

TM STUDY 98-0126-2

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 404
Primary Dermal Irritation/Corrosion Study

COMPOUND:

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

Start of Test: March 18, 1998

Completion of Test: March 21, 1998

Final Report Date: March 25, 1998

Study Director:	<u>Michael Kukulinski</u>	<u>3/25/98</u>
	Michael Kukulinski, B.S., L.A.T.G.	Date
Quality Assurance Unit:	<u>Robert F. Locke</u>	<u>3-25-98</u>
	Robert F. Locke, M.S., L.A.T.G.	Date
Sponsor:	<u>William A. Ayres</u>	<u>4-2-98</u>
	Mr. William A. Ayres	Date

STATEMENT OF DATA CONFIDENTIALITY CLAIM

A. STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS:

No claim of confidentiality is made for any information contained in this study.

Company: AEP

Company Agent: William A. Ayres Date: 4-2-98
Mr. William A. Ayres

B. STATEMENT OF DATA CONFIDENTIALITY CLAIMS:

Information claimed confidential has been removed to a confidential appendix and its cited by cross-referenced number in the body of the study.

Company: AEP

Company Agent: William A. Ayres Date: 4-2-98
Mr. William A. Ayres

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

FINAL REPORT -- QAU STATEMENT

STUDY TITLE: OECD Primary Dermal Irritation Study of TM 98-0126-2

This study was conducted in accordance with EPA Good Laboratory Practice Standards. The Tox Monitor Quality Assurance Unit reviewed the protocol and inspected the study on the dates listed below, to assure the accuracy and integrity on the study. The results have been reviewed by the Study Director, who certifies that the information contained in this report is consistent with the data

Inspection Dates:

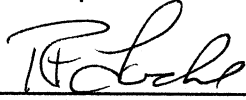
March 18, 1998
March 21, 1998
March 25, 1998

Personnel Involved:

Robert F. Locke
Robert F. Locke
Robert F. Locke

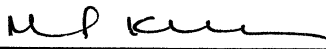
I certify that this study was conducted in compliance with Good Laboratory Practice Standards and that this report accurately reflects the study results.

Final Report QAU Audit Completed: March 25, 1998



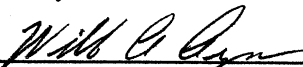
Robert F. Locke
QAU Monitor

3-25-98
Date



Michael Kukulinski
Study Director

3/25/98
Date



Mr. William A. Ayfes

4-2-98
Date

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SUMMARY

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, Lot #97044-6, was tested for primary dermal irritation/corrosion 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 applied by placing 0.5 ml to an unabraded site on a clipped area of each of six albino rabbits.

The application sites were graded for indication of skin reactions at 4-1/2, 24, 48 and 72 hours after sample application. The primary skin irritation index was 0.04.

Based upon the results of this study the test material, SoyGold 1100, CAS No. 67784-80-9, Lot #97044-6, is not a dermal irritant.

I. Method

Test material

The test material,¹ a clear amber yellow liquid, was identified as SoyGold 1100, CAS No. 67784-80-9, Lot #97044-6.

Animals and Husbandry

Male and female New Zealand White Rabbits² approximately eight to ten weeks old were used for this study. The rabbits were obtained from Kuiper Rabbitry, Gary, Indiana.

The rabbits weighed from 2.30 to 2.72 kilograms at the start of the study and were individually housed in stainless steel cages in a temperature, humidity and light controlled room. The rabbits were nulliparous and non-pregnant. Each rabbit was assigned a test animal number which appeared as an ear tag and also appeared on a cage card visible on the front of each cage. The rabbits were maintained according to the recommendations contained in the National Academy Press 1996: "Guide for the Care and Use of Laboratory Animals". They were conditioned for at least five days prior to study initiation. Purina Rabbit Chow and water were available ad libitum. All animals used for this study were considered to be in good health at study initiation.

Compound Administration

The day before study initiation, electric clippers were used to remove the hair from the left side of the trunk, from the midline of the back to the abdomen. A 0.5 ml aliquot of the test article (a clear amber yellow liquid) was then applied the following day to an area approximately 6 square centimeters on the side of the test animal. The application site is located approximately 5-7 centimeters down from the backbone, to assure good skin contact. The test material was then covered with a 2 layer gauze patch held in place with non-irritating Kendall Curity Standard Porous Tape and the patch was then covered with a semi-occlusive plastic overwrap secured in place with Kendall Curity Standard Porous Tape for the duration of the exposure period. At the end of the 4 hour contact period, excess material was removed from the site; the site being observed and scored.

The study was terminated at the end of 72 hours.

Clinical Observations

Dermal irritation readings for erythema and edema were performed approximately 30 minutes after patches were removed, and 24, 48 and 72 hours after treatment. Grading and scoring of irritation are performed in accordance with the Draize scoring system.

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.

Sacrifice

All test animals were sacrificed by injection of Beuthanasia-D Special euthanasia solution and discarded following completion of the study.

II. Results & Conclusion³

Primary dermal irritation score calculations are presented in Table 2.

The primary skin irritation index for the OECD procedure was calculated to be 0.04 .

Based upon the results of this study the test material, SoyGold 1100, CAS No. 67784-80-9, Lot #97044-6, is not a dermal irritant.

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

Primary Dermal Irritation Study in Rabbits
Table 1
Evaluation of Skin Reactions

^a
 REACTION

	Value
Erythema and Eschar Formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness to slight eschar formation injuries in depth)	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raisings)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

^aother adverse changes at the skin sites will be recorded of present

DESCRIPTIVE RATING

INDEX	DESCRIPTIVE RATING
0	Non-irritant
2 or less	Slight Irritant
2 - 5	Moderate Irritant
5 or more	Severe Irritant

REFERENCE

Draize, J.H. "Dermal Toxicity". Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity, Assoc. of Food and Drug Officials of the U.S. Topeka, Kansas, 1975 pp. 46-59.

TABLE 2

PRIMARY DERMAL IRRITATION

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

SAMPLE PREPARATION: Dosed Neat.

SAMPLE DESCRIPTION: A Clear Amber Yellow Liquid

OBSERVATIONS: All animals healthy prior to testing.

INTACT SITES - OBSERVATION TIME (HOURS)

Rabbit #	Initial Bwt (kg)	Final Bwt (kg)	Sex	ER 4-1/2	ED 4-1/2	ER 24	ED 24	ER 48	ED 48	ER 72	ED 72
628	2.36	2.46	F	0	1	0	0	0	0	0	0
629	2.61	2.72	F	0	0	0	0	0	0	0	0
630	2.30	2.39	F	0	0	0	0	0	0	0	0
631	2.41	2.48	F	0	0	0	0	0	0	0	0
632	2.72	2.82	F	0	0	0	0	0	0	0	0
633	2.32	2.44	M	0	0	0	0	0	0	0	0
Ave:				0	0	0	0	0	0	0	0
Total				0.17		0		0		0	

4 1/2 Hours = 0.17
 24 Hours = 0.00
 48 Hours = 0.00
 72 Hours = 0.00

Primary skin irritation index (4.5, 24, 48 & 72 hr score avg)=0.04

ER = Erythema
 ED = Edema

APPENDIX

PROTOCOL FOR:

**PRIMARY DERMAL IRRITATION/CORROSION STUDY IN THE ALBINO RABBIT
OECD 404**

STUDY NO.

TM 98-0126-2

SPONSOR:

A. G. Environmental Products
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TESTING FACILITY:

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TM/2/26/98