Technical Information | **Stepan**

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MAMMALIAN TOXICOLOGY OF SODIUM LAURYL SULFOACETATE

Applicable to these current Stepan products:

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

Toxicological Information:

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

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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