Technical Information

Stepan

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MAMMALIAN TOXICOLOGY OF SODIUM LAURYL SULFOACETATE

Applicable to these current Stepan products:

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	LATHANOL® LAL Powder	LATHANOL® LAL Flake	LATHANOL® LAL Coarse

Toxicological Information:

Test/Conditions	Results/Classification	<u>References</u>
Mammalian Toxicology:		
Acute Oral Toxicity (rat) (14 day) (gavage) n = 5/dose/sex	LD50 (lethal dose) > 2 to < 5 mg/kg (slightly toxic orally as a 33% suspension)	Stepan Study No. 97-005A, 97-005E
Acute Dermal Toxicity (rabbit) (14 day) n = 5/dose/sex	LD50 > 2 mg/kg (slightly toxic dermally as a 33% suspension)	Stepan Study No. 97-005D
Primary Eye Irritation (rabbit) (21 day observation) n=6	$MMS^{1} = 37/110$ (moderately irritating to eyes as a powder at 24 hr observation)	Stepan Study No. 97-005C
Primary Dermal Irritation/Corrosivity Study (rabbit) (4 hr exposure) n=6	PII ² = 2.09/8 (mildly irritating to skin as a powder)	Stepan Study No. 97-005B
Mucous Membrane Irritation (rabbit) (7 day observation n=3/sex	Not irritating as a 1% aqueous solution	JACT*
Skin Sensitization Magnusson & Kligmann Maximisation test (guinea pig) (topical) (3 wks.)	Not a skin sensitizer as a 2% solution	Stepan Study No. 12-012A
Skin Sensitization Buehler method (guinea pig) (topical) (3 wks.)	Not a skin sensitizer as a 2.1% cream	JACT

Test/Conditions	Results/Classification	References
Phototoxicity Study	Not phototoxic	JACT
(guinea pigs) n=3	at 3%	
28-Day Oral Toxicity Study	No treatment-	JACT
(rats) (gavage) n=5/sex/dose	related effects observed	
	at 50 mg/kg/day	
Subchronic Oral Toxicity	No treatment-	JACT
(90 days)(rat)(gavage)	related effects observed	
	at 75 mg/kg/day	
Mutagenicity Study	Not mutagenic	Stepan Study No. 12-011E
(Ames) (OECD method 471)		& JACT
Mutagenicity Study	Not clastogenic	Stepan Study No. 03-006C
(Chromosome aberration)	Not clastogerile	Stepan study No. 03 000C
(OECD method 475)		
Mutagenicity Study	Not mutagenic	Stepan Study No. 13-004E
(Mouse lymphoma assay)	_	
(OECD method 476)		
Reproduction/Development	2	
Toxicity (rats) (gavage) (39 days for	NOAEL ³ = 1000 mg/kg body	
males, 42-46 for females)	weight/day	Stepan Study No. 04-015A
n=10/sex/dose		
(OECD method 422)		
Developmental Toxicity		
(rats)(gavage)(15-day exposure)	NOAEL (developmental) = 1000	Stepan Study No. 18-002H
n=77 dams, 1146 fetuses	mg/kg body weight/day	
(OECD method 414)		
Clinical Studies:		
Skin Irritation	Not a skin irritant	
(single insult patch test) (human) n=100	as a 3% solution	JACT
Repeated Insult Patch Test	Irritation observed in 79	
(RIPT)	subjects, reaction considered	JACT
(human) (3 weeks)	nonallegenic	JACI
n=152	Horianegeriic	
In-Use Test	Irritating but not sensitizing to	JACT
(human) (4 weeks) (n=47)	human skin at 1-2%	
21-Day cumulative irritation	Mild material - no	Stepan Study No.
study (RIPT)	experimental irritation	03-002A
(human) (3 weeks) (n=25)		

- 1. MMS=Maximum Group Mean Draize Score
- 2. PII=Primary Skin Irritation Index
- 3. NOAEL = No observed adverse Effect Level

Conclusion:

The Cosmetic Ingredient Review (CIR) Expert Panel has concluded that Sodium Lauryl Sulfoacetate is safe as presently used in cosmetic products.

References:

*Journal of the American College of Toxicology (JACT), vol. 6(3), 1987, pp. 261-277.

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