

10-21-88

IRB BRANCH REVIEW - TSS

Record Number(s)

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IN 9/17/88 CUT 10/21/88

EFFICACY

FILE OR REG. NO. 39508-E

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

DATE DIV. RECEIVED 9/12/88

DATE OF SUBMISSION 9/7/88

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DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) SODIUM MONOFLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK  
PROTECTION COLLAR

COMPANY NAME New Mexico Department of Agriculture

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 1.04% Sodium monofluoroacetate solution in livestock  
protection collar

1  
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Efficacy Review: SODIUM MONOFLUOROACETATE (COMPOUND 1080) IN THE LIVESTOCK  
PROTECTION COLLAR, 39508-E  
New Mexico Department of Agriculture  
Las Cruces, NM 88003

200.0 INTRODUCTION

200.1 Uses

A 1.04% Sodium Monofluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel which is attached to Velcro bands which hold the pouches in place in the throat regions of sheep or goats subject to predatory attacks by coyotes.

200.2 Background Information

See efficacy review of 3/21/88 and EPA's letter of 4/11/88. In the current submission, NMDA has provided revised labeling, revised certification program material (including the answers for the applicator certification examination), a revised monitoring plan, and an example of the collar (empty).

201.0 DATA SUMMARY

The revised materials generally are improvements over their respective previous versions, although some problems still remain. The most notable of these is the need to make all text consistent regarding disposal of collars. If, as appears to be the case, NMDA wants all leaking or otherwise unrepairable collars to be returned to NMDA for proper disposal, all statements bearing upon collar disposal must point in this direction. As NMDA has adapted their labeling from the labels and bulletins of other current and would-be collar registrants, some of which direct users to bury collars, there is much language in the technical bulletin that discusses burial of collars.

There are some problems with the materials supplied for the first time in this submission. Some of the answers in the key for the examination appear to me to be dead wrong (see "CONCLUSIONS"). The collar example supplied has the following text printed on two of the four straps:

"DANGER-PELIGRO  
1080  
EPA. REG. No. 39508-E  
SER. NO. NM0000"

According to the typed representation of the labeling for individual collars, this text is to be "Attached to Each Collar by Adhesives and/or Staples". As the adhesive and staple methods have their drawbacks for use on collars, I have no major objection to the writing of this language on straps as long as the text is legible, the text is located away from the free ends of the collar so that it would not be abridged if the applicator were to shorten the straps as permitted by the technical bulletin, and the language is printed in "permanent" ink. The language on the straps of the sample collar submitted was apparently put on with a common felt-tipped marker. I was able to smear the text using spit and a finger.

As requested by EPA, NMDA has added a form for state personnel to use to collate results obtained from forms filled out for individual ranches. Although only a hand-written version was submitted, the form seems to be adequate.

## 202.0 CONCLUSIONS

1. The text of the labeling on the example of the collar that you supplied is adequate, but its method of attachment to the sample is not. According to the typed representation of the labeling for individual collars, this text is to be "Attached to Each Collar by Adhesives and/or Staples". As the adhesive and staple methods have their drawbacks for use on collars, the text may be written on collar straps as long as the text is legible, the text is located away from the free ends of the collar so that it would not be abridged if the applicator were to shorten the straps as permitted by the technical bulletin, the language is printed on at least two straps, and the language is printed in "permanent" ink. The language on the straps of the sample collar submitted was apparently put on with a common felt-tipped marker and could easily be smeared by use of saliva and a finger.
2. The comments below pertain to various portions of the technical bulletin.
  - a. Contents
    - (1) Note that the "USE RESTRICTIONS" appear on pages 13-16, not 13-17.
  - b. DON'TS
    - (1) In 4th and 8th "DONT'S, change "(see page 17)" to "(see page 16)".
    - (2) In 6th and 7th "DONT'S, change "(see pages 16-17)" to "(see page 16)".
  - c. Section I
    - (1) If it is truly your intent that collars be returned to NMDA for proper disposal, the text of Section I (pages 9-10), your use restrictions (12 & 13), your container label, and your examination questions must consistently reflect this policy. As these documents are currently written, users are told in some places to bury collars and in other places to return them to NMDA. Burial is acceptable to EPA if it is to NMDA. Whatever policy you choose to adopt for collar disposal, make sure that it is reflected consistently in all relevant documents.
  - d. Section II
    - (1) In last sentence of restriction 7, insert "be" between "not" and "removed".

3

- (2) In restriction 10, change "English/Spanish or other second language appropriate for the region" to "(English/Spanish)".
- (3) If you want users to return punctured, leaking, or otherwise irreparable collars to NMDA, revise last sentence of restriction 12 to read

"Leaking, punctured, or otherwise unrepairable collars must be returned to the New Mexico Department of Agriculture for proper disposal."

and amend first paragraph of restriction 13 to read

"Dispose of other 1080 wastes (contaminated leather clothing, animal remains, wool, hair, vegetation, water, and soil) under three feet of soil, at a safe location, preferably on property owned or managed by applicator and at least 1/2 mile from human habitations and water supplies."

You use restrictions and technical bulletin should also describe the proper procedures to be followed in returning punctured, leaking, or irreparable collars to NMDA for disposal.

- 3. We take issue with the correctness of the answers given in the key for your applicator certification test for the following items:

- a. Multiple Choice Item 7

As Compound 1080 is highly soluble in water, it is also true that 1080 is "not insoluble in water".

- b. Multiple Choice Item 17

We suspect that price of collars (about \$16-20 each) and availability of labor for moving and collaring sheep would be important factors, along with the feasibility of alternate control methods, to be considered before deciding to use the collar. Therefore, we believe that "D. All of the above" is the best answer for this item.

- c. Multiple Choice Item 13

The answer ("Bury immediately") given as correct for this question is contradicted by your label which states

"Return damaged, irreparable and/or leaking collars to the New Mexico Department of Agriculture at Las Cruces for disposal."

## d. Multiple Choice Item 27

The LD<sub>50</sub> of 1080 for the coyote is about 0.12 mg/kg body weight, with the LD<sub>99</sub> probably being below 0.20 mg/kg body weight. A 30-pound coyote has a mass of about 13.5 kg. One cc of collar solution should have a mass of about 1 gram (or 1000 mg) as the solution is primarily water. It would take about 1.6 mg of 1080 to kill a typical 30-kg coyote and probably less than 3 mg each to kill virtually all 30-kg coyotes. As the solution is about 1% 1080, each cc should contain 10 mg of 1080, or enough to kill several 30-kg coyotes. The answer given as correct for this item actually corresponds to the total amount of solution in a small collar.

## e. Multiple Choice Item 32

The answer in the key is clearly wrong as use of collars is prohibited in open range (restriction 8).

## f. True or False Item 52

Use restriction 2 permits use of collars by noncertified applicators if done under the direct supervision of a certified applicator.

William W. Jacobs  
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October 21, 1988

5