TDMS DATA EVALUATION RECORD PAGE OF

CASE PM

CHEM Chlorsulfuron

002643

BRANCH TB DISC TOPIC Skin Irritation & Sensitization - Guinea Pigs

FORMULATION Technical (information known to reviewer)

FICHE/MASTER ID CONTENT CAT

Primary Skin Irritation And Sensitization Tests On Guinea Pigs, Haskell Laboratory Report No. 794-76, Goodman, N.C.

SUBST. CLASS =

OTHER SUBJECT DESCRIPTORS

DIRECT RVW TIME = 1 1/4 hours START-DATE END DATE

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Conclusion:

A. Core Minimum (Number of sensitization treatments; 4 vs. 10)
B. Category IV
C. Technical chlorsulfuron is neither a skin irritant nor sensitizer on guinea pigs.
D. This study generally conforms to EPA proposed guidelines in section 163.81-6 Dermal sensitization study (43 Federal Register 37361, 8/22/78) with some modifications.

Methods:

1 Drop ($\simeq$ 0.05 ml) each of a 30% and 3% suspension (wt./vol.) of the test material in propylene glycol was applied and lightly rubbed in on the shaved intact shoulder skin of 10 male albino guinea pigs. The induction phase for sensitization was a series of four sacral intradermal injections given, one each week over a three-week period, which consisted of 0.1 ml of a 1% solution (wt./vol) of test material in dimethyl phthalate. Following a two-week rest period, the test animals were challenged for sensitization by applying, and lightly rubbing in, 1 drop ($\simeq$ 0.05 ml) each of a 30% and 3% suspension (wt./vol) of test material in propylene glycol on the shaved intact shoulder skin. A group of 10 previously unexposed guinea pigs received similar applications at the time of challenge to provide a direct comparison of the challenge reactions of skin of similar age.

Results:

The chlorsulfuron produced no irritation when tested as a 30% and 3% suspension in propylene glycol on the shaved intact skin of male albino guinea pigs. No sensitization was observed at challenge. There was no mortality.

Discussion:

The methods, scientific principles, validity of conclusions, and adequacy of data for conclusions were adequate for the study. Four rather than ten sensitizing treatments as proposed in the guidelines were injected, but years of experience has shown the above procedure to be adequate for detecting skin sensitizers.