TM STUDY No. 09-030-1

CONDUCTED FOR:

The Magic Touch
Benzstrasse 17
64807 Dieburg
Germany

BY:

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

STUDY PERFORMED:

FHSA/CPSC Design, 16 CFR 1500
Primary Eye Irritation Study

COMPOUND:
Tattoo 2.1 Decals

Final Report Date: April 20, 2009

Study Director: _____ 4/20/09
Michael Kukulinski, B.S., L.A.T.G. Date

Quality Assurance Unit: _____ 4/20/09
Robert F. Locke, M.S., L.A.T.G. Date

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

FINAL REPORT -- QAU STATEMENT

STUDY TITLE: FHSA/CPSC Primary Eye Irritation Study

The Quality Assurance Unit monitored the testing and reporting of this study. The Quality Assurance Unit reviewed protocols and inspected the data 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.

Final Report QAU Audit Completed: April 20, 2009

Robert F. Locke, M.S., L.A.T.G.
QAU Monitor

4/20/09
Date

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

4/20/09
Date

SUMMARY

The Magic Touch sample identified as Tattoo 2.1 Decals was tested for eye irritation in accordance with FHSA/CPSC Guidelines. The test material was cut into 1" squares. 10 grams of test article and 10 grams of distilled water were placed into an extraction flask and heated for 24 hours @ 100°F in a constant temperature oven. The liquid was cooled and used for dosing.

The Magic Touch sample extract was administered into one eye of each of six albino rabbits. The eyes were observed and scored at 24, 48, and 72 hours.

Instillation of sample extract into the eyes of rabbits produced minimal eye irritation reactions in three of the test animals. In accordance with FHSA/CPSC Guidelines, The Magic Touch test material identified as Tattoo 2.1 Decals would not be considered an eye irritant.

I. **Method**

Test Material

The test material was identified as Tattoo 2.1 Decals.

Animals and Husbandry

New Zealand White Rabbits[1] ten to twelve weeks old were used for this study. The rabbits were obtained from Kuiper Rabbitry, Gary, Indiana.

The rabbits were individually housed in stainless steel cages in a temperature, humidity, and light controlled room. 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 acclimated for at least 4 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. Animals were dosed by instilling 0.1 ml of test material extract into the eye. The contralateral eye served as the untreated control for each rabbit.

Observation and Grading

The eyes are examined at 24, 48, and 72 hours after treatment. At these intervals the extent and degree of irritation were scored.

Data Reporting and Evaluation

The general technique of evaluation and scoring follows recommendations of J.H. Draize, G. Woodard, and H.O. Calvery, Journal of Pharmacology and Experimental Therapeutics, vol. 82, pg. 377 (1944) and Sec. 191, 12 of the Federal Hazardous Substances Labeling Act Regulations Guide for Grading Eye Irritation.

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[1] Albino rabbit and ocular route of administration used in this study in accordance with federal standards.

II. Results and Conclusion[2]

Individual eye irritation scores and other findings are presented in Table 2.

Instillation of the sample extract into the eyes of rabbits produced minimal irritation in two of the six test animals. In accordance with FHSA/CPSC Guidelines, The Magic Touch test material identified as Tattoo 2.1 Decals would not be considered an eye irritant.

[2] Raw data will be stored in the archives of Tox Monitor Laboratories, Inc.

TABLE 1

SCALE FOR SCORING ON OCULAR LESIONS

CORNEA	
No ulceration or opacity	0
Scattered or diffused areas of opacity (other than slight dulling or normal luster, details of iris clearly visible)	1
Easily discernible translucent area, details of iris slightly obscured	2*
Nacreous area, no details of iris visible, size of pupil barely discernible	3*

IRIS	
Normal	0
Markedly deepened folds, congestion, swelling, moderate circumcorneal injection (any of these or a combination thereof), iris still reacting to light (sluggish reaction is positive)	1*
No reaction to light, hemorrhage, gross destruction (any or all of these)	2*

CONJUNCTIVA	
Redness (refers to the palpebral and bulbar conjunctivae excluding the cornea and iris)	
Vessels normal	0
Some vessels definitely injected	1
Diffuse, crimson red, individual vessels not easily discernible	2*
Diffuse, beefy red	3*

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 more than half closed	4*

* Starred figure denotes positive irritation in accordance with FHSA/CPSC Regulations.

TABLE 2

CLIENT: The Magic Touch

SAMPLE: Tattoo 2.1 Decals

SAMPLE PREPARATION: The test material was cut into 1" squares. 10 grams of test article and 10 grams of distilled water were placed into an extraction flask and heated for 24 hours @ 100°F in a constant temperature oven. The liquid was cooled and used for dosing.

RABBIT NUMBER 693

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	1	0	0
CHEMOSIS	0	0	0

RABBIT NUMBER 694

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	1	0	0
CHEMOSIS	0	0	0

RABBIT NUMBER 695

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	0	0	0
CHEMOSIS	0	0	0

RABBIT NUMBER 696

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	0	0	0
CHEMOSIS	0	0	0

RABBIT NUMBER 697

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	1	0	0
CHEMOSIS	0	0	0

RABBIT NUMBER 698

HOURS AFTER TREATMENT	24	48	72
CORNEA	0	0	0
IRIS	0	0	0
ERYTHEMA	0	0	0
CHEMOSIS	0	0	0

TM STUDY No. 09-030-2

CONDUCTED FOR:

The Magic Touch
Benzstrasse 17
64807 Dieburg Germany

BY:

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

STUDY PERFORMED:

FHSA/CPSC Design, 16 CFR 1500
Primary Dermal Irritation

COMPOUND:

Tattoo 2.1 Decals

Final Report Date: April 20, 2009

Study Director: _____ 4/20/09
Michael Kukulinski, B.S., L.A.T.G. Date

Quality Assurance Unit: _____ 4/20/09
Robert F. Locke, M.S., L.A.T.G. Date

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

FINAL REPORT - QAU STATEMENT

STUDY TITLE: FHSA/CPSC PRIMARY DERMAL IRRITATION STUDY

The Quality Assurance Unit monitored the testing and reporting of this study. The Quality Assurance Unit reviewed protocols and inspected the data 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.

FINAL REPORT QAU AUDIT COMPLETED: April 20, 2009

RF Locke 4/20/09

Robert F. Locke, M.S., L.A.T.G. — Date
QAU Monitor

MP Kuk 4/20/09

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

SUMMARY

The Magic Touch sample identified as Tattoo 2.1 Decals was tested for primary dermal irritation in accordance with FHSA/CPSC Guidelines.

The Magic Touch sample was moistened and applied directly to unabraded and abraded skin sites on a clipped area of each of six albino rabbits. The test sites were occluded and the test material remained on the skin for a 24 hour contact period.

The application sites were graded for indications of skin reactions at 24 and 72 hours after sample application.

The primary dermal irritation score was 0.08, indicating that The Magic Touch sample identified as Tattoo 2.1 Decals is not a primary dermal irritant in accordance with FHSA/CPSC Guidelines.

I. Method

Test Material

The test material was identified as Tattoo 2.1 Decals.

Animals and Husbandry

New Zealand White Rabbits[1] approximately ten to twelve weeks old were used for this study. The rabbits were obtained from Kuiper Rabbitry, Gary, Indiana. The rabbits were individually identified by ear tags. The rabbits were individually housed in stainless steel cages in a temperature, humidity, and light controlled room. 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 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 study initiation.

Compound Administration

The day before study initiation electric clippers were used to remove the hair from the abdomen and the sides of six rabbits. Two sites, one unabraded skin and one abraded skin, approximately 1" square each were designated for application of test material. Two temporary tattoo decals were applied to the skin, adhesive side down, and moistened with water to remove the paper backing. The entire site was covered with a 4 mil plastic wrap and secured with adhesive tape. At the end of the 24 hour contact period, excess material was removed from the sites.

Clinical Observations

Dermal irritation observations were performed at 24 and 72 hours after the test material was applied to the sites. Grading and scoring of irritation were performed in accordance with the Draize Scoring System.

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[1] Albino rabbit and dermal route of administration used in this study in accordance with Federal Standards.

II. Results and Conclusion[2]

Primary dermal irritation score calculations are presented in Table 2.

The primary dermal irritation score was calculated to be 0.08 indicating that The Magic Touch sample identified as Tattoo 2.1 Decals is not a primary dermal irritant in accordance with FHSA/CPSC Guidelines.

[2] Raw data will be stored in the archives of Tox Monitor Laboratories, Inc.

TABLE 1

CLIENT: The Magic Touch

SAMPLE: Tattoo 2.1 Decals

SAMPLE PREPARATION: Tattoo decal was applied directly to the skin, adhesive side down, and the paper backing was moistened with water and removed.

PRIMARY DERMAL IRRITATION

	24 HOURS				72 HOURS			
	UNABRADED		ABRADED		UNABRADED		ABRADED	
RABBIT NUMBER	ER	ED	ER	ED	ER	ED	ER	ED
693	0	0	0	0	0	0	0	0
694	0	0	0	0	0	0	0	0
695	0	0	1	0	0	0	0	0
696	0	0	0	0	0	0	0	0
697	0	0	1	0	0	0	0	0
698	0	0	0	0	0	0	0	0
AVERAGE	0	0	0.33	0	0	0	0	0

PRIMARY DERMAL IRRITATION SCORE: 0.08

ER = Erythema
ED = Edema

TABLE 2

EVALUATION OF DERMAL REACTIONS

A. ERYTHEMA AND EDEMA FORMATION:	
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

B. EDEMA FORMATION:	
Very slight edema (barely perceptible)	1
Slight edema (edges of area will be defined by definite raising)	2
Moderate edema (area raised appox 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond are of exposure)	4

* The value recorded for each reading is the average value of the animals subject to the test.

FHSA/CPSC Regulations: A primary skin irritant is a substance which results in an empirical primary irritation score of 5 or more.

PRIMARY DERMAL IRRITATION DESCRIPTIVE RATING

Mean Primary Irritation Score (values)	Descriptive Rating
0	Non-Irritating
0.1 - 0.5	Minimally Irritating
0.6 - 1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 - 5.0	Moderately Irritating
5.1 - 6.5	Severely Irritating
6.6 - 8.0	Extremely Irritating

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.