



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 25, 2020

Dana Wernsman
Federal Registrations Manager
Bayer CropScience LP
800 N. Lindbergh Road
St. Louis, MO 63167

Subject: PRIA Label Amendment – New Use on Isoxaflutole-Resistant Soybeans
Product Name: TECHNICAL ISOXAFLUTOLE
EPA Registration Number: 264-566
Application Date: July 6, 2010
Decision Number: 437491

Dear Ms. Wernsman:

The application referred to above, submitted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable under FIFRA sec 3(c)(5) with the following conditions:

1. 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.
2. The registered new use of isoxaflutole on isoxaflutole-resistant soybeans will **automatically expire on March 25, 2025** unless the agency amends this condition otherwise.
3. You must develop and follow an Herbicide Resistance Management Plan as described in Appendix A.
4. You must submit annual reports to the Agency by January 15th of each year beginning in 2021 as outlined in Appendix A Section D, "Reporting Component," until the Agency amends this condition otherwise.
5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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) 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions, please contact Grant Rowland by phone at 703-347-0254, or via email at rowland.grant@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Kenny', with a long horizontal flourish extending to the right.

Daniel Kenny, Chief
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Appendix A – Herbicide Resistance Management Plan and Reporting Requirements for Isoxaflutole Use on Isoxaflutole Resistant Soybeans

APPENDIX A

Herbicide Resistance Management Plan and Reporting Requirements for Isoxaflutole Use on Isoxaflutole Resistant Soybeans

Bayer CropScience LP (Bayer) must comply with the following:

A. Educational Component

1. Develop and implement an education program for users of this product that identifies appropriate best management practices (BMPs) to avoid and control weed resistance, and convey to users the importance of following BMPs.

The following are examples of BMPs:

Crop selection and cultural practices

- Understand the biology of the weeds present.
- Use a diversified approach towards weed management focused on preventing weed-seed production and reducing the number of weed seeds in the soil seed-bank.
- Emphasize cultural practices that suppress weeds by using crop competitiveness.
- Plant into weed-free fields, keep fields as weed-free as possible, and note areas where weeds were a problem in prior seasons.
- Incorporate additional weed-control practices whenever possible, such as mechanical cultivation, biological management practices, crop rotation, and weed-free crop seeds, as part of an integrated weed-control program.
- Do not allow weed escapes to produce seeds, roots, or tubers.
- Manage weed seed at harvest and post-harvest to prevent a buildup of the weed seed-bank.
- Prevent field-to-field and within-field movement of weed seed or vegetative propagules.
- Thoroughly clean plant residues from equipment before leaving fields.
- Prevent an influx of weeds into the field by managing field borders.
- Fields should be scouted before application to ensure herbicide and application rates will be appropriate for the weed species and weed sizes present.
- Fields should be scouted after application to confirm herbicide effectiveness and to detect weed escapes.
- If resistance is suspected, treat weed escapes with a different mechanism-of-action herbicide or use non-chemical methods to remove weed escapes.

Herbicide selection

- Use a broad spectrum soil-applied herbicide with a mechanism of action that differs from this product as a foundation in a weed control program.

- A broad-spectrum weed-control program should consider all of the weeds present in the field. Weeds should be identified through scouting and field history.
 - Difficult-to-control weeds may require sequential applications of herbicides with alternative mechanisms of action.
 - Fields with difficult-to-control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action.
 - Apply full rates of this herbicide for the most difficult to control weeds in the field. Applications should be made when weeds are at the correct size to minimize weed escapes.
 - Do not use more than two applications of this herbicide or any herbicide with the same mechanism of action within a single growing season unless mixed with another mechanism of action herbicide with overlapping spectrum for the difficult to control weeds.
 - Report any incidence of non-performance of this product against a particular weed species to Bayer or its representatives.
2. Include at least one written communication to users of this product each year regarding herbicide-resistance management.
 3. Provide a copy of the education materials to EPA upon request.

B. Field Detection and Remediation Components

1. If any user informs Bayer or its representatives of a lack of herbicide efficacy in a weed species listed on product labeling, then Bayer or its representatives must make an effort to evaluate the field for suspected resistance to this product by applying the criteria below, as set forth in Norsworthy, *et al.*, “Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations” Weed Science 2012 Special Issue: 31-62;

Criteria for Determining Suspected Herbicide Resistance

- 1) *Failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; and/or*
 - 2) *A spreading patch of non-controlled plants of a particular weed species; and/or*
 - 3) *Surviving plants mixed with controlled individuals of the same species.*
2. If one or more of the above criteria are met, then:
 - a. Provide the user with specific information and recommendations to control and contain suspect weeds, including re-treatment and/or other non-chemical controls, as appropriate. If requested by the user, Bayer will become actively involved in implementation of weed control measures.
 - b. Request, at the time of the initial determination that one or more of the above criteria are met and prior to any application of alternative control practices, that the user

- provide access to the relevant field(s) to collect specimens of the suspect weeds (potted specimens or seeds) for potential further evaluation in the greenhouse or laboratory, and to collect such specimens if possible (or, alternatively, request that the user provide such specimens to Bayer at Bayer's expense).
- c. Conduct greenhouse or laboratory studies to confirm resistance as soon as practicable following sample collection, if technically feasible.
 - d. To the extent possible, contact or visit the user in an appropriate timeframe after implementation of the additional weed control measures in order to evaluate success of such measures.
 - e. If the additional weed control measures were not successful in controlling the suspected-resistant weeds, then:
 - i. Work with the user to determine the reason(s) why the additional control measures were unsuccessful;
 - ii. Offer to provide technical expertise on how to control and contain the suspected-resistant weeds, including re-treatment and/or other non-chemical controls, as appropriate; and
 - iii. Report annually the inability to control the suspected-resistant weeds to relevant stakeholders.
3. Keep records of all field evaluations for suspected resistance for a minimum of three years, and provide a copy to EPA upon request.

C. Evaluation Component

1. Conduct annual surveys to determine whether users have encountered any perceived issues with non-performance or lack of efficacy of this product, and if so, how users have responded. This survey must be based on a statistically-representative sample of users. The sample size and geographical resolution should be adequate to allow analysis of responses within regions, between regions, and across the United States.
2. Analyze the survey results each year, and modify the following for the upcoming growing season, as appropriate:
 - a. Efforts aimed at achieving compliance with BMPs;
 - b. Responses to incidents of suspected weed resistance and confirmed weed resistance; and

- c. The education program. At the initiative of either EPA or Bayer, both parties shall consult about possible modifications to the education program.

D. Reporting Component

1. Submit reports to EPA by January 15th of each year, beginning in 2019, with information on:
 - a. Annual sales of this product by state;
 - b. Annual sales of soybean seed containing isoxaflutole-resistant trait by state;
 - c. The current education program. The first report shall include the current education program and its associated materials. Subsequent annual reports shall include updates of any aspect of the education program and associated materials that have materially changed since submission of the previous annual report;
 - d. Summary of efforts aimed at achieving compliance with the BMPs;
 - e. Investigation and remediation of cases on suspected-resistant weeds. Summary of determinations as to whether any reported lack of herbicide efficacy was due to suspected-resistance, any follow-up actions taken, and if available, the final outcome (e.g., evaluation of success of additional weed control measures) regarding each case of suspected-resistance. The annual report shall list the cases by county and state;
 - f. Summary of the status of any laboratory and greenhouse testing performed by or at the direction of Bayer, in response to cases of suspected-resistance, performed in the previous year. Data pertaining to such testing need not be included in the annual reports, but such data must be made available to EPA upon request; and
 - g. The annual survey, including whether users are implementing herbicide resistance BMPs, and a summary of Bayer's annual review and any modifications based on the survey results.
2. Following submission of the annual report, Bayer shall meet with EPA at EPA's request in order to evaluate and consider the information contained in the report.

TECHNICAL ISOXAFLUTOLE

For Manufacturing Purposes Only

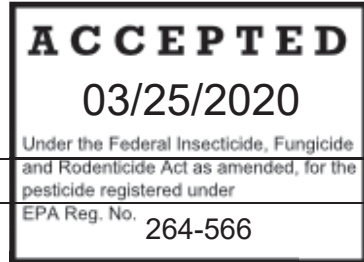
ACTIVE INGREDIENT:

Isoxaflutole [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole].....98.0%

OTHER INGREDIENTS:.....2.0%

EPA Reg. No.: 264- 566

EPA Est. No.: 070631-FIN-001



KEEP OUT OF REACH OF CHILDREN CAUTION

For **EMERGENCY** Information ONLY Call 24 Hours A Day 1-800-334-7577

See [Back][Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none">• Immediately call a poison control center or doctor 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:	<ul style="list-style-type: none">• 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.
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.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
<p>For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	

NOTE TO PHYSICIAN: No specific antidote is available. All treatments should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed, inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors (dust or spray mist). Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

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 law to use this product in a manner inconsistent with its labeling.

Only for formulation into a herbicide for use in field corn and isoxaflutole-resistant soybean. Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

STORAGE AND DISPOSAL

STORAGE: Do not store with foodstuff. Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Rigid, Non-refillable containers small enough to shake (i.e., with capacities 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. Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

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

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information 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 application equipment or mix tank. 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 application equipment or rinsate collection system 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, 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 application equipment or mix tank. 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 application equipment or rinsate collection system. Repeat this procedure two more times. Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

Refillable container – Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows. 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 application equipment or mix tank. 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 application equipment or rinsate collection system 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, 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 application equipment or mix tank. 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 application equipment or rinsate collection system. Repeat this procedure two more times. Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

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. See Container Disposal instructions under Storage and Disposal.

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.

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.

NET CONTENTS: 1,102 Pounds (500 KG Sacks)



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

TECHNICAL ISOXAFLUTOLE (PENDING) 06/28/10, 03/25/2020