



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 17, 2021

Christine Villegas  
Senior Regulatory Affairs Manager  
Bayer U.S.- Crop Science  
700 Chesterfield Pkwy W  
Chesterfield, MO 63017

Subject: Registration Review Label Mitigation for METALAXYL  
Product Name: GAUCHO XT FLOWABLE  
EPA Registration Number: 264-971  
Application Date: 06/28/2018  
Decision Number: 580524

Dear Ms. Villegas:

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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. 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.

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If you have any questions about this letter, please contact Srijana Shrestha by phone at 202-566-2329, or via email at [shrestha.srijana@epa.gov](mailto:shrestha.srijana@epa.gov).

Sincerely,

A handwritten signature in blue ink, appearing to read 'Linda Arrington', with a stylized flourish at the end.

Linda Arrington, Branch Chief  
Risk Management and Implementation Branch 4  
Pesticide Re-Evaluation Division  
Office of Pesticide Programs

Enclosure: Stamped Label

IMIDACLOPRID	GROUP	4A	INSECTICIDE
METALAXYL	GROUP	4	FUNGICIDE
TEBUCONAZOLE	GROUP	3	FUNGICIDE

# GAUCHO<sup>®</sup> XT FLOWABLE

Contains Petroleum Distillate.

## ACTIVE INGREDIENTS:

Imidacloprid: 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine	12.7%
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	0.82%
Tebuconazole: Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol	0.62%
<b>OTHER INGREDIENTS:</b>	<b>85.86%</b>
<b>TOTAL:</b>	<b>100.0%</b>

Contains 1.16 pounds of imidacloprid, 0.075 pounds of metalaxyl and 0.056 pounds of tebuconazole per gallon.

EPA Reg. No. 264-971

EPA Est.

## 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)

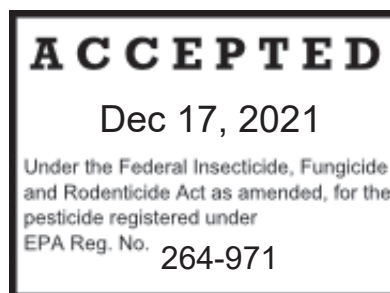
Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

### FIRST AID

<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>

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:** Contains petroleum distillate – vomiting may cause aspiration pneumonia.



## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if swallowed, absorbed through skin or inhaled. Avoid contact with eyes, skin or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, socks and shoes and chemical-resistant gloves (such as barrier laminate, nitrile rubber  $\geq 14$  mills, and viton  $\geq 14$  mills). Follow manufacturer's instructions for washables. 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 toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

#### ENVIRONMENTAL HAZARDS

This product is highly toxic to birds and aquatic invertebrates. For terrestrial uses, 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 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.

## 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.

This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Follow all cautions and limitations on labeling of all products used in mixtures.

### 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 agriculture 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 interval. 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 (drilled) 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 reentry 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 (such as barrier laminate, nitrile rubber  $\geq 14$  mills, and viton  $\geq 14$  mills), shoes plus socks, protective eyewear.

### USE RESTRICTIONS

- 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.
- 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 food for man or feed for animals. Refer to 21CFR, Part 2.25. Any dye or colorant added to treated seed must be cleared for use under 40CFR, Part 180.1001.

### RESISTANCE MANAGEMENT RECOMMENDATION

For resistance management, please note that Gaucho XT Flowable contains a Group 3 (demethylation inhibitors) and a Group 4 (phenylamides) fungicide. Any fungal population may contain individuals naturally resistant to Gaucho XT Flowable and other Group 3 or 4 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Gaucho XT Flowable also contains a Group 4A (neonicotinoid) insecticide. Any insect population may contain individuals naturally resistant to Gaucho XT Flowable and other Group 4A insecticides. The resistant individuals may dominate the insect population if these insecticides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide and/or insecticide resistance, take one or more of the following steps:

- Rotate the use of Gaucho XT Flowable or other Group 3 and 4 fungicides and Group 4A insecticides within a growing season sequence with different groups that control the same pathogens or pests.
- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Use tank mixtures with insecticides from a different group that are equally effective on the target pest when such use is permitted. Do not rely on the same mixture repeatedly for the same pest population. Consider any known cross-resistance issues (for the targeted pests) between the individual components of a mixture. In addition, consider the following recommendations provided by the Insecticide Resistance Action Committee (IRAC):
  - Individual insecticides selected for use in mixtures should be highly effective and be applied at the rates at which they are individually registered for use against the target species.
  - Mixtures with components having the same IRAC mode of action classification are not recommended for insect resistance management.
  - When using mixtures, consider any known cross-resistance issues between the individual components for the targeted pest(s).
  - Mixtures become less effective if resistance is already developing to one or both active ingredients, but they may still provide pest management benefits.

- The insect resistance management benefits of an insecticide mixture are greatest if the two components have similar periods of residual insecticidal activity. Mixtures of insecticides with unequal periods of residual insecticide activity may offer an insect resistance management benefit only for the period where both insecticides are active.
- Adopt an integrated disease management program for fungicide use and an integrated pest management program for insecticides 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 after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens/pests.
- For further information or to report suspected resistance contact Bayer CropScience LP at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance.

## SPECIFIC CROP USE DIRECTIONS

### Wheat, Oats

**Insect Control:** Early season protection of seedlings against injury by Aphids (including Bird cherry-oat, English grain, Greenbug, and Russian wheat aphid) Wireworms and Hessian fly.

**Disease Control:** Early season disease control of *Pythium* damping-off, Stinking smut, Flag smut, Loose smut, Early season *Septoria* disease complex, Early season *Rhizoctonia* root rot, Early season common root rot, Early season *Fusarium* foot rot, Early season suppression of powdery mildew, Early season suppression of wheat leaf rust and improves emergence of seed infected with *Fusarium* scab. Apply 3.4 to 4.5 fluid ounces per hundred weight of seed prior to planting as a slurry treatment. Ensure thorough coverage. Do not graze or feed livestock on treated areas for 45 days after planting.

### Barley

**Insect Control:** Early season protection of seedlings against injury by Aphids (including Bird cherry-oat, English grain, Greenbug, and Russian wheat aphid) and Wireworms.

**Disease Control:** Early season disease control of *Pythium* damping-off and Covered smut, Loose smut, Barley stripe (suppression), Early season *Rhizoctonia* root rot, Early season common root rot, Early season *Fusarium* foot rot, Early season suppression of powdery mildew, Early season suppression of barley leaf rust and improves emergence of seed infected with *Fusarium* scab. Apply 3.4 to 4.5 fluid ounces per hundred weight of seed prior to planting as a slurry treatment. Ensure thorough coverage. Do not graze or feed livestock on treated areas for 45 days after planting.

## ROTATIONAL CROPS

Treated areas may be replanted with any crop specified on an imidacloprid label, or any crop for which a tolerance exists for the active ingredient, as soon as practical following the last application. The following plant-back intervals are required for listed crops:

ROTATIONAL PLANT-BACK INTERVALS*				
IMMEDIATE PLANT-BACK				30-DAY PLANT-BACK
Artichoke	Crambe	Oats	Soybean	Cereals, including: buckwheat rice
Barley	Cucurbits	Okra	Strawberry	
Brassica (cole) leafy veg.	Eggplant	Pepinos	Sugarbeet	
Borage	Flax	Pepper	Sunflower	
Bulb Veg	Ground cherry	Popcorn	Tomatillo	
Canola	Leaf petiole veg.	Potato	Tomato	
Cilantro	Leafy veg.	Rapeseed	Triticale	
Corn, Field	Legume veg. (succulent	Rye	Veg. Root and Tuber	
Corn, Sweet	or dried, including soybean)	Safflower	Watercress	
Cotton	Millet	Sorghum	Wheat	
Cranberry	Mustard Seed			

\* Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.  
 \* For all other crops not listed on an Imidacloprid label, or for crops for which no tolerance for the active ingredient has been established, a 12-month plant-back interval is required.

NOTIFICATION of the crop rotational restriction must be conveyed to the grower by appropriate seed tag labeling or bag printing on all seed units.

## SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with Gaucho XT Flowable must be labeled with the following statements:

This seed has been treated with Gaucho XT Flowable, which contains 12.7% of Imidacloprid, 0.62% of Tebuconazole, and 0.82% of Metalaxyl.

- Do not use treated seed for food, feed, or oil purposes.
- Store treated seeds away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seed.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Leftover treated seed may be buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment wash waters.
- Treated seed must be adequately covered with soil at planting.
- Dispose of seed packaging or containers in accordance with local requirements. Do not use empty seed bags for any other purpose.
- To reduce seed dust which can drift onto blooming crops or weeds, ensure that planting equipment is functioning properly in accordance with manufacturer's recommendations. Surplus seed or empty seed containers should be stored or disposed according to local federal regulations.
- Treated at manufacturer's recommended rate.

## **STORAGE AND DISPOSAL**

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

### **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 DISPOSAL**

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons)  
2.5 gal

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. 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. Dispose of rinsed empty container in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

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

Non-refillable container. Do not reuse or refill this container. After emptying product from container, contact Bayer CropScience Customer Service Center (1-800-527-4781) with return authorization for container return instructions. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Offer for recycling, if available. Dispose of rinsed empty container in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.



## 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.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

**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 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:

GAUCHO is a registered trademark of Bayer Group.

## PRODUCED FOR



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

GAUCHO® XT Flowable (PENDING) 05/31/2018, 06/26/2018, 08/29/2019, 06/30/2021, 12/09/2021