



## MAMMALIAN TOXICOLOGY OF AMINE OXIDES

### Applicable to these current Stepan products:

AMMONYX® CO AMMONYX® LO-A AMMONYX® M AMMONYX® SO	AMMONYX® DO AMMONYX® LO-BR AMMONYX® MCO	AMMONYX® LO AMMONYX® LO Special AMMONYX® MO
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### Applicable to these inactive Stepan products:

AMMONYX® C	AMMONYX® DMCD-40	
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### Toxicological Information:

<u>Test/Conditions</u>	<u>Results/Classification</u>	<u>References</u>
Acute Oral Toxicity (rat)(gavage)(14 days)	LD <sub>50</sub> > 600 mg/kg bw as is (slightly toxic)	ECHA REACH dossiers & HPV Assessment
Acute Dermal Toxicity (rabbit) (14 days) n=6/sex/dose	LD <sub>50</sub> > 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<sup>(2)</sup>, 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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