PRODUCT

EasyDECON 200-531X

STUDY TITLE

Acute Dermal Toxicity Study in Rats- Limit Test

DATA REQUIREMENT

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

AUTHOR

Jennifer Durando, B.S.

STUDY COMPLETED ON

June 9, 2008

PERFORMING LABORATORY

Eurofins | Product Safety Laboratories

LABORATORY STUDY NUMBER

24400

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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: **EFT HOLDINGS, INC.**

Company Agent:

Name	Title
KEVIN J IRVINE	Vice President & GM

Signature

Date: 6/12/08

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

EasyDECON 200-531X

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

Study Director: Jennifer Durando

Jennifer Durando, B.S.
Eurofins | Product Safety Laboratories

6/12/08
Date

Submitter: _____
Signature

_____
Date

Sponsor: _____
Signature

6/12/08
Date

QUALITY ASSURANCE STATEMENT

The Eurofins | Product Safety Laboratories' Quality Assurance Unit reviewed this study for adherence to EPSL'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	Mar 7, 2007[1]; May 13, 2008	Mar 7, 2007; May 13, 2008
In-process inspection: *Day 5 in-life observations*	Apr 14, 2008	May 13, 2008
Raw data audit	May 13, 2008	May 13, 2008
Draft report review	May 13, 2008	May 13, 2008

Annamarie LaPorte
Quality Assurance Auditor
Eurofins | Product Safety Laboratories

June 9 2008
Date

[1] EPSL'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.RAT
AGENCY:	EPA (FIFRA)
STUDY NUMBER:	24400
SPONSOR:	EFT HOLDINGS, INC. 1012 Oster Drive, Suite A Huntsville, AL 35816
TEST SUBSTANCE IDENTIFICATION:	EasyDECON 200-531X Lot #T-1003 1) Penetrator 2) Fortifier 3) Booster
DATE RECEIVED:	February 25, 2008
EPSL REFERENCE NOS.:	1) 080225-6D 2) 080225-7D 3) 080225-8D
STUDY INITIATION DATE:	February 26, 2008
DATES OF TEST:	April 9-23, 2008
NOTEBOOK NO.:	08-87: pages 87-87B, 88-96

1. PURPOSE

To provide information on health hazards likely to arise from a short-term exposure to EasyDECON 200-531X by the dermal route.

2. SUMMARY

An acute dermal toxicity test was conducted with rats to determine the potential for EasyDECON 200-531X 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 (as prepared) is greater than 5,000 mg/kg of body weight in male and female rats.

Five thousand milligrams of the prepared test substance per kilogram of body weight was 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 exposure to the test substance and gained body weight during the study. Other than dermal irritation (erythema, edema and/or eschar), desquamation and/or hyperkeratosis noted for all dose sites throughout the study, there were no other clinical findings recorded for any animal over the course of the study. 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

Three individual components of the test substance, identified as EasyDECON 200-531X, Lot #T-1003, were received from the Sponsor on February 25, 2008 and further identified as follows:

Name and Part Number	EPSL Reference Number
Penetrator (part 1)	080225-6D
Fortifier (part 2)	080225-7D
Booster (part 3)	080225-8D

The test substance components were stored at room temperature. Immediately prior to application, as per the Sponsors instructions, 49% part 1 by weight, 49% part 2 by weight and 2% part 3 by weight were mixed together by EPSL (see Section 8, Amendment #1). The prepared test mixture was considered the test substance and was used within 8 hours of mixing. Documentation of the methods of synthesis, fabrication, or derivation of the test substance is retained by Baum's Castorine, P.O. Box 230, 200 Mathew Street, Rome, NY 13442.

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

Composition: Akyl Dimethyl Benzyl Ammonium Chlorides – 2%
Hydrogen Peroxide – 3.9%
Diacetin – 2%
Other Ingredients – 92.1%

Physical description: Clear liquid

pH: 9.8

Solubility: Soluble in water, methanol, ethanol and acetone.

Stability: Test substance was expected to be stable for the duration of testing. The prepared sample must be used within 8 hours after mixing.

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 (8-9 weeks)/males 216-242 grams and females 158-189 grams at experimental start.

3.B.5 Source: Received from Ace Animals, Inc., Boyertown, PA on April 1, 2008.

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 and Relative Humidity Ranges: 19-23°C and 42-66%, respectively.

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

4.A.4 Acclimation Period: 8 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 regularly and the records are kept on file at Eurofins | 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 24400, 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 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 naive rats (five males and five females; not previously tested) were selected for test.

B. Dose Calculations

Individual doses were calculated based on the initial body weights, taking into account the specific gravity (as determined by EPSL) of the prepared test substance.

C. Application of Test Substance

Five thousand mg/kg of body weight of the prepared test substance was applied evenly over a dose area of approximately 2 inches x 3 inches (approximately 10% of the body surface) and covered with a 2-inch x 3-inch, 4-ply gauze pad. 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 Eurofins | Product Safety Laboratories, 2394 US Highway 130, Dayton, New Jersey 08810. The primary scientist for this study was Cynthia Bodnar. 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 based on the following testing guideline:

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

7. QUALITY ASSURANCE

The final report was audited for agreement with the raw data records and for compliance with the protocol, Eurofins | 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. AMENDMENTS TO PROTOCOL

1) As per the Sponsor's instructions prior to the start of the study, the sample for application was prepared by Eurofins | Product Safety Laboratories. The sample was a mixture of the penetrator (49%), fortifier (49%) and booster (2%). This mixture was to be applied within 8 hours of preparation.

2) Due to his unavailability from 5/30/08 through 6/22/08 (vacation), George E. Moore will be replaced by Jennifer Durando as the Study Director of this study. This change was required in order to finalize this report in a timely manner.

9. DEVIATIONS FROM FINAL PROTOCOL

None.

10. 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 Eurofins | Product Safety Laboratories, is maintained in the Eurofins | Product Safety Laboratories Archives. EPSL 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 may request continued archiving by EPSL.

11. 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 exposure to the test substance and gained body weight during the study. Other than dermal irritation (erythema, edema and/or eschar), desquamation and/or hyperkeratosis noted for all dose sites throughout the study, there were no other clinical findings recorded for any animal over the course of the study. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

12. CONCLUSION

Under the conditions of this study, the single dose acute dermal LD_{50} of EasyDECON 200-531X (as prepared) is greater than 5,000 mg/kg of body weight in male and female rats.

SIGNATURE

EasyDECON 200-531X

I, 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.

Jennifer Durando — 6/9/15

Jennifer Durando, B.S.
Study Director
Eurofins | Product Safety Laboratories

Date

TABLE 1: INDIVIDUAL BODY WEIGHTS AND DOSES

Animal No.	Sex	Body Weight (g)			Dose[1]
		Initial	Day 7	Day 14	mL
3201	M	231	263	320	1.1
3202	M	216	261	329	1.0
3203	M	222	256	311	1.0
3204	M	242	264	312	1.1
3205	M	242	280	344	1.1
3206	F	160	196	236	0.76
3207	F	170	192	225	0.80
3208	F	177	227	241	0.84
3209	F	189	196	227	0.89
3210	F	158	207	224	0.75

[1] The test substance was applied as prepared by ESPL. Specific gravity: 1.060 g/mL.

TABLE 2: INDIVIDUAL CAGE-SIDE OBSERVATIONS

Animal Number	Findings	Day of Occurrence
MALES		
3201, 3204	Active and healthy	0 (1-4 hrs)
	Erythema present at dose site	1-2
	Edema present at dose site	1-4
	Hyperkeratosis noted at dose site	5-7
	Desquamation noted at dose site	8-11
	Orange/pink staining at dose site	1-14
3202, 3205	Active and healthy	0 (1-4 hrs), 13-14
	Erythema present at dose site	1-2
	Edema present at dose site	1-4
	Desquamation noted at dose site	5-11
	Orange/pink staining at dose site	1-12
3203	Active and healthy	0 (1-4 hrs)
	Erythema present at dose site	1-2
	Edema present at dose site	1-4
	Desquamation noted at dose site	5-8
	Orange/pink staining at dose site	1-14
FEMALES		
3206, 3207	Active and healthy	0 (1-4 hrs)
	Erythema present at dose site	1-3
	Edema present at dose site	1-4
	Hyperkeratosis noted at dose site	5-8
	Desquamation noted at dose site	9-14
	Orange/pink staining at dose site	1-13
3208, 3210	Active and healthy	0 (1-4 hrs)
	Erythema present at dose site	1-3
	Edema present at dose site	1-4
	Hyperkeratosis noted at dose site	5-11
	Desquamation noted at dose site	12-14
	Orange/pink staining at dose site	1-13
3209	Active and healthy	0 (1-4 hrs)
	Erythema present at dose site	1-3
	Edema present at dose site	1-4
	Hyperkeratosis noted at dose site	5-8
	Eschar present at dose site	9-12
	Desquamation noted at dose site	13-14
	Orange/pink staining at dose site	1-13

TABLE 3: INDIVIDUAL NECROPSY OBSERVATIONS

Animal Number	Tissue	Findings
MALES		
3201 – 3205	All tissues and organs	No gross abnormalities
FEMALES		
3206 – 3210	All tissues and organs	No gross abnormalities