Technical Information

Stepan

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MAMMALIAN TOXICOLOGY OF AMINE OXIDES

Applicable to these current Stepan products:

AMMONYX® CO	AMMONYX® DO	AMMONYX® LO		
AMMONYX® LO-A	AMMONYX® LO-BR	AMMONYX® LO Special		
AMMONYX® M	AMMONYX® MCO	AMMONYX® MO		
AMMONYX® SO				
Applicable to the second section Change and destroy				

Applicable to these inactive Stepan products:

IAMMONIVY® C IAMMONIVY® DMCD-40			
	AMMONYX® C	AMMONYX® DMCD-40	

Toxicological Information:

Test/Conditions	Results/Classification	<u>References</u>
Acute Oral Toxicity (rat)(gavage)(14 days)	LD ₅₀ > 600 mg/kg bw as is (slightly toxic)	ECHA REACH dossiers & HPV Assessment
Acute Dermal Toxicity (rabbit) (14 days) n=6/sex/dose	LD ₅₀ > 2000 mg/kg as is (slightly toxic)	ECHA REACH dossiers & HPV Assessment
Primary Eye Irritation (rabbit)(7 days) n=6	Severe irritation @ ≥ 28% active. Minimally irritating @ 1%	ECHA REACH dossiers & HPV Assessment
Primary Skin Irritation (rabbit)(n=6)(24 hr)	Irritation is concentration dependent. (a) moderately to severely irritating at 30% active (b) Minimally irritating @ 1%	ECHA REACH dossiers & HPV Assessment
Skin sensitization (guinea pigs) Buehler method	Not a skin sensitizer	ECHA REACH dossiers & HPV Assessment
Sensitization study (Human Patch Test)(24 hr occlusion) N=141	Not a contact sensitizer (at 0.3% active)	HPV Assessment
Geno Toxicity in Vitro/Vivo (Ames test)(chromosomal	Non-mutagenic	ECHA REACH dossiers & HPV Assessment

aberration)(micronucleus test)		
Subchronic toxicity study (90-day)(rat)(oral feed)	NOAEL*= 63 - 88 mg/kg/day	ECHA REACH dossiers & HPV Assessment
Carcinogenicity Study (rat)(oral)(2 years) Doses: 0, 4.24, 42.3 or 87.4 mg/kg bw/dy (males) 0, 5.23, 52.6, 107 mg/kg bw/day (females)	No evidence of carcinogenic response	ECHA REACH dossiers & HPV Assessment
Repro/Developmental Toxicity (rat)(oral feed) continuous exposure Doses: 0, 40, 100, 250 mg/kg bw/day	NOAEL = 40 mg AO/kg bw/day (overall) NOAEL= 100 mg AO/kg bw/day (repro/developmental)	ECHA REACH dossiers & HPV Assessment

Notes: *NOAEL = No observed adverse effect level.

Conclusion:

On the bases of the available animal and clinical data ⁽²⁾, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that the dodecyl dimethyl amine oxide (C12) and octyl decyl dimethyl amine oxide (C18) are safe as cosmetic ingredients for rinse-off products under present condition of use for use in leave-on products, Lauramine Oxide should be limited to 3.7% and Stearamine Oxide to 5%.

References:

- 1. ECHA REACH Dossiers for Amine Oxides
- 2. HPV-SIDS Initial Assessment Report (2006)

AMMONYX® is a registered trademark of Stepan Company.

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