



## MAMMALIAN TOXICOLOGY OF ALKYL SULFATES

### Applicable to these current Stepan products:

POLYSTEP® B-3	POLYSTEP® B-5	STEPANOL® ALS 25
STEPANOL® ALS 70	STEPANOL® AM	STEPANOL® AM-CIT/MIT
STEPANOL® AM 30-KE	STEPANOL® AMV	STEPANOL® AMV PCK
STEPANOL® DCFAS-F	STEPANOL® DCFAS-N	STEPANOL® DCFAS-P
STEPANOL® DCX	STEPANOL® DX	STEPANOL® LCP
STEPANOL® LCP-E	STEPANOL® ME-DRY	STEPANOL® ME-DRY-E
STEPANOL® SLS PASTE™	STEPANOL® WA-100 NF/USP	STEPANOL® WA-EXTRA
STEPANOL® WA-EXTRA-X	STEPANOL® WA-EXTRA HP	STEPANOL® WA-EXTRA HP-X
STEPANOL® WA-EXTRA K	STEPANOL® WA-EXTRA PCK	STEPANOL® WAT
STEPANOL® WAT-E	STEPANOL® WAT-K	STEPANOL® ALS 25-B/MB
STEPANOL® DX-AS 165N	STEPANOL® WA-EXTRA PC	STEPANOL® DX-165
STEPANOL® WA-EXTRA HA	STEPANOL® SLS HP	STEPANOL® WA-100

### Applicable to these inactive Stepan products:

STEPANOL® WA-SPECIAL	STEPANOL® WAC	STEPANOL® WAQ
STEPANOL® WAC-LCP		

### Toxicological Information:

<u>Test/Conditions</u>	<u>Results/Classification*</u>	<u>References</u>
Acute oral toxicity (rat)(gavage)(14 days)	LD <sub>50</sub> > 500 mg/kg to < 2000 mg/kg based on percent active and carbon chain distribution (slightly toxic)	ECHA REACH Dossiers & HPV Assessment of Alkyl sulfates, Alkane sulfonates and alpha-Olefin sulfonates
Acute dermal toxicity (rabbit)(14 days)	LD <sub>50</sub> > 2000 mg/kg @ 30% active	ECHA REACH Dossiers & HPV Assessment
Primary eye irritation (rabbit)(7 days)	Moderate to severe irritation @ ≥ 5% concentration; moderately to mildly irritating @ < 5%; irritating potential decreases with increasing chain length and decreasing concentration.	ECHA REACH Dossiers, HPV Assessment, JACT
Primary skin irritation	Moderately to severely	ECHA REACH Dossiers,

(rabbit)(4 hr contact time)	irritating @ $\geq$ 5%	HPV Assessment, JACT
Skin Irritation (human) (Up to 4 hr exposure) (occlusive patch)	Irritating @ 20%	HPV Assessment
Use Control Study (human)(n=52)(4 weeks)	No irritation observed @ 2.5%	JACT
Skin sensitization (Buehler method- guinea pigs/LLNA)	Not a skin sensitizer	ECHA REACH Dossiers & HPV Assessment
Sensitization Study (human repeat insult patch test) (24 hr. occlusion)(86 < n < 116)	Not a contact sensitizer as a 0.1, 0.25, 0.3, 0.5, or 4% solution	HPV Assessment
Genotoxicity (in-vitro & in-vivo)	Non-mutagenic	ECHA REACH Dossiers & HPV Assessment
Sub-chronic oral toxicity (rat) (13 weeks) (gavage) doses: 0.07, 0.14, 0.28, 0.56, 1.13, 2.25% in diet (58, 113, 228, 470, 961, 1944 mg/kg bw/day for males)(66, 131, 261, 506, 1070, 2218 mg/kg bw/day for females)	NOAEL (combined) = 488 mg/kg bw/day (0.56% in the diet)	ECHA REACH Dossiers & HPV Assessment
Sub-chronic dermal toxicity (mice)(13 weeks) doses: 0, 200, 400, 500, 600 mg/kg bw/day (0, 5, 10, 12.5, 15% a.s.)	NOAEL = 400 mg/kg bw/day (corresponding to a 10% solution)	ECHA REACH Dossiers & HPV Assessment
Chronic Oral (rat)(2 years)(diet) doses: 11, 113, 1125 mg/kg bw/day	No effects at dose levels up to 1125 mg/kg bw/day; non-carcinogenic	ECHA REACH Dossiers & HPV Assessment
Reproductive toxicity; first study (mice)(oral); doses: 30, 100, 300 mg/kg bw/day Second study: 1% for 2 weeks (b) 0.1% for 6 weeks	NOAEL > 300 mg/kg bw/day (first study) NOAEL = 1000 mg a.i./kg bw/day (second study) AS are not considered to be reproductive hazards.	ECHA REACH Dossiers & HPV Assessment
Developmental/Teratogenicity (rat)(gavage) duration: day 6-5 of gestation; dosage: 0,63,125,250, 500 mg/kg bw	NOAEL = 250 mg/kg bw/day (maternal + offspring)	ECHA REACH Dossiers & HPV Assessment

\*NOAEL = No Observed Adverse Effect Level

Note: Toxicity testing summarized above, have been conducted in the pH range of 7.5-8.5.

### Conclusion:

The Cosmetic Ingredient Review (CIR) Expert Panel has concluded that Sodium Lauryl Sulfate “appears to be safe in formulations designed for discontinuous brief use followed by thorough rinsing. In products intended for prolonged contact with skin, concentrations should not exceed 1%.”

## References:

1. ECHA REACH Dossiers for Alkyl Sulfates.
2. Alkyl Sulfates, Alkane Sulfonates and Alpha Olefin Sulfonates; SIDS Initial Assessment 2007.
3. Journal of the American College of Toxicology (JACT), Vol. 2 No. 7, 1983, pp. 127-181.

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