

IRB BRANCH REVIEW - TSS

8-29-88

Record Number(s)

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IN CUT

EFFICACY

FILE OR REG. NO. 13808-T

PETITION OR EXP. PERMIT NO.

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DATA ACCESSION NO(S) none

PRODUCT MGR. NO. 16

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

COMPANY NAME South Dakota Department of Agriculture

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 1.04% Sodium Monofluoroacetate (Compound 1080)

solution in Livestock Protection Collar

1/4

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,
13808-T
South Dakota Department of Agriculture
Pierre, SD 57501

200.0 INTRODUCTION

200.1 Use

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

200.2 Background Information

This is a new registration application. It is a "me-to", however, as similar registrations have been granted to various state and federal agencies and to the manufacturer of the collar, Rancher's Supply, Inc., Alpine, TX. Most of the data for the collar were developed in the Animal Damage Control (ADC) research program, recently transferred from the U.S. Department of the Interior to the Animal Plant Health Inspection Service (APHIS), USDA.

In the current submission, SDDA has provided labeling (including the container label and a technical bulletin), a Confidential Statement of Formula (CSF), a "monitoring plan" for use of the collar, and assorted forms and authorizations.

201.0 DATA SUMMARY

The proposed container label and technical bulletin are basically adequate, although a few minor changes are needed (see "CONCLUSIONS"). The center panel includes, after the ingredient statement, the phrase

"Contains Rhodamine B dye as a marker".

This statement does not identify Rhodamine B as one of EPA's "inerts of concern", although the presence of the substance in the formulation is noted. It is likely that few animals would survive the active ingredient in this product only to be harmed by Rhodamine B.

The most serious problem that I can find with the labeling is one that is largely of EPA's creation. Due of the Agency's "Cheshire cat" policies regarding Endangered Species' statements on labels, SDDA refers on its container label and in the early portions of its technical bulletin to a use restriction that deals with Endangered Species. However, the restriction (which apparently had been #16) has been removed from the technical bulletin, and the succeeding restrictions have been renumbered. Although this action is technically legal, it has caused blank citations in the proposed labeling and, far more importantly, leaves the labeling with no concrete directions regarding what to do to avoid hazards to Endangered Species. There are Endangered Species concerns in South Dakota, although the Livestock Protection Collar might not pose much of a direct threat to animals such as the black-footed ferret.

202.0 CONCLUSIONS

The following comment applies to the proposed container label:

1. The second paragraph under "ENDANGERED SPECIES CONSIDERATIONS" refers to "restriction No. 16". The restriction of that number in your proposed technical bulletin deals with limitations on the numbers of collars that may be used for pastures of given sizes. Apparently a restriction has been deleted and the remaining restrictions renumbered.

The following comments apply to the proposed container label:

Page 1

1. In the first "DO", change "instructions" to "Technical Bulletin".
2. In the fourth "DO", change "(Section II.)" to "(Section I.2)".

Page 2

1. In the fourth "DON'T", change "(See Section II,17.)" to "(See Section II.16.)".
2. In the sixth "DON'T", change "(See Section II,19.)" to "(See Section I.18.)".
3. The ninth "DON'T" refers to an "Endangered Species" restriction (16) that does not appear in the proposed technical bulletin.

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1. In the second paragraph of "I.5", change "you" to "your" and substitute the name of the specific agency or agencies that should be contacted in South Dakota for "State Pesticide or Environmental Control Agency".

Page 12

1. In "Use Restriction 6", replace "appropriate regulatory agency" with "U. S. Environmental Protection Agency*" and add the name of any agencies in South Dakota to which such poisonings also should be reported. At the bottom of the page on which this restriction appears, put another asterisk (*) followed by "William H. Miller, Registration Division (TS-767C), U. S. Environmental Protection Agency, Washington, DC 20460".

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1. In "Use Restriction 14", state the name of the South Dakota agency or agencies that should be contacted.

The following comments pertain to the proposed monitoring plan:

1. In "Objective A", change "Insure that" to "Determine whether".
2. In "Objective G", change "when" to "whether".
3. The form "INDIVIDUAL COLLAR SUMMARY REPORT" does not appear to provide under the heading "DATES COLLAR CHECKED (Minimum of Once a Week)" sufficient space for listing dates for the multiple inspections that are required.
4. Under part "2" of the form "L P COLLAR ACCIDENT REPORT FORM", note that there is no true antidote for Sodium Fluoroacetate. Therefore, the item "WAS ANTIDOTE USE(sic)" is biologically incorrect (in addition to the grammatical problem). This item should be replaced with a section which permits summarization of the treatments given. Results of treatments could be discussed under "REMARKS".

William W. Jacobs,
Rodenticide Reviewer, PS
IRB
August 29, 1988

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