LBD/2/1/71

Hercules MB-120 Formula

Active Ingredients

Didecyl dimethyl ammonium chloride	12.5 %

Inert Ingredients

[redacted]

Use Slime control in water cooling towers

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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Hercules Microbiological Compound MB 120 consists of a 12.5 percent solution of didecyl dimethyl ammonium chloride [redacted] The product is for use in slime control in water cooling towers. This is an industrial use.

The toxicological data presented are for the active ingredient, didecyl dimethyl ammonium chloride. No data are presented for the formulation. The lack of data for the formulation is no cause for concern since the formulation consists solely of [redacted] of the quaternary ammonium compound. The toxicity of the formulation, except dermal and eye irritation, can be extrapolated directly from these data.

The toxicity of the active ingredient is exactly what is to be expected from this type of quaternary ammonium compound. The acute dermal and oral toxicities are relatively low while the eye and skin irritant properties of the compound are high.

There is no method of extrapolating the dermal and eye irritant properties of the 12.5 percent solution from the data on the concentrated product. One may expect that the formulation is a severe eye irritant. In lieu of data to the contrary, the label should bear the signal word "Warning"

rather than the signal word "Caution". The first aid methods described on the label are adequate.

When used according to label directions, Hercules Microbiological Compound MB 120 should pose no undue human health hazard.

L.B. Dale,Jr.

Twenty Day Subacute Dermal Toxicity (Rabbits)

Two rabbits were used at each of three dosage level of 615, 246, and 123 mg/kg of body weight of didecyl dimethyl ammonium chloride. The material was applied dermally to either the intact or abraded skin of the clipped flanks. The test material was applied daily for twenty days. The survivors were held for an additional two weeks for observation at which time they were sacrificed and autopsied.

Body weights, food consumption, excretions and behavior were observed daily. Blood and urine studies were conducted at the beginning of the study, at the 20 day interval and prior to autopsy. Gross and histopathology were recorded.

The initial observed effect was eschar formation followed by blackening and hardening of the skin at the treated site at all dosage levels. This skin was sloughed in those animals surviving the 18th day of treatment. Three rabbits died during the study. The hemoglobin and hematocrit reduced during the study and slowly recovered after dosing was ceased. The leucocyle count increased during the study and gradually decreased after dosing was stopped. Very little change was noted in the urine chemistry.

Twenty Day Subacute Dermal Toxicity (Continued)

Gross pathology increased with increased dosage.

Histopathological examination of major tissues and organs revealed nothing of significance except the skin.

Acute Intravenous Toxicity (Mouse)

Solutions of didecyl dimethyl ammonium chloride were prepared in distilled water in concentrations from 0.5-1.0 percent. Dilutions of the stock solution in distilled water were administered intravenously in groups of 10 mice, weighing 19 to 26 grams, at dosage levels of 15.8, 25.0, 39.8, and 63.1 mg/kg of body weight. The mice were observed closely during the first 24 hours and held under observation for a period of one week following injection.

The acute intravenous LD_{50} of didecyl dimethyl ammonium chloride in mice was found to be 35 ± 6.2 (24 hours) and 33 ± 5.1 mg/kg of body weight.

Acute Oral Toxicity (Mouse)

Solutions of didecyl dimethyl ammonium chloride were prepared in distilled water in concentrations ranging from 5 to 25 percent. The undiluted solutions, and/or

Acute Oral Toxicity (Continued)

dilutions of the stock solutions in distilled water, were administered orally by stomach tube to groups of 10 mice, weighing 18 to 25 grams, at dosage levels of 250, 500, 794, 1000, and 2000 mg/kg of body weight. The mice were fasted 4 hours before medication. The mice were observed closely during the first 24 hours and held under observation for a period of one week following dosing for manifestations of delayed toxicity.

The acute oral toxicity (LD_{50}) of didecyl dimethyl ammonium chloride in mice was found to be 1290 ± 228 (24 hours) and 810 ± 146 mg/kg of body weight.

Acute Dermal Irritation (Rabbit)

The effect of applying 0.5 ml of the liquid or 0.5 gm of the powder to the intact and abraded skin on the back of the rabbit were determined by a modification of the method of Draize, et al.

The Primary Irritation Score of didecyl dimethyl ammonium chloride was found to be 7.67 on intact skin and 7.33 on abraded skin. The combined average was 7.5. The material is a corrosive.

Acute Eye Irritation (Rabbit)

Solutions dicecyl dimethyl ammonium chloride were prepared

Acute Eye Irritation (Continued)

in 0.9 percent sodium chloride solution at pH of 5-7. Dilutions of these solutions were made in 0.9 percent sodium chloide solution. The effects of instillation of didecyl dimethyl ammonium chloride solutions into rabbits eyes were determined by the rabbit eye irritation test (J.A. Ph. A., Sci. Ed., 39: 147; 1950). Each concentration of each of the six samples was instilled into the right eye of each rabbit, the left eye served as the unmedicated control.

The Threshold Irritation Concentration (TIC), that concentration which first produced irritation was found to be 0.063%, equivalent to 0.0316 as the quaternary.

Acute Dermal Toxicity (Rabbit)

The backs of four rabbits were treated at dosage levels of 775, 975, 1230, 1550, and 1950 mg/kg of body weight. The backs and flanks of the animals were clipped free of hair and single test doses were applied and kept in situ for 24 hours. Animals which died were autopsied immediately. Survivors were autopsied 14 days after product application. Gross changes in food intake, excretion, appearance and behavior were noted. Gross pathology was reported.

The initial observed effect of the test material was

eschar formation followed by blackening and hardening of the skin on the treated area. It appeared that the skin would have been sloughed in a few days if the survivors had not been sacrificed 14 days after treatment.

Those animals receiving doses greater than 1550 mg/kg failed to eat or drink beginning on the third and fourth day after treatment, but food consumption was resumed in three survivors receiving 1230 mg/kg or more on the fifth day. Progressive weight loss was observed in those animals which died. Deaths occurred on days 6 through 9. Lethargy was noted prior to death, and excretion was greatly decreased. Severe gross pathology was noted in the animals receiving the higher doses.

The acute dermal LD_{50} of didecyl dimethyl ammonium chloride in albino rabbits was found to be 1300 mg/kg with confidence limits of 1048 to 1612 mg/kg. The slope function is 1.14 with confidence limits of 0.99 to 1.33.

Acute Oral Toxicity (Continued)

dilutions of the stock solutions in distilled water, were administered orally by stomach tube to groups of 10 mice, weighing 18 to 25 grams, at dosage levels of 250, 500, 794, 1000, and 2000 mg/kg of body weight. There was no significant difference in the oral toxicity at 24 hours and 7 days.