

TM STUDY 98-0126-4

CONDUCTED FOR:

AG Environmental Products L.L.C.
9804 Pflumm Road
Lenexa, Kansas 66215

BY:

Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

STUDY PERFORMED:

OECD Guideline 402
Acute Dermal Toxicity Study

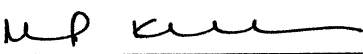
COMPOUND:

SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6

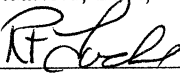
Start of Test: March 30, 1998

Completion of Test: April 14, 1998

Final Report Date: April 15, 1998

Study Director: 
Michael Kukulinski, B.S., L.A.T.G.

4/15/98
Date

Quality Assurance Unit: 
Robert F. Locke, M.S., L.A.T.G.

4/15/98
Date

Sponsor: 
Mr. William A. Ayres

4-28-98
Date

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Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
Oak Park, Illinois 60302

FINAL REPORT - - - QAU STATEMENT

III.

STUDY TITLE: OECD Acute Dermal Toxicity Study of TM 98-0126-4

The Quality Assurance Unit monitored the testing and reporting of this study in accordance with Good Laboratory Practice Regulations 40 CFR 160. The Quality Assurance unit reviewed protocols and inspected the data periodically at the dates listed below, to assure the accuracy and integrity of the study. All reviews of data were reported to the study director and all data from this study will be returned and stored in the testing facility. The results reported herein accurately reflect the raw data.

Inspection Dates:


March 31, 1998
April 14, 1998

Personnel Involved:

Robert F. Locke
Robert F. Locke

I certify that this final report has been conducted in accordance with Good Laboratory Practice Regulations and in accordance with the submitted protocols.


Final Report QAU Audit Completed: April 15, 1998



Robert F. Locke
QAU Monitor

4/15/98

Date



Michael Kukulinski
Study Director

4/15/98

Date



Mr. William A. Ayres

4-28-98

Date

SUMMARY

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6, a clear amber yellow liquid, was tested for acute dermal toxicity in accordance with OECD Guidelines.

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6, a clear amber yellow liquid, was administered by dermal application at a dose of 2.0 g/kg body weight to five male and five female rabbits. There was no mortality during the 14 day observation period.

The gross pharmacotoxic observations following test article administration were limited to the skin at the test article application sites and included; erythema, edema and scaling of the epidermis.

Based upon the results of this study, the acute dermal LD50 of SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6 is greater than 2 g/kg body weight.

I. Method

Test Material

The test material¹, a clear amber yellow liquid, was identified as SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6

Animals and Husbandry

Young, adult male and female New Zealand Albino Rabbits², 8 to 12 weeks old and weighing between 2.08 to 2.39 kilograms were obtained from Kuiper Rabbitry, Gary, Indiana. The females were nulliparous and nonpregnant. Rabbits were housed individually in stainless steel cages in a temperature, humidity, and light controlled room. The rabbits were maintained according to the recommendations contained in the DHEW Publication No. 86-23 (NIH): "Guide for the Care and Use of Laboratory Animals". Purina Rabbit Chow and water were available ad libitum. The rabbits were acclimated at least 4 days prior to treatment. The rabbits were individually identified by an ear tag.

Treatment Levels and Number of Animals

Initial testing with 5 males and 5 females was performed at a dose level of 2 g/kg. If mortality does not exceed 50% at this dose level, no further dose levels will be tested. If mortality is produced, additional dose levels may be performed to obtain data for calculations of the acute dermal lethal dosage (LD50) at the sponsors direction. There was no mortality at 2 g/kg body weight.

Animal Preparation

Twenty-four hours before application of the test material, the dorsal and ventral areas of the trunks of the rabbits were shaved (electric clippers), the areas shaved were approximately 30% of the total body surface area. The 24-hour period between shaving and application of the material allows recovery of the stratum corneum from any disturbance caused by the shaving.

Dosing

The test material (a clear amber yellow liquid) was administered by dermal application at a dose of 2 g/kg body weight to five male and five female rabbits. The test material was dosed neat.

1 Stable under the conditions of the test protocol (private communication sponsor)

2 Albino rabbit and dermal route of administration used in this study in accordance with OECD Guidelines.

All animals were weighed on the day of dosing. Based upon the animal's body weight the test material is applied uniformly over approximately 10 percent of the total body surface area and covered with two layers of porous gauze dressing. A sleeve of plastic sheeting is fitted over the shaven trunk of the animal and secured in place with non-irritating Kendall Curity Standard Porous tape. The test animals are then returned to their cages for the 24 hour contact period. The test material remains in contact with the skin for a 24 hour period after which time the wrap is removed and any remaining test article is wiped off.

Observations and Duration of Testing

All test animals were observed frequently during the day of dosing and once daily for 14 days following dosing for any toxic or deleterious effects. The primary pharmacotoxic observations were limited to the skin at the application sites and included; erythema, edema and scaling of the epidermis. See Table 2 for individual animal observations. The weight of each animal was determined prior to dosing, at 7 days, and at the end of the 14 days.

Sacrifice and Necropsy

All test animals at the end of the test period were sacrificed by an injection with Beuthanasia-D Special solution. A complete gross necropsy was conducted on the animals that died during the course of the study and all survivors. See Table 3 for individual animal data.

Statistical Analysis

At the end of the observation period, if significant mortality occurs, calculations of the LD50 and 95% confidence limits may be performed by the method of moving averages, using the tables constructed by Weil, (Weil C.C.: Table for Convenient Calculations of Median Effective Dose (LD50 and ED50) and Instruction in Their use). Biometrics, 8, 249 (1952).

II. Results & Conclusion³

Dosing and mortality data are presented in Table 1. The administration of test sample by dermal application at a dose of 2 g/kg body weight to male and female rabbits produced no mortality in any of the ten test animals.

Based upon the results of this study, the acute dermal LD50 of SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6 is greater than 2 g/kg body weight.

³ Raw data will be stored in the archives of Tox Monitor Laboratories, Inc.

TABLE 1

ACUTE DERMAL TOXICITY DATA

SAMPLE: SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6

SAMPLE DESCRIPTION: Amber yellow Liquid

SAMPLE PREPARATION: Dosed neat.

DOSE LEVEL: 2.0 g/kg

OBSERVATIONS: All animals healthy prior to testing.

RABBIT NUMBER	SEX	INITIAL BWT (kg)	DOSE GRAM	7 DAY BWT (kg)	14 DAY BWT (kg)	FATE
677	F	2.20	4.40	2.33	2.37	Survived
678	F	2.39	4.78	2.44	2.62	Survived
679	F	2.37	4.74	2.47	2.58	Survived
680	F	2.34	4.68	2.38	2.49	Survived
681	F	2.25	4.50	2.38	2.55	Survived
689	M	2.32	4.64	2.50	2.75	Survived
690	M	2.28	4.56	2.32	2.61	Survived
691	M	2.08	4.16	2.08	2.25	Survived
692	M	2.26	4.52	2.48	2.62	Survived
693	M	2.32	4.64	2.44	2.68	Survived

TABLE 2

GROSS PHARMACOTOXIC OBSERVATIONS

SAMPLE: SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6

TEST PERFORMED: Acute Dermal Toxicity

SPECIES: Rabbit

DOSAGE LEVEL: 2.0 g/kg

OBSERVATION TIME

Sex	Animal No.	HOURS			DAYS														
		1	2.5	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
F	677	√	√	√	LM	LM	LM	LM	L	O	O	O	√	√	√	√	√	Q	√
F	678	√	√	√	LM	LM	L	L	O	O	√	√	√	√	√	√	√	√	√
F	679	√	√	√	LM	LM	LM	L	O	O	√	√	√	√	√	√	√	√	√
F	680	√	√	√	LM	L	L	O	O	√	√	√	√	√	√	√	√	√	√
F	681	√	√	√	LM	LM	L	O	O	√	√	√	√	√	√	√	√	√	√
M	689	√	√	√	L	LM	LM	L	O	O	O	√	√	√	√	√	√	√	√
M	690	√	√	√	L	L	L	L	O	O	√	√	√	√	√	√	√	√	√
M	691	√	√	√	L	L	L	O	O	√	√	√	√	√	√	√	√	√	√
M	692	√	√	√	LM	LM	LM	L	L	O	O	O	√	√	√	√	√	√	√
M	693	√	√	√	L	LM	LM	L	O	O	O	√	√	√	√	√	√	√	√

- X - Dead
- √ - Normal
- A - Uncoordinated Movement
- B - Lacrimation
- C - Salivation
- D - Loose Stool
- E - Retching
- F - Piloerection
- G - Hypothermic to touch

- H - Hypoactive
- I - Prostrate
- J - Tremors
- K - Labored Respiration
- L - Erythema
- M - Edema
- O - Eschar & Coriaceousness
- P - Chemical Burns
- Q - Scar Tissue