



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

FEB 18 1985

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sodium Monofluoroacetate (1080)
TOX. Chemical #770

TO: William Miller, PM #16
Insecticide Rodenticide Branch/RD (TS-767)

THRU: Robert B. Jaeger, Section Head
Review Section #1
Toxicology Branch/HED (TS-769) *2/19/85*

FROM: Ray Landolt
Review Section #1
Toxicology Branch/HED (TS-769) *2-19-85*

Registration No.: 6704-IL
Livestock Protection Collar
U.S.D.I. Fish and Wildlife Service Letters
of January 2, 1985 and January 29, 1985. *2/19/85*

Action Requested:

1. Review of primary dermal and eye irritation studies on the 1.0% aqueous use formulation of 1080.
2. Review of an acute dermal toxicity study on the technical formulation of 1080.
3. Review of the revised label, use restrictions, and instruction for use and warning sign submitted in support of the use of 1080 in the Livestock Protection Collar.

Recommendation:

1. The previous concerns of the Toxicology Branch for the use of sodium monofluoroacetate (1080) in the Livestock Protection Collar are resolved.

2. The Note to Physician paragraph on the label recommends treatment with ethanol. With reference to the publication "Recognition and Management of Pesticide Poisonings", 3rd edition, page 64, item 5 lists ethanol as not effective.

3. Page 9 of the instructions for use of the Livestock Protection Collar, the reference to the decontamination of contaminated animals and clothing should be consistent with the use restrictions.

Toxicity Data

I. Primary Eye Irritation

U.S.D.I. Fish and Wildlife Service December 1984, Acc. No. 256084.

A. Procedure:

A dose of 0.1 ml of a 10.0 mg/ml water solution (without Rhodamine B dye), equivalent to 1.0 mg of compound 1080 was placed in the conjunctival sac of the right eye of three male and three female young adult New Zealand White rabbits weighing approximately 3.0 kg. The animals were observed immediately, at 1, 24, 48 and 72 hours. The eyes were not washed. All animals were fitted with plastic collars and caged individually. The use formulation, 10 mg/ml in deionized water, was assayed at pH 7.5.

B. Results:

1. All treated animals were negative for primary eye irritation.
2. One male rabbit died 2 hours and 34 minutes following the application of the test material with classic symptoms of 1080 poisoning including mild convulsions. Accidental ingestion was suspected.

C. Conclusions:

1. Classification of Data - Guideline
2. Negative for primary eye irritation
3. Toxicity Category IV

II. Primary Dermal Irritation
U.S.D.I. Fish and Wildlife Service, December 1984, Acc.
No. 256084.

A. Procedure:

A dose of 0.5 ml of a 10.0 mg/ml water solution (without Rhodamine B dye), equivalent to 5.0 mg of compound 1080, was applied to a gauze pad and secured with adhesive tape to the shaven dorsal surface of three male and three female young adult New Zealand White rabbits for a four hour exposure period. Dressing was semiocclusive. The animals weighed approximately 3.0 Kg. All animals were fitted with plastic collars and caged individually. Following the four exposures, the dressing was removed and the treated areas were sponged with tap water to remove the test material and then dried. Observations were made immediately, then at 24, 48 and 72 hours. The use formulation, 10 mg/ml in deionized water, was assayed at pH 7.24.

B. Results:

1. All animals were negative for primary dermal irritation.
2. No signs of toxicity or death were reported.

C. Conclusions:

1. Classification of Data - Guideline
2. Negative for primary dermal irritation
3. Toxicity Category IV

III. Acute Dermal Toxicity

U.S.D.I. Fish and Wildlife Service, January 1985, Acc.
No. 256440.

A. Procedure:

Four dose levels with five male and five female New Zealand White rabbits (weighing 2.3 to 3.49 kg) per level were dosed with the technical material (98.75%) at 31.25, 62.5, 250 and 500 mg/kg. The dosage levels were corrected to 100% active ingredient applied dermally. The technical material, a fine white powder, was moistened with deionized water, applied to the shaven dorsal ventral area then wrapped with a gauze pad and semioclusive dressing. All animals were fitted with plastic collars to prevent ingestion and housed individually. The animals were observed for signs of toxicity during the initial 12 hours exposure, at 24 hours then twice daily for 14 days. Following the 24 hours exposure the dressings were removed the treated area washed with warm water and the animals were fitted with plastic collars before returning them to cleaned cages. Tissue samples were taken and preserved, but not processed.

B. Results:

1. LD₅₀, males 277.1 mg/kg (118.3-589.7)
female 324.2 mg/kg (not available)
2. Signs of toxicity: Lethargy and diarrhea were observed following dermal application accompanied by mild convulsions of 10 to 15 seconds duration preceeding death. At the 250 mg/kg level the animals died between 1 and 7 hours after the test material was applied. The survivors at all levels gained weight during the 14 day observation period.
3. Necropsy: Extensive hemorrhage of the thymus and bilateral hypostatic congestion of the lungs were observed in those animals that died during the initial 12 hour observation period.
4. Area exposed dermally: The average value reported at the 250 mg/kg level was 34 mg/cm².

C. Conclusions:

1. Classification of Data - Guideline
2. Toxicity Category II

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