

### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

October 27, 2025

Victoria Kleczewski Regulatory Product Manager Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, NC 27419

Subject: PRIA Label and CSF Amendment – To designate Chemispol (EPA Establishment

No. 104180-CZE-1) as a new unregistered manufacturing source for

Brodifacoum.

Product Name: Brodifacoum Concentrate II

EPA Registration Number: 100-1080

Application Date: 10/9/2024

Case Number: 632706

#### Dear Victoria Kleczewski:

The amended label and Confidential Statement(s) of Formula (CSFs) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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(s):

- Basic CSF dated 01/23/2017
- Alternate CSF 1 dated 09/17/2024

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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 FIFRA 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) lists 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.

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 Andrés Garzón at (202) 266-2690 or at GarzonMoreno. Andres @epa.gov.

Sincerely,

Melissa Bridges, Product Manager 7 Invertebrate-Vertebrate Branch 3 Registration Division (7505T) Office of Pesticide Programs

**Enclosure** 

(Master)

#### **Brodifacoum Concentrate II**

For formulation only into registered rodenticides used in and around buildings and transport vehicles, and in sewers

Active Ingredient:

Brodifacoum

3-[3-(4'-bromo[1,1'-biphenyl]4-yl)-1,2,3,4-tetra-hydro-1-

Total: 100.00%

## KEEP OUT OF REACH OF CHILDREN.



Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA	Reg.	No.	100-1080	
EPA	Est.			

Product of the United Kingdom

(contains Bitrex logo)

Formulated in USA

	_ pounds
Net Weiaht	

ACCEPTED

10/27/2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 100-1080

# PRECAUTIONARY STATEMENTS

## **Hazards to Humans and Domestic Animals**



May be fatal if swallowed or inhaled. Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Do not breathe spray mist. Remove and wash contaminated clothing before reuse. Avoid exposure to this product during pregnancy. Repeated inhalation, dermal contact or oral ingestion may result in accumulative toxicity.

	FIRST AID			
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Contains an anticoagulant rodenticide (brodifacoum)				
Have the product container or label with you when calling a poison control center or doctor, or				
going for treatment.				
If swallowed	Call a poison control center or doctor immediately for treatment advice.			
	Have person sip a glass of water if able to swallow.			
	Do not induce vomiting unless told to do so by the poison control center			
	or doctor.			
	Do not give anything by mouth to an unconscious person.			
If on skin or	Take off contaminated clothing.			
clothing	Rinse skin immediately with plenty of water for 15–20 minutes.			
	Call a poison control center or doctor for treatment advice.			
If inhaled	Move person to fresh air.			
	If person is not breathing, call 911 or an ambulance, then give artificial			
	respiration, preferably by mouth–to–mouth, if possible.			
	Call a poison control center or doctor for further treatment advice.			
If in eyes	Hold eye open and rinse slowly and gently with water for 15–20			
	minutes.			
	Remove contact lenses, if present, after the first 5 minutes, then			
	continue rinsing eye.			
	Call a poison control center or doctor for treatment advice.			
	SYNGENTA HOTLINE NUMBER			
F	or 24-Hour Medical Emergency Assistance (Human or Animal)			
or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident)				
Call				
	1-800-888-8372			

## **NOTE TO PHYSICIAN OR VETERINARIAN**

This product may reduce the clotting ability of the blood and cause bleeding. If poisoning occurs, give Vitamin  $K_1$  intramuscularly or orally. For humans, Vitamin  $K_1$  is antidotal at doses of 10-20 mg (not mg/kg). For animals, Vitamin  $K_1$  is antidotal at 2-5 mg/kg. Give repeated doses up to two weeks, based on prothrombin times. In severe cases, give blood transfusions or Vitamin K1 intravenously.

## **Environmental Hazards**

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in 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 sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of this product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

#### **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 for

- 1. the following uses: in and around buildings, inside transport vehicles, and in sewers (Norway rat, roof rat, and house mouse);
- 2. uses for which USEPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and
- 3. 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 products.

#### STORAGE AND DISPOSAL

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

### **Pesticide Storage**

Store in locked storage area. Keep container closed when not in use. Do not store near food or feed. In case of spill or leak on floor or paved surfaces, soak up with sand, earth or synthetic absorbent. Remove to chemical waste area.

## **Pesticide Disposal**

Pesticide wastes are toxic. 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 label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

#### **Container Handling**

Refillable container. Refill this container with pesticide only. Do not use this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean container before final disposal, empty the remaining contents from this container into formulation equipment. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into formulation equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Bitrex® trademark of Macfarlan Smith Ltd., Edinburgh, Scotland.

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For non-emergency (e.g. current product information) call Syngenta Crop Protection at 1-866-796-4368.

Manufactured for: Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

Brodifacoum Concentrate II 1080 MAS 0908 AMEND-B SEPT2024-CL-jab-10/22/25 000100-01080.20240918B.BRODIFACOUM\_CONCENTRATE\_II.AMEND.0924-CL