich the wrapping was removed and any residual test material was washed off the skin. The animals were observed for 14 days.

Results

LD_{50} > 5 ml/kg (1/4 animals died)
Toxic Signs: not reported; (animal lost weight)
Necropsy: none performed
TOX Category: III
Classification: Core-Minimum Data
(1) necropsies were not performed; toxic signs if any, were not reported; however, since this was the largest dose that could be applied the dermal toxicity of the test material has been adequately characterized in female rabbits.

William Greear
William Greear

EPA FORM 1320-6 (REV. 3-76)