Technical Information | **Stepan**

Stepan Company
Northfield, Illinois 60093
Telephone 847 446 7500

MAMMALIAN TOXICOLOGY OF CETRIMONIUM CHLORIDE

Applicable to these current Stepan products:

AMMONYX® CETAC	AMMONYX® CETAC-30	

Toxicological Information:

Test/Conditions	Results /Classification	Reference
Mammalian Toxicology		
Acute Oral Toxicity (rat) (14 day)	a. LD_{50} = 250 to 300 mg/kg (moderately toxic) b. LD_{50} > 5 g/kg (5% active) (practically non-toxic)	IJT* Stepan Study No. 90-007D
Primary Eye Irritation (rabbit) (n=6) (unwashed eye)	MMTS[1] = 53/110 (extremely irritating to eyes @ 5% active) and minimal eye irritation @ 0.1%	Stepan Study No 90-007E IJT
Primary Dermal Irritation (rabbit) (screen) (24 hr. occlusion)	5.42/8 (severely irritating to skin at 5% active) and minimal skin irritation @ 0.1%	Stepan Study No. 90-007A IJT
Subchronic Dermal Toxicity 28-Day Percutaneous Study (rabbit) n=5/sex Dose: 2ml/kg/day solution (from 0.5% w/v solution)	No deaths occurred. Slight to moderate erythema observed. No systemic toxicity observed.	IJT
Reproductive/Developmental Toxicity (rabbit) n=20 Dose: 2 ml/kg of 0.5%, 1%, and 2% (v/v) 100% active for 2 hr. on days 7-18 of gestation.	The reproductive parameters and the incident of fetal malformations and developmental variations were not significantly different from controls.	IJT
Mutagenicity Testing		

a. Ames Test (Salmonella typhimurium strain) b. Chromosomal Aberration Assay (CHC) c. Cell Transformation Assay (Syrian golden hamster embryo cells)	Negative Negative. Negative.	IJT IJT IJT
Clinical Studies Repeated Insult Patch Test a. (human) (n=114) occlusive patch containing 0.3 ml of 0.25% (w/v) centrimonium chloride (100% active was applied, 24 hr. exposure 3x/week for 3 weeks. Seventeen days following the last application a challenge patch of 0.25% test material was applied to untreated site). b. (human) (n=101) 0.8% centrimonium chloride (25% active in a hair conditioner was tested as a 10% (w/v) ag. solution. c. (human) (n=107) 1.6% centrimonium chloride (25% active) in a hair conditioner was tested as a 10% (w/v) ag. solution.	Mild irritation was observed in several subjects during induction. No sensitization was observed. Mild enythema observed during induction in several subjects. No sensitization reactions were observed. One subject had slight irritation during induction. No sensitization reactions were observed.	IJT
Conclusion: Based on the available animal and clinical data, the Cosmetic Ingredient Review (CIR) Expert Panel has concluded that centrimonium chloride is safe for use in rinse-off products and is safe for use at concentrations of up to 0.25% in leave-in products. [1]MMTS = Maximum Mean Total Score		

References:

*International Journal of Toxicology (IJT), Vol. 16, No. 3, 1997; 195-200.

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