Technical Stepan Information

Stepan Company

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MAMMALIAN TOXICOLOGY OF ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDES (ADBAC)

Applicable to these current Stepan products:

BTC® 50	BTC® 65	BTC® 776	
BTC® 824	BTC® 8248	BTC® 8249	
BTC® 835	BTC® 8358	STEPANQUAT® 50 NF	
STEPANQUAT® 65 NF	STEPANQUAT® 8358	BTC® 8358 F	
Applicable to these inactive Stepan products:			
BTC® 2565	BTC® 2568	BTC® 824 P100	
STEPANQUAT® 835			

Toxicological Information:

Test/Conditions	Results/Classification	<u>References</u>
Acute Oral Toxicity (rat)(14 day) n=5/sex/dose	LD ₅₀ (Lethal Dose) is between 50 and 500 mg/kg (moderately toxic orally at 50% active)	Stepan Study No. 87-005E
Acute Dermal Toxicity (rabbit) (14 day) n=5/sex/dose	LD _{₅0} is found to be greater than 2000M mg/kg (slightly toxic dermally)	Stepan Study No. 87-005F
Acute Inhalation Toxicity (rat) (4hr exposure, 14 day observation) n=5/sex/dose	0.054 mg/L < LD _{₅0} < 0.51 mg/L (extremely toxic)	Stepan Study No. 99-015A
Primary Eye Irritation (rabbit) (21 day) n=6	29.9% 110.0 @ 1% active (moderately irritating)	Stepan Study No. 05-002C
Repeated Eye Instillation (rabbit)(3 weeks) n=6/group	Slight irritation @ 2.5 & 5.0 ppm	Stepan Study No. 88-026A

Primary Skin Irritation (rabbit)(24 hr. contact time) n=9	PII= 6.54/8.0 (severly irritating to skin @ greater than 5% active)	Stepan Study No. 04-002C
Skin Irritation Study (rat) (2 weeks) (repeated dermal applications)	No skin irritation was observed at concentrations less or equal to 0.1%	Stepan Study No. 5036

Test/Conditions	Results/Classification	<u>References</u>
Photoallergy Study (modified Buehler test) (guinea pig)	There was no evidence of photoallergy or contact sensitization at 0.25%. @0.4 ml of 1% w/w mixture of test substance in distilled water.	Stepan Study No. 05-019/
Subchronic Dermal Toxicity (rat)(90 Day)	No systemic toxicity observed at 20 mg/kg/day.	Stepan Study No. 90-012/
Repeated Oral Dose (mice)(dietary)(90 days)	NOEC (No Observed Effect Concentration) = 500 ppm	Stepan Study No. 88-040
Chronic Oral Toxicity (dog)(diet)(1 year)	No effects for systemic toxicity observed at 400 ppm. No specific target organ toxicity observed. Treatment had no effect on survival.	Stepan Study No. 94-014,
Chronic/Oncogenicity Study (mouse)(diet)(78 week) n=60	No effects levels were determined to be at or less than 500 ppm. No specific target organ toxicity observed. Treatment did not have any affect on survival or tumor incidence.	Stepan Study No. 91-067
Chronic/Oncogenicity Study (rat)(diet) (104 weeks) n=60	No-effect levels were determined to be at 1000 ppm. No specific target organ toxicity was observed. Treatment did not have any effect on survival or tumor incidence.	Stepan Study No. 91-066
Developmental Toxicity (rat)(gavage) n=100	No effect levels at 10 mg/kg/day were determined for maternal toxicity. Treatment had no effects on fetal development.	Stepan Study No. 92-013

Developmental Toxicity (rabbit)(gavage) n=64No effect levels at 3 mg/kg/day were determined for maternal toxicity. Treatment had no effects on fetal development.Stepan Study No.

Test/Conditions	Results/Classification	<u>References</u>
Two-Generation Reproduction Study (rat)(diet) n=28/dose/sex	No effect levels for parental and neonatal toxicity were determined to be at or less than 1000 ppm. Treatment did not have an effect on any of the reproductive parameters.	Stepan Study No. 90-016A
Mutagenicity (Ames Test)	Not mutagenic	Stepan Study No. 01-035A
CHO/HGPRT Forward Mutation Assay (Mutagenicity Test)	Not mutagenic	Stepan Study No. 89-025A
Primary Hepatocyte Unscheduled DNA Synthesis Assay (Mutagenicity Test)	Not mutagenic	Stepan Study No. 89-019A
Unscheduled DNA Synthesis-Independant Repeat (Genotoxicity Test) (rat liver cells)	Not mutagenic	Stepan Study No. 92-012A

Expert Panel Review of benzalkonium chloride, an ADBAC quat: The Cosmetic Ingredient Review (CIR) Expert Panel concluded that benzalkonium chloride at concentrations up to 0.1% free, active ingredient, is safe as a cosmetic ingredient as presently used.

PPI¹=Primary Skin Irritation Index

References:

*Journal of the American College of Toxicology (JACT), vol. 8 (4), 1989, pp. 600-609.

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