

IRB BRANCH REVIEW - TSS

Record Number(s)

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CUT

EFFICACY

FILE OR REG. NO. 56228-10

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 11/4/88

DATE OF SUBMISSION 10/28/88

DATE SUBMISSION ACCEPTED 12/15/88

TYPE PRODUCTS(S): I, D, H, F, N, R^x, S _____

DATA ACCESSION NO(S) none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) COMPOUND DRC-1339 CONCENTRATE

COMPANY NAME U. S. DEPARTMENT OF AGRICULTURE

SUBMISSION PURPOSE Extensive expansion of use sites/patterns. species claimed.

CHEMICAL & FORMULATION 98.0% Stralicide "concentrate"

Efficacy Review: COMPOUND DRC-1339 CONCENTRATE, 56228-10
Animal Plant and Health Inspection Service (APHIS)
U. S. Department of Agriculture (USDA)
Hyattsville, MD 20782

200.0 INTRODUCTION

200.1 Uses

A 98.0% 3-Chloro-p-toluidine hydrochloride (Starlicide) concentrate labeled "FOR REFORMULATING PURPOSES ONLY" but bearing directions for mixing and applying baits to control starlings and unspecified types of blackbirds in hog feedlots, poultry feedlots, and cattle feedlots.

200.2 Background Information

See product jacket. The first application for registration for this product was submitted 9/14/64 by the U. S. Department of the Interior (USDI). Initial registration of this product, also by USDI, took place on 3/24/67. The original registration number was 6704-56. On 10/24/67, the product's formulation was changed from a 75% Starlicide (Compound DRC-1339) concentrate to a 98% Starlicide concentrate. The only Confidential Statement of Formula (CSF) now in the product jacket is dated 10/17/66 and is for a 75% a.i. concentrate.

The current submission requests wholesale changes to the product use directions and changes, without apparent request, the nominal claim of Starlicide content to 97.0%. Many of these changes address uses that have been accepted on "Special Local Needs" (under § 24[c] of FIFRA) labels issued by various states. The proposed changes would greatly expand the use of this material. I suggest that each change not now on a § 3 registered label be treated as a new use and be routed to HED and EFED for evaluations and determinations regarding needs for additional data to assess the "incremental risks" of the proposed new uses.

201.0 DATA SUMMARY

No efficacy data were submitted. Efficacy data would be required to support any claim to control pests judged to be of significance to public health and, at the Agency's discretion, to support any other claims.

The proposed changes to the registration are as follows:

1. A formulation change to make the nominal concentration of Starlicide in the product 97.0% instead of 98.0%.

This change is not mentioned in the cover letter for the submission of 10/28/88 nor was there a revised Confidential Statement of Formula included with that submission. That submission did refer to a submission of 8/25/88, of which there is no record in the product file. It is possible that a revised CSF was included in the submission of 8/25/88.

2. Replacing the current "USE RESTRICTIONS" sentence

"A slow acting avicide for control of starlings and blackbirds."

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with

"GENERAL INFORMATION: Compound DRC-1339 Concentrate is a slow acting avicide for the control of blackbirds, starlings, ravens, crows, magpies, and feral pigeons. Birds ingesting treated bait(s) die within one to three days."

This change provides more information, but also expands label claims to include four types of birds not on the current label ("ravens, crows, magpies, and feral pigeons"). With each of these new species come new use sites, whether stated or implied on the label.

3. Creation of a new "USE RESTRICTIONS" section which reads

"Application of treated bait(s) in any problem area should be made only after careful observation of bird feeding habits to locate preferred feeding sites, determine the optimum time of application, and evaluate hazards of the application to desirable or protected animals. DO NOT apply bait(s) in areas where there is danger of consumption by endangered species. Prebaiting may be necessary to obtain successful results. When baiting is completed, remove all unconsumed bait material and dispose of in accordance with applicable state or federal laws. Carcasses of dead or dying birds that are found should be collected and either burned or buried according to applicable laws.

NOTE: WHEN CONTROLLING BLACKBIRDS, CROWS, MAGPIES, AND RAVENS, IT MAY BE NECESSARY TO OBTAIN A KILL-PERMIT FROM THE U.S. FISH AND WILDLIFE SERVICE AND/OR THE APPLICABLE STATE WILDLIFE AGENCY."

Some of this material replaces a much shorter section ("APPLICATION") on the current label that refers only to precautions associated with control of starlings and blackbirds. While providing useful information, the new text must be edited and might have to be changed further if certain of the proposed claims are not accepted by EPA.

4. Replacing current mixing directions with a section entitled "FORMULATION DIRECTIONS" which appears under the headings "BLACKBIRDS AND STARLINGS" and "FOR CONTROL IN FEEDLOTS". The new section preserves the current methods for preparing pelleted or grain baits and specifically identifies as acceptable carriers "poultry pellets, grains (rice, corn, soybean), or other applicable bird food items." This section also contains the following new text

"When using very large baits (less than 2500/lb) or very small baits (more than 25,000/lb) the amount of Compound DRC-1339 Concentrate must be adjusted to make one bait lethal."

The additional detail provided by the new text is helpful, but the retention of the open-ended "other applicable bird foods" is not. That language leaves too much room for error.

The direction to adjust the amount of Starlicide to be used in very large or very small baits so that one bait is lethal is also open-ended. The label provides no guidance regarding how much toxicant is needed per bait partical for to be lethal to each of the target species claimed. However, once such an amount of toxicant were added per bait, the bait would become "lethal". Adding more toxicant to the mixture would result in each bait still being "lethal". Therefore, this direction has no upper limit. The label should provide target ranges of mg product per bait (or some other unit per pound of bait) that would be appropriate for very large baits and another such range that would be appropriate for very small baits.

5. Directions for mixing one part of treated bait with 5-10 parts placebo have been moved to the "FORMULATION DIRECTIONS" section from the directions "FOR CATTLE FEEDLOTS". The new label makes dilution of bait mandatory for feedlot uses. Under the old label, dilution was a recommended option.

Making dilution of "hot" bait with placebo bait mandatory seems to me to be a significant improvement.

6. The heading "FOR CATTLE FEEDLOTS" has been changed to "APPLICATION IN CATTLE FEEDLOTS". The text of this section has been altered due to the relocation of the dilution directions and to the imperative nature of the new dilution directions. As will be developed below, this section has also been altered by the "subtraction" of "DAIRY FEEDLOTS" from the category "CATTLE FEEDLOTS". Other minor changes have also been made.

Because "DAIRY FEEDLOTS" have been removed from the category "CATTLE FEEDLOTS", the latter category should be changed to something like "BEEF CATTLE FEEDLOTS".

7. The heading "POULTRY AND HOG FEEDLOTS" has been changed to "APPLICATION IN POULTRY, SWINE, AND DAIRY FEEDLOTS". The text of this section has been changed by capitalizing the word "PERIMETER" and by deleting the following non-sentence

"Baiting times, rates, and dilution with other feeds recommended for cattle feedlots."

Actually, application rates for feedlot uses are not specified on either label. Directions call for baits to be scattered "thinly and uniformly over dry and frozen areas" or to be placed in "feeding stations". The directions do not indicate the amounts of bait to be scattered per unit area, anything about the type of feeding station to be used, or the amount of bait to be used per station.

The term "DAIRY FEEDLOTS" should be changed to "DAIRY CATTLE FEEDLOTS".

8. Addition of directions for mixing and applying egg baits for "RAVENS, MAGPIES, AND CROWS" for "CONTROL OF DEPREDATION ON NEWBORN LIVESTOCK". Hard-boiled or soft-boiled chicken or turkey eggs are to be injected with 1 ml of a solution made from dissolving 10 g of the concentrate in 100 ml of "warm potable water". Treated eggs are to be placed in "sets" of 1-4 eggs each, with no more than "36 eggs per bait site". Sets "should give the appearance of bird nests" and may be placed within 10 feet of animal-carcass "draw stations". Baits are to be checked every three days and retrieved after three days of exposure (presumably because the eggs would be spoiled by that time).

Treated eggs are likely to be attractive to animals other than the target Corvids (e.g., skunks, raccoons, coyotes, badgers, Franklin's ground squirrels, etc.) claimed on the label. The incremental risks associated with all new uses must be evaluated by EFED.

I found labels for three § 24(c) registrations for use of egg baits to control Corvids. OR-850002 is limited to control of ravens preying upon nests of sandhill cranes in the area of the Malheur National Wildlife Refuge. NV-860003 is to be used "to protect shorebird, waterfowl, and new born lambs from raven predation." These products are to be mixed according to the formula proposed on the new label for 56228-10. ID-860002 (ravens and magpies) has somewhat different mixing instructions.

9. Addition of directions for mixing and applying meat baits for "RAVENS, MAGPIES, AND CROWS" for "CONTROL OF DEPREDATION ON NEWBORN LIVESTOCK". One gram of concentrate is to be mixed with 5 g of powdered sugar. This mixture is then to be sprinkled or poured over 200 1/2 in³ meat cubes which are to be mixed or tumbled "until meat cubes are evenly covered." These baits are to be placed "in small clusters at preselected sites not to exceed 75 baits per site." If draw stations are used, "baits may be placed on or near the animal carcass". Meat baits

" . . . must be observed continuously from a 0.4 to 0.8 km (1/4 to 1/2 mile) distance to ensure that no desired or protected animals consume treated baits during each baiting period. Baits must be retrieved each day no later than one hour after sunset."

To assume that someone observing a draw station from at least 1/4 mile away could "ensure" that nontarget animals did not consume any treated baits is ludicrous. Even with a high-power spotting scope, the baits would be difficult to see. While most nontarget vertebrates could be seen, an observer's deterrent powers would be limited if a protected animal (e.g., a bald eagle) suddenly appeared at the carcass and picked up a treated meat cube. It is highly doubtful that an observer would notice everything that happens at the carcass, particularly if the bait exposure period were for many hours and there was no relief. About the most that could really be expected from having an observer 1/4-1/2 mile away would be to keep nontarget exposures from happening very often. It might be more efficient to shoot corvids than to pay a people to observe bait draw stations all day and to try to scare away nontarget birds.

I found some § 24(c) products with directions for preparing meat baits (ID-780011, OR-780014, and WA-860011). These products have mixing directions similar to those proposed for 56228-10, but baiting directions permit up to 150 baits per site and have no requirement for continuous on-site observation.

A § 3 registration for this use pattern would greatly expand the potential for nontarget exposure resulting from this use pattern. I am not aware that the hazards associated with use of Starlicide meat baits have been monitored for any of the § 24(c) meat-bait products.

10. Addition of claims for control of BLACKBIRDS, CROWS, AND STARLINGS" for "REDUCING HEALTH, NUISANCE, OR OTHER ECONOMIC PROBLEMS". For this use, 45 g (1.6 oz) of concentrate would be mixed with 600 ml (1.3 pts) "warm potable water" and then poured over 4.5 kg (10 lbs) of

" . . . desired bait material such as oat groats, cracked or whole corn, wheat, or pig starter pellets."

This is supposed to give a 1.0% Starlicide bait which would then be diluted at a rate of one unit of treated bait to 5-10 units of placebo. This bait also would be

" . . . thinly scattered over dry or frozen areas frequented by target birds and where bait application poses a minimum hazard to non-target animals and humans."

Due to the "HEALTH" claim, efficacy data are needed to support this proposed label change. It would not surprise me if APHIS responds to this news by deleting the word "HEALTH". As APHIS must also define the sites for this use pattern, deleting "HEALTH" might not get rid of the need for efficacy data. If the sites proposed include sites such as buildings, urban roosts, etc., the "public health" nature of the claim would remain. The most "sellable" justification for controlling birds in such areas is to reduce threats to public health.

As with the other "grain-type" bait uses, application rates must be defined for this use.

11. Addition of claims for control of "PIGEONS" for "CONTROL IN AND AROUND STRUCTURES". For this use 28 g (1 oz) of concentrate would be mixed with 340 ml (12 oz) "warmed potable water" and poured over "baits such as hen scratch, cracked or whole corn, or pig started pellets". This process is claimed to give a 0.36% Starlicide bait which would then be diluted at a rate of one unit of treated bait to 5-10 units of placebo. This bait would be applied according to the following directions

"Place in feeders or scatter thinly and uniformly on window ledges, steel girders, or other bait sites that are closed to the public, but are frequented by pigeons."

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This is clearly a "public health" use pattern for which efficacy data would be required. Note that these application directions also fail to indicate the amount of bait to be used per unit area.

The proposed label amendments cannot be accepted at this time. The proposed new use patterns, or uses very similar to them, are covered by § 24(c) labels including those mentioned above plus IN-840005 and a host of California county labels issued by the California Department of Food and Agriculture (CDFA) beginning in 1976. However, the degree of Federal regulatory control over § 24(c) labels is limited by several logistical barriers including constraints institutionalized in FIFRA, the lack of quality review in many states, the procedural difficulties that exist in OPP associated with rejection of § 24(c) labels, and the unwillingness of some states to pass along suggested label changes. Many § 24(c) registrations were "pocket accepted" when the Agency failed even to circulate them for review within the prescribed 90 day period.¹ This problem was most acute before the responsibility for handling § 24(c) products was assigned to the PM Teams. Most products which were not circulated for review in a timely fashion (if at all) were submitted in the 1970s and early 1980s. That time period includes the dates of issue of many of the § 24(c) registrations which have set the "precedents" for the uses which APHIS seeks to add to the label of 56228-10.

Few § 24(c) registrations are supported by anything close to the complement of data needed for a § 3 registration for similar use patterns. This fact, plus the logistical barriers mentioned above, has given rise to the Insecticide-Rodenticide Branch's disparaging nickname for the § 24(c) registration process: "Special Local Loophole".

While it is laudable of APHIS to pursue § 3 registrations for uses now covered under § 24(c) labels, EPA cannot permit this to happen without addressing the incremental risks and new data requirements that would result from expansion of the label for 56228-10. In this context, it is noteworthy that the U.S. Fish and Wildlife Service (USDI) office in Fort Worth, TX, wrote a lengthy letter to the Texas Department of Agriculture on the subject of expanded uses of Starlicide under a 24(c) application from APHIS. Although the specific uses under discussion were not made clear in USDI's letter (dated 11/14/88), the comments and recommendations would apply to most Starlicide label expansions. The current submission for 56228-10 must be routed to EFED for review.

¹ A significant result of such lack of review at the federal level were the "pocket acceptances", beginning in 1976, of many Starlicide § 24(c) registrations whose labels state that the products are "GENERAL CLASSIFICATION" pesticides. These registrations were issued by CDFA to county agricultural authorities within the State. § 3 registrations for Starlicide and § 24(c) registrations in other states are "RESTRICTED USE PESTICIDES". "Restricted" classification is based both on the hazards of the chemical to nontarget animals (especially birds) and on the need for use of the material to be limited to persons who have training in the use of pesticides for bird control, who are familiar with the relevant statutes (FIFRA, Migratory Bird Treaty Act, Endangered Species Act), and who "know their birds" well enough to distinguish target from nontarget species.

202.0 CONCLUSIONS

The proposed changes to the registration and label of this product cannot be accepted at this time. The items below identify the Agency's major concerns. Not all possible label adjustments will be addressed at this time as you may choose to delete or greatly modify much of the currently proposed text as a result of our comments in these major areas.

1. Your proposed revised label claims that this product is 97.0% 3-Chloro-p-toluidine hydrochloride while the current label claims that the product is 98.0% active ingredient. Explain this discrepancy and provide an accurate Confidential Statement of Formula (CSF) for this product.
2. The proposed changes to the use directions for this product would incorporate many uses now permitted only in limited numbers of localities under "Special Local Needs" (§ 24[c]) registrations. The § 24(c) uses which you seek to add to your Federal (§ 3) registration for 56228-10 have not been critically evaluated for incremental risks and are not now supported by full complements of wildlife safety and, where required, efficacy data.
3. Submit efficacy data to support all "public health" use patterns, including all uses to control feral pigeons (European rock dove, Columba livia) and claims for abatement of problems associated with "blackbirds", crows and starlings in and around buildings or communities.
4. The label must specify the sites where this product may be used for each area. The proposed revised label for 56228-10 approaches adequate specification of sites only for the feedlot uses. Site lists must define sites, or site categories, where the product may be used and must be "bounded" in the sense that potential users and enforcement officials can understand clearly where the product may and where it may not be used.
5. List of suitable bait materials must also be circumscribed. The proposed language that would permit baits to be used in feedlots to be made from "poultry pellets, grains . . . , or is other applicable bird food items" too open-ended because the category "other applicable bird food items" could include anything that any type of bird might eat, including items that would be more readily accepted by nontarget species than by target birds.
6. The direction for feedlot applications to adjust the amount of Starlicide to be used in very large or very small baits so that one bait is lethal is also far too open-ended. The label provides no guidance regarding how much toxicant is needed per bait partical for to be lethal to each of the target species claimed. However, once such an amount of toxicant were added per bait, the bait would become "lethal". Adding more toxicant to the mixture would result in each bait still being "lethal". Therefore, this direction has no upper limit. The label could provide target ranges of mg product per bait (or some other unit per pound of bait) that would

be appropriate for very large baits and another such range that would be appropriate for very small baits. Alternatively, the label could prohibit use as carriers, "bird" foods that have particle sizes that are too large or too small. A statement such as

"Do not mix this product with very large bait materials (less than 2500 particles/lb) or very small bait materials (more than 25,000 particles/lb)."

would not requiring users to figure out, for example, how much bait per particle it takes to kill a starling, and could aid them in selecting suitable bait materials. However, the "particles/lb" approach might be impractical, particularly for small baits, as it would require users to weigh accurate amounts of candidate carriers and to count numbers of particles in fixed-weight samples of each. Many potential users might prefer to skip this chore and "eyeball it" with regard to appropriate bait size, a procedure that could lead to unacceptable errors. For larger carriers, you probably could give an appropriate upper limit on particle dimensions (or volumes). For small materials, you might do better with a statement limiting carriers to materials that are as large as or larger than a grain of rice (or whatever example gives an appropriate lower size limit).

5. To avoid confusions with other types of cattle and other types of dairy animals, change "APPLICATION IN CATTLE FEEDLOTS" to "APPLICATION IN BEEF CATTLE FEEDLOTS" and "APPLICATION IN POULTRY, SWINE, AND DAIRY FEEDLOTS" to "APPLICATION IN POULTRY, SWINE, AND DAIRY CATTLE FEEDLOTS".
6. Directions for applying baits to be made from materials other than eggs or meat cubes indicate that bait should be thinly scattered over areas. Such instructions tell users how to put the bait out but do not indicate how much bait to apply per unit area. As one person's "thin" may be another's "heavy", add to the baiting directions appropriate limits (ranges) to the amount of bait to be applied per unit area (of convenience or of common understanding).
7. The egg and meat baits could pose significant hazards to nontarget species if used extensively and/or irresponsibly. These baits are likely to be attractive to some species with relatively low numbers and reproductive potentials.

Although the stipulation that meat baits must be observed continuously while in the field might have some positive effects in detecting the arrival of certain nontarget species and hastening their departures, there are logistical limitations to the method proposed. Even with a spotting scope, 1/4 - 1/2 mile is too great a distance to provide an optimum combination of visual acuity, separation of bait from humans, and feasibility of scaring off nontarget species. An observer would be likely to become bored or distracted some of the time and, therefore, to fail to intervene quickly. About the most that could be hoped for from this approach is that it would scare off most nontarget species of concern most of the time.

So that the Agency may better assess the usefulness of egg and meat baits and the appropriateness of the proposed mixing and application directions, submit any available reports and tables of results of experimental and operational use of these baits under current § 24(c) registrations.

NOTE TO PM: Proposed revisions to the label would expand the use of this material greatly. Therefore, this submission must be routed to EFED and HED for incremental risk assessment and determination of additional data needs.

Both the current label and the proposed label bear mixing and application directions PLUS the statement "FOR REFORMULATING PURPOSES ONLY". Isn't the latter statement only to be used on "manufacturing use products", which have no mixing or use directions and no "classification"?

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
December 31, 1988