CASE PM

CHEM Chlorsulfuron

002640

BRANCH TB DISC TOPIC Skin Irritation & Sensitization Guinea Pig

FORMULATION Formulated, 75% active

FICHE/MASTER ID CONTENT CAT

Primary Skin Irritation and Sensitization Test On Guinea Pigs, Haskell Laboratory Report No. 1073-80, Silber, L. S.

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; four vs. ten).
B. Category IV
C. The chlorsulfuron formulation, is at most, a slight skin irritant and not a skin 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:

Following a range-finding study 0.05 ml of a 60% and 6% suspension of test material in dimethyl phthalate (DMP) was applied and lightly rubbed on shaved, intact shoulder skin of ten unexposed guinea pigs. The induction phase for sensitization was a series of four sacral intradermal injections of 0.1 ml of a 1.0% suspension in DMP, one each week beginning two days after treatment for primary irritation. After a thirteen-day rest period, the test guinea pigs were challenged for sensitization by applying and lightly rubbing in 0.05 ml of a 60% and a 6% suspension of test material in DMP on shaved, intact shoulder skin. At the same time ten unexposed guinea pigs (controls) of the same age received identical topical applications.

Results:

The chlorsulfuron formulation caused no skin irritation during the range-finding study. There was no skin irritation at 60% or 6% during the primary irritation test at 24 or 48 hours. No sensitization response was shown at 60% concentration during challenge. However, slight irritation occurred at 60% in both the test and control pigs at challenge.

	Concentration in DMP			
Challenge Test	Test Animals		Control Animals	
	60%	6%	60%	6%
	3+		2+	
24	7 neg.	10 neg.	8 neg.	10 neg.
48	10 neg.	10 neg.	10 neg.	10 neg.

+ is mild

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.