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DATA EVALUATION REPORT

MRID No.: 141303
PC No.: 020502
RD Record No.: S479723
EPA ID No.: 020502
Tox Chem No.: 755
Project No.: D210864

I. SUMMARY

Study Type: (81-1/81-5) Acute oral LD_{50}-rat/Primary dermal Irritation - rabbit

Chemical: Sodium chlorite

Synonyms: AKTA-CLOR 25

Sponsor: Rio Linda Chemical, Rio Linda, CA

Testing Facility: Northview Pacific Laboratories
Berkely, CA

Title of Reports: (1) Acute Oral Toxicity Test
(2) Primary Skin Irritation Test

Author: [Illegible writing]

Study No.: (NVP)-X4C020-G

Report Issued: April 10, 1984

Executive Summary: (1) All 10 rats gavaged once with test article at 5000 mg/kg died four hours post-dosing.

(2) 4/6 Test animals manifested severe necrosis and eschar formation, persisting to 14 days post-dose.

TB-I Evaluation: (1) Invalid
(2) ACCEPTABLE - TOX. CAT. I

(1)

II. DETAILED REVIEW:

A. Test Material: AKTA-CLOR 25 (25% solution of sodium chlorite)

Description: [Not provided]
Batches (Lots): [not provided]
Purity (%): 25
Solvent/carrier/diluent: Deionized water

B. Test Organism: (1) Rodent: (2) Lagomorph

Species: Rat:Rabbit
Strain: [Not provided]:New Zealand White (NZW)
Age: [Not provided]:[Not provided]
Weights - males/females: 152-242g: 2.2-2.4kg
Source: [Not provided]:[Not provided]

C. Study Design (Protocol): This study was designed to assess the toxic potential of the test article when administered as a single dose to rats (orally) or rabbits (topically), according to established (published) procedures and FIFRA/OECD Test guidelines.

A Statement of Quality Assurance measures (inspections/audits) was provided.

A Statement of adherence to good Laboratory Practice (GLP) was provided.

D. Procedures/Methods of Analysis:

(1) (81-1) Acute Oral Toxicity: Ten rats (5M:5F) were gavaged once orally at 5000 mg/kg test article, while 2 additional rats (1M:1F) served as controls (administered the vehicle, deionized water). Animals were observed daily, weighted weekly (or at death).

(2) (81-5) Primary Dermal Irritation: Six rabbits (sex not specified) were inuncted over a "portion of their dorsal surfaces" (clipped free of hair the day before, but area of application not specified) with 0.5 ml of test article neat, and covered with cotton gauze, over which the entire trunk was wrapped with non-occlusive dressing. After 4 hours, all wrappings were removed, and residual test material rinsed from sites of application. Animals were observed and scored for irritation (by Draize categories) at 5, 24, 48 and 72 hours, 7 and 14 days post-application.

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E. Results:

(1) Acute Oral Toxicity: All 10 test animals died within the first hour after dosing, appearing pale and lethargic immediately after the administration of test compound, followed by severe diarrhea and nasal discharge of a clear yellow fluid. At necropsy, skin was purplish-black, lungs were brown in color and surrounded by a clear fluid, other internal organs (spleen, kidney, liver) "appeared darker in color then normal," and the stomach was filled with liquid.

(2) Primary Dermal Irritation: Five hours after application, four of the six treated animals showed patches of gray necrotic skin at the test site, which persisted 24 hours later in two of these four, whereas the other two had "deep pitted wounds" appearing at the 24-hour examination.

By 48 and 72 hours post-dose, the two with necrosis only (ie, no pitted wounds) manifested yellowish areas where grayish areas had previously been observed. [The investigator suggested this was "probably the beginning of the healing process."] The pitted wounds at the test sites of the more severely affected animals began to form scabs at this time, as the surrounding skin dried out and became "crunchy to the touch."

At 7 days post-dose these four affected animals had formed eschars and necrotic tissue at test sites, which persisted to the 14-day examination.

The investigator concluded that the test article was corrosive to rabbit skin, with severe dermal effects persisting to 14 days (Draize score = 4 in four affected animals).

F. TB-I Evaluation:

(1) Acute Oral Toxicity: UNACCEPTABLE

Only one dose was tested (5000 mg/kg) which resulted in 100% mortality four hours after gavage.

(2) Primary Dermal Irritation: ACCEPTABLE

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