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C. Edward Knittle

USDA/APHIS, Denver Wildlife Research Center

Edward W. Schaffer Jr.

USDA/APHIS, Denver Wildlife Research Center

Kathleen A. Fagerstone

USDA/APHIS, Denver Wildlife Research Center

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STATUS OF COMPOUND DRC-1339 REGISTRATIONS

C. EDWARD KNITTLE, EDWARD W. SCHAFER, JR., AND KATHLEEN A. FAGERSTONE, USDA/APHIS, Denver Wildlife Research Center, Denver, Colorado 80225.

ABSTRACT: Compound DRC-1339 is a restricted-use, slow-acting avicide that is registered to control a number of avian pests. It is unique because of its selective high toxicity to most pest birds, low-to-moderate toxicity to most mammals and predatory birds, and lack of known secondary hazards when used on baits. The most widely known product containing DRC-1339 is Purina Mills' Starlicide Complete[®], a pelleted bait used to control blackbirds and starlings in feedlots. Other DRC-1339 registrations are held by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS), for the use of nonpelletized baits at feedlots and for the control of gulls in or near their nesting colonies. Over 20 State Special Local Need 24(c) registrations have also been issued to APHIS for special DRC-1339 uses. To consolidate these registrations, APHIS has submitted data to amend its feedlot registration for blackbirds and starlings, and applied for three registrations for control of 1) raven and crow depredations on livestock and for wildlife protection, 2) pigeons in and around structures, and 3) blackbirds, starlings, and crows at pre-roosting staging areas. Because most of the submitted data were collected in the 1960s and 1970s, none of it was produced under the Environmental Protection Agency's (EPA) Good Laboratory Practices (GLP) regulations; therefore, new data will probably be needed to support these registrations. Future data needs and procedures for collecting valid information for DRC-1339 are suggested.

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INTRODUCTION AND HISTORY

Compound DRC-1339 is a hydrochloride salt of 3-chloro-4-methylbenzenamine (CPT), which has been developed and registered for use as an avicide based on its differential toxicity between bird and mammal species (Schafer 1981). This compound is unique because of its high toxicity to most pest birds, but low-to-moderate toxicity to most predatory birds and almost all mammalian-species (DeCino et al. 1966, Schafer 1981).

DRC-1339 98% Concentrate (EPA Reg. No. 602-134) and Starlicide Complete[®] (EPA Reg. No. 602-136), a DRC-1339-treated pelleted grain product used to control blackbirds and starlings in feedlots, were first registered in 1967 by Ralston-Purina, and are now held by Purina Mills, Inc., St. Louis, Missouri. At about the same time, the U.S. Fish and Wildlife Service obtained two EPA registrations for using DRC-1339 98% Concentrate to control pest birds. The first was for treating grain baits (other than Starlicide pellets) to use in feedlots to control blackbirds and starlings (EPA Reg. No. 6704-56); the second was for bread baits to control two problem gull species in and near their nesting colonies along the east coast of the United States (EPA Reg. No. 6704-77). These registrations were transferred to U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Damage Control Program (USDA/APHIS/ADC), in January 1986, and now have EPA registration numbers of 56228-10 and 56228-17, respectively. (DRC-1339 and Starlicide are commonly, but inaccurately, used interchangeably. DRC-1339 is actually the active ingredient in Starlicide).

The primary mode of action of DRC-1339, following its ingestion by susceptible bird species (oral LD50s of 1 to 20 mg/kg), is not well understood. It appears that DRC-1339 causes irreversible necrosis of the kidney and the affected bird is subsequently unable to excrete uric acid. DRC-1339 itself is rapidly metabolized, excreted, and is apparently not accumulated in body tissues. Death usually occurs from uremia 1 to 3 days after most of the DRC-1339 has left the body. Because of this, dead or dying birds intoxicated by

DRC-1339 pose little risk of secondary poisoning to nontarget scavengers (DeCino et al. 1966, Palmore 1978, Cunningham et al. 1979). In nonsensitive bird and mammal species (oral LD50s of 250 to 1000 mg/kg), central nervous system depression and the attendant cardiac or pulmonary arrest is the cause of death (Felsenstein et al. 1974).

DRC-1339 has proven to be efficacious and reasonably safe in its uses; however, primary nontarget hazards at or near baited sites should be of utmost concern to users. A number of studies on bait consumption by primary nontarget species (birds that may feed directly on DRC-1339-treated baits on bait sites) has indicated that if the proper use directions are followed, the only major risks from exposure to treated baits are to target species (Besser et al. 1967, Ford 1967, Royall et al. 1967, Simpson 1972, Kreps 1974). Numerous instances of gallinaceous birds, sparrows, and other nontarget species feeding on bait sites have been documented with no or few reported mortalities even following extensive searches for affected nontargets. These authors attribute this selectivity to the choice of chemical, type of bait materials used, dilution of baits with untreated material to minimize overexposure, and placement of bait. Therefore, it is important that observations of potential bait sites and bait consumption should be conducted prior to most DRC-1339 bait applications to determine the abundance and kinds of nontargets present. Treatment should be withheld if a significant hazard exists.

Secondary hazards (those resulting from the consumption of birds killed by ingesting DRC-1339 baits) have been assessed through numerous laboratory and field studies. Instances of dogs, swine, foxes, avian predators and scavengers, and cats preying or scavenging on DRC-1339-killed birds have not resulted in any documented secondary poisoning in the field (Besser et al. 1967, Ford 1967, Royall et al. 1967). Laboratory studies by DeCino et al. (1966) and Lefebvre et al. (1979), have verified the relative lack of secondary hazards. Kreps (1974), however, documented instances of possible secondary poisoning of crows that had fed on the gut contents of pigeons killed with Starlicide baits.

It should be noted that secondary hazards may exist for a limited number of nontarget species such as cats and owls which are as sensitive to DRC-1339 as are most target species (Schafer 1984).

CURRENT STATUS

Reregistration

In October 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to require the reregistration of all pesticide active ingredients registered before 1984 within a 9-year period. During 1989, the EPA published in the Federal Register, four lists of compounds for which reregistration will be required. List A consisted of pesticides that had Registration Standards formerly issued, List B contained pesticides that are primarily used on food crops (DRC-1339 was on List B even though it is not registered for food uses), List C contained pesticides registered for nonfood uses that were of environmental or toxicological concern, and List D contained pesticides that were of little environmental or toxicological concern. This reregistration effort applies primarily to the technical product (active ingredient).

Five chronological phases were established for lists B, C, and D, establishing dates and requirements for interaction between the registrant and the EPA. Phase 1 was the publication of the list of pesticides. Phase 2 required registrants to delineate the requirements they felt were necessary to reregister a pesticide and a commitment for how data were to be provided. For DRC-1339, the Phase 2 response date was August 24, 1989, and Purina Mills committed to provide data for its indoor nonfood uses only, although some of the data will come from APHIS. The due date for most of these data is August 24, 1990. On January 19, 1990, APHIS agreed to provide terrestrial nonfood use data to support its registrations. Most of these data are due by January 19, 1991. Phase 3 provides for collecting, reformatting, and submitting previously generated data to support the reregistration effort. APHIS and Purina Mills do not expect to be able to use any previously generated data; however, the due date for Phase 3 is May 24, 1990. Phase 4 allows for an initial EPA review of all submitted data and requests by EPA for additional data through Data Call-Ins. Phase 5 is the review of final data submissions and a decision to reregister or cancel. Fiscal year 1990 costs for Purina Mills and APHIS to provide the data to the EPA is \$175,000, exclusive of basic operating costs.

A confounding factor for all reregistration activities is the lack of a validated analytical method for the technical material, assays for water and prepared baits, and trace methods to determine residues in soil, vegetation, and tissue. The DWRC and Purina Mills have committed their resources to developing these analytical methods.

Registrations

Presently there are four Section 3 registrations for the use of DRC-1339. As stated earlier, Purina Mills holds the registrations for DRC-1339 Technical and for Starlicide Complete[®]. APHIS holds two registrations for end-use products—one to control gulls, and one for baits, other than pellets, to control blackbirds and starlings in feedlots. The APHIS registration for controlling herring gulls (Larus argentatus) and great black-backed gulls (L. marinus) in their breeding colonies was amended in February 1989 to 1) include the ring-billed gull (Larus delawarensis), 2) specify hand broadcast or placement of baits, and 3) expand its use

to all coastal areas of the U.S. The APHIS registration for controlling blackbirds and starlings at feedlots was amended in September 1989 to specify the types and size of baits that may be used.

Because of the effectiveness and safety of DRC-1339 for controlling pest birds, and the limited uses addressed in the current Section 3 registrations, there has been a proliferation of state Special Local Need registrations, also known as 24(c) registrations. Over 20 24(c)s have been issued by various state agencies for terrestrial nonfood uses by APHIS personnel or persons under their direct supervision. These 24(c)s deal with bird problems such as: 1) pigeons, starlings, and crows in and around structures; 2) ravens, crows, and magpies killing or wounding newborn livestock, and destroying the eggs or killing young of nesting waterfowl and endangered species; 3) the use of certain kinds of baits that are not addressed in the current Section 3 label to control blackbirds and starlings in animal feedlots; and 4) baiting pre-roosting staging areas to control large populations of crows, starlings, and blackbirds which cause health, economic, or nuisance problems, and crop damage.

APHIS is attempting to consolidate these 24(c) registrations into a manageable package. In October 1989, pertinent laboratory and field data were submitted to the EPA to amend the feedlot label to: 1) include the word "FEEDLOTS" in the title, 2) specify and clarify sites where baits may be used, 3) include its use in dairy lots, 4) specify suitable bait materials that may be used, 5) specify baiting and dilution rates, and 6) add tri-colored blackbirds (Agelaius tricolor) and yellow-headed blackbirds (Xanthocephalus xanthocephalus) as target species. In October and November 1989, and January 1990, field data were submitted to the EPA to support three new Section 3 registration applications for DRC-1339 end-use products. The first submission covered the use of DRC-1339-treated egg and meat-cube baits for control of common and white-necked ravens and common crows where depredations are occurring to newborn livestock, to the eggs of nesting waterfowl, and to protect federally designated threatened or endangered species. The second submission was for control of feral pigeons causing health, nuisance, or other economic problems in and around structures or in noncrop areas. The third submission dealt with the control of six of the most common blackbird species, starlings, and common crows involved in crop damage and other economic problems, by baiting their pre-roosting, noncrop staging areas. APHIS has asked that these registrations be granted conditionally and contingent upon APHIS's submission of supportive data previously requested by the EPA and included under APHIS reregistration efforts. The EPA is reviewing these data to determine their validity and usefulness.

APHIS may also request an amended gull registration by expanding DRC-1339 use to airports and landfills, and to expand its use to inland problem gull nesting areas.

DISCUSSION

Because most of the existing data on DRC-1339 were collected in 1960s and 1970s, nothing that has been submitted to the EPA was collected under GLP requirements (CFR 40 Part 160) which went into effect in 1983 and 1989. In addition to the data already committed to by APHIS for reregistration, it is possible that the EPA will request additional data on field efficacy, nontarget hazards, and residues in soil, vegetation, and tissues.

Users of DRC-1339 may need to collect data for residues, field efficacy, and nontarget hazards during experimental and operational uses. These data should be collected consistently and in considerable detail. Baiting operations should also be well planned in advance. For field efficacy data, the determination of target bird mortality following DRC-1339 control operations is the most difficult parameter to estimate. Because DRC-1339 is a slow-acting toxicant (mortality may not occur for 24 to 72 hours post-ingestion), sick and dead target birds can be found at considerable distances from bait sites. There are numerous methods of making mortality estimates, but each has its weaknesses. Included among these methods are: 1) mathematical extrapolations from bait consumption; 2) the use of toxic markers (fast-acting toxic baits used in high dilution rates, e.g., 1:250, where birds consuming such baits would die on-site); 3) radio-telemetry and leg or patagial tags which require that birds be handled and instrumented or tagged before treatment; 4) fluorescent markers on treated baits that may be retained and identified in the crop, gizzard, or gullet; 5) transect searches of roosting habitat and peripheral habitat near bait sites; and 6) flightline counts. The latter is probably the weakest method because of variations in counts among observers, inconsistency within an individual observer, lack of access to good viewing areas to make counts, and other confounding factors such as roost interchange among bird populations and the possible onset of migration. Habitat searches also pose significant problems because of the inconspicuousness of small target and nontarget animals in thick cover, and because scavengers remove many carcasses.

Nontarget data collection should include pre- and post-treatment identification and censuses of nontarget animals, particularly species at risk near bait sites. Consideration should be given to searching selected areas on and adjacent to bait sites, and in and around loafing and cover habitat within at least a 1-mile radius of baited areas where animals may congregate if affected by DRC-1339-treated baits. Most of the techniques mentioned in the previous paragraph can also be used for nontargets. Scavenging animals, both wild and domestic, should be included in these searches because of the potential for their consumption of dead birds, although the risk of secondary intoxication appears to be low.

Data collected from experimental and operational baiting programs should include size of area baited, type of substrate where bait is applied, kind and quantity of treated and diluted bait used, dilution rate, specific mixing procedures and any variations, estimates on the amount of consumption and how they are determined, and estimates of target bird and nontarget animal mortality and how they are determined.

Effective residue sampling schemes are difficult to design to acquire analytical data that meets GLP requirements. Until validated analytical methods are developed, collecting residue samples does not serve a useful purpose and should not be considered in planned DRC-1339 baiting operations.

In summary, there are considerable data available on the uses and effects of DRC-1339 as a pest bird management tool, but most of these cannot be used to support the current registration/reregistration process. Because of GLP requirements, observations and data collected from future experimental and operational programs will need to be concise, well documented, and consistently collected by users. These efforts will also enhance the quantity and quality of data submitted to the EPA for registration/reregistration purposes.

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