

5/14/78

003619

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CFSWELL 103.16 Ex 17-FV

Registration Human Safety

view

Pharm. Joseph

T. J. Davis

TOX Reviewer C. H. Rodriguez

003619

Alt #	Date	Product No.	Use-Classification	TOX CAT.
1839-20	5-4-78	BTC-2125 P.40		I

COMPARISON:

☐ register☐ other (explain)

Revise the precautionary labeling for this product according to the S-76 A Enclosure. The teratogenic study on (BTC 471) must be submitted or referenced. Submit as Route Derm. LD50

Route Oral (Rat)	LD50 g/kg	TECH. INFORMATION	USE DILUTION	DATA
	0.43 g/kg			garcia

Toxic signs:

Not given.

Comments:

Classification: Core-Minimum Std.

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Route Dermal (Rabbit)	LD50.			
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Toxic signs:

Comments:

Not submitted or referenced.

Route Inhalation ()	LD50			
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Toxic signs:

Comments:

Not required.

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Primary Eye Irritation (Rabbit) Draize score:									
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Comments:

Not submitted, however 40% concentration of quaternary ammonium compound in the rabbit eye has demonstrated to be corrosive and to cause corneal damage, therefore is required.

Primary Skin Irritation (Rabbit) Draize score:									
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Comments:

Not submitted, however 40% concentration of quaternary ammonium compounds in the rabbit has demonstrated to be a severe skin irritant, therefore is not required.

Other Studies: Teratogenic (BTC 471).

The oral administration to female rats at dosage levels of 5, 15 or 50 mg/kg of body weight from days 6 to 15 of gestation was not associated with any dose related effects on implantation, gestation or terata in the fetuses.

Classification: Core-Minimum Std.

J. F. W. 5/15/78