

OR 2/14/77

2-15-77
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Registration Human Safety Review

PM: TAYLOR-25

TOX Reviewer: Levy

EPA #	Date	Product Name	Use Classification	Toxic Category
39496-E	2/14/77	ALFOL 10 ALCOHOL (m-deanol)		

RECOMMENDATION: OBJECT TO REGISTRATION. ACUTE IRRITATION STUDY AND Repeat of Eye IRRITATION IS Required. ALTOXIC signs should be reported. Individual ANIMAL TOXICITY data IS required, including results of exploratory studies (oral LD50 for instance). Required label changes will be suggested when all data is in. ~~Animal should have been individually dosed.~~

Route	Species	LD50	TECH	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
Oral	(Rat)						
		LD50			>26g/kg		NO

Toxic signs: No deaths + Diarrhea, MALAISE, Bloody nasal discharge + Alopecia were reported, EXPLORATORY data NOT submitted, but is required - specify doses, effects & deaths, if any, since animals were group housed.

Route	Species	LD50	TECH	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
Dermal	(Rabbit)						
		LD50			2-4g/kg		yes

Toxic signs: INACTIVITY & weakness, DERMAL IRRITATION, focal hemorrhage of gastric mucosa & clear viscous fluid in peritoneal cavities of animals which died.

Route	Species	LC50	TECH	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
Inhalation	()						
		LC50					

Comments: NOT submitted.

Route	Species	TECH	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
Primary Eye Irritation	(Rabbit)					NO

Comments: 6 Rabbits were exposed to aml. formulation which was washed out at 24 hours. Increasing irritation noted at 72 hours. Individual animal data for each possible scored effect category or at least 9 animals IS required.

Route	Species	TECH	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
Primary Skin Irritation	(Rabbit)	primary irritation score = 5.1				yes

Comments: Erythema & Edema at 24 hours. Dryness & desquamation & pustular eruptions occurred later & persisted 14 days in some rabbits. Marked erythema & edema at 72 hours. TOX category II

Other Studies: