

US EPA ARCHIVE DOCUMENT

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06-15-95
for - Kit Jamell 12-16-96

DATA EVALUATION REPORT

MRID No.: 142357
PC No.: 020502
RD Record No.: S479723
EPA ID No.: 020502
Tox Chem No.: 755
Project No.: D210864

I. SUMMARY

Study Type: (81-5) Primary dermal irritation - rabbit

Chemical: Sodium chlorite

Sponsor: Rio Linda Chemical, Rio Linda, CA

Testing Facility: Northview Pacific (NVP) Laboratories
Berkeley, CA

Title of Report: Primary Skin Irritation

Author: M. J. Deenihan

Study No.: (NVP) X4C021-G

Report Issued: April 24, 1984

Executive Summary: 0.5 Gram of test article was applied (neat) to the clipped dorsum of New Zealand White rabbits and left in place for 4 hours. Animals were observed for 14 days post-dose.

All animals showed severe dermal effects, beginning five hours post-dose, and persisting to 14 days.

TB-I Evaluation: ACCEPTABLE - TOX. CAT. I

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II. DETAILED REVIEW:

A. Test Material: Sodium chlorite

Description: Powder
Batches (Lots): [Not provided]
Purity (%): [Not provided]
Solvent/carrier/diluent: Neat

B. Test Organism: Lagomorph

Species: Rabbit
Strain: New Zealand White (NZW)
Age: "Young"
Weights - 2 to 2.5 kg (sex not specified)
Source: [Not provided]

C. Study Design (Protocol): This study was designed to assess the primary irritant potential of the test article when administered topically to NZW rabbits 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: 0.5 Gram of the test article was applied neat (undiluted) to the clipped dorsum (area of application not provided) of six NZW rabbits (sex not specified), and covered with cotton gauze patches moistened with a few drops of water. Then the entire trunk of each animal was wrapped with a non-occlusive dressing. After four hours, all dressings were removed, and residual test compound rinsed from test sites.

Animals were observed and scored for skin irritation (according to the Draize categories) at 5, 24, 48 and 72 hours, 7 and 14 days post-dose.

E. Results: Five hours post-dose, all six animals showed gray (pre-necrotic) test areas, persisting to 24 hours in four of the six, at which time the gray areas were turning into wounds in two of the four, with scab formation by 48 hours (Report Table II). Eschar formation and/or red welts were observed in these four affected animals at 72 hours, and in all six animals by seven days. A week later (Study Day-14), the wounds in four had healed to dry eschar, while the remaining two

still manifested deep wounding surrounded by active eschar.

The investigator concluded that the undiluted test article caused severe dermal irritation and eschar formation in rabbit skin, irreversible 14 days post-dose.

F. TB-I Evaluation: ACCEPTABLE, as demonstrating severe dermal irritation (TOX. CAT. I) in rabbit skin treated with 0.5 gram of sodium chlorite powder.