

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 3, 2018

Ms. Jennifer Klika Regulatory Affairs Manager Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704

Subject: PRIA Label and CSF Amendment – Amendment of the manufacturing process

Product Name: Technical Bromethalin EPA Registration Number: 12455-92

Application Date: 06/28/2018 Decision Number: 542399

Dear Ms. Klika:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Additionally, you must submit a new five batch analysis of technical bromethalin when the full scale commercial production of the technical is implemented. Based on the new five batch analysis, if necessary, the basic CSF may be required to be revised.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF:

#### • Basic CSF dated 06/27/2018

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,

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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.

Your release for shipment of the product 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, please contact Paul Di Salvo by phone at 703-347-0322, or via email at disalvo.paul@epa.gov.

Sincerely,

Venus Eagle, Product Manager 01 Invertebrate and Vertebrate Branch 3 Registration Division (7505P)

Office of Pesticide Programs

Enclosure: Stamped Label

## TECHNICAL BROMETHALIN

A RODENTICIDE ONLY FOR FORMULATING OTHER REGISTERED PRODUCTS FOR THE FOLLOWING SITES: IN AND AROUND STRUCTURES AND INSIDE TRANSPORT VEHICLES TO KILL NORWAY RATS, ROOF RATS, AND HOUSE MICE

ACTIVE INGREDIENT

Bromethalin (CAS # 63333-35-7) 98.00%

OTHER INGREDIENTS 2.00%

TOTAL 100.00%

EPA REG. NO. 12455-92

EPA EST. NO. 12455-WI-1

# KEEP OUT OF REACH OF CHILDREN DANGER



**NET CONTENTS: 1 pound (lb)** 

**NET WEIGHT: 1 pound (lb)** 

### ACCEPTED

10/03/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 40455 00

12455-92

Manufactured By:



Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704

FIRST AID	
If Swallowed:	<ul> <li>Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.</li> </ul>
	<ul> <li>Have person sip a glass of water if able to swallow.</li> </ul>
	<ul> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If Inhaled:	Remove person to fresh air.
II IIIIuicu.	• If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth, if possible.
	<ul> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
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.</li> </ul>
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
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 1-877-854-2494 immediately for treatment advice.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### NOTE TO PHYSICIAN OR VETERINARIAN

Bromethalin is not an anticoagulant rodenticide. Bromethalin uncouples oxidative phosphorylation in the mitochondria. If swallowed, absorbed or inhaled by humans, domestic animals or pets, this material would likely cause numbness, incoordination and respiratory distress. If ingested, limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** Fatal if swallowed. Fatal if absorbed through the skin. Fatal if inhaled. Do not breathe dust. Corrosive. Causes skin burns. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear coveralls worn over short-sleeved shirt and short pants, chemical-resistant footwear, socks, a minimum of a NIOSH-approved particulate filtering facepiece respirator (TC-84A), protective eyewear, and chemical resistant gloves made of barrier laminate, butyl rubber  $\geq 14$  mils, nitrile rubber  $\geq 14$  mils, neoprene rubber  $\geq 14$  mils, natural rubber  $\geq 14$  mils, polyethylene, polyvinyl chloride (PVC)  $\geq 14$  mils, or viton  $\geq 14$  mils. Remove and wash contaminated clothing before reuse. Avoid exposure to this product during pregnancy.

#### **User Safety Requirements**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying the bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

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

#### Only for Formulation into a Rodenticide Product for:

- 1. The following uses: in and around man-made structures, inside transport vehicles (ships, trains, aircraft) to control Norway rats, roof rats, and house mouse;
- 2. Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of the registration; and
- 3. Uses for Experimental Use Permits that are in compliance with the requirements of the U.S. Environmental Protection Agency.

Formulators using this product are responsible for obtaining EPA registration for their formulated product.

#### STORAGE AND DISPOSAL

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

**Pesticide Storage:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals. Sweep up spillage carefully and dispose of as indicated below.

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

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or dispose of empty container in a sanitary landfill, or by incineration

**WARRANTY:** To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.