United States Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7501C)

Pesticide Fact Sheet

Name of Chemical: **Nicarbazin**
Reason for Issuance: **Conditional Registration**
Date Issued: **November 2005**

1. DESCRIPTION OF CHEMICAL

Chemical Name:	Nicarbazin ($C_{19}H_{18}N_6O_6$), a complex of two compounds, 4,4'-dinitrocarbanilide (DNC) and 4,6-dimethyl-2-pyrimidinol (HDP)
Common Name:	Nicarbazin
EPA PC Code:	085712
Chemical Abstracts Service (CAS) Number:	330-95-0
Year of Initial Registration:	2005
Pesticide Type:	Egg Hatch Reduction in Resident Canada Geese (*Branta canadensis*)
U.S. Producer:	Innolytics, LLC.
Products:	OvoControl-G (EPA Reg. No. 80224-3; 0.25% bait) Nicarbazin 30% Granulated premix (EPA Reg. No. 80224-2)
Mode of Action:	Nicarbazin interferes with the formation of the vitelline membrane, separating the egg yolk and egg white. The exact mode of action is unknown, although it is thought nicarbazin interferes with cholesterol metabolism in the formation of the membrane. Eggs from treated birds are described as mottled in appearance, reflecting a porous vitelline membrane. The effect on hatchability is a function of time and dose and the effect is reversible.

2. USE PATTERNS AND FORMULATIONS

Application Sites: The use of OvoControl G is limited to sites in urban areas such as office parks, recreational parks, golf courses, schools, hospitals, restaurants, and commercial and industrial sites. Urban is defined as a municipality and its adjacent areas with a population of 50,000 or more. It may also be used at land airports holding FAA certifications under 14 Code of Federal Regulations 139.101 and having a wildlife hazard management plan under 14 Code of Federal Regulations 139.337.

Types and Methods of Application: Bait may be applied with bait pans, broadcast directly on the ground by hand or with mechanical feeders (up to a 20 ft radius). Mechanical feeders must be attended and triggered by the applicator daily, with the exception that unattended mechanical feeders may be used at land airports which have FAA certification under 14 CFR 139.101 and a wildlife hazard management plan under 14 CFR 139.337.

Application Rate: Application rate is 50 grams per goose per day. Beginning three weeks prior to first anticipated egg-laying, a small amount of bait is offered (7 grams per goose), and the amount is increased each day, as geese become acclimated to the bait. Baiting continues throughout the nesting period, which lasts 8 to 10 weeks.

3. SCIENCE FINDINGS

Nicarbazin product chemistry, toxicology, ecological effects and environmental fate data necessary to support the registration and use pattern are discussed below.

Product Chemistry:

Nicarbazin ($C_{19}H_{18}N_6O_6$) is a complex of two compounds, 4,4'-dinitrocarbanilide (DNC, 302.25 molecular weight) and 4,6-dimethyl-2-pyrimidinol (HDP, 124.14 molecular weight). DNC is considered to be the active component, while HDP aids in absorption (Table 1).

Table 1: Nicarbazin - Product Chemistry Summary

Physical Property	Nicarbazin Technical Grade	OvoControl-G
CAS Reg No.	330-95-0	330-95-0
Molecular weight	426.38	NA
Color	light yellow	yellowish-tan
Physical State	fine powder	solid, round to oblong, semi-soft kibbles
Melting point, °C	265-275 ^{0}C (with decomposition)	NA

Physical Property	Nicarbazin Technical Grade	OvoControl-G
Odor	characteristic	None to slight grain odor
Stability to normal and elevated temperatures, metals and metal ions	nicarbazin is inherently stable under extreme conditions	NA
UV/VIS absorption max, nm	nicarbazin produces a band of absorption in the range of 300-360 mm	NA
Aqueous solubility, ppm	slightly soluble in dimetylsulphoxide (DMSO) and dimethylformamide (DMF); insoluble in water and methanol, however it decomposes slowly when mixed with them	NA
pH	5-7 (1% suspension in water)	NA
Vapor Pressure	expected to be zero at ambient temperatures (based on high melting point)	NA
Flammability/explodability	NA	neither flammable or explodable based on formulation ingredients
density	0.5 g/ml	25-33 lbs/bushel
storage stability	NA	must be submitted upon completion for both products
corrosion characteristics	NA	must be submitted upon completion for both products

Toxicology:

Based on acute toxicity data, OvoControl-G and Nicarbazin 30% Granulated Premix are Toxicity Category IV for oral, dermal, inhalation and primary dermal sensitization and Toxicity category III for primary eye irritation. See toxicity endpoints in Table 2 below. The following precautionary label language is required:

CAUTION: Causes moderate eye irritation. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

Nicarbazin has been a Food and Drug Administration (FDA) approved veterinary drug for use as an anticoccidial agent in broiler chickens since 1955. FDA has established a tolerance of 4 parts per million for nicarbazin residues in uncooked chicken muscle, skin, liver, and kidney (21 Code of Federal Regulations 556.445). FDA has established a feed

additive tolerance of 125 ppm in chickens (21 Code of Federal Regulations 558.366) for use of nicarbazin in feed to prevent outbreaks of faecal and intestinal coccidiosis.

To address toxicity data requirements, EPA relied on the Joint Food and Agriculture Organization/World Health Organization (WHO) Expert Committee on Food Additives 1988 nicarbazin summary report. Based on the WHO data summary, additional toxicological testing on this chemical for use to reduce egg hatchability in resident Canada geese is not required. The toxicology information summarized in the report is listed in Table 2.

Table 2: Nicarbazin Toxicity Profile

Study Type	Results
Acute Inhalation Toxicity - rat	LC_{50} > 0.147 mg/L
Acute Dermal Toxicity - rat	LD_{50} > 5,000 mg/kg
Primary Eye Irritation - rabbit	moderate irritant (category III)
Primary Dermal Irritation - rabbit	not an irritant
Dermal Sensitization - guinea pig	not a contact sensitizer
Chronic Feeding, 2 year - dog	NOEL 240 mg/kg/day based on slight bile-duct effect
Chronic Feeding, 2 year - rat	NOEL 400 mg/kg/day based on no effects at highest dose tested
Reproductive Toxicity - rat	NOEL 400 mg/kg/day based on no effects at highest dose tested
Developmental Toxicity - rat	NOEL 200 mg/kg/day for maternal and fetal toxicity
Mutagenicity	Not mutagenic
Carcinogenicity	Not carcinogenic

Metabolism studies were reviewed by the Joint Food and Agriculture Organization/World Health Organization (WHO) Expert Committee on Food Additives. Residue depletion studies in chickens showed rapid elimination from the birds at five to seven days after withdrawal.

The potential for human exposure and mammals (e.g. dogs) is anticipated to be low from the use of nicarbazin fed to resident Canada geese. The WHO studies indicate that non-target mammals (including humans) would have to consume prohibitively large amounts of the product to produce any toxic effects. Based on the rat acute oral LD_{50} toxicology data, an acute single ingestion for a child (15kg or 33lbs) would have to exceed 60 kilograms (132 pounds) of bait and for a dog (10kg or 23lb.) 40kg (88lbs) of bait to cause lethal effects in 50% of the population.

On a chronic basis, using the results of a 2 year chronic study in rats (NOEL = 400 mg/kg bw/day, based on HDT no treatment related toxicity), the no-effect quantities of bait on a daily consumption basis are 2.4 kg (5.2 lbs) and 1.6 kg (3.5 lbs) for the rest of their lives. Again, the consumption of bait on a daily basis is not realistic and consumption values are not physically possible.

Label restrictions markedly reduce inadvertent exposure to children and pets because uneaten bait is not expected and any leftover bait must be removed. Also, once geese are acclimated to the bait, consumption typically takes place quickly and completely. By the end of the initial 21 day period, the daily dose (based on flock size) must be entirely consumed within 2 hours of application or treatment must cease.

Ecological Effects:

Terrestrial Animal Routes of Exposure:

Feeding on nicarbazin bait placed in terrestrial environments is expected to be a route of primary exposure to non-target species. Exposure via this route is expected to occur primarily to birds and mammals, although it is possible for other terrestrial animals such as reptiles and terrestrial amphibians to be exposed if they consume the bait. Terrestrial species may also ingest nicarbazin and DNC by drinking contaminated water (e.g., rainwater in bait pans, puddled water on the ground, pond water). Bait deposited in water bodies may also be directly consumed by terrestrial species that feed in water (e.g., non-target waterfowl).

Secondary exposure is also possible, but the extent to which this may occur is unknown. Since it is expected to remain in soil, nicarbazin and DNC released into the terrestrial environment from bait or feces will be available to soil macroinvertebrates for uptake or consumption. Terrestrial animals that feed on soil macoinvertebrates may receive exposure via this pathway. Secondary exposure may also occur to predators and scavengers consuming tissues and/or eggs of animals that have ingested bait. This exposure may raise the potential for risk to species that consume eggs of animals that have consumed the bait.

Terrestrial Animal Exposure Assumptions:

For the screening level assessment, very conservative assumptions were made. It was assumed that 2500 ppm nicarbazin bait would be available for a nontarget animal to consume on a 24 hour basis, and up to 13 weeks as the sole food source.

Terrestrial Animal Toxicity and Risk:

Nicarbazin is characterized as practically non-toxic to the Northern bobwhite and slightly

toxic to the mallard on an acute/subacute basis (Table 3)

Table 3. Nicarbazin Acute Avian Toxicity to Birds

Test species	Percent Nicarbazin	Toxicity value
Mallard	>99 (both moieties)	LC50 = 3680 ppm[a]
Northern bobwhite		LC50 >5720 ppm[b]
		LD50 >2250 mg/kg bw

[a] mortality was 80% at 5720 ppm ai, 10% at 1968 ppm nicarbazin, and 0% at the control and ≤802 ppm ai test levels; treatment-related signs of toxicity were evident by day 2

[b] single mortalities (10%) were observed at the 1968 and 5720 ppm nicarbazin levels and may have been caused by exposure; effects were first observed between Days 5 and 6 and included wing droop, ruffled appearance, and/or foot lesions (from picking)

The acute risk quotient (RQ = 0.7) for acute effects to birds slightly exceeds the acute high risk level of concern (LOC = 0.5) based on the conservative, screening level risk assessment. The risk estimate assumes exposure.

The likelihood of this exposure occurring is minimized by label restrictions. Several label restrictions are imposed which will ensure a markedly reduced exposure to non-target birds, reptiles and mammals. (See Labeling Restrictions).

Terrestrial Animal Chronic Toxicity and Risk:

Although there are no guideline reproduction studies available for nicarbazin, several laboratory and field studies have shown that this chemical causes reproductive effects in several bird species. These data clearly demonstrate that low concentrations of nicarbazin fed in the diet will adversely impact avian reproduction (which is to be expected given its mode of action). For example, significantly reduced egg production and hatchability of fertile eggs was reported at a dietary concentration of 25 ppm when fed to chickens for only four days, and eggshell pigmentation was reduced after only two days of feeding. These effects were even more pronounced at dietary concentrations of 50 and 100 ppm. In several studies, negative impacts on egg hatchability in chickens fed 20 ppm nicarbazin in the diet for only 9 to 10 days have been reported in several studies. In another study, mortality occurred in chickens fed 1600 and 2500 ppm nicarbazin in food ration, and depressed growth and reduced egg hatchability was seen at lower concentrations.

Based on worst-case findings of the published literature studies, a no observable adverse effect concentration (NOAEC) of 10 ppm is presumed due to adverse affects on egg hatching at 20 ppm.

Based on the reproductive NOAEC of 20 ppm, the avian chronic effects RQ is $\geq$ 250. The concentration of nicarbazin in the bait (2500 ppm) exceeds the level shown to cause adverse reproductive effects in chickens, quail, and mallards after exposures of a few days to two weeks in the laboratory.

The chronic risk estimate is very conservative, as it assumes that the bait would be available for nontarget animals to consume on a 24 hour basis, up to 13 weeks as the sole food source.

The likelihood of this exposure is low, and is further minimized by label restrictions. Several label restrictions are imposed which will ensure a markedly reduced exposure to non-target birds, reptiles and mammals. (See Labeling Restrictions).

Aquatic Animal Routes of Exposure:

Nicarbazin and DNC deposited on land may reach aquatic environments and standing water via runoff. Unconsumed bait deposited on the ground or in water will likely undergo physical breakdown, releasing nicarbazin and/or DNC into the water column in both water bodies and standing water. DNC will be deposited in the aquatic environment through defecation by treated Canada geese. In addition, aquatic species may ingest nicarbazin and DNC by drinking contaminated water, or may be exposed via uptake through gills/integument. Bait deposited in water bodies may also be directly consumed by aquatic species (fish, invertebrates, and aquatic phase amphibians). Secondary exposure may occur to predators and scavengers consuming tissues and/or eggs of animals that have ingested bait.

Aquatic Animal Exposure Assumptions:

Based on conservative aquatic modeling (Table 4), predictions are that DNC will accumulate over time in the pond. In the water column, yearly average DNC concentrations rise to between 2 and 4 ppb in a FL turf and PA turf scenario. Benthic pore water concentrations are similar. Concentrations in benthic sediment show approximately the same pattern, rising to about 0.20 to 0.25 ppm. Concentrations from 70 daily applications (rather than 26, as modeled) can be expected to be proportionately (3 times) higher.

Table 4: Input Parameters for Aquatic Exposure Modeling for Dinitrocarbanilide (DNC)

Input Parameter	Value	Reference
Aqueous Solubility, ppb	520	10x value at pH7; to ensure that PRZM-EXAMS runs correctly.
Organic Carbon Partitioning Coefficient, mL/g	1650	estimated by EPISuite
Chemical Application Method (CAM)	4	reflects granular application (soil applied, user-defined incorporation depth, uniform with depth)
Incorporation Depth, cm	1	assumed: must be > 0.0 for CAM = 4
Application Rate, kg/ha	0.0248 kg/ha (0.022 lb/acre)	Label: max. 200 ounces (12.5 lb) product/acre/day, adjusted for 0.25% nicarbazin content; 71% DNC content in nicarbazin
Application Efficiency, %	50	Assumes geese consume all bait expressed, and 50% of applied bait (DNC) is excreted in feces onto ground, of that a small percentage (approx. 5%) runs off into water.

Input Parameter	Value	Reference
Number of Applications, interval	26 at 1-day intervals; 70 implied by daily feeding for 10 weeks	26 is the maximum number allowed by pe4v01 graphical user interface for PRZM/EXAMS
Hydrolysis Half-life	stable	MRID 46445305
Soil Half-life, days	301	MRID 46416449
Water Half-life, days	602	2x soil value as per Input Parameter Guidance, if no data available; benthic half-life assumed to be the same

The modeling above is based on results of an acceptable hydrolysis study of the separate components DNC and HDP, and two supplemental field dissipation studies. The DNC portion degrades slowly in soil with half-life of approximately one year, and does not volatilize or leach through the soil. It may run-off with storm water, probably sorbed to soil particles. Once the nicarbazin complex is separated, it is likely that DNC and HDP will have different fate profiles, as HDP is far more water-soluble than DNC. It is highly hydophilic ($\log K_{ow}$ of -0.94). HDP absorbs visible light, and so may be photodegraded.

Aquatic Animal Toxicity and Risk:

Based on the results of these acute toxicity studies, nicarbazin is practically nontoxic to aquatic animals on an acute basis (Table 5). The acute risk quotient is not exceeded. Acute effects in fish and invertebrates are not expected based on submitted data. The main potential risk to aquatic animals is likely to be to sediment-dwelling organisms and also chronic exposure of aquatic organisms. There are no data to assess those potential risks.

Table 5: Nicarbazin - Acute Aquatic Toxicity

Test species	Percent Nicarbazin (moiety)	Toxicity
Rainbow trout	99.4 (HDP)	96-h LC_{50} >110 ppm
	98.0 (DNC)	96-h LC_{50} >69 ppb
Bluegill	99.4 (HDP)	96-h LC_{50} >122 ppm
	98.0 (DNC)	96-h LC_{50} >72 ppb
Water flea	99.4 HDP	48-h EC_{50} >107 ppm
	98.0 DNC	48-h EC_{50} >93 ppb

There is uncertainty as to the potential exposure to aquatic ecosystems due to runoff of bait

or fecal deposition.

The significance of any such potential impacts needs to be considered in the context of the ecological value of urban water bodies that presumably are associated with populations of resident geese that exceed the urban ecosystem's carrying capacity. Aquatic loading from goose defecation (untreated) probably represents much more of an ecological risk than would nicarbazin entering the aquatic environment. The environmental exposure from the use of nicarbazin to reduce egg hatchability will be small when compared to the poultry use. A label restriction "Do not apply within 20 feet of any body of water, including lakes, ponds or rivers." is required for this product

Endangered Species Assessment

The endangered species assessment is incomplete at this time. Given that the label instructions control to a great degree the availability of the product to nontarget species, the Agency believes risks to threatened and endangered (T&E) species are low.

In order to avoid and minimize potential impacts to Threatened and Endangered (T&E) species, it is a requirement that the permit applicant must contact the local United States Fish and Wildlife Service (USFWS) Ecological Services Office for assistance in determining the likelihood of effects to T&E species.

Landowners or wildlife management agencies must first contact the USFWS Migratory Bird Permit Office responsible for the region where the geese are located to ontain a federal permit before bait is dispensed. Information on any T&E species that occur in the area must be provided to the USFWS Migratory Bird Permit Office with the application. The permit applicant must also identify the Certified Applicator who will apply the bait.

Product Efficacy:

OvoControl-G is intended for use in reducing egg-hatchability in resident Canada geese. The applicator initiates baiting a minimum of 21 days prior to first nesting, which is in mid-February to early March depending on locality. During initial baiting, as geese become accustomed to the bait and delivery system, a small amount of bait is administered per goose (about 7 grams). The amount is increased each day until the rate of 50 gram per goose is attained. The amount of bait administered per site is based on visual observation of flock size. If the geese cannot be acclimated to the bait site, use is to be discontinued. Applicators should feed geese at daybreak in close proximity to where they feed Bait is administered throughout the entire nesting season, which lasts 8 to 10 weeks.

The application rate is 50 grams (2 oz) per goose per day, and is supported by numerous laboratory and small plot studies conducted by the National Wildlife Research Center (NWRC) of the Animal and Plant Health Inspection Service (APHIS). In order to be effective, female geese must feed on the bait consistently during the time the eggs are being formed. A 2004 field study conducted by the NWRC in the state of Oregon showed an

overall reduction in resident Canada geese egg-hatch of approximately 36% - 50% when compared to controls.

OvoControl-G is not intended to be used alone, but rather as part of an integrated pest management program for the control of resident Canada geese.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

In many urban and suburban areas and for reasons not fully understood, Canada geese populations have become resident - remaining year round. Geese have been classified a public health pest by EPA due to the potential spread of disease through feces, possible human injury from attacks, and threat to public safety from encounters with aircraft. Geese can also cause large amounts of property damage. Burgeoning populations of resident Canada geese have become a serious environmental and public health issue.

Typically, conflicts with Canada geese have been resolved through trapping and relocation, egg addling, aversive conditioning strategies (*e.g.*, dogs harassing birds), physical and natural barriers, and lethal controls. There is significant controversy on current Canada geese management, particularly the killing of adult and juvenile birds during molting. Animal welfare groups and often the public have questioned the rationale and justification for lethal controls. Other than several repellents/deterrents, EPA does not have any currently registered products for Canada geese control.

Nicarbazin provides a new tool for pest control operators and wildlife management personnel. It is not intended nor will it be effective as a sole means of controlling populations of resident Canada geese. When used with other control methods, nicarbazin will aid in long-term population control.

Nicarbazin has been approved for use in the poultry industry since 1955 and approximately 10 million kilograms of the active ingredient has been fed to 80 billion broiler chickens in the U.S. During 2003, broiler chickens in the U.S. consumed approximately 250,000 kilograms of nicarbazin. If 100,000 resident Canada geese are treated with 50g of 2500 ppm nicarbazin bait/goose/day for 10 weeks, the total amount of nicarbazin would be 350 kilograms annually. The environmental exposure from the use of nicarbazin to reduce egg hatchability will be small when compared to the poultry use.

The registration of nicarbazin has strong support from organizations such as the U.S. Department of Agriculture (APHIS/NWRC), the Birdstrike Committee (a volunteer organization directed by a steering committee consisting of 2-3 members from each of the Federal Aviation Administration, Department of Defense, USDA and aviation industry), and the Humane Society of the United States.

Based on the limited use pattern/exposure scenario, the submitted data are deemed adequate to support nicarbazin registration.

Avoiding nontarget exposure is the primary concern with use of OvoControl-G. Reduction in egg hatchability is the primary concern if nontarget birds are exposed to nicarbazin. On the basis of label requirements, it can be reasonably assumed that exposure and resultant risk to non-target and endangered species would be low. Labeling requirements include:

- restricted-use classification;
- applicator must obtain a permit for use from the USFWS prior to use;
- applicator must monitor site and keep daily written records of nontargets observed feeding on the bait;
- use is restricted to urban areas and approved airports. Urban is defined as a municipality with a population of 50,000 or more and its adjacent areas.
- unattended mechanical feeders may only be used at approved airports, the applicator must be present to trigger feeder on a daily basis;
- several label directions and restrictions designed to minimize nontarget exposure (see Labeling Requirements)
- bait cannot be applied within 20 feet of any body of water, including lakes, ponds or rivers.

Labeling Restrictions

To mitigate risk to nontarget animals, the following label requirements have been imposed:

- Restricted-use classification of OvoControl-G due to potential risk to nontarget species. OvoControl-G label requirements are:

  Restricted Use Pesticide (Due to Potential Risk to Nontarget Wildlife Species)
  For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

- Requiring a Migratory Bird Treaty Act permit and consultation with wildlife officials to determine if listed species occur in a proposed use area. Applicators must obtain a permit from the U.S. Fish and Wildlife Service prior to any applications. USFWS will evaluate the potential adverse impacts on the constituent elements of critical habitats prior to issuing a permit. OvoControl-G label requirements are:

  Federal Permit Requirement and Threatened or Endangered Species Considerations

  In order to avoid and minimize potential impacts to Threatened and Endangered (T&E) species, the permit applicant must contact the local USFWS Ecological Services Office (contact

information can be found at http://www.fws.gov/endangered) for assistance in determining the likelihood of effects to T&E species.

The federal Migratory Bird Treaty Act protects Canada geese. Landowners or wildlife management agencies seeking to control resident Canada geese using OvoControl G must contact the U.S. Fish and Wildlife Service (USFWS) Migratory Bird Permit Office responsible for the region where the geese are located for a federal permit before bait is dispensed. Permit application forms and contact information are available at http://www.fws.gov/forms/3-200-13.pdf. Information on any T&E species that occur in the area must be provided to the USFWS Migratory Bird Permit Office with the migratory bird application. Once it has been determined that no additional permits (e.g., for take of T&E species) will be required, allow 90 days for processing. The permit applicant must also identify the Certified Applicator who will apply the bait.

! Limiting application to urban areas only and certain land airports. OvoControl-G label requirements are:

The use of OvoControl G is limited to sites in urban areas such as office parks, recreational parks, golf courses, schools, hospitals, restaurants, and commercial and industrial sites. Urban is defined as a municipality and its adjacent areas with a population of 50,000 or more. May only be used at land airports holding FAA certifications under 14 Code of Federal Regulations 139.101 and a wildlife hazard management plan under 14 Code of Federal Regulations 139.337.

! Limitations on use of unattended mechanical feeders. Unattended mechanical feeders may only be used at airports (as described above). For all other sites, mechanical feeders must be triggered by the applicator on a daily basis. OvoControl-G label requirements are:

Mechanical feeders must be attended and triggered by the applicator daily. Unattended mechanical feeders may be used at land airports which have FAA certification under 14 CFR 139.101 and a wildlife hazard management plan under 14 CFR 139.337."

! Limitations on geographical use. OvoControl-G label requirements are:

Not for use in Hawaii, Guam, American Samoa, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

! Precautions limiting aquatic exposure. OvoControl-G label requirements are:

Do not apply within 20 feet of any body of water, including lakes, ponds or rivers.

! Non-target observations and written records. OvoControl-G label requirements are:

The applicator must maintain daily and weekly records on baiting and document the amount of bait applied and confirm that bait is consumed within 2 hours. Records must also document an estimate of the amount of bait remaining after two hours or the amount of a previous day's bait observed prior to baiting. The records must also document the method used to clean and remove uneaten bait.

For the migratory bird permitting, written records must be kept regarding date, time, number and identification of non-target species feeding on the bait. These records must be provided to the landowner.

- Reducing the likelihood of nontarget exposure to uneaten bait. The applicator must follow label instructions to minimize the potential for nontarget wildlife to feed on the bait. OvoControl-G label requirements are:

  By the end of the initial 21 day period, the daily dose (based on flock size) must be entirely consumed within 2 hours of application. If uneaten bait remains after 2 hours of application, cease treatment.

  If geese cannot be habituated to the feeding program (at least 1 ounce (25 grams) OvoControl G/goose/day) within 21 days, discontinue treatment at that particular site.

  Do not apply more OvoControl-G than the geese will eat in a single feeding, as this may result in non-target species exposure to left over bait. Do not apply bait at sites where non-target wildlife are observed feeding on OvoControl-G during the first 21 days.

  If non-targets consistently feed on bait during treatment, delay baiting until local wildlife authorities can determine if unacceptable risks exist to non-target species. It may be a violation of state and federal law to feed treated bait to protected nontarget species.

  After the initial 21 days of baiting, observations must be made to ensure that the geese are continuing to consume the bait within 2 hours of application. After the initial 21 day acclimation period, target population estimates and 2 hour observations for nontarget species must be made weekly. The amount of bait being applied must be increased or decreased according to the number of geese observed at the site during the target population estimate. During treatment (day 22+), if the applicator finds uneaten bait left over at the site from the previous day's feeding, the applicator must remove it, a target population estimate must be performed, and the daily application rate must be adjusted accordingly. Additionally, the applicator must resume 2 hour observation for nontarget species, every two days, until the bait is again consumed within 2 hours of application. If uneaten bait is found at the site for five consecutive observations, cease treatment.

  This product will reduce hatchability and adversely affect other aspects of reproduction in all avian species.

- Use in grass that is typically mowed to increase bait consumption and allow observation of uneaten bait. OvoControl-G label requirements are:

  Application to grass must be made in grass that is typically mowed to increase access to bait.

5. CONFIRMATORY DATA REQUIREMENTS

There are no confirmatory data requested for nicarbazin based on the labeled uses.

6. CONTACT PERSON AT EPA

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Appendix I

GLOSSARY OF TERMS AND ABBREVIATIONS

CAS	Chemical Abstracts Service
DNC	4,4'-dinitrocarbanilide
EPA	U.S. Environmental Protection Agency
FAA	Federal Aviation Administration
g/ml	grams per milliliter
HDP	4,6-dimethyl-2-pyrimidinol
K_{ow}	Octanol-Water Partition Coefficient
kg/ha	Kilogram Per Hectare
lb/acre	Pound Per Acre
lbs	Pounds
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Limit of quantitation
mg/kg	Milligram Per Kilogram
mg/kg/bw	Milligram Per Kilogram Per Bodyweight
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
ml	Milliliter
MOE	Margin of Exposure
MRID	Master Record Identification (number), EPA's system of recording and tracking studies submitted
NA	Not Applicable
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level

NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration

GLOSSARY OF TERMS AND ABBREVIATIONS (Continued)

ppb	Parts Per Billion
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RQ	Risk Quotient
µg	micrograms
µg/L	Micrograms Per Liter
µL/g	Microliter per gram
USDA	United States Department of Agriculture

Appendix II

CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REGISTRATION OF NICARBAZIN

MRID	Citation
46416400	Innolytics, LLC (2004) Submission of Product Chemistry, Toxicity, Fate, Efficacy and Environmental Fate Data in Support of the Application for Registrations of OvoControl-P, Nicarbazin 30% Granulated Premix, and OvoControl-G. Transmittal of 43 Studies.
46416401	Wolf, E.; MacDonald, A. (2004) Product Identity and Composition, Certification of Ingredient Limits, and Discussion of Impurities of Nicarbazin and Nicarbazin 30% Granulated Premix. Project Number: NICARBAZIN/04/22. Unpublished study prepared by Exponent. 51 p.
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