

TM STUDY 98-0126-1

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 60303

STUDY PERFORMED:

OECD Guideline 405
Acute Eye Irritation/Corrosion Study

COMPOUND:

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

Start of Test: April 5, 1998

Completion of Test: April 9, 1998

Final Report Date: April 10, 1998

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

4/10/98
Date

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

4/10/98
Date

Sponsor: William A. Ayres
Mr. William A. Ayres

4-12-98
Date

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Tox Monitor Laboratories, Inc.
33 West Chicago Avenue
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FINAL REPORT - - QAU STATEMENT

STUDY TITLE: OECD Acute Eye Irritation/Corrosion Study

The Quality Assurance Unit monitored the testing and reporting of this study in accordance with Good Laboratory Practice Regulations (40 CFR Part 160). The Quality Assurance Unit reviewed the protocol and inspected the data periodically on 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 at the testing facility. The results reported herein accurately reflect the raw data.

Inspection Dates:


April 8, 1998
April 9, 1998

Personnel Involved:

Robert F. Locke
Robert F. Locke

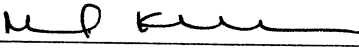
I certify that this final report has been conducted in accordance with Good Laboratory Practice Regulations and in accordance with the submitted protocols.

Final Report QAU Audit Completed: April 10, 1998



Robert F. Locke
QAU Monitor

4-10-98
Date



Michael Kukulinski
Study Director

4/10/98
Date



Mr. William Ayres

4-12-98
Date

SUMMARY

AG Environmental Products L.L.C., sample identified as SoyGold 1100, CAS No. 67784-80-9, Lot # 97044-6, was tested for eye irritation 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 instilled into one eye of each of six albino rabbits. The eyes were observed and scored at 1, 24, 48, and 72 hours.

There was no positive eye irritation reactions in any of the test animals and the maximum mean irritation score was 4.0/110.0 at the one hour observation, classifying the test article as being mildly irritating to the eyes.

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

The rabbits weighed from 2010-2125 grams 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. 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". They were conditioned for at least four 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 the study initiation.

Treatment Levels and Number of Animals

Six rabbits were selected and individually identified with ear tags. 24 hours before the start of the study both eyes of the experimental animals selected for testing were examined for preexisting ocular lesions. Animals were then dosed by instilling 0.1 ml of test material into the conjunctival sac of one eye and then holding the eye lids together for one second to prevent loss of the material. The contralateral eye served as the untreated control for each rabbit.

Observation and Grading

The eyes were examined at 1, 24, 48 and 72 hours after treatment. If there is no evidence of irritation at 72 hours the study will be ended. Additional examinations will be performed up to a maximum of 21 days, if persistent corneal involvement or other ocular irritation is present. 2% sodium fluorescein and ultraviolet light provided via a Spectroline, Model Q-12, Long Wave UV-365nm, 10X Magnifier, were employed to reveal possible corneal injury commencing with the 24 hour observation. There was no irritation present at the 72 hour observation, therefore the study was ended.

Sacrifice

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

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

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

II. Results & Conclusion³

Individual eye irritation scores, body weights, and other findings are presented in Table 2. Group mean eye irritation scores are presented in Table 3.

There was no positive eye irritation reactions in any of the six test subjects and the maximum group mean score was 4.0/110.0 at the 1 hour observation, classifying the test article as being mildly irritating to the eyes.

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

TABLE 1

SCALE FOR SCORING ON OCULAR LESIONS

	Values
I. CORNEA:	
(A)	
Opacity-degree of density (area most dense taken for readings)	
No opacity	0
Scattered or diffuse area, details of iris clearly visible	1*
Easily discernible translucent area, details of iris slightly obscured	2*
Opalescent areas, no details of iris visible, size of pupil barely discernible	3*
Opaque, iris invisible	4*
(B)	
Area or cornea involved	
One-quarter (or less) not zero	1
Greater than one-quarter, but less than half	2
Greater than half, but less than three quarters	3
Greater than three-quarters, up to whole area	4
Score= A x B x 5	Total Maximum = 80
II. IRIS:	
(A)	
Normal	
Markedly deepened rugae, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive)	0
	1*
No reaction to light, hemorrhage, gross destruction (any or all of these)	2*
Score= A x 5	Total Maximum = 10

SCALE FOR SCORING ON OCULAR LESIONS CON'T.

III. CONJUNCTIVA:	
(A)	
Redness (refers to palpebral and bulbar conjunctiva excluding cornea and iris)	
Vessels normal	0
Vessels definitely injected above normal	1
More diffuse, deeper crimson red, individual vessels not easily discernible	2*
Diffuse beefy red	3*
(B)	
Chemosis	
No swelling	0
Any swelling above normal (includes nictitating membrane)	1
Obvious swelling with partial eversion of lids	2*
Swelling with lids about half closed	3*
Swelling with lids about half closed to completely closed	4*
(C)	
Discharge	
No discharge	0
Any amount different from normal (does not include small amount observed on the inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to the lids	2
Discharge with moistening of the lids and hairs and considerable area around the eye	3
Score = (A+B+C)x2	Total Maximum = 20

The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctiva
 Total maximum score possible = 110

*starred figures indicate positive effect.

Scale according to: Draize, J.H. (1965). Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics.

TABLE 2

INDIVIDUAL EYE IRRITATION SCORES

Rabbit # 740
 Initial Body Weight (grams) 2070
 Terminal Body Weight (grams) 2165

Treatment: No wash
 Dose: 0.1 ml

OBSERVATIONS - HOURS

	1	24	48	72
I. Grade for Ocular Lesions				
Cornea:				
Opacity	-	0	0	0
Area	-	0	0	0
Subtotal (Ax5)	-	0	0	0
Iris:	0	0	0	0
Subtotal (Ax5)	0	0	0	0
Conjunctiva:				
Redness	1	1	0	0
Chemosis	0	0	0	0
Discharge	1	0	0	0
Subtotal (A+B+C)x2	4	2	0	0
Total Scores:	4	2	0	0
II. Sodium Fluorescein Exam				
% of corneal surface positive	-	0	0	0