



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

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

March 1, 2023

Christie Villegas
Senior Regulatory Affairs Manager
Bayer U.S. – Crop Science, Research & Development
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Subject: PRIA Label Amendment – Adding seed treatment use for (Crop Group 15) Cereal Grains, Except Rice and (Crop Group 16) Forage, Fodder, and Straw of Cereal Grains Group, except Field Corn, Popcorn, and Sweet Corn.
Product Name: Tetraniliprole Technical
EPA Registration Number: 264-1194
Application Date: May 18, 2021
Decision Number: 576267

Dear Christie Villegas:

The application referred to above, submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable under FIFRA section 3(c)(5).

You must submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

During the review of this action, it was noted that an analytical reference standard is currently available for this technical; however, a standard of the isotopically-labeled IS (BCS-CL73507-13C2, D3) is not available and must be submitted within 6 months from the date of this letter.

Please submit each gram of analytical standard in 10 aliquot vials of 100 mg each. Each aliquot vial must be sealed, and labeled with the name of the analytical standard, percent purity, lot number and expiration date. The reference standard should be sent to the Biological and Economic Analysis Division's Analytical Chemistry Branch (BEAD/ACB), to the attention of either Craig Vigo or Thuy Nguyen at the address listed below, along with a letter of transmittal. Please note that the full 9-digit ZIP Code is required, or the mail will be returned to the registrant.

USEPA
National Pesticide Standards Repository
Analytical Chemistry Branch/BEAD/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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.

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 Ralph Narain at 202-566-2853 or at Narain.Ralph@epa.gov.

Sincerely,



Deanna (Dee) Colby, Chief
Invertebrate & Vertebrate Branch 3
Registration Division
Office of Pesticide Programs

Enclosure: Stamped label

Tetraniliprole Technical

An Insecticide for Formulating Use Only

ACTIVE INGREDIENT(S):

TETRANILIPROLE: 1-(3-chloropyridin-2-yl)-N-[4-cyano-2-methyl-6-(methylcarbamoyl)phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamid **96.77%**

OTHER INGREDIENTS: **3.23%**

TOTAL: **100.00%**

*CAS No. 1229654-66-3

EPA Reg. No. 264-1194

EPA Est. _____

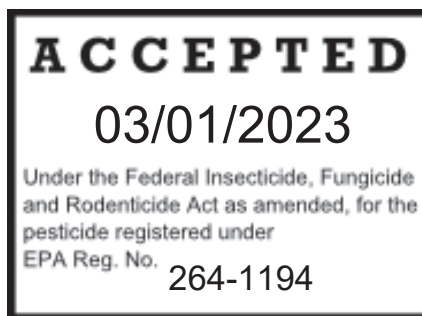
Net Contents: _____ pounds

Batch Code:

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577
For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

[Please refer to back panel for additional precautionary statements and directions for use.]



PRODUCED FOR



Bayer CropScience LP
800 N. Lindbergh Blvd.
St. Louis, MO 63167
1-866-99BAYER (1-866-992-2937)

FIRST AID

If swallowed:	<ul style="list-style-type: none">• 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 a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• 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.• Call a poison control center or doctor for treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed, or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters 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 into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

GROUND WATER ADVISORY

This chemical has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.

SURFACE WATER ADVISORY

This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having a high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs, will reduce the potential for loading of tetraniliprole from run-off water and sediment.

Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read the entire label before using this product.

FORMULATION INSTRUCTIONS

- Each formulator is responsible for obtaining EPA registration for his own end use products.
- Technical information on formulations of this product as well as its physical and chemical characteristics may be obtained from Bayer CropScience.

ONLY FOR FORMULATION INTO AN INSECTICIDE FOR THE FOLLOWING USES:

- 1) **Terrestrial Food and Feed Crops:** Tuberous and Corm Vegetables (Crop Subgroup 1C); Leafy Vegetables (Crop Group 4-16); Brassica Head and Stem (Crop Group 5-16); Soybean; Fruiting Vegetables (Crop Group 8-10); Citrus (Crop Group 10-10); Pome Fruits (Crop Group 11-10); Stone Fruits (CropGroup 12-12); Small Fruit Vine Climbing except Fuzzy Kiwifruit (Crop Subgroup 13-07F); Tree Nuts (Crop Group 14-12); Corn (Sweet, Field, Pop and corn grown for seed);
- 2) **Terrestrial Nonfood Crops :** Tobacco and Sod Farms;
- 3) **Terrestrial Non Food Use, Residential and Commercial Outdoor :** Turfgrass in and around residential and commercial buildings, golf courses and sports fields.
- 4) **Seed Treatment Uses:** Corn; Soybean; Cereal Grains (Crop Group 15) Excludes Rice & Wild Rice, and Grain, Cereal, Forage, Fodder and Straw (Crop Group 16) Excludes Field Corn, Popcorn, and Sweet Corn.
- 5) Any other uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and;
- 6) Uses for experimental purposes that are in compliance with US EPA requirements.

Formulators who use this product are responsible for providing data to support their own registrations.

STORAGE AND DISPOSAL

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

Pesticide storage

Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, in a locked storage area.

Handle and open container in a manner as to prevent spillage. If container is leaking, invert to prevent leakage. If the container is leaking or material is spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Emergency Response Telephone No. is (800) 334-7577, or contact Chemtrec at (800) 424-9300.

Pesticide disposal

Pesticide wastes are toxic. Improper disposal of excess pesticide 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 handling

Manufacturing Use Products in Non-Refillable Plastic Containers

Rigid, Non-refillable HDPE plastic containers that are too large to shake

Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Drums and Kegs

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[OR]

Non-Rigid, Non-refillable polyethylene plastic containers that are too large to shake

Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

FBC, Drums, and Kegs

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[OR]

Manufacturing Use Products in Refillable Plastic Containers

Rigid, Refillable HDPE plastic containers that are too large to shake

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center [(1-800-527-4781)] or rinse and either recycle or dispose of the container as follows:

Drums and Kegs

Triple rinsing 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 triple rinse the containers before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

[OR]

Non-Rigid, Refillable polyethylene plastic containers that are too large to shake

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center [(1-800-527-4781)] or rinse and either recycle or dispose of the container as follows:

FBC, Drums, and Kegs

Triple rinsing 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 triple rinse the containers before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

TO THE EXTENT ALLOWED BY APPLICABLE LAW, THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH IN SECTION(S) [(1) – (4)] OF THE MANUFACTURING USE DIRECTIONS. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN [(1) – (4)] OF THE MANUFACTURING USE DIRECTIONS.

ANY FORMULATOR OR BUYER WHO USES THIS PRODUCT IN FORMULATIONS FOR ANY USE OTHER THAN THOSE STATED IN [(1) – (4)] OF THE MANUFACTURING USE DIRECTIONS ASSUMES ALL LIABILITY FOR CLAIMS AND ACTIONS ARISING OUT OF, CONNECTED WITH OR RESULTING FROM SUCH USE AND AGREES BY SO USING THIS PRODUCT TO INDEMNIFY AND HOLD HARMLESS THE MANUFACTURER FROM SUCH CLAIMS AND ACTIONS.

THIS DISCLAIMER AND INDEMNITY IS IN ADDITION TO, NOT IN LIEU OF, THE BELOW DISCLAIMER AND LIMITATIONS.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

Tetraniliprole Technical (PENDING) 05/18/2021, 10/24/2022