

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 20, 2019

Gordon Sargent Regulatory Manager Nufarm Americas Inc 4020 Aerial Center Parkway Morrisville, NC 27560

Subject: Registration Review Label Mitigation for Metalaxyl

Product Name: Salient TM 5.0

EPA Registration Number: 55146-160

Application Dates: 5/31/2019 Decision Numbers: 555257

Dear Mr. Sargent:

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 Metalaxyl Interim Decisions, 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.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label 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.

Page 2 of 2 EPA Reg. No. 55146-160 Decision No. 555257

If you have any questions about this letter, please contact Darius Stanton by phone at 703-347-0433, or via email at Stanton.Darius@epa.gov.

Sincerely,

Linda Arrington, Branch Chief

Risk Management and Implementation Branch 4

Pesticide Re-Evaluation Division

Office of Pesticide Programs

Enclosure

DIFENOCONAZOLE GROUP 3 **FUNGICIDE TEBUCONAZOLE** METALAXYL 4 **FUNGICIDE GROUP**

Salient™ TM 5.0

Seed Treatment

FOR USE ON BARLEY, OATS, TRITICALE, AND WHEAT FOR PROTECTION OF SEEDLINGS AGAINST LISTED SOILBORNE DISEASES

[ALTERNATE BRAND NAMES: SALIENT TM 5.0 Seed Treatment Fungicide, LANCASTER Seed Treatment, LANCASTER F Seed Treatment, APPRISE Seed Treatment]

ACTIVE INGREDIENT:

TOTAL:	100 00%
OTHER INGREDIENTS:	94.20%
Tebuconazole:	0.39%
Metalaxyl:	1.84%
Difenoconazole:	3.57%

Contains:

0.31 pound Difenoconazole per gallon (37.2 grams per liter)

0.16 pound Metalaxyl per gallon (19.2 grams per liter)

0.034 pound Tebuconazole per gallon (4.1 grams per liter)

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE INSIDE BOOKLET FOR ADDITIONAL PRECAUTIONARY STATEMENTS, AND DIRECTIONS FOR USE

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

EPA REG. NO.	55146-16	30
EPA EST. NO.		

Manufactured For **NUFARM AMERICAS INC. AGT DIVISION** 11901 S. Austin Ave. Alsip, IL 60803



ACCEPTED

Sep 20, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 55146-160

Net Contents:_	Gal. (L)				
[Designation	as "NONREFIL	LABLE o	r "REFILLAB	LE" for cor	ıtainers > 5	GAL1

	FIRST AID
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 IN EYES	 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	 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	 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.

HOT LINE NUMBER

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.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- · Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride (PVC), Viton).

Note: Persons involved in bagging treated seed, sewing or moving bags of treated seed, or cleaning up bagging areas or seed treatment equipment are pesticide handlers and must wear the PPE required on this label for pesticide handlers.

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.

PHYSICAL AND CHEMICAL HAZARDS

DO NOT place product near or allow product to come into contact with strong oxidizing substances (such as potassium permanganate).

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to mammals, fish, and aquatic invertebrates. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply when weather conditions favor drift from treated areas. 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. 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

BOOKLET

sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Cover or incorporate spilled treated seeds.

Groundwater Advisory Statement: Metalaxyl and Tebuconazole are known to leach through soil into groundwater 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 groundwater contamination.

Surface Water Advisory: This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to runoff that contains this product. 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 contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted within 48 hours.

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 application rate 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, butyl rubber, nitrile rubber, neoprene rubber, polyvinylchloride (PVC) or Viton.
- · Shoes plus socks.

USE RESTRICTIONS

- **DO NOT** use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting.
- The maximum application rate for metalaxyl- and mefenoxam-containing products (including seed treatments, foliar applications, soil application) is 12.3 lb per acre per calendar year. **DO NOT** apply more than 12.3 lb of active ingredient, metalaxyl per acre per calendar year.
- Only for use in commercial seed treatment establishments in liquid or slurry treaters. Not allowed for "on-farm" use.
- DO NOT use treated seed for feed, food, or oil purposes.
- Store treated seed away from feeds and foodstuffs. Treated seed must not be used for or mixed with food or animal feed or processed for oil. Seed commercially treated with this product must be labeled in accordance with all applicable requirements of the Federal Seed Act.
- **DO NOT** allow children, pets, or livestock to have access to treated seed.
- Treated seed must be planted into the soil at a depth greater than 1 inch.
- DO NOT graze or feed livestock on green barley forage until 31 days after planting.
- DO NOT graze or feed livestock on green wheat, oats, or triticale for 55 days after planting.
- DO NOT use the same auger for treating seed that will handle commercial or feed grains.
- If excess treated seed remains after planting, dispose of it by burying away from bodies of water.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and, (2) no measurable residues remain in ethanol by-products that are used in agronomic practice.

ROTATIONAL CROPS

DO NOT plant any crop other than those on this label within 30 days to fields in which treated seeds were planted.

RESISTANCE MANAGEMENT RECOMMENDATIONS

Salient TMI contains difenoconazole and tebuconazole, Group 3 fungicides and; metalaxyl, a Group 4 fungicide. Difenoconazole and tebuconazole belong to the DMI class of chemistry. Metalaxyl belongs to the phenylamide class of chemistry.

Fungal populations may contain individuals naturally resistant to active ingredients in Salient TMI 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 such as an alternation with fungicides of a different mode of action and/or tank mixes established for the crop and use area.

Use should be based on an IPM program that includes field sanitation, scouting, historical information related to pesticide use, and crop rotation. The IPM program should also consider cultural, biological, and other chemical control practices.

Nufarm encourages responsible product stewardship to ensure effective long term control of the fungal diseases on this label.

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

PRODUCT INFORMATION

Apply as a seed treatment using standard slurry or mist-type seed treatment equipment. Uniform application to seed is necessary to ensure seed safety and best disease protection. Seed must be sound and well cured prior to treatment. Product must be diluted with sufficient water to ensure complete seed coverage. Consult a seed treatment specialist regarding slurry rates for the crop to be treated with this product

The following table lists the maximum recommended total slurry volumes by crop.

Сгор	Maximum Fl. Oz. Slurry / 100 lbs. of Seed
Wheat, Oats*, Triticale, and Barley	16

^{*} Not approved for use in California

SEED TREATMENT

This product is a mixture of the fungicides Difenoconazole, Tebuconazole, and Metalaxyl. When used on listed crops, this product aids in the control or suppression of the following seed, seedling and soilborne diseases on seed and young seedlings of Barley, Oats, Triticale, and Wheat.

CROP	DISEASE CONTROL	RATE
Barley Oats* Triticale Wheat	Control of seed rots such as Penicillium and Aspergillus and seedborne Fusarium Scab and Septoria. Control of Dwarf bunt, Karnal bunt*, Stinking smut (Common bunt), Flag smut, Loose smut, Covered smut of barley. Control of early season Barley stripe, <i>Pythium</i> damping-off, <i>Septoria</i> disease complex, Rhizoctonia root rot, Common root rot (Cochiliobolus spp.), Fusarium foot rot.	5.0 – 7.5 fluid ounces per 100 pounds of seed
	Early season suppression of powdery mildew, wheat leaf rust, and Septoria leaf blotch.	

APPLICATION DIRECTIONS: Apply prior to planting as a slurry treatment in sufficient fluid for adequate coverage. This product is to be used in liquid or slurry treaters only. Mix thoroughly before use or use entire container at one time. Ensure thorough coverage.

TANK MIXES: All tank mixes should be pre-tested to determine physical compatibility between formulations. Follow the most restrictive precautions and limitations on the labeling of all products used in mixtures. It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture.

*Not approved for use in California

SEED BAG LABELING REQUIREMENTS

Seed commercially treated with this product must be labeled in accordance with all applicable requirements of the Federal Seed Act. The user of this product is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

THE FEDERAL SEED ACT REQUIRES THAT BAGS CONTAINING TREATED SEEDS BE LABELED WITH THE FOLLOWING STATEMENTS:

- This seed has been treated with Salient TM 5.0 (difenoconazole, metalaxyl, and tebuconazole).
- DO NOT use for feed, food, or oil purpose.

THE US ENVIRONMENTAL PROTECTION AGENCY REQUIRES THE FOLLOWING STATEMENTS ON BAGS CONTAINING SEEDS TREATED WITH Salient TM 5.0 (difference on azole, metalaxyl, and tebuconazole):

- Groundwater Advisory: Metalaxyl and Tebuconazole are known to leach through soil into groundwater 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 groundwater contamination.
- Store treated seed away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes plus socks, and chemical resistant gloves when opening this bag or handling (e.g. loading, pouring) treated seed.
- Treated seed must be planted into the soil at a depth greater than 1 inch.
- Dispose of seed packaging in accordance with local requirements.
- DO NOT graze or feed livestock on green barley forage until 31 days after planting.
- DO NOT graze or feed livestock on green wheat, oats, or triticale for 55 days after planting.
- DO NOT contaminate water bodies when disposing of planting equipment wash water.
- **DO NOT** allow children, pets, or livestock to have access to treated seed.
- **DO NOT** plant any crop other than those on this label within 30 days to fields in which treated seeds were planted.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Store treated seed in a cool, dry location.
- DO NOT store leftover treated seed where there is a chance of it becoming mixed with untreated seed.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticides remain in the ethanol by-products that are used in agronomic practice.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool place, **DO NOT** store in direct sunlight. Protect from freezing temperatures. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

[Note to Reviewer: The following statement will be included on all Final Printed Labels bearing multiple Container Handling statements] "NOTE: This product is available in multiple containers. Refer to the Net Contents section of this products labeling for the applicable "Nonrefillable" or "Refillable" designation. Follow the container handling instructions below that apply to your container type / size."

[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 if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill or by incineration, or by other procedures approved by State and local authorities, 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. 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 and continue to drain for 10 seconds after the flow begins to drip. 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. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill or by incineration, or by other procedures approved by State and local authorities, or, if allowed by State and local authorities, by burning. If burned stay out of smoke.

[Refillable containers 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. 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. For final disposal, offer for recycling if available. If recycling or reconditioning is not available, puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

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 PARTICULARTRADE 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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TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BYTHE BUYER, USER, OR ITS CUSTOMERS.TOTHE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

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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[Salient is a trademark of Nufarm Americas Inc.]

[NOT INCLUDED IN FINAL PRINTED LABELING]

LABEL HISTORY

File Name	Revision Mark	Comment
055146-00xxx.20170920.DRAFT	RV092017	DRAFT MASTER LABEL
055146-00RAN.20180530.DRAFT	RV053018	CHANGES REQUESTED BY EPA
055146-00RAN.20180604.DRAFT	RV060418	CHANGES REQUESTED BY EPA
055146-00160.20180607.MASTER	RV060718	SECTION 3 APPROVAL
055146-00160.20190513.DRAFT LABEL.	RV	Revisions as per Interim Reg Review 0081