549C
CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 2 1992

009730

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: **Iprodione- Primary skin irritation in rabbits**

TO: Kathryn Davis/Barbara Briscoe PM 72
Special Review and Reregistration Division (H7508W)

FROM: K. Clark Swentzel K. Clark Swentzel 9/14/92
Toxicology Branch II
HED (H7509C)

THROUGH: Marcia van Gemert, Ph.D. Marcia van Gemert 9/15/92
Branch Chief
Toxicology Branch II
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ID NO. 109801-000264
CASE: 816345
BARCODE: D179396
MRID NO. 418673-02
SUBMISSION: S419591
PC No. 109801
CASWELL NO. ~~549C~~ 470A
REGISTRANT: Rhone-Poulenc

Requested action

Review subject study

Conclusions

The administration of 0.5 g iprodione to the skin of rabbits did not induce irritation in any of the 6 animals tested.

Toxicity category: IV

Core classification: minimum. This study satisfies the minimum requirements set forth under the Subdivision F Guidelines for a primary dermal irritation study in rabbits (81-5).

Reviewed by: K. Clark Swentzel K. Clark Swentzel 9/14/92
Tox. Branch II, Section II (H7509C)
Secondary Reviewer: Marcia van Gemert, Ph.D. Marcia van Gemert 9/15/92
Tox. Branch II (H7509C)

DATA EVALUATION REPORT 009730

STUDY TYPE: Primary skin irritation in rabbit Tox. Chem. No. 470A

MRID NO. 418673-02

TEST MATERIAL: 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide

SYNONYMS: Iprodione, Iprodine, Glycophene, Chipco 26019, Anfor, RP-26019, Rovral

STUDY NO. 3147.108

SPONSOR: Rhone-Poulenc

TESTING FACILITY: Springborn Laboratories, Inc.

TITLE OF REPORT: Primary Skin Irritation Study in Rabbits with Iprodione

AUTHOR: K. Bonnette

REPORT ISSUED: April 10, 1991

COMPLIANCE STATEMENTS: Signed and dated Quality Assurance and GLP Compliance Statements were included on pages 4 and 3 of the report, respectively.

CONCLUSION

The administration of 0.5 g iprodione to the skin of rabbits did not induce irritation in any of the 6 animals tested.

MATERIALS AND METHODS

Animals and Animal husbandry

Young adult New Zealand white rabbits (sex not indicated; 2.0 - 2.6 kg at the initiation of the study) were purchased from Mohican Valley Rabbitry (Loudonville, Ohio) for this study. The rabbits were individually housed in suspended stainless steel cages in an environment-controlled room. The test protocol indicated that the environmental parameters were: a 12-hour light cycle, a relative humidity of 40 - 60% and a room temperature of 61 - 70°F. Agway Prolab Rabbit Ration and water were provided to each animal ad libitum. The rabbits were individually identified using plastic ear tags and cage cards. All animals were acclimated to the laboratory environment for a period of five days prior to initiation of the study.

Test Material

The test material was described as a white granular solid (I.D.# S91.001.3147). The Certificate of Analysis indicated a purity of 96.2%.

Protocol

The fur was clipped from the dorsal test site of each rabbit on the day prior to dosing. The animals were weighed on the day of dosing and a test site (approximately 1 in^2) was selected. A dose of 0.5 g of the test material was applied to each selected site. Immediately after the test material was applied, the test site was moistened with 0.5 ml of distilled water and a gauze patch was placed over the treated site and secured to the adjacent skin with non irritating tape. A tubular stockinette sleeve (semi-occlusive binding) was then place around the trunk of the animal and secured at the cut edges with tape.

Following an exposure period of 4 hours, the stockinette sleeve and patch were removed from each animal. Each test site was then wiped with gauze moistened with distilled water to remove residual test material. Each test site was examined for signs of erythema and edema at approximately 1, 24, 48 and 72 hours. The test sites were graded at each interval according to the Dermal Irritation grading system presented on page 11 of the report (appended). The protocol called for the erythema and edema scores for all animals to be added for the 1, 24, 48 and 72 hour intervals and the total divided by 24 to determine the Primary Irritation Index.

RESULTS

Neither erythema nor edema was observed on the skin of any rabbit at any observation interval (1, 24, 48 or 72 hours).

Conclusion
The administration of 0.5 g iprodione to the skin of rabbits did not induce irritation in any of the 6 animals tested.

Toxicity category: IV

Core classification: minimum. This study satisfies the minimum requirements set forth under the Subdivision F Guidelines for a primary dermal irritation study in rabbits (81-5).