

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 23, 2019

Kim Fredricks Authorized Company Agent U.S. Fish and Wildlife Service Arlington Square Building MS 725 Washington D.C. 20240

Subject: Registration Review Label Mitigation for Nicolsamide Product Name: Bayluscide 70% Wettable Powder Sea Lamprey Larvicide EPA Registration Number: 6704-87 Application Date: January 22, 2019 Decision Number: 553576

Dear Kim Fredricks:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Niclosamide Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions about this letter, please contact Darius Stanton by phone at 703-347-0433, or via email at <u>Stanton.darius@epa.gov</u>.

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Sincerely,

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Linda Arrington, Branch Chief Risk Management and Implementation Branch 4 Pesticide Re-Evaluation Division Office of Pesticide Programs

Enclosure

#### [Front Panel]

#### RESTRICTED USE PESTICIDE

Due to Aquatic Organism Toxicity, Need for Specialized Equipment and Highly Specialized Applicator Training.

For retail sale to, and use only by, USDI, FWS, State Fish and Game, Fisheries and Oceans Canada, and Provincial Certified Applicators trained in sea lamprey control or persons under their direct supervision.

## **BAYLUSCIDE 70% WETTABLE POWDER-SEA LAMPREY LARVICIDE**

Active Ingredient:	
Niclosamide, Aminoethanol Salt <sup>1</sup>	70.0%
Inert Ingredients:	30.0%
TOTAL:	100.0%
<sup>1</sup> Niclosamide, Active Equivalent (a.e.) = $59.0\%$	

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### FIRST AID

Have label with you when obtaining treatment advice.

If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center, doctor or 1-800-858-7378 immediately for treatment advice.</li> </ul>
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor immediately for treatment advice.</li> </ul>

ACCEPTED

Aug 23, 2019 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the

EPA Reg. No. 6704-87

If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor immediately for treatment advice.</li> </ul>
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See Left Panel for additional precautionary statements.

Manufactured For:

Fish and Wildlife Service United States Department of Interior 18<sup>th</sup> and C Streets, NW Washington, DC 20240

EPA Reg. No. 6704-87

EPA Est.

Batch No.

Net Contents \_\_\_\_\_lbs.

#### [Left Panel]

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Acute Hazards: Harmful if absorbed through skin or inhaled. Causes moderate eye irritation.

**Hazard Avoidance:** Do not get in eyes, on skin, or on clothing. Avoid breathing dust. Wear protective clothing as listed under "Personal Protective Equipment". Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT:

Handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves [such as barrier laminate, butyl rubber, nitrite rubber, neoprene rubber, or polyvinyl chloride (PVC), Viton]
- Socks and shoes

#### User Safety Requirements:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### User Safety Recommendations:

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

#### ENVIRONMENTAL HAZARDS

This chemical is toxic to fish and aquatic invertebrates. Nontarget organisms (such as freshwater clams and mussels) may be killed at rates recommended on this label. Directions for use must be strictly followed to minimize hazards to non-target organisms. **Do not** contaminate water by the cleaning of equipment or disposing of equipment washwaters.

## [Right Panel]

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### **READ THIS LABEL:**

Read the entire label and Sea Lamprey Control Document No. SLC-92-001 [Standard Operating Procedures for Application of Lampricides in the Great Lakes Fishery Commission Integrated Management of Sea Lamprey (*Petromyzon marinus*) Control Program] for correct rates of application. This product must be used strictly in accordance with both label's precautionary statements and applicable use directions, as well as with all applicable State and Federal laws and regulations.

Before using this product, obtain all necessary permits.

## **GENERAL INFORMATION:**

This product contains a fast-acting fish toxicant which kills sea lamprey larvae in 1-2 hours. The mode of action is uncoupling of oxidative phosphorylation. As many types of nontarget species are potentially vulnerable to Bayluscide, it is necessary to use care and to follow the requirements of this label to minimize impacts.

## **USE RESTRICTIONS:**

## Use Pattern:

Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide may be used as an additive in combination with TFM (EPA Reg. No. 6704-45) for control of sea lamprey (*Petromyzon marinus*) in waters in the Great Lakes Basin, the Lake Champlain system, and the Finger Lakes. Application of Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide may be made as a simultaneous addition with TFM to reduce the amount of TFM required or as a subsequent addition downstream to enhance TFM larvicidal activity.

## **Pre-Application Notification:**

Prior to and during the application of this chemical, take all appropriate actions to notify public water users including notification actions specified in the application manual referred to above.

## Aerial Application:

Aerial application of this product is prohibited.

#### Pretreatment Surveys:

Prior to using Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide-TFM, pretreatment surveys must be made to determine populations of larvae. All waters selected for treatment must first be analyzed on site to determine both the minimum concentration of material required to kill lamprey larvae and the maximum concentration that can be applied without causing undue fish mortality. "Analysis" constitutes live animal toxicity tests or the use of a regression established by past toxicity tests and the total alkalinity and pH of the water.

## Lethal Concentration:

Lethal concentration may vary depending upon water chemistry and temperature. Carefully calculate stream discharge and add the amount of lampricide necessary to kill lamprey larvae with minimal fish mortality. Use application devices that accurately deliver Bayluscide at calculated rates. Bayluscide concentrations will be monitored by high-performance liquid chromatography to insure that minimum lethal concentrations for sea lampreys are maintained and calculated maximum concentrations are not exceeded.

## **Application Directions:**

Prior to and during the application of this chemical, take appropriate actions to notify public water users including notification actions specified in the Sea Lamprey Control Document No. SLC-92-001. When using Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide as an additive in combination with TFM, mix in proportions that result in a final concentration of Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide of not more than 2% of TFM by weight (based on active ingredient). Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide may be added to TFM in two ways:

1. One method of application is to apply both lampricides at the primary application site. TFM is metered into the stream while Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide is applied with a separate pump system in amounts calculated to deliver the desired ratio of Bayluscide to TFM.

2. A second application method is to apply Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide into an existing TFM bank. Because a TFM bank can be diluted by ground water, swamp seepage, untreated tributaries, occasional rain, or other conditions that cannot be included when the application rates are calculated, the toxicity of the bank in the stream must be raised by the addition of TFM or Bayluscide. The latter may be used in place of TFM. In these situations, TFM alone is pumped into the stream at the primary application site. Bayluscide 70% Wettable Powder-Sea Lamprey Larvicide is introduced into the TFM bank at a point or points downstream in amounts calculated to produce the desired Bayluscide to TFM ratio.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

**STORAGE:** Store only in original container, in a dry place inaccessible to children, pets, and domestic animals and where spills and leakage can be contained.

**SPILLS:** Handle and open container in a manner that will prevent spillage. If the container is leaking or material is spilled for any reason or cause, contain spill with a barrier of absorbent material. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away. For decontamination procedures or any other assistance that may be necessary, contact Chemtrec at 1-800-424-9300.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spilled bait, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL**: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available or puncture and dispose in sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.