**Technical Information** | **Stepan**

Stepan Company

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# MAMMALIAN TOXICOLOGY OF ALKYL SULFATES

## Applicable to these current Stepan products:

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|---|---|---|
| POLYSTEP® B-3 | POLYSTEP® B-5 | STEPANOL® ALS 25 |
| STEPANOL® ALS 25-B/MB | 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 HP | STEPANOL® WA-EXTRA K |
| STEPANOL® WA-EXTRA PCK | STEPANOL® WAT | STEPANOL® WAT-E |
| STEPANOL® WAT-K | STEPANOL® DX-AS 165N | STEPANOL® WA-EXTRA PC |
| STEPANOL® DX-165 | STEPANOL® WA-EXTRA HA | |

Applicable to these inactive Stepan products:

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

## Toxicological Information:

| **Test/Conditions** | **Results/Classification*** | **References** |
|---|---|---|
| Acute oral toxicity (rat)(gavage)(14 days) | $LD_{50}$ > 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) | $LD_{50}$ > 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 (rabbit)(4 hr contact time) | Moderately to severely irritating @ ≥ 5% | ECHA REACH Dossiers, HPV Assessment, JACT |
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| 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 Sufonates; SIDS Initial Assessment 2007.
3. Journal of the American College of Toxicology (JACT), Vol. 2 No. 7, 1983, pp. 127-181.



Last Update: June 30, 2020 Revision Reference: TX014.05