

TM STUDY # 98-0126-6

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:

DERMAL SENSITIZATION STUDY IN ALBINO GUINEA PIGS

COMPOUND:

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

Start of Test: March 16, 1998

Completion of Test: April 17, 1998

Final Report Date: April 21, 1998

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

4/21/98
Date

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

4/21/98
Date

Sponsor: Mr. William A. Ayres
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: _____

Company Agent: _____ Date _____
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.
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FINAL REPORT - - QAU STATEMENT

STUDY TITLE: OECD Dermal Sensitization Study of TM 98-0126-6

The Quality Assurance Unit monitored the testing and reporting of this study in accordance with EPA Good Laboratory Practice Standards as set forth in 40 CFR Part 160. 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 18, 1998
March 25, 1998
April 16, 1998
April 21, 1998

Personnel Involved:


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

I certify that this study was conducted in compliance with Good Laboratory Practice Standards (40 CFR 160) and that this report accurately reflects the study results.



Robert F. Locke
QAU Monitor

3/21/98
Date



Michael Kukulinski
Study Director

4/21/98
Date

Mr. William A. Ayres
Sponsor Representative

Date

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ABSTRACT

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6, was tested for dermal sensitization potential utilizing a Buehler Design Guinea Pig Sensitization Protocol. The test article, SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6, was a clear amber yellow liquid. The test material was tested for sensitization potential by placing the test article (0.4 ml) directly into Hilltop Chambers and applying them to the shaved left trunk of ten albino guinea pigs. The chamber was then overwrapped (around the entire trunk) with Micropore and surgical tape. The animals were unwrapped after a 6-hour exposure period (initial dose). Two additional induction doses were conducted following the same procedure, at weekly intervals.

Two weeks after the final application the animals received a topical challenge dose (6 hour contact) at a naive site located on the right trunk. Animals were scored for irritation at 24 and 48 hours after initiation of the challenge application.

Using a similar regimen, ten guinea pigs received 0.4 ml of an appropriate concentration of 1-Chloro-2,4-dinitrobenzene to serve as a positive control.

Average scores for the three induction doses were 0.14 for SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6 and 0.46 for 1-chloro-2,4-dinitrobenzene.

Ten guinea pigs served as a negative control group, and remained untreated through the induction phase. Six negative control animals received only the challenge dose (exposure period same as test group) of the test material.

Average scores for the challenge dose were 0.05 for SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6, and 0.08 for the challenged negative control. The average score for the challenge dose of 1-chloro-2,4-dinitrobenzene was 1.85.

The challenge dose of SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6 elicited very faint erythema in two of the ten guinea pigs. Six negative control animals were also challenged with SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6 which elicited a very faint erythema in two of the six guinea pigs. The challenge dose of 1-chloro-2,4-dinitrobenzene resulted in a positive reaction in 10/10 guinea pigs characterized by a grade 1 - 3 erythema.

Based on comparisons of the reactions exhibited by the test group, negative control group, and the positive control group to challenge doses, SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6 would not be considered a dermal sensitizing agent.

I. INTRODUCTION

The purpose of this study was to assess the dermal sensitization potential of SoyGold 1100, CAS No. 67784- 0-9, Lot # 97044-6, administered by dermal application.

Justification for Selection of Test System: The albino guinea pig has been used extensively as an animal model for dermal sensitization studies.

II. MATERIAL AND METHODS

Test Material

The test material was a clear amber yellow liquid identified as SoyGold 1100, CAS No. 67784-0-9, Lot # 97044-6.

Records of the test article stability, purity, source, and other data required by Federal Regulations are maintained by the Sponsor.

Animals and Animal Husbandry

Young adult male Hartley albino guinea pigs were used for this study and weighed between 242 and 331 grams at study initiation. The guinea pigs were obtained from Kuiper Rabbitry, Gary, Indiana.

The guinea pigs used for this study were identified by cage cards and were individually housed in stainless steel cages in a temperature, humidity, and light controlled room. The animals were maintained according to the recommendations contained in DHHS Publications No. 86-23 (NIH): Revised 1985, "Guide for the Care and Use of Laboratory Animals." They were conditioned for at least 5 days prior to initiation of the study. Purina Guinea Pig Chow and water were available ad libitum. All animals used for this study appeared to be in good health at study initiation.

Pilot Study

Prior to the start of the study, a pilot study using three guinea pigs from the same allotment as those to be used for the study and weighing 275, 310 & 266 grams respectively, was initiated to determine the proper concentration of the test material for the induction & challenge phases of the study. Applications of test material concentrations at 100%, 75%, 50%, & 25% for a six hour contact period elicited erythema of grades 0 -1 at the 100% concentration sites. No irritation was present at the 75%, 50% & 25% concentration sites. Therefore, the test article was dosed "neat" for the induction phase of the study and as a 75% concentration in mineral oil, the lowest non-irritating dose for the challenge phase of the study. See Table for Guinea Pig Pilot Study results.

Listed below are the results of the pilot study listing the tabulated 24 hour erythema scores for the three test subjects at the various concentrations tested:

Test Article Concentrations (%)(dilutions prepared with mineral oil)

Response Grade	100%	75%	50%	25%
0	1	3	3	3
0.5	1	0	0	0
1	1	0	0	0
2	0	0	0	0
3	0	0	0	0

Concentrations for the positive control animals were 0.1% w/w in 80% aqueous ethanol for induction phase, and 0.05% w/w in acetone for the challenge phase as determined to be appropriate from previous dermal sensitization studies.

Dose Administration

The test material was administered topically to ten guinea pigs according to the method of Buehler (Buehler, E.V., Delayed contact hypersensitivity in the guinea pig. Arch. Dermatol. 91:171-175, 1965), and Ritz and Buehler, in Current Concepts in Cutaneous Toxicity. Edited by V.A. Dril & P. Lazar. p.25 Academic Press, New York, 1980.

Induction:

An area of approximately 5 x 5 cm was shaved using electric clippers on the left trunk of each animal the day prior to dosing. The test article, a clear amber yellow liquid, was dosed "neat" for the induction phase of the study. 0.4 ml of the test material was placed directly into a Hilltop Chamber, the chamber overwrapped (around the entire trunk) with Micropore, and further secured with an overwrap of surgical tape. Each animal was unwrapped after a 6 hour exposure period. The test site was then wiped with a moistened paper towel to remove any remaining test material. Animals were treated once weekly for a total of three treatments. Using the same regimen, ten guinea pigs received 0.4 ml of a 0.1% w/w solution of 1-chloro-2,4-dinitrobenzene in 80% aqueous ethanol, to serve as a positive control. Animals were clipped one day prior to each test article application.

Challenge:

Two weeks after the final induction dose, each animal received a challenge dose (6 hour contact period) on a 5 x 5 cm shaved site (naive) located on the right trunk. For the challenge dose, the test article was dosed as a 75% solution in mineral oil, the highest non-irritating concentration as determined by the pilot study. Animals were scored for irritation at 24 and 48 hours following completion of the challenge application.