Technical Information

Stepan

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MAMMALIAN TOXICOLOGY OF ALKYL DIMETHYL BENZYL/ETHYL BENZYL AMMONIUM CHLORIDES

Applicable to these current Stepan products:

BTC® 2125 M-80% BTC® 2125M	BTC® 2125 M P40 AGENT 2248-14	SO/SAN® 30M

Applicable to these inactive Stepan products:

BTC® 2125	BTC® 2125-80%	BTC® 2125 P40

Toxicological Information:

Test/Conditions	Results/Classification	References
Acute Oral Toxicity (rat)(14 day) n=5/sex/dose	LD_{50} (Lethal Dose) is between 50 and 500 mg/kg (moderately to slightly 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
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 Study (rabbit) (24 hr. contact time) n=9	PII=6.54/8.0 (severely 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 1%.	Stepan Study No. 5036

Test/Conditions	Results/Classification	References
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. 05-019A
Subchronic Dermal Toxicity (rat)(90 Day)	No systemic toxicity observed at 20 mg/kg/day.	Stepan Study No. 90-012A
Repeated Oral Dose (mice)(dietary)(90 days)	NOEC = 500ppm	Stepan Study No. 88-040A
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. 94-014A
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. 91-067A
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. 91-066A
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. 92-013A
Developmental Toxicity (rabbit)(gavage) n=64	No effect levels at 3 mg/kg/day were determined for maternal toxicity. Treatment had no effects on fetal development.	Stepan Study No. 92-014A

Test/Conditions	Results/Classification	References
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-Independent Repeat (Genotoxicity Test) (rat liver cells)	Not mutagenic	Stepan Study No. 92-012A

Expert Panel Review of benzalkonium chloride, an alkyl dimethyl benzyl ammonium chloride 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.

[1]PII=Primary Skin Irritation Index

References:

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

Last Update: 2.8.10 Revision Reference: TX017.04

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