

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460	EPA REGISTRATION NO. 35975-4	DATE OF ISSUANCE 10/1/87
	TERM OF ISSUANCE	
	NAME OF PESTICIDE PRODUCT Sodium Fluoroacetate (Compound 1080) Livestock Protection Collar	

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION  
 (Under the Federal Insecticide, Fungicide,  
 and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Montana Department of Livestock  
 6th and Roberts  
 Helena, MT 59620

161 / 195549  
 18 / 1  
 161 / 193235  
 18 / 1

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The Livestock Protection Collar (3" mL) is conditionally registered in accordance with FIFRA section 3(c)(7)(A) under the following conditions:

1. You will submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Monitoring Study

You will submit within two (2) years of issuance of this registration, the results of the first twelve (12) months of the monitoring study. You must follow the monitoring study protocol enclosed in your August 8, 1986 submission and received by the Agency on August 19, 1986. Also, you must incorporate the modifications noted below. Each year thereafter, you will submit the results of the previous year's monitoring. Four years after issuance of this registration, the Agency will determine if the study may be discontinued.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
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The data resulting from the monitoring study must be submitted in a standard format according to PR Notice 86-5 (enclosed). This information is to be submitted to:

Product Manager (16)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)  
Environmental Protection Agency  
Washington, DC 20460

- a. Our concern about "Objective A" (as designated in a previously submitted version of your monitoring plan) is that it appeared that your monitoring plan was designed to bring people into compliance with the Use Restrictions and other labeling for the Livestock Protection Collar. In our view, Federal and State pesticide laws, the label, and the certification program are there to influence people to use the Livestock Protection Collar (and other pesticides) properly. The main objective of the monitoring program should be to determine whether they actually do comply.
- b. The monitoring reporting forms appear to be reasonably complete except for the accident report form. This form solicits information on treatments but not on the medical outcome of the human incidents. For animal incidents, the form assumes that a death has occurred. The form should be modified so that medical outcome and medical treatment information is solicited for all human and animal incidents, including those that are not fatal.

3. Information on the Collars

- a. Each Livestock Protection Collar will bear the following information:

DANGER  
PELIGRO  
1080  
EPA Registration No. 35975-4  
Unique serial number for each collar

- b. The metal engraving method is acceptable for putting serial numbers and other pertinent information on individual collars. We require that you test some collars filled with water to determine whether the plate could cut into the rubber bladders. It is possible that the location of the plate might divert coyotes' attacks from the throat region (or to uncollared sheep).

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4. Labeling

a. Make the labeling changes listed below before you release the product for shipment.

(1) Delete the following:

EPA Establishment Number 6704-ID-1

EPA Registration Number 6704-85

(2) Add the following information:

EPA Establishment Number 35975-MT-1

EPA Registration Number 35975-4

b. The following comments relate to our draft of your technical bulletin, which you sent back to us on May 7, 1987:

(1) The "DO'S AND DON'TS" section of your bulletin is adequate, but the sections to which the reader is referred are inappropriate for your manual. Make the following changes:

(a) On 7th "DO," reference should be to "Section III. 13."

(b) On 8th "DO," reference should be to "Section III. 14."

(c) On 9th "DO," references should be to "Section II. D. 4 and 5 and to Section III. 15 and 16."

(d) On 10th "DO," reference should be to "Section III. 9."

(e) On 12th "DO," reference should be to "Section III. 8."

(f) On 14th "DO," reference should be to "Section III. 17."

(g) On 4th "DON'T," reference should be to "Section III. 11 and 12."

(h) On 5th "DON'T," reference should be to "Section III. 11."

- (i) On 6th "DON'T," reference should be to "Section III. 18."
  - (j) On 7th "DON'T," reference should be to "Section III. 21."
  - (k) On 8th "DON'T," reference should be to "Section III. 15."
  - (l) On 9th "DON'T," reference should be to "Section III. 10."
  - (m) On 10th "DON'T," reference should be to "Section III. 18."
- (2) Check the bulletin for typographical, grammatical, and referencing errors. In scanning it, we found the following (page numbers are those used in our letter of April 3, 1987):
- (a) Page 12, line 11, change "tested" to "tests."
  - (b) Page 15, line 46, change "having" to "have."
  - (c) Page 18, line 19, change "Section III. 8." to "Section III. 11."

Submit five (5) copies of your final printed labeling, which includes the Technical Bulletin, before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

#### 5. Reports

- a. The registrant submits to EPA<sup>1,2</sup> by February 15 each year the number of collars sold by county and State. The reporting period is January 1 to December 31.

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<sup>1</sup>William H. Miller, Registration Division (TS-767C), EPA, Washington, DC 20460.

<sup>2</sup>Mike Wood, Office of Compliance Monitoring (EN-342), EPA, Washington, DC 20460.

- b. The registrant submits production information (pounds or gallons produced) for this product for the fiscal year in which the use for predator control is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15 following the end of the preceding fiscal year. This information is to be submitted to:

Registration Support and Emergency  
Response Branch  
Registration Division (TS-767C)  
Environmental Protection Agency  
Washington, DC 20460

6. Agents

Within thirty (30) days of issuance of this registration, the registrant shall submit to the Agency a list, subject to EPA approval, of agents authorized to sell and/or distribute the 1080 Livestock Protection Collars, and the locations where the 1080 toxic collars will be sold and/or distributed. Any changes and/or amendments to the list must be submitted to, and approved by, the Agency prior to instituting these changes.

7. Data Requirements to Support Continued Registration of the 1080 Livestock Protection Collar

On February 3, 1987, the Agency mailed a Data Call-In (DCI) Notice under FIFRA section 3(c)(2)(B) to the USDA/APHIS/ADC requesting that the following studies either be repaired or repeated (copy enclosed). Satisfaction of these data requirements, and the due dates for submittal of the data, is also a condition of this registration.

<u>Guideline Citation No.</u>	<u>Study</u>	<u>Date Due</u>
81-4	Sodium Fluoroacetate (Compound 1080), Primary Eye Irritation of the Toxic Collar Solution to Rabbits, U.S. EPA Accession No. 144399.	November 6, 1987
81-5	Sodium Fluoroacetate (Compound 1080), Primary Skin Irritation of Toxic Collar Solution to Rabbits, U.S. EPA Accession No. 144400.	November 6, 1987

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<u>Guideline Citation No.</u>	<u>Study</u>	<u>Date Due</u>
71-5	Estimated Doses of Sodium Fluoroacetate (Compound 1080) Delivered to Coyotes by Toxic Collars, November 15, 1984. U.S. EPA Accession No. 144402.	February 6, 1990
71-5	Primary Hazard of the 1080 Toxic Collars <sup>2</sup> to Skunks and Golden Eagles, December 21, 1984. U.S. EPA Accession No. 144401.	February 6, 1990

8. Biological Opinion From the Office of Endangered Species

Within 30 days after receipt from the Office of Endangered Species (OES) by way of the Agency a final Biological Opinion, you must amend the registration of your product to reflect any restrictions on the sale, distribution, or use of 1080 products required or recommended by the Biological Opinion and you must agree to carry out such other actions, including submission to EPA of additional data, as are required or recommended in the Biological Opinion.

If these conditions are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Also, our staffs have agreed that the USDA Animal Damage Control Service personnel will facilitate efforts by collar users to contact local Endangered Species Offices in order to comply with the endangered species provisions of the labeling.

A stamped copy of the label is enclosed for your records.

William H. Miller  
Product Manager (16)  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)

Enclosures

**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 fluoroacetyl 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 sounds 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. Induce 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.

BEST AVAILABLE COPY

**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 degrading coyotes.

Active Ingredient - Sodium fluoroacetate ..... 1.04%  
Inert Ingredients ..... 98.96%  
TOTAL: 100.00%

\*Contains Rhodamine B 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 leathers, 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, MT 59620

U.S. PAT. 3,842,806 EPA ESTABLISHMENT NO. 6704-1D-1  
EPA REGISTRATION NO. 6704-85

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

**NOTICE**

Seller makes no warranty 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. In EPA Letter Dated

OCT 1 1987

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

35974-5

DIR

It is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to use a pesticide in a manner inconsistent with its labeling. The use of this pesticide in a manner inconsistent with its labeling may result in criminal or civil penalties. Do not re-label, dilute, or leak. Follow all instructions on the label. Put collars on pastures where expected to be used with the User Guide contained in the label.

STOR

Do not contaminate or dispose of. **STORAGE:** Store in original container from food, feed, chemicals, or by humans. When snow or impractical, store in a leak-proof container for up to 90 days. **PESTICIDE:** acutely hazardous materials as a by 1080 (car leather clothing at a safe location and managed mile from humans. Alternatively, environmental representative for guidance hazardous waste.

CONTAINER

Metal container uncontaminated puncture and rinse. Plastic container puncture and above.

**COLLAR DISPOSAL:** unserviceable than 10 collars buried in trench at least 10 feet