CONDUCTED FOR:

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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:
Hashmi Kohl Aswad

Final Report Date: May 4, 2009

Study Director: _____ 5/4/09
Michael Kukulinski, B.S., L.A.T.G. Date

Quality Assurance Unit: _____ 5/4/09
Robert F. Locke, M.S., L.A.T.G. Date

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

FINAL REPORT - QAU STATEMENT

STUDY TITLE: FHSA/CPSC ACUTE DERMAL TOXICITY

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 with be returned and stored at the testing facility.

FINAL REPORT QAU AUDIT COMPLETED: May 14, 2009

RF Locke

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

5/14/09
Date

M P Kuk

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

5/14/09
Date

All animals were weighed on the day of dosing. Based upon the animals' body weight the test material was applied uniformly over approximately 10 percent of the total body surface area, covered with two layers of porous gauze dressing and a sleeve of plastic sheeting was fitted over the shaved trunk of the animal and secured in place with non-irritating surgical tape. The test animals were then returned to their cages for the 24 hour contact period. The test material remained in contact with the skin for a 24 hour period after which time the wrap was removed and any remaining test article wiped off.

Observations 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. The time at which any pharmocotoxic signs appear, disappear and their duration were recorded. No mortality occurred during the 14 day observation period. See Table 2 for individual animal observations. The weight of each animal was determined prior to dosing, at 7 days, and at the end of the 14 days.

Sacrifice and Necropsy

All test animals at the end of the test period were sacrificed by an injection with Beuthanasia-D Special solution. A complete gross necropsy was conducted on the animals. Necrosis and edema was observed at the application site in all of the test animals at necropsy. See the attached necropsy report for individual animal data.

Statistical Analysis

At the end of the observation period, calculations of the LD50 and 95% confidence limits are performed, if necessary, 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, 249 (1952).

II. Results & Conclusion[3]

Dosing and mortality data are presented in Table 1. The administration of test sample by dermal application at a dose of 2.0 g/kg body weight to male and female rabbits produced no mortality, indicating that the dermal LD50 of the sample is greater than 2.0 g/kg body weight. The product is not toxic by dermal application.

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