Product Safety Laboratories
2394 Highway 130
Dayton, NJ 08810
Tel: 732.438.5100
Fax: 732.355.3275
e-mail: PSL@productsafetylabs.com

PRODUCT

Stalosan F

STUDY TITLE

Acute Dermal Toxicity Study in Rats - Limit Test

DATA REQUIREMENT

U.S. EPA Health Effects Test Guidelines, OPPTS 870.1200 (1998)

AUTHOR

Daniel J. Merkel, B.S.

STUDY COMPLETED ON

March 10, 2005

PERFORMING LABORATORY

Product Safety Laboratories

2394 Highway 130

Dayton, New Jersey 08810

LABORATORY STUDY NUMBER

16448

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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: **ARCH ANGEL LLC**

Company Agent:

_____	_____
Name	Title
_____	_____
Signature	Date

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Stalosan F

This study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA) with the following exception: Specific information related to the stability, characterization, identity and verification of the test substance concentration as received and tested is the responsibility of the study Sponsor (see Test Substance section).

Study Director: _____
Daniel J. Merkel, B.S.
Product Safety Laboratories

3/10/05
Date

Submitter: _____
Signature

_____
Date

Sponsor: _____
Signature

_____
Date

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QUALITY ASSURANCE STATEMENT

The Product Safety Laboratories' Quality Assurance Unit reviewed this study for adherence to PSL's Standard Operating Procedures, the study protocol, and all applicable GLP standards. This final report was found to be an accurate representation of the work conducted. Records of QA findings are kept on file. The summary below provides verification of statements made in the final report section that addresses Quality Assurance audits.

QA activities for this study:

QA Activity	Date Conducted	Date Findings Reported To Study Director And Management
Protocol review	1/26/04[1], 2/1/05	1/26/04, 2/1/05
In-process inspection: *22 hour in-life observations*	12/2/04	2/1/05
Raw data audit	2/1/05	2/1/05
Draft report review	2/1/05	2/1/05
Final report review	3/10/05	3/10/05

Louise N. Caruso

Louise N. Caruso, B.S.
Quality Assurance Auditor
Product Safety Laboratories

[1] PSL's "generic" protocol used for this study was reviewed by the Quality Assurance group on this date.

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ACUTE DERMAL TOXICITY STUDY IN RATS - LIMIT TEST

PROTOCOL NO.:	P322
AGENCY:	EPA (FIFRA)
STUDY NUMBER:	16448
SPONSOR:	ARCH ANGEL LLC 636 Hampshire, Suite 208 Quincy, IL 62301
TEST SUBSTANCE IDENTIFICATION:	Stalosan F Lot #1 Batch 63
TEST SUBSTANCE DESCRIPTION:	Pinkish powder
DATE RECEIVED:	November 8, 2004
PSL REFERENCE NO.:	041108-3D
STUDY INITIATION DATE:	November 15, 2004
DATES OF TEST:	December 1 - 15, 2004
NOTEBOOK NO.:	04-94: pages 208-225

1. PURPOSE

To provide information on health hazards likely to arise from a short-term exposure to Stalosan F by the dermal route.

2. SUMMARY

An acute dermal toxicity test was conducted with rats to determine the potential for Stalosan F to produce toxicity from a single topical application. Under the conditions of this study, the single dose acute dermal LD_{50} of the test substance is greater than 5,000 mg/kg of body weight in male and female rats.

Five thousand milligrams per kilogram of body weight of the test substance was moistened with distilled water and applied to the skin of ten healthy rats for 24 hours. The animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days. Body weights were recorded prior to application and again on Days 7 and 14 (termination). Necropsies were performed on all animals at terminal sacrifice.

All animals survived, gained body weight, and appeared active and healthy. There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behavior. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

3. MATERIALS

A. Test Substance

The test substance, identified as Stalosan F, Lot #1 Batch 63, was received on November 8, 2004 and was further identified with PSL Reference Number 041108-3D. The test substance was a pinkish powder and was stored at room temperature. In order to insure adequate contact with the skin, the sample was applied as a dry paste (60% w/w mixture in distilled water). Preliminary sample preparation conducted by PSL indicated mixtures in excess of 60% (i.e., 70%-90%) were too dry to assure adequate skin contact. Documentation of the methods of synthesis, fabrication, or derivation of the test substance is retained in Denmark.

The following information related to the characterization of the test substance was provided by the Sponsor unless otherwise noted:

Composition: not given

pH: 3.5 (as a 1% w/w solution) [1]

Solubility: Slightly soluble in water.

Stability: Test substance was expected to be stable for the duration of testing.

Expiration Date: Not applicable.

B. Animals

3.B.1 Number of Animals: 10

3.B.2 Sex: 5 Males and 5 Females. Females assigned to test were nulliparous and non-pregnant.

3.B.3 Species/Strain: Rats/Sprague-Dawley derived, albino

3.B.4 Age/Body weight: Young adult (10-11 weeks)/males 344-360 grams and females 212-224 grams at experimental start.

3.B.5 Source: Received from Ace Animals, Inc., Boyertown, PA on November 9, 2004.

[1] As determined by Product Safety Laboratories (from PSL study numbers 16446 and 16445 for the active ingredient and pH, respectively).

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4. METHODS

A. Husbandry

4.A.1 Housing: The animals were singly housed in suspended stainless steel caging with mesh floors which conform to the size recommendations in the most recent *Guide for the Care and Use of Laboratory Animals DHEW (NIH)*. Litter paper was placed beneath the cage and was changed at least three times per week.

4.A.2 Animal Room Temperature Range: 19-23°C

4.A.3 Photoperiod: 12-hour light/dark cycle

4.A.4 Acclimation Period: 22 days

4.A.5 Food: Purina Rodent Chow #5012

4.A.6 Water: Filtered tap water was supplied *ad-libitum* by an automatic water dispensing system.

4.A.7 Contaminants: There were no known contaminants reasonably expected to be found in the food or water at levels which would have interfered with the results of this study. Analyses of the food and water are conducted at least once a year and the records are kept on file at Product Safety Laboratories.

B. Identification

4.B.1 Cage: Each cage was identified with a cage card indicating at least the study number and identification and sex of the animal.

4.B.2 Animal: A number was allocated to each rat on receipt and a stainless steel ear tag bearing this number was attached to the animal. This number, together with a sequential animal number assigned to study 16448, constituted unique identification.

5. PROCEDURE

A. Preparation and Selection of Animals

On the day prior to application, a group of animals was prepared by clipping (Oster model #A5-small) the dorsal area and the trunk. After clipping and prior to application, the animals were examined for health, weighed (initial) and the skin checked for any abnormalities. Ten healthy rats (five males and five females) were selected for test.

B. Dose Calculations

Individual doses were calculated based on the initial body weights, taking into account the concentration of the test mixture.

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C. Application of Test Substance

Prior to application, the test substance was moistened with distilled water to achieve a dry paste by preparing a 60% w/w mixture. Five thousand mg/kg of body weight of the test substance was then applied to a 2-inch x 3-inch, 4-ply gauze pad and placed on a dose area of approximately 2 inches x 3 inches (approximately 10% of the body surface). The gauze pad and entire trunk of each animal were then wrapped with 3-inch Durapore tape to avoid dislocation of the pad and to minimize loss of the test substance. The rats were then returned to their designated cages. The day of application was considered Day 0 of the study.

After 24 hours of exposure to the test substance, the pads were removed and the test sites were gently cleansed of any residual test substance.

D. Body Weights

Individual body weights of the animals were recorded prior to test substance application (initial) and again on Days 7 and 14 (termination).

E. Cage-Side Observations

The animals were observed for mortality, signs of gross toxicity, and behavioral changes during the first several hours after application and at least once daily thereafter for 14 days. Observations included gross evaluation of skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behavior pattern. Particular attention was directed to observation of tremors, convulsions, salivation, diarrhea, and coma.

F. Necropsy

All rats were euthanized via CO_2 inhalation on Day 14. Gross necropsies were performed on all animals. Tissues and organs of the thoracic and abdominal cavities were examined.

6. STUDY CONDUCT

This study was conducted at Product Safety Laboratories, 2394 Highway 130, Dayton, New Jersey 08810. The primary technician for this study was Jacek Ochalski, D.V.M. This study was conducted to comply with the Good Laboratory Practice (GLP) regulations as defined in:

- 40 CFR 160: U.S. EPA GLP Standards: Pesticide Programs (FIFRA)

and in accordance with:

- U.S. EPA Health Effects Test Guidelines, OPPTS 870.1200 (1998)

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7. QUALITY ASSURANCE

The final report was audited for agreement with the raw data records and for compliance with the protocol, Product Safety Laboratories Standard Operating Procedures and appropriate Good Laboratory Practice Standards. Dates of inspections and audits performed during the study and the dates of reporting of the inspection and audit findings to the Study Director and Facility Management are presented in the Quality Assurance Statement.

8. DEVIATIONS FROM FINAL PROTOCOL

None.

9. FINAL REPORT AND RECORDS TO BE MAINTAINED

The original, signed final report will be forwarded to the Sponsor. A copy of this signed report, together with the protocol and all raw data generated at Product Safety Laboratories, is maintained in the Product Safety Laboratories Archives. PSL will maintain these records for a period of at least five years. After this time, the Sponsor will be offered the opportunity to take possession of the records or will be charged an archiving fee for continued archiving by PSL.

10. RESULTS

Individual body weights and doses are presented in Table 1. Individual cage-side and necropsy observations are presented in Tables 2 and 3, respectively.

All animals survived, gained body weight, and appeared active and healthy. There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behavior. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

11. CONCLUSION

Under the conditions of this study, the single dose acute dermal LD_{50} of Stalosan F is greater than 5,000 mg/kg of body weight in male and female rats.

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SIGNATURES

Stalosan F

We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.

Daniel J. Merkel, B.S.
Study Director
Product Safety Laboratories

3/10/05
Date

Gary Wnorowski JO 3/10/05
Gary Wnorowski, B.A., M.B.A.
President
Product Safety Laboratories

3/10/05
Date

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TABLE 1: INDIVIDUAL BODY WEIGHTS AND DOSES

Animal No.	Sex	Body Weight (g)			Dose[1]
		Initial	Day 7	Day 14	g
8895	M	360	386	436	3.0
8896	M	355	380	428	3.0
8897	M	347	374	414	2.9
8898	M	350	377	424	2.9
8899	M	344	369	400	2.9
8900	F	220	233	253	1.8
8901	F	217	229	248	1.8
8902	F	215	226	250	1.8
8903	F	224	234	258	1.9
8904	F	212	220	247	1.8

[1] Applied as a dry paste (60% w/w mixture in distilled water).

TABLE 2: INDIVIDUAL CAGE-SIDE OBSERVATIONS

Animal Number	Findings	Day of Occurrence
MALES		
8895-8899	Active and healthy	0-14
FEMALES		
8900-8904	Active and healthy	0-14

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TABLE 3: INDIVIDUAL NECROPSY OBSERVATIONS

Animal Number	Tissue	Findings
MALES		
8895-8899	All tissues/organs	No gross abnormalities
FEMALES		
8900-8904	All tissues/organs	No gross abnormalities