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Dr. Owen James, D.V.M.
State of Montana
Department of Livestock
Capitol Station
Helena, MT 59620

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Dear Dr. James:

Subject: Sodium Fluoroacetate (Compound 1080) Livestock
Protection Collar
EPA Registration No. 35975-4
Your Submissions of November 13, 1993; December 3, 1993;
January 13, 1994; January 27, 1994

We have reviewed the submissions identified above. Our comments are listed below

1. The label was submitted on January 27, 1994, for the individual collars is acceptable.
2. The label submitted on January 13, 1994, for the container in which collars are shipped is basically acceptable, but the changes listed below must be made before the product is released for shipment.
 - a. The nominal concentration for Sodium Fluoroacetate shown on the label must be 1.00%, not 1.04% (which had been the nominal concentration when Rhodamine B was used as the marking agent in this product's formulaton).
 - b. The use restriction pertaining to endangered species which is cited in the "ENVIRONMENTAL HAZARDS" portion of the container label must be 18, not 15.
 - c. Change "gastilc" to "gastric" in the fifth sentence of the "TREATMENT" paragraph under "NOTE TO PHYSICIAN."

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- d. In the "RESTRICTED USE PESTICIDE" box, insert "Due To High Acute Toxicity and the Need for Highly Specialized Applicator Training" between "RESTRICTED USE PESTICIDE" and the paragraph beginning "Collars shall be sold"
- e. Make sure the entire disclaimer statement appears on labels shipped with the collars.

Note that the "DIRECTIONS FOR USE" section should appear only once on the label.

- 3. The technical bulletin submitted on November 24, 1993, was not reviewed in detail as it was replaced by another proposed revised technical bulletin submitted in January of 1994. The technical bulletin submitted in November of 1993 has not been accepted.
- 4. The technical bulletin submitted on January 13, 1994, is basically acceptable, but certain changes to the bulletin must be made before collars are released for shipment. The changes that are needed to the bulletin accepted in this letter are listed immediately below.
 - a. On the "DO" page (1), delete the asterisk in the third "DO" and the asterisked material at the bottom of the page. With the acceptance of this revised bulletin, larger-size collars will become available.
 - b. As the large and the small collars contain the same amount of 1080 solution, the fourth sentence in the first paragraph under "II.B. TOXIC PROPERTIES OF SODIUM FLUOROACETATE (COMPOUND 1080)" must be changed to read

"Each Livestock Protection Collar contains 2 to 6 lethal doses."
 - c. The cross-references in the second paragraph of "II.B." should read "Sections II.D.4., II.D.5., III.D.(15), and III.D.(16)". Note that the numbers are presented differently in Section II and Section III. These should be modified to be consistent.
 - d. End the third sentence of the third paragraph of II.D.3. ("Monitoring collared livestock," page 6) with "entirety." Delete "or their use."
 - e. In first line of first paragraph of II.D.5., change "leading" to "leaking."
 - f. In Use Restriction 9's asterisked footnote, change the address for notifying EPA to

"Robert A. Forrest, Registration Division (7505C),
Office of Pesticide Programs, U.S. Environmental
Protection Agency, 401 M St. SW, Washington, D.C.
20460".

- g. Insert an appropriately corrected (see above) copy of the container label in place of the label current in APPENDIX A.

- 5. We have reviewed the monitoring report which you submitted on December 3, 1993. We concur with the report's conclusion that collar use in Montana has been so limited that it is difficult to draw many conclusions. We feel that the requirement to submit monitoring reports should be extended until at least one year of significant use of large and small collars has been monitored and reported.

Submit five (5) copies of each component of final printed labeling before releasing product for shipment.

Sincerely yours,

Robert A. Forrest
Product Manager 14
Insecticide-Rodenticide Branch
Registration Division (7505C)

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND
DOMESTIC ANIMALS**

DANGER

May be fatal if swallowed. Wear waterproof gloves when handling collars. Wash hands after handling collars or animals that have been contaminated with 1080 solution. Do not use contaminated animals for food or feed.

ENVIRONMENTAL HAZARDS

This product is very highly toxic to wildlife. Birds and mammals feeding on carcasses of contaminated livestock may be killed. Keep out of any body of water. Apply this product only as specified on this label.

Endangered Species Considerations:

NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of a member of an endangered species.

The use of 1080 in the Livestock Protection collar has been determined to pose a hazard to several endangered species. See technical bulletin (use restriction No. 15) for specific areas where the 1080 collar cannot be used or approval must be obtained from the U.S. Fish and Wildlife Service prior to use.

NOTE TO PHYSICIAN

WARNING SYMPTOMS: 1080 poisoning results from the transformation of fluoroacetate into fluorocitrate within cell mitochondria. Poisoning is characterized by a symptom-free latent period of 1/2 to 2 hours or longer between ingestion and onset of symptoms (nausea, vomiting, diarrhea, and hyperactive behavior leading to convulsions, coma, and cyanosis). Ventricular fibrillation is commonly noted and is the primary cause of death. Early symptoms include alteration of heart sound and premature, weak contractions.

TREATMENT: No effective antidote is known but symptomatic treatment may be effective. Establish respiration; create artificial airway if necessary. Check adequacy of tidal volume. Initiate emesis. If patient is comatose, convulsing, or has lost the gag reflex, endotracheal intubation should precede gastric lavage with large bore tube. Administer activated charcoal and magnesium sulfate. Treat seizures with IV diazepam. Monitor cardiac function closely. Treatment with glyceryl monoacetate (monoacetin) may be effective; however, it is experimental and unproven in humans. **CONSULT NEAREST POISON CONTROL CENTER FOR CURRENT INFORMATION.** Symptoms of non-lethal intoxication will usually subside within 12-24 hours.

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RESTRICTED USE PESTICIDE

Collars shall be sold or transferred only by registrants or their agents and only to certified Livestock Protection Collar applicators. Collars may be used only by specifically certified Livestock Protection Collar applicators or by persons under their direct supervision.

**ONLY FOR USE IN MONTANA
SODIUM FLUOROACETATE
(COMPOUND 1080)
LIVESTOCK PROTECTION COLLAR**

For use on sheep or goats to kill depredating coyotes.

Active Ingredient - sodium fluoroacetate 1.04%
Inert Ingredients* 98.96%
TOTAL: 100.00%

*Contains Tartrazine dye as a marker.

KEEP OUT OF REACH OF CHILDREN

DANGER  **POISON**

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Induce vomiting at once with an emetic such as syrup of Ipecac; use as directed. If emetic is not available, drink 1-2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. **PROMPT TREATMENT IS MANDATORY. GET MEDICAL ATTENTION IMMEDIATELY.**

IF ON SKIN: Wash the exposed area twice with soap and water.

IF IN EYES: Wash eyes with plenty of water for at least 15 minutes.

IF ON CLOTHING: Remove contaminated clothing and wash before re-use. Dispose of all contaminated leather, including shoes, boots, and gloves, according to the "Pesticide Disposal" section. See disposal instructions on side panel.

**SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS.**

MANUFACTURED FOR: Montana Department of Livestock
Capitol Station
Helena, Montana 59620

U.S. PAT. 3,842,806 EPA ESTABLISHMENT NO. 35975 MT-1
EPA REGISTRATION NO. 35975-4

NET CONTENTS: 30.4 grams (1.1 oz.) per collar.

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

MAR 14 1994

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
35975-4**

NOTICE

Seller makes no warranty, expressed or implied, concerning the use of this product other than that indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

It is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act to sell or transfer this product in a restricted use container to anyone who is not a certified Livestock Protection Collar applicator. It is also a violation to use this product in a restricted use container in a manner not consistent with the label. Do not use this product on animals that have been contaminated with 1080 solution. Do not use contaminated animals for food or feed. Put collars on animals in areas where depredation by coyotes is known to occur. Use this product only as directed in the instructions accompanying the label.

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in original container. Do not store in food, feed, or other containers.

When snow or ice covers, apply up to one collar per animal. Proof containers.

PESTICIDE: This product is highly toxic and hazardous. It is a Federal offense to use this product in a manner that results in the death of a member of an endangered species.

Dispose of carcasses, clothing, and other contaminated materials in a safe manner. Do not use the applicator in residential areas.

Alternatively, you may contact the Montana Department of Livestock, Capitol Station, Helena, Montana 59620, for more information on disposal of waste.

CONTAINER:

Metal containers may contain residues of this pesticide. Do not reuse metal containers for food or feed.

Plastic containers may be reused for other purposes, provided they are thoroughly cleaned and do not contain residues of this pesticide.

COLLAR DISPOSAL: Collars may be disposed of in a trench, ground, or other suitable location.

DIRECTIONS FOR USE

It is a violation of State and Federal Law to use this product in a manner inconsistent with its labeling or the Compound 1080 cancellation order. Misuse may result in civil or criminal enforcement action.

DO NOT REMOVE TOXICANT FROM COLLARS. DO NOT USE TORN, DAMAGED OR LEAKING COLLARS. Dispose of damaged collars in accordance with the "Storage and Disposal" instructions on this label.

Put collars on the necks of sheep or goats in fenced pastures where coyote predation is occurring or is expected to occur. Use collars only in accordance with the User Instructions and Use Restrictions contained in the accompanying Technical Bulletin.

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