

TM STUDY 98-0126-5

CONDUCTED FOR:

A. G. 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 Inhalation Toxicity Study


COMPOUND:


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

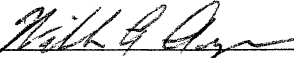
Start of Test: March 17, 1998

Completion of Test: March 31, 1998

Final Report Date: April 6, 1998

Study Director:  4/6/98  
Michael Kukulinski, B.S., L.A.T.G. Date

Quality Assurance Unit:  4/6/98  
Robert F. Locke, M.S., L.A.T.G. Date

Sponsor:  4-28-98  
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: AG ENVIRONMENTAL

Company Agent: William A. Ayres Date: 4-28-98  
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: \_\_\_\_\_

Company Agent: \_\_\_\_\_ Date: \_\_\_\_\_  
Mr. William A. Ayres

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

FINAL REPORT - - - QAU STATEMENT

STUDY TITLE: EPA/FIFRA Acute Inhalation Toxicity of TM 98-0126-5

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 of 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 17, 1998  
March 31, 1998  
April 6, 1998


Personnel Involved:

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

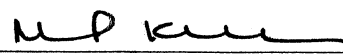
I certify that this study was conducted in accordance with Good Laboratory Practice Standards and that this report accurately reflects the study results.

Final Report QAU Audit Completed:

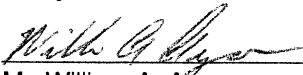
April 6, 1998

  
\_\_\_\_\_  
Robert F. Locke  
QAU Monitor

4/6/98  
Date

  
\_\_\_\_\_  
Michael Kukulinski  
Study Director

4/6/98  
Date

  
\_\_\_\_\_  
Mr. William A. Ayres

4-28-98  
Date

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## SUMMARY

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

A. G. 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 inhalation toxicity at a targeted level of 2.0 mg/L of air by exposing five male and five female rats for a four hour period. The actual gravimetric concentration of the study was 2.04 mg/L of air.

The acute inhalation LC50 was found to be greater than an actual gravimetric concentration of 2.04 mg/L of air for a four hour period. All test animals were alive when removed from the chamber at the end of the four hour exposure. All test animals survived the 14 day observation period.

The inhalation LC-50 of A. G. Environmental Products, L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, Lot #97044-6, was found to be greater than 2.04 mg/l of air for a 4 hour period.

I.

**Method**

**Test Material**

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

**Animals and Husbandry**

Young, adult male and female Sprague-Dawley<sup>2</sup> derived rats 6 to 10 weeks old and weighing between 224-277 grams were obtained from Harlan Sprague Dawley, Indianapolis Indiana. The rats were housed individually in stainless steel wire-bottom cages in a temperature, humidity, and light controlled room. The females were nulliparous and non-pregnant. Each rat 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". Except for described periods associated with exposure, Purina Laboratory Rat Chow and water were available ad libitum. They were conditioned for at least five days prior to study initiation. All animals used for this study were considered to be in good health at the study initiation.

**Compound Administration**

Male and female albino rats were divided into equal numbers (5 males/5 females) for the test group. All animals were assigned an identifying number and individually housed prior to exposure and during the 14 day observation period. Food and water were withheld during the exposure. The initial test material exposure concentration was targeted at a concentration level of 2.0 mg/L of air for a four hour period, or the maximum attainable atmosphere. The gravimetric concentration of the study was 2.04 mg/L of air. The actual total exposure time was 4 hours & 22 minutes to allow for chamber equilibration.

**Sample Preparation and Generation**

The test material (a clear amber yellow liquid) was administered neat and was generated as an aerosol by using a Spraying System Co. (Wheaton, IL) Model 1/4JSS atomizing nozzle assembly equipped with a fluid cap No. 1250. The nozzle siphoned the test article from a reservoir and operated at 16-17 psi of air during the 4-hour exposure period. The exposure was conducted in a stainless steel chamber measuring 68.2 x 68.2 x 68.2 cm. Room air entered the top of the chamber and exited through the bottom. The aerosol entered the chamber through a hole in the rear of the chamber and passed immediately through an atomization plenum. The plenum was used to improve the distribution of the aerosol within the chamber and to reduce the size dispersity of the aerosol.

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<sup>1</sup> Stable under the conditions of the test protocol, (private communication sponsor)

<sup>2</sup> Albino rat and inhalation route of administration used in this study in accordance with federal standards.

### **Observations**

The rats were observed for mortality and pharmacotoxic signs frequently during the day of exposure and daily thereafter for 14 days. See Table 6 for individual test animal data. Body weights were obtained at study initiation and at 7 & 14 days post-administration. See Table 5. Gross necropsy examination was performed on all test subjects at the end of the 14 day observation period.

### **Pathology**

All animals were sacrificed by carbon dioxide asphyxiation at 14 days and subjected to a gross necropsy. See Necropsy Report for individual data.

### **Concentration Measurements**

Nominal concentration was calculated by dividing the total amount of test material used during the test period by the total air volume. Actual concentration determinations were taken every 30 minutes during the four hour period.

The "actual" concentration of this study was determined by gravimetric analysis based on samples taken at 30 minute intervals from the breathing zone of the test animals. The analytical concentration was determined by using a pre-weighed 25 mm Gelman glass fiber filter #66075 which was placed into a filter holder manufactured by Gelman Instrument Co. The filter holder was fitted with a stainless steel tube which was designed to be placed through a port in the chamber, which positioned the filter into the breathing zone of the test animals. The filter assembly was then attached via rubber tubing to an Anderson Sampler Pump, Model #10-709 and a measured volume of chamber atmosphere was withdrawn and the particles being collected on the 25 mm glass fiber filter. The filter holder was then immediately withdrawn from the chamber and the filter was removed and weighed. The increase in the filter weight when divided by the volume of air sampled yields the actual gravimetric concentration for the sample. This procedure was repeated at 30 minute intervals for the duration of the exposure.

### **Chamber Parameter Measurements**

**Airflow:** Airflow was monitored continuously during the exposure period. The chamber was operated at a flow of at least 10 air changes per hour. Airflow was determined by the reading taken from a calibrated Dwyer Magnehelic pressure gauge.

**Chamber Temperature:** The inside chamber temperature was monitored and recorded regularly during the exposure period.

**Chamber Humidity:** Humidity inside the chamber was monitored and recorded regularly during the exposure period.

The temperature and humidity measurements were performed using a calibrated Abbeon Relative Humidity and Temperature Indicator, Model #HTAB-176, Abbeon Cal Inc., 123 Gray Avenue, Santa Barbara, Ca, and a Taylor Instruments Wet Bulb/Dry Bulb Hygrometer, Mason Type Tool No. T66978. CAV. No. 1.