UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: September 12, 1978

SUBJECT: Data review. FSD-40 Disinfectant, Sanitizer, Fungicide, Deodorizer
EPA#5736-AV Caswell#331A

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Registration#EPA-5736-AV

DuBois Chemicals
3630 E. Kemper Road
Sharonville, OH 45241

Formulation

Active Ingredients

Didecyl dimethyl ammonium chloride	7.5%
Isopropanol	3.0%

Inert Ingredients

[redacted]

Conclusions:

1) The following toxicity studies are acceptable:

a) Acute Oral LD_{50}
b) Acute Dermal LD_{50}
c) Primary Dermal Irritation
d) Primary Eye Irritation
e) Subacute Dermal Dosing
f) Teratology Evaluation

2) In addition to the above accepted studies, a Dermal sensitization study is required.

Review of Data

[redacted]

Toxicity tests were conducted by Wells Laboratories, Inc. 25-27 Lewis Ave., Jersey City, N.J. 07306 and referenced by DuBois Chemical, unless otherwise noted.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Acute Oral LD_{50}, Mouse

250, 500, 794, 1,260, or 2000 mg/kg formulation administered by intubation to groups of 10 mice each. Observed 7 days.

Results: Acute Oral LD_{50} = 664 mg/kg

Con. lim. = ± 56. mg/kg

Toxicity Category: III Supplemental

Classification data; the animal sex was not stated, observation period should have been at least 14 days.

Acute Dermal LD_{50}, Rabbit

Formulation applied to intact and abraded skin of 4 rabbits/each of 5 dose levels, maintained in place 24 hrs. Animals observed 14 days.

Results:

Dose	Dead/treated
775	0/4
975	0/4
1230	2/4
1550	3/4
1950	4/4

The larger doses produced symptoms of severe injury in terms of weight loss, failure to consuming food and water, legarthy and excretion. Progressively more pathology observed at dosed > 1230 mg/kg.

Acute dermal LD_{50} = 1,300 mg/kg.
Con. lim. = 1,048 to 1,612 mg/kg.

Toxicity Category: II

Classification: Core Minimum Data

a. no distinction between treated intact or abraded skin
b. sex not identified
c. should have employed at least 4 animals/sex dose level.

Primary Eye Irritation

0.1 ml formulation instilled in 1 eye of each of 6 rabbits. Animals observed through 7 days.

Results: Corneal and conjunctival irritation persisting through 7 days.

Toxicity Category: I

Classification: Core Guidelines Data

Primary Dermal Irritation

0.5 gm or 0.5 ml product applied to abraded and intact skin of 6 rabbits. Anamids observed 72 hours.

Results: Severe erythema and edema at 24 hours. Severe, erythema and moderate to severe eschar formation accompanied by severe edema at 72 hours.

Primary Skin Irritation Index = 8

Toxicity Category: I

Classification: Core Guidelines Data

Subacute Dermal Dosing

615, 246, or 123 mg/kg formulation applied to intact or abraded skin/ each of two rabbits/dose level for 20 days. Survivors held additional 2 weeks. Body weights, food consumption, excretion and behavior observed daily. Blood and urine studies conducted at beginning, at 20 days, and prior to autopsy.

Results: 1 of 2 animals/treatment group died. Gross pathology increased during experiment. Histopathological examination of major tissues and organs revealed nothing of significance, excepting the skin.

Classification: Core Minimum Data

a. used only 2 animals/dose level
b. sex of animals not stated
c. no distinction made between treatment of intact and abraded skin, or to both.

Teratology Study, Rats

Performed by Food and Drug Research Labs. for Lonza Chemical. Test No. 5155.

Experimental Dosings

Group	No. females bred	Test Material	dose (mg/kg)
A	51	water	-
B	52	aspirin	250
C	25	formulation	10
D	24	"	25
E	24	"	50

Dams treated by gavage daily from day 6 through 15 of gestation.days

Results

1. No deletrious effect on gestation
2. Did cause more dams to resorb one or more fetuses at the 50 mg/kg level.
3. Heavier fetus weights for formulation treated dams not attributable to soft tissue or skeletal abnormalities.
4. Fewer skeletal findings in the test chemical groups than observed in controls.
5. Incidence of soft tissue findings no greater in test chemical treated groups than in controls.

No teratological findigns could be attributed to the formulation tested at dose up to 50 mg/kg.

Classification: Core Guidelines Data

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