

Record Number(s)

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D198641  
D199151  
D197559

2/7/94  
2/7/94  
1/26/94  
IN 12/14/93 OUT 3/14/94

EFFICACY

FILE OR REG. NO. 35975-4

PETITION OR EXP. PERMIT NO. \_\_\_\_\_

DATE DIV. RECEIVED 12/8/93, 12/13/93, 1/19/94, 2/3/94

DATE OF SUBMISSION 11/24/93, 12/3/93, 1/13/94, 1/27/94

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TYPE PRODUCT(S): I, D, H, F, N, R, X S

DATA ACCESSION NO(S): none

PRODUCT MER. NO. 14

PRODUCT NAME(S) SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR

COMPANY NAME Montana Department of Livestock

SUBMISSION PURPOSE Add use of large-size collar (still containing 30 ml of 1080 solution) and provide monitoring report.

CHEMICAL & FORMULATION 1.00% Sodium Fluoroacetate solution in Livestock Protection Collar

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,  
35975-4  
Montana Department of Livestock (MDL)  
Helena, MT 59620

## 200.0 INTRODUCTION

### 200.1 Uses

A 1.00% Sodium Monofluoroacetate (Compound 1080) solution in a two-pouched rubber vessel which is attached to Velcro or elastic bands which hold the pouches in place in the throat regions of sheep and goats subject to predatory attacks by coyotes. Use of this "Restricted" product is limited to the State of Montana.

### 200.2 Background Information

See efficacy reviews of 9/30/86, 4/21/87, 5/21/87, 7/12/89, 10/23/89, 5/24/90, 10/16/91, 2/6/92, and 11/5/93, along with other information in product jacket. I was able to secure waivers of registration maintenance fees for this product for 1992 and 1993. MDL submitted monitoring reports for the calendar years 1988, 1989, and 1990 but had not submitted any since, until an item discussed in this review was provided. EPA has excused the Texas Department of Agriculture (TDA) from requirements to file additional annual reports for the product (46779-1) used in Texas, but this determination did not extend to registrants of other Livestock Protection Collar products.

The first of the current submissions consists of an amendment application form dated 11/24/93, a "Certification with Respect to Citation of Data" form bearing the same date, and five copies of a proposed revised technical bulletin. This submission is a follow-up to the submissions that were discussed in the efficacy review of 11/5/93 and EPA's letter of 11/16/93. Contrary to directives in EPA's letter of 11/16/93, MDL did not submit separate copies of the label which goes on the container in which collars are to be shipped, nor did MDL submit copies of the small label that goes on the collar itself. On 1/12/94, I spoke with Dr. Owen James, Montana's Assistant State Veterinarian, about this problem. Dr. James said that he would ship the missing labels to EPA on or before 1/13/94.

On 12/3/93, Dr. James submitted a letter with which was enclosed information pertained to the monitoring of collar use in Montana in 1991 and 1992.

Dr. James submitted additional proposed revised labeling on 1/13/94. These items included copies of the container label and the technical bulletin. This submission did not include copies of the label for the collar itself.

On 1/27/94 (following a telephone conversation with me), Dr James submitted copies of the label for individual collars.

MDL is attempting to amend this product's registration to allow used of large-size collars as well as small collars under the registration number 35975-4. Similar amendments have been accepted for other toxic-collar registrants.

Amendments have been granted for APHIS's collar (56228-22), Rancher's Supply's collar (46779-1), and Wyoming Department of Agriculture's collar (35978-8) with the understanding that the amount of 1080 solution used is to be the same (30 ml total: 15 ml per reservoir) for both sizes of collars.

## 200.0 DATA SUMMARY

Much of the monitoring information supplied by Dr. James on 12/3/93 is summarized in Table 1. This information came from a report attributed to the Montana Department of Agriculture (MDA) which is the State lead agency for pesticide regulation in Montana and the agency charged with monitoring use of 35975-4. MDA summarizes this report with the following comments:

"The use of LP Collars in Montana has been too limited to make meaningful conclusions on parameters that affect the effectiveness of the collars. The limited information seems to suggest that attempting to use too small of a target flock is less effective than [sic] using larger flocks. However, several of the coyotes were taken with flocks of less than 10 animals."

MDA also reports that, as of 12/31/92, there were 28 licensed collar applicators in Montana. Of these two were identified as "Commercial," 17 as "Private," and 9 as "Government (USDA, APHIS, ADC; not actively using collars)."

MDA also states that all punctured collars were disposed of "by burial on each applicator's property."

The proposed revised technical bulletin in the application of 11/24/93 appears to be an amended version of the proposed revised technical bulletin discussed in the efficacy review of 11/5/93. This proposed revised bulletin lacks the text which pertains specifically to Montana's State Laws which appears in the USE RESTRICTIONS portion of the technical bulletin on MDL's current label. After I discussed this issue with Dr. James, he concluded that it would be better to keep this language in the bulletin. On 1/13/94, he submitted one copy of a proposed revised technical bulletin which includes the Montana-specific Use Restriction language. As it appears that the proposed revised technical bulletin submitted on 1/13/94 is intended to supplant that which was submitted on 11/24/93, this review considers in detail only the most recently submitted bulletin.

The technical bulletin submitted on 1/13/94 contains some slight errors which should be corrected before collars are shipped under the new labeling (see "CONCLUSIONS").

MDL's submission of 1/13/94 did include separate copies of a proposed container label, but MDL failed to submit any copies of the label used on the collar itself. Instead, MDL submitted additional copies of the warning signs that are placed where collars are applied. This circumstance occasioned another call to Dr. James, who promised to send collar labels shortly thereafter. On 1/27/94, Dr. James submitted collar labels. These labels are acceptable.

Table 1. Summary of year-by-year information included in 1992 monitoring report for use of Livestock Protection Collars in Montana, prepared by Montana Department of Agriculture.

DATA CATEGORY	YEAR					TOTALS
	1988	1989	1990	1991	1992	
# Applicators Buying Collars	6	4	0	?	0	10+?
# Collars Bought	45	90	0	50	0	185
# Counties Where Collars Used*	3	5	3	?	1	6?
Total # Collar-use Days	1185	1110	630	1140	7	4072
Avg. # Days of Use/Collar	26	41	30	30	7	—
# Collars Ruptured	3	0	1-3	5	1	10-12
# Believed Due to Coyotes	3	0	1-3	4	1	9-11
# Ruptured by Other Causes	0	0	0	1	0	1
Days of Use Until Collars Ruptured	<7	-	<7	?	<7	<7?
# Collars Lost	2	0	2	2	0	6
Days of Use Until Collars Lost	<7	-	<7?	<7	-	<7?
# Dead Coyotes Found and Attributed to Collar	1	0	0	0	0	1
# Nontarget Animals Found Dead and Attributed to Collar	0	0	0	0	0	0

\* This row of data includes values obtained from prior monitoring reports. The report for 1992 only presented county information for 1992.

The container labels submitted on 1/13/94 were basically acceptable, but a few changes are needed (see "CONCLUSIONS"). The requirement to expand the "RESTRICTED USE PESTICIDE" statement was precipitated by EPA's PR Notice 93-1. The small errors in the "ENVIRONMENTAL HAZARDS" and "NOTE TO PHYSICIAN" sections also occur on the currently accepted container label.

#### 202.0 CONCLUSIONS

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."
  - 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.

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- 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.

William W. Jacobs  
Biologist  
Insecticide-Rodenticide Branch  
March 14, 1994