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

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DEC 15 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Sodium Monofluoroacetate (Compound 1080), Lab Audit Report; [TOX CHEM No. 770].

FROM: Ray Landolt
Review Section # 1 12/8/86
Toxicology Branch/HED (TS-769)

THRU: R. Bruce Jaeger, Section Head
Review Section#1
Toxicology Branch/HED (TS-769) 12/8/86

TO: William Miller, PM#16
Insecticide/Rodenticide Branch
Registration Division (TS-767) 12/14/86

Action Requested: Review Lab Audit report (7/14/86) of studies conducted by Denver Wildlife Research Center for Primary Eye and Skin Irritation.

Recommendation: The difficiencies cited in the lab audit report are sufficient to find that these two studies do not support the Toxicity Category IV labeling for the primary eye and skin irritaion effects of a 1% formulation of sodium fluoroacetate.

Background Information:
Primary Eye and Primary Skin Irritation studies were submitted by the Denver Wildlife Research Center (Acc# 256084, 12/84) in support of the registration of sodium fluoroacetate used in the Toxic Collar (EPA Reg. No 6704 IL).

The test protocols for these studies appeared to follow the test guidelines 81-4 and 81-5 identified in NTIS publication Pesticide Assessment Guidelines, Subdivision F Hazard Evaluation: Human and Domestic Animals, pages 51-59, dated 1982. These studies were reviewed by TB (R. Landolt) 2/18/85 and judged acceptable.

Deficiencies cited in the lab audit report for the Primary Eye and Skin Irritation studies:

1. Absence of documentation of animals and their assignment to study.

2. Lack of records for daily observations of animals and treatment procedures.

3. Inadequate record keeping.

4. Absence of dates and initials in the records of observation and scores for irritation response.

5. Absence of data on environmental conditions in which the tests were done.

6. The raw data does not distinguish between treated and untreated eyes and dermal areas.

7. The studies were not properly authenticated that the irritation responses were secored by an experienced/qualified examiner.

8. Data gaps related to the characterization, analyses, receipt, distribution, preparation, and documentation of the test substance were identified.

9. The organization of the raw data was such that it was not possible to distinguish between data recorded promptly as they were generated and those that were transcribed.

As a result of these findings Toxicology Branch classifies the the two studies as CORE: Supplementary.