



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 29, 2025

Prachi Pandya
Regulatory Manager
Nufarm Americas Inc.
4020 Aerial Center Parkway
Morrisville, NC 27560

Subject: Label Amendment - Registration Review Mitigation for Metalaxyl
Product Name: Sativa M RTU
EPA Registration Number: 55146-112
Application Date: July 19, 2022
Decision Number: 597359

Dear Prachi Pandya:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Metalaxyl Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. 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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact Concepción Rodríguez by phone at 202-566-0820, or via email at rodriguez.concepcion@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. K. Muhammad-Perch', with a long horizontal flourish extending to the right.

Maryam K. Muhammad-Perch, Team Lead
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

ACCEPTED

07/29/2025

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 55146-112

METALAXYL **GROUP 4** **FUNGICIDE**

SATIVA™ M RTU

Seed Treatment

**AIDS IN CONTROL OR SUPPRESSION OF CERTAIN SEED, SEEDLING AND
SOILBORNE DISEASES FOR BARLEY, OATS, TRITICALE AND WHEAT.**

ACTIVE INGREDIENT:

Tebuconazole: Alpha-[2-4(chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol.....0.499%
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester.....0.668%

OTHER INGREDIENTS98.833%
TOTAL100.000%

Contains:

0.042 pound Tebuconazole per gallon (5.0 grams per liter).
0.056 pound Metalaxyl per gallon (6.7 grams per liter).

KEEP OUT OF REACH OF CHILDREN

CAUTION / PRECAUCIÓN

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 INSIDE BOOKLET FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 55146-112
EPA EST. NO.

Manufactured For
NUFARM AMERICAS INC.
AGT DIVISION
150 Harvester Drive
Burr Ridge, IL 60527



NET CONTENTS: Gal. (L)

055146-00112_20250619

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION / PRECAUCIÓN**

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical resistance selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks.
- Chemical-resistant gloves: barrier laminate or nitrile rubber \geq 14 mils or neoprene rubber \geq 14 mils or Viton \geq 14 mils.

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.

USER SAFETY RECOMMENDATIONS

Users Should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 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.
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 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 by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
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 the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
<p style="text-align: center;">HOT LINE NUMBER</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.</p>	

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish, estuarine and marine invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

Groundwater Advisory: Metalaxyl is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Maximum usage when applying both metalaxyl and mefenoxam containing products to the same crop within the same season: Do not apply more than the maximum yearly total for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

Exception: If the seed is treated with the product and the treated seed is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: coveralls, chemical-resistant gloves made of barrier laminate or nitrile rubber \geq 14 mils or neoprene rubber \geq 14 mils or Viton \geq 14 mils. and shoes plus socks.

RESISTANCE MANAGEMENT:

Sativa™ RTU contains metalaxyl, a Group 4 fungicide and tebuconazole, Group 3 fungicide. Metalaxyl belongs to the phenylamide class of chemistry which interferes with fungal RNA synthesis. Tebuconazole belong to the DMI class of chemistry.

Fungal populations may contain individuals naturally resistant to active ingredients in Sativa™ RTU and if used repeatedly in the same fields, then resistant members may eventually dominate the population. Because resistance development cannot be predicted, the use of this product should conform to sound resistance management strategies.

The following steps may delay the development of fungicide resistance:

- Rotate the use of Sativa™ RTU or other Group 3 fungicides within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicides from a different group that are effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.

For additional information on Fungicide Resistance Management:

- Contact Nufarm Americas Inc representatives at 1-800-345-3330
- Contact your local extension specialist or certified crop advisor.
- Visit the Fungicide Resistance Action Committee (FRAC) at <http://www.frac.info>

SEED TREATMENT

This product is a combination of the systemic fungicides which aid in the control or suppression of the following seed, seedling and soilborne diseases of Barley, Oats, Triticale and Wheat.

CROP	DISEASE	RATE
Barley Oats Triticale Wheat	Stinking Smut, Flag Smut, Loose Smut, Early Season <i>Septoria</i> Disease Complex, General Seed rots, <i>Pythium</i> Damping-off, Early Season <i>Rhizoctonia</i> Root Rot, Early Season Common Root Rot, Seedborne <i>Fusarium</i> Scab, Early Season <i>Fusarium</i> Foot rot, Early Season Suppression of Powdery Mildew and Rust.	5.0 to 6.5 fluid ounces per 100 pounds of seed
APPLICATION DIRECTIONS: Make applications using standard slurry or mist-type seed treatment equipment. In some instances, a water and chemical slurry dilution may enhance coverage. A 1 part Sativa™ M RTU with 1 part water dilution may be used. This product is for commercial or on-farm application. Do not use this product for direct application into planter boxes. Uniform application to seed is necessary to ensure seed safety and best disease control. Seed should be sound and well cured prior to treatment. Consult your area agronomist regarding planting depth recommendations for the particular variety to be planted.		

In California: Registered only for use in commercial seed treating establishments. Not allowed for "on-farm" use.

NOTE: The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as a food for man or feed for animals. Refer to 21 CFR, Part 2.25. Any dye added to treated seed must be cleared for use under 40 CFR, Part 180.1001.

SEED LABELING

TO MEET U.S. FEDERAL SEED ACT REQUIREMENTS, ALL SEED TREATED WITH THIS PRODUCT SHOULD BE LABELED:

- TREATED SEED.
- DO NOT USE FOR FOOD, FEED OR OIL PURPOSES.
- Treated with Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol (Tebuconazole) and Metalaxyl.
- Seed labeling must contain the following restriction: "Barley, wheat, oat and triticale green forage may be grazed or harvested for hay 31 days after seeding."

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Store in cool dry location. Do not store in direct hot sunlight. Do not store above 90°F for prolonged periods of time. After prolonged storage in intense cold, allow product to return to approximately 75°F before using.

PESTICIDE DISPOSAL: This pesticide's 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 at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

[Nonrefillable Containers 5 Gallons or Less:] Nonrefillable container. Do not reuse or refill this container. Triple 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. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

[Nonrefillable Containers Larger than 5 Gallons:] Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. 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. Fill the container 1/4 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. 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.

[Refillable Container Larger than 5 Gallons:] Refillable container. Refill this container with pesticide only. Do not reuse 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 the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water and, if possible, spray all sides while adding water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

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