

TM STUDY 98-0126-3

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 401  
Acute Oral Toxicity Study


COMPOUND:

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


Start of Test: March 10, 1998

Completion of Test: March 24, 1998

Final Report Date: March 25, 1998

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

3/25/98  
Date

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

3-25-98  
Date

Sponsor:   
Mr. William A. Ayres

4-2-98  
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:

AC ENVIRONMENTAL

Company Agent:

Will B. Ayres  
Mr. William A. Ayres

Date 4-2-98

**B. STATEMENT OF DATA CONFIDENTIALITY CLAIMS:**

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

Company:

\_\_\_\_\_

Company Agent:

Mr. William A. Ayres

Date \_\_\_\_\_

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

FINAL REPORT - - - QAU STATEMENT

STUDY TITLE: OECD Acute Oral Toxicity of TM 98-0126-3

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 10, 1998  
March 24, 1998  
March 25, 1998

Personnel Involved:

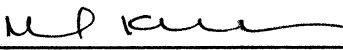
Robert F. Locke  
Robert F. Locke  
Robert F. Locke

I certify that this study was conducted in accordance 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. Ayres

4-2-98  
\_\_\_\_\_  
Date

TABLE OF CONTENTS

	<u>PAGE</u>
CONFIDENTIALITY STATEMENT	2
QAU STATEMENT	3
SUMMARY	5
I. Method	6
II. Results & Conclusion	7
III. Necropsy Report	8
Table 1: Individual Data	9
Table 2: Gross Pharmacotoxic Observations	10
Appendix Protocol	

### SUMMARY

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

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, a clear amber yellow liquid, was administered by gavage at a dose of 5 g/kg body weight to five male and five female rats. No deaths occurred during the 14 day observation period.

The acute oral LD50 was found to be greater than 5 g/kg body weight.

I. Method

Test Material

The test material<sup>1</sup>, 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 Sprague-Dawley derived rats<sup>2</sup> 6 to 10 weeks old and weighing between 212 - 282 grams were obtained from Harlan Sprague Dawley, Indianapolis, Indiana. The females were nulliparous and nonpregnant. The rats were housed individually in stainless steel cages in a temperature, humidity, and light controlled room. Each animal 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 rats were maintained according to the recommendations contained in the National Academy Press 1996: "Guide for the Care and Use of Laboratory Animals". Purina Rat Chow and water were available ad libitum. The rats were acclimated at least five days prior to treatment.

Treatment Levels and Number of Animals

Initial testing with 5 males and 5 females was performed at a dose level of 5 g/kg body weight. 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 oral lethal dosage (LD50) at the sponsors direction. There was no mortality in any of the ten test subjects at a dose level of 5 g/kg body weight.

Fasting

All test animals were fasted overnight prior to dosing.

Dosing

The test material was an amber yellow liquid. The test substance was administered orally to fasted (overnight) animals (five males/five females per dose group) according to individual body weights. A dosage volume of 5 g/kg was administered via a metal dosing cannula. The test material was dosed neat.

---

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

2 Albino rat and oral route of administration used in this study in accordance with OECD Guidelines.

#### Observation 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. See Table 2 for individual observations. Body weights were obtained at study initiation and at 7 & 14 days post-administration. See Table 1 for individual data.

#### Sacrifice and Necropsy

All test animals at the end of the observation period were sacrificed by CO<sub>2</sub> asphyxiation. A complete gross necropsy was conducted on the animals. See the attached necropsy report for any findings.

#### Statistical Analysis

At the end of the observation period, if significant mortality occurs, calculations of the L50 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, (1952).

## II. Results & Conclusion<sup>3</sup>

Dosing and mortality data are presented in Table 1. The administration of the test article by oral gavage at a dose of 5 g/kg body weight to male and female rats produced no mortality in any of the ten test animals, indicating that the LD50 of test article is greater than 5 g/kg body weight.

---

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

**NECROPSY REPORT**

The test group consisted of ten rats (5 males and 5 females) targeted at 5 g/kg body weight. All rats were sacrificed and necropsied as per the schedule.

Listed below are the findings.

<b>RAT #/SEX</b>	<b>TIME</b>	<b>FINDINGS</b>
857/M	Final Sac.	No gross changes observed.
858/M	Final Sac.	No gross changes observed.
859/M	Final Sac.	No gross changes observed.
860/M	Final Sac.	No gross changes observed.
861/M	Final Sac.	No gross changes observed.
862/F	Final Sac.	No gross changes observed.
863/F	Final Sac.	No gross changes observed.
864/F	Final Sac.	No gross changes observed.
865/F	Final Sac.	No gross changes observed.
866/F	Final Sac.	No gross changes observed.

TABLE 1

ACUTE ORAL TOXICITY

**CLIENT:** AG Environmental Products L.L.C.

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

**SAMPLE DESCRIPTION:** Amber Yellow Liquid

**SAMPLE PREPARATION:** Dosed Neat.

**OBSERVATIONS:** All animals healthy prior to testing.

Rat Number	Sex	INITIAL Bwt (gm)	Dose gm/kg	Dose in Grams	7 Day Bwt (gm)	14 Day Bwt (gm)	Fate
857	M	280	5.0	1.40	306	350	Survived
858	M	272	5.0	1.36	338	383	Survived
859	M	268	5.0	1.34	335	370	Survived
860	M	282	5.0	1.41	348	389	Survived
861	M	273	5.0	1.37	349	396	Survived
862	F	212	5.0	1.06	244	263	Survived
863	F	248	5.0	1.24	283	295	Survived
864	F	240	5.0	1.20	278	280	Survived
865	F	238	5.0	1.19	282	293	Survived
866	F	254	5.0	1.27	304	336	Survived

**TABLE 2**

**GROSS PHARMACOTOXIC OBSERVATIONS**

**CLIENT:** AG Environmental Products L.L.C.

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

**TEST PERFORMED:** Acute Oral Toxicity

**SPECIES:** Rat

**DOSAGE LEVEL:** 5.0 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		
M	857	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
M	858	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
M	859	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
M	860	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
M	861	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
F	862	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
F	863	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
F	864	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
F	865	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
F	866	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	

- 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** - Hunched Posture
- M** -
- O** -
- P** -
- Q** -

**APPENDIX**

**PROTOCOL FOR:**

**ACUTE ORAL TOXICITY STUDY IN THE SPRAGUE DAWLEY RAT  
OECD 401**

**STUDY NO.**

TM 98-0126-3

**SPONSOR:**

A.G. Environmental Products  
9804 Pflumm Road  
Lenexa, Kansas 66215

**TESTING FACILITY:**

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

TM/2/26/98