



MAMMALIAN TOXICOLOGY OF ALPHA SULFO METHYL ESTERS (SMES)

Applicable to these current Stepan products:

ALPHA-STEP® BSS-45 ALPHA-STEP® PS-65	ALPHA-STEP® MC-48 ALPHA-STEP® PS-85P	ALPHA-STEP® PC-48
---	---	-------------------

Applicable to these inactive Stepan products:

ALPHA-STEP® BSN-15	ALPHA-STEP® ML-40	
--------------------	-------------------	--

Toxicological Information:

<u>Test/Conditions</u>	<u>Results/Classification</u>	<u>References</u>
Mammalian Toxicology:		
Acute Oral Toxicity (rat) (gavage) (14 day) n=5/sex/dose		
a. neat material (waxy solid)	LD ₅₀ (Lethal Dose) > 2000 mg/kg (slightly toxic orally)	Stepan Study No. 94-006A
b. liquid (36.34% active)	LD ₅₀ > 5 g/kg (practically non-toxic orally)	Stepan Study No. 93-008C
Acute Dermal Toxicity (rat) (14 day) n=5/sex/dose (neat material – waxy solid)	LD ₅₀ > 2000 mg/kg (slightly toxic dermally)	Stepan Study No. 94-006B
Primary Eye Irritation (rabbit) (14 day) n=6		
a. neat material (waxy solid)	MMS ¹ = 61/110 (severely irritating to eyes)	Stepan Study No. 94-006C
b. liquid (36.34% active)	MMS = 39/110 (severely irritating to eyes)	Stepan Study No. 93-008A

<u>Test/Conditions</u>	<u>Results/Classification</u>	<u>References</u>
c. liquid (10% active) Primary Skin Irritation (rabbit) (4 hr. contact time) n=6	MMS = 39/110 (moderately irritating to eyes)	Stepan Study No. 95-007A
a. neat material (waxy solid)	PII ² = 0.5/8 (minimally irritating to skin @ 4 hr. contact time)	Stepan Study No. 94-006D
c. liquid (36% active)	PII = 6.42/8 (severely irritating to skin @ 24 hr. contact time)	Stepan Study No. 93-008B
d. liquid (10% active)	PII = 0.5/8 (minimally irritating to skin @ 4 hr. contact time)	Stepan Study No. 95-004B
Sensitization Study (Magnesson-Kligman) (guinea pig) (neat material)	Not a sensitizer (according to ED labeling regulations)	Stepan Study No. 94-006E
Repeat Insult Patch Test (Dermal sensitization Study) (human) n=103	Not a sensitizer @ 0.75%	Stepan Study No. 95-001A
A 28-day Subchronic Oral Toxicity (neat material) (rat) (gavage) n=10/dose (doses: 15, 150, 1000 mg/kg/day)	No systemic toxicity observed. (gastric effects only)	Stepan Study No. 94-006J
Micronucleus Test in the Mouse (mouse) n=10/dose (neat material)	Non-genotoxic under the conditions of the test.	Stepan Study No. 94-006K
Reverse Mutation Assay (Ames Test) (neat material)	Non-mutagenic under the conditions of the test.	Stepan Study No. 94-006L

References:

1. HPV challenge program submission for Fatty Acid, C12-18 Me Esters, Sulfonated, Na Salts. Nov. 2008.
2. Gode, von P., Guhl, W., and Steber, J., Oekologische Bewertung von -Sulfofettsaeremethylester. Fat Sci. Technol., 1987, 89: 548-552.
3. OECD SIDS Hexadecanoic Acid, 2-Safo, 1-Methylester, Sodium Salt, 2003.
4. Masuda, M., Environmental Aspects of Detergent Materials-Biodegradation of Detergent Surfactants. Oils-Fats-Lipids, 1995, 3:649-653.
5. Steber, J., and Wierich, P., The Environmental Fate of Fatty Acid Sulfomethyl Esters. Tenside Surf. Det., 1989, 46: 406-411.
6. European Directive 67/548/EEC, Annex VI, 5.2.1.3.

ALPHA-STEP® is a registered trademark of Stepan Company.

Last Update: 2.17.12

Revision Reference: TX046.05

Last Modified by: Barbara Gomez on 02/17/2012 02:18:04 PM