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VOLUME ____ OF ____ OF SUBMISSION
91-HS-16

ACUTE DERMAL TOXICITY STUDY IN RABBITS
EPA GUIDELINES NO. 81-2

AUTHOR - Janice O. Kuhn, Ph.D.

STUDY COMPLETED ON May 24, 1991

CONDUCTED BY STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, Texas 77478

LABORATORY STUDY NUMBER 8005-91

VOLUME 1 OF 1 OF STUDY

PAGE 1 OF 13

Submitted To: National Forest Service
Fire Suppression Research
Intermountain Fire Sciences Lab
P.O. Box 8089
Missoula, Montana 59807-8089

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d) (1) (A), (B), or (C).

Company: National Forest Service

Company Agent: _____ Date: _____

_____ _____

Title Signature

These data are the property of National Forest Service, and as such, are considered to be confidential for all purposes other than compliance with FIFRA 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality which may exist under any other statute or in any other country.

CERTIFICATION OF GOOD LABORATORY PRACTICES

To the best of my knowledge, the Good Laboratory Practice statement found on page 5 of this volume, and signed by the study director, is truthful and accurate.

VERIFICATION OF A COMPLETE AND UNALTERED COPY OF REPORT

To the best of my knowledge, this report as provided by the testing laboratory is complete and unaltered.

_____
Signature of Agent of Submitter/Sponsor

_____ _____
Date

Submitter/Sponsor:

National Forest Service
Fire Suppression Research
Intermountain Fire Sciences Lab
P.O. Box 8089
Missoula, Montana 59807-8089

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STILLMEADOW, Inc. GLP Compliance Statement

This study was designed and performed in STILLMEADOW, Inc.'s AAALAC accredited laboratory under Pesticide Assessment Guidelines promulgated by the U.S. Environmental Protection Agency (EPA Publication 540/9-84-014) and was in compliance with Good Laboratory Practice Standards (40 CFR 160, revised at 48 FR 53946, Nov. 29, 1983; 54 FR 34052, effective Oct. 16, 1989).

Project Director: _____

Janice O. Kuhn, Ph.D.
Toxicologist
STILLMEADOW, Inc.

Affirmation of Quality Assurance
Stillmeadow Project Number: 8005-91
Test Material: 91-HS-16
Study: Rabbit Acute Dermal Toxicity
Date Inspected: April 25, 1991
Phase of Study Inspected: Dosing
Inspector: Tracy C. Wooten

This office has inspected at least one phase of the study listed above and has reviewed the raw data versus the final report. Based on the inspection and on the review of the data, this office is confident that the protocol described in the final report was followed throughout the course of the study, except for the deviation noted below, and that the final report accurately reflects the raw data.

Tracy C. Wooten
Quality Assurance Unit
STILLMEADOW, Inc.

Date: May 24, 1991

Protocol deviation: The protocol states that the animals will be acclimated for at least one week before treatment. Due to the availability of animals, the animals in this study were acclimated for only 3 days. This deviation did not affect the outcome of the study.

Project Director:

Janice C. Kuhn, Ph.D.
Toxicologist
STILLMEADOW, Inc.

I. SUMMARY

An acute dermal toxicity study was conducted on male and female albino rabbits using test material 91-HS-16.

Five males and five females were selected for testing. The exposure areas were treated with 2020 mg/kg (2.00 ml/kg) of undiluted test material and were then occluded for 24 hours.

No animals died during the study. The acute dermal LD_{50} for 91-HS-16, as indicated by the data, is greater than 2020 mg/kg (2.00 ml/kg) when administered undiluted to the intact skin of albino rabbits.

Project Director: Janice C. Kuhn

Janice C. Kuhn, Ph.D.
Toxicologist
STILLMEADOW, Inc.

Date: May 24 1991

Report Prepared By: Connie Pavatte
Data Services
STILLMEADOW, Inc.

STILLMEADOW, Inc. Technical Staff: JoLynne Bright
Forrest Chang
Lori Leeper
Hailin Wu

II. INTRODUCTION

The objective of this study was to determine the acute dermal toxicity potential of the test material in accordance with Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals, Series 81-2, EPA Publication, EPA 540/9-84-014, November, 1984. This study was conducted for National Forest Service, using 91-HS-16. The animals were treated with the test material as follows:

Dose	Male Treatment		Female Treatment		Termination Date	
(mg/kg)	Date	Time	Date	Time	Males	Females
2020	4/25/91	9:20 A.M.	4/25/91	9:23 A.M.	5/09/91	5/09/91

The protocol, raw data, and a copy of this report are kept on file permanently in the STILLMEADOW, Inc. archives.

III. MATERIALS AND METHODS

Unless otherwise noted, the methods stated in the approved protocol are the same as those described in the following text.

A. Test Material

Label: 91-HS-16
Received From: National Forest Service
Fire Suppression Research
Intermountain Fire Sciences Lab
P.O. Box 8089
Missoula, Montana 59807-8089
Date Received: March 14, 1991
Quantity Received: 897.0 g (Gr.Wt.)
Physical Description: Clear, colorless liquid
Storage: Room temperature
Treatment Temperature: Room temperature
Density: 1.0085 g/ml
Purity and Composition: Not provided by sponsor
Stability: Not provided by sponsor
Concentration Administered: 100% as received

III. MATERIALS AND METHODS (cont.)

B. Experimental Animals

Species: Rabbit
Strain: New Zealand White
Justification of Species: The rabbit is conventionally used to provide information on which human hazard can be judged
Source: Ray Nichols Rabbitry, Lumberton, Texas
Quantity and Sex: Five males and five females (nulliparous and non-pregnant)
Acclimation Period: 3 days
Animal Identification: Ear tags
Weight When Tested: Males (2.000-2.650 kg)
Females (2.200-2.900 kg)
Age: Young adult (3 to 6 months of age)

C. Animal Husbandry

Cage Type: Suspended, wire bottom, stainless steel
Housing: One per cage
Transfer to Clean Cages: Weekly
Litter Pan Lining: Paper
Litter Pan Lining Change: Daily
Food: Purina Rabbit Chow; presented in measured amounts
Water Type: Tap; available ad libitum
Water System: Automatic

Experimental Design

Healthy albino rabbits were released from quarantine. Each animal was prepared on the day prior to treatment by clipping the dorsal surface of the trunk free of hair to expose not less than 10% of the total body surface area. Care was taken to avoid abrading the skin. Only those animals with exposure areas free of pre-existing skin irritation or defects were used for this study. Five males and five females were selected for testing. The animals were returned to their cages.

All animals were treated with 2020 mg/kg (2.00 ml/kg) of undiluted test material. Surgical gauze (10 x 10 cm and two layers thick) was applied to the trunk of each animal and held in place with non-irritating adhesive tape

III. MATERIALS AND METHODS (cont.)

to keep the test material in contact with the skin of the exposure area. The entire trunk of each animal was then wrapped with a semi-permeable dressing (orthopedic stockinette) to retard evaporation of volatile substances and to prevent possible ingestion of the test material. The wrappings were held in place with non-irritating adhesive tape. The test material was then introduced under the wrappings and gauze by means of a syringe and spread evenly over the exposure area. The tape was resealed, and the animals were again returned to their cages.

After 24 hours, the wrappings and gauze were removed from the animals. The exposure areas were gently washed with room temperature tap water and a clean wet cloth to remove as much remaining test material as possible. The animals were again returned to their cages.

Observations for signs of pharmacologic and/or toxicologic effects and mortality were made at 1/2, 3 and 6 hours after treatment and at least once daily thereafter for 14 days (day of treatment considered Day 0). Individual body weights were recorded on Days 0, 7 and 14. A gross necropsy examination was conducted on each animal at termination of the study.

IV. RESULTS AND DISCUSSION

Individual body weights, times of death, and gross necropsy findings are presented in Table 1. Pharmacologic and/or toxicologic signs are presented in Table 2.

Observations for pharmacologic and/or toxicologic signs were made frequently throughout the study. Prominent in-life observations included decreased defecation and diarrhea.

The gross necropsy examination conducted on each animal at termination of the study revealed no observable abnormalities.

No animals died during the study. The acute dermal LD_{50} for 91-HS-16, as indicated by the data, is greater than 2020 mg/kg (2.00 ml/kg) when administered undiluted to the intact skin of albino rabbits.

Table 1
RABBIT ACUTE DERMAL TOXICITY
Body Weights, Times of Death, and Gross Necropsy
Test Material: 91-HS-16
Dose Level: 2020 mg/kg (2.00 ml/kg)

Animal Number	Body Weights (kg) Day 0	Day 7	Final	Time of Death*	Gross Necropsy Findings
1194-M	2.575	2.800	2.925	Day 14	NOA
1196-M	2.350	2.450	2.800	Day 14	NOA
1198-M	2.650	3.075	3.275	Day 14	NOA
1200-M	2.425	2.775	2.750	Day 14	NOA
1202-M	2.000	2.475	2.550	Day 14	NOA
1207-F	2.200	2.875	3.000	Day 14	NOA
1209-F	2.575	2.725	3.025	Day 14	NOA
1211-F	2.500	2.725	2.900	Day 14	NOA
1213-F	2.900	2.800	2.925	Day 14	NOA
1217-F	2.700	3.000	3.150	Day 14	NOA

* - Indicates time of discovery after death (day of dosing considered Day 0; Day 14 is terminal sacrifice). If discovery was between scheduled observations, the time of death was considered to be the next scheduled observation time.
NOA - No Observable Abnormalities
M - Male; F - Female

Table 2
RABBIT ACUTE DERMAL TOXICITY
Pharmacologic and/or Toxicologic Signs
Test Material: 91-HS-16
Dose Level: 2020 mg/kg (2.00 ml/kg)
Sex: Males and Females

	Time After Treatment																
	HOURS			DAYS													
Reaction and Severity	.5	3	6	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Males																	
Diarrhea (s)	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
Females																	
Decreased defecation	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Diarrhea (s)	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0

v - very slight; s - slight; m - moderate; e - extreme

Note: Numbers indicate surviving animals exhibiting reaction. Time of death indicates time of discovery after death. If discovery was between scheduled observations, death is presented under next observation time.