

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 9, 2020

Jessica Fernandez Federal Registrations Manager Bayer U.S. LLC 700 Chesterfield Pkwy W Chesterfield, MO 63017

Subject: PRIA Label Amendment – Adding new seed treatment use of fluopyram on rapeseed subgroup 20A Product Name: Fluopyram Technical EPA Registration Number: 264-1077 Application Date: December 12, 2018 Decision Number: 547724

Dear Ms. Fernandez:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec 3 (c)(5). You must submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

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 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.

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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 Aswathy Balan by phone at 703-347-0510, or via email at <u>balan.aswathy@epa.gov</u>.

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Shaja B. Joyner, Product Manager 20 Fungicide-Herbicide Branch Registration Division 7505P

FUNGICIDE

FLUOPYRAM Technical

FOR FORMULATION PURPOSES ONLY

Formulators who use this product are responsible for obtaining EPA supplemental distributor registration for their formulated product.

ACTIVE INGREDIENT:

Fluopyram*: N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide	98.6%
	<u>1.4%</u>
TOTAL:	100.0%

*CAS Number 658066-35-4

EPA Reg. No. 264-1077

EPA Est. No.

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KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice.
	 Do not induce vomiting unless told to do so by a poison control center or doctor.
	Have person sip a glass of water if able to swallow.
	 Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
	For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. ency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Treat Symptomatically.

For Product Use Information Call 1-866-99BAYER (1-866-992-2937)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. 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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Formulators and other handlers must wear long sleeved shirt and long pants, shoes plus socks, and chemical-resistant gloves made of any of any waterproof material such as natural rubber \geq 14 mils.

USER SAFETY REQUIREMENTS

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

ENVIRONMENTAL HAZARDS

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 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

This product may be used only for formulation into a fungicide and/or nematode control product for the uses listed below:

The following approved uses:

- Foliar uses: Artichoke, globe; Berry, low growing, except cranberry, subgroup 13-07G; Brassica, Head and Stem, Subgroup 5A; Brassica Leafy Greens, Subgroup 5B; Bushberry subgroup 13-07B; Caneberry subgroup 13-07A; Carrot; Cherry subgroup 12-12A; Corn, field, grain; Corn, pop, grain; Corn, sweet, [kernel plus cob with husks removed]; Cottonseed subgroup 20C; Dill seed; Fruit, citrus, group 10-10; Fruit, pome, group 11-10; Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F; Ginseng; Grain, cereal, group 15 (except corn and rice); Herb subgroup 19A; Hop, dried cones; Leafy greens subgroup 4A; Leaf petioles subgroup 4B (except watercress); Legume Vegetables (except cowpea and dried peas); Melon subgroup 9A; Nut, tree, group 14-12; Onion, bulb, subgroup 3-07A; Onion, green, subgroup 3-07B; Peach subgroup 12-12B; Pepper/eggplant subgroup 8-10B; Plum subgroup 12-12C; Peanut; Rapeseed subgroup 20A; Soybean; Squash/cucumber subgroup 9B; Sugarbeet, roots; Sunflower subgroup 20B; Tomato subgroup 8-10A; Vegetable, root, except sugarbeet, subgroup 1B; Vegetable, tuberous and corm, subgroup 1C.-
- Soil uses : Berry, low growing, except cranberry, subgroup 13-07G; Brassica, Head and Stem, Subgroup 5A; Brassica, Leafy Greens, Subgroup 5B; Bushberry subgroup 13-07B; Caneberry subgroup 13-07A; Cherry subgroup 12-12A; Corn, field, grain; Corn, pop, grain; Corn, sweet, [kernel plus cob with husks removed].; Cottonseed subgroup 20C; Fruit, citrus, group 10-10; Fruit, pome, group 11-10; Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F; Grain, cereal, group 15 (except corn and rice); Hop, dried cones; Legume Vegetables (except cowpea and dried peas); Melon subgroup 9A; Nut, tree, group 14-12; Onion, bulb, subgroup 3-07A; Onion, green, subgroup 3-07B; Peach subgroup 12-12B; Plum subgroup 12-12C; Peanut; Pepper/eggplant subgroup 8-10B; Rapeseed subgroup 20A; Soybean; Squash/cucumber subgroup 9B; Sugar Beet; Sunflower subgroup 20B; Tobacco; Tomato subgroup 8-10A; Vegetable, root, except sugarbeet, subgroup 1B; and Vegetable, tuberous and corm, subgroup 1C.
- 3. Seed treatment uses on: Rapeseed subgroup 20A; Corn; Cottonseed subgroup 20C; Peanuts; Sorghum; Soybean and Wheat.
- 4. Turf on golf courses, sod farms, sport fields, residential, institutional, municipal, commercial, and other turfgrass areas.
- 5. Ornamentals in residential and commercial landscapes, interiorscapes, field grown and container ornamentals in nurseries and greenhouses, lathhouses, shadehouse, containers and other enclosed structures.

- 6. Christmas Trees
- 7. Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
- 8. Uses for experimental purposes that are in compliance with U.S. EPA requirements.

This product may be used to formulate products for specific use(s) not listed on this label only if the formulator, user group, or grower has complied with U.S. EPA requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross contamination with other pesticides.

PESTICIDE DISPOSAL: Pesticide wastes may be toxic. Improper disposal of unused pesticide, spray mixture, or rinse water is a violation of federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

CONTAINER HANDLING

Dilutable Manufacturing Use Products in Non-Refillable Plastic Containers

Rigid, Non-refillable containers (equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure 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 1/4 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.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

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

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs) 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:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into manufacturing equipment. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into manufacturing equipment. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.- Snyder 120 Next Gen, Bonar B120, 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.

Dilutable Manufacturing Use Products in Non-Refillable Metal Containers

Nonrefillable 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:

Liquid dilutables in containers small enough to shake (5 gallons or less)

Triple Rinse as follows: Empty the remaining contents into manufacturing equipment 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 manufacturing equipment for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less)

Triple Rinse as follows: Empty the remaining contents into manufacturing equipment. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into manufacturing equipment or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds)

Triple Rinse as follows: Empty remaining contents into manufacturing equipment. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into manufacturing equipment or store rinsate for later use or disposal. 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.

Non-Dilutable Manufacturing Use Products in Non-Refillable Containers

Manufacturing Use Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Manufacturing Use Products in Non-rigid, Non-Refillable Containers

Nonrefillable container. Do not reuse or refill this container. Completely empty container into manufacturing equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Manufacturing Use Products in Refillable Containers

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:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure 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 pressure rinse the container before final disposal, empty the remaining contents from the IBC into manufacturing equipment. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into manufacturing equipment while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, 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.

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

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

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) 1-6 OF THE DIRECTIONS FOR USE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN 1-6 OF THE DIRECTIONS FOR USE.

ANY FORMULATOR OR BUYER WHO USES THIS PRODUCT IN FORMULATIONS FOR ANY USE OTHER THAN THOSE STATED IN 1-6 OF THE DIRECTIONS FOR USE 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.

IMPORTANT: READ BEFORE USE

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. 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.

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Fluopyram Technical is specially formulated and sold by Bayer CropScience LP for the control of various pathogens according to the directions on this label. The purchase price of Fluopyram Technical includes a prepaid license under which purchaser agrees to employ the purchased quantity of Fluopyram Technical only for the above-specified uses and to provide notice of the terms and conditions of this license to any subsequent purchaser. Uses of Fluopyram Technical other than those specified on this label are not licensed through the purchase of this product.

NET CONTENTS:

PRODUCED FOR



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

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