



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

September 27, 2023

Robyn Clark
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419

Subject: Registration Amendment – Amended Terms and Conditions, and Revised Labeling
Product Names: Fortenza, Fortenza Red, Minecto Duo Insecticide, Minecto Pro, Mainspring GNL, Zyrox Fly Granular Bait, Spinner Insecticide, Ference, Mainspring Flora and A16901B Residential Insecticide
EPA Registration Numbers: 100-1420, 100-1418, 100-1421, 100-1592, 100-1543, 100-1541, 100-1424, 100-1551, 100-1585 and 100-1423
Application Date: June 15, 2023
Decision Numbers: 593337, 593338, 593342, 593343, 593341, 593344, 594352, 593336, 593339 and 593334

Dear Ms. Clark:

The amended labels referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable. Accordingly, EPA has approved the requested registration amendments, provided Syngenta Crop Protection, LLC (“Syngenta”) complies with all terms and conditions listed below.

Terms and Conditions

Syngenta must comply with all the following terms and conditions. Release for shipment of these products constitutes acceptance of the below conditions. If these conditions are not complied with, the registrations will be subject to cancellation in accordance with FIFRA section 6.

Endangered Species Protection and Formal Consultation

1. For this action, EPA conducted effects determinations under the Endangered Species Act (ESA). In its final effects determinations (included in a biological evaluation), EPA made may affect, likely to adversely affect (LAA), determinations for certain listed species and designated critical habitats for products containing cyantraniliprole (including this product). For these LAA determinations, EPA also assessed the potential likelihood of jeopardy or adverse modification in its effects determination, consistent with 50 C.F.R. § 402.40(b)(1). EPA predicted no potential likelihood of jeopardy for listed species or adverse modification for designated critical habitat. On September 25, 2023, EPA initiated formal consultation with the

Services. The Services will make the final determination as to the potential for jeopardy for listed species or adverse modification for designated critical habitat in any final biological opinions issued at the completion of consultation.

If, following formal consultation with Service(s), additional modifications are identified in any applicable Biological Opinion, EPA will notify Syngenta in writing within 45 calendar days of the issuance of the Biological Opinion of any necessary changes. Within 30 calendar days of receiving EPA's notice, Syngenta must submit an amendment application incorporating the necessary changes, including amended labels. Alternatively, Syngenta may respond by submitting a request for voluntary cancellation of this product. If Syngenta fails to comply with this term, Syngenta has agreed in prior written acceptance of these terms that EPA may cancel the registration under an expedited process under FIFRA 6(e).

Implementation of Revised Labeling

2. To ensure the prompt adoption of the mitigations in this registration amendment in newly produced product and previously produced product that is still under Syngenta's control, Syngenta must submit state registrations for approval, in all states where products are currently registered, for the products with the labeling associated with this approval letter no later than November 30, 2023.
3. In accordance with 40 C.F.R. § 152.130(c), product may be distributed or sold by Syngenta under the previously approved labeling for no longer than 12 months from the date of this letter or 75 days after the final state approval from those submitted under Term #2, whichever is earlier.
4. Nothing in Terms #2-3 should be read to obligate Syngenta to provide additional labeling for product that bears the previously approved label but is not under Syngenta's control as of the date of this letter. However, Syngenta should conduct outreach for users of this product to update them on the forthcoming changes to the label and their importance in mitigating potential effects to listed species and avoiding violations of the Endangered Species Act.

EPA's Rationale for Approving This Registration Amendment

FIFRA section 3(c)(5) requires EPA to unconditionally approve a registration amendment if:

- "its composition is such as to warrant the proposed claims for it";¹
- "its labeling and other material required to be submitted comply with the requirements of [FIFRA]";²

¹ FIFRA § 3(c)(5)(A), 7 U.S.C. § 136a(c)(5)(A). Here, EPA reviewed the proposed labeling and determined that the claims made for the product were consistent with composition of the product based on the data submitted.

² FIFRA § 3(c)(5)(B), 7 U.S.C. § 136a(c)(5)(B). Here, EPA reviewed the submitted labeling and other materials submitted and found them to be compliant with the requirements of FIFRA. Additionally, there are no data gaps.

- “it will perform its intended function without unreasonable adverse effects on the environment”;³ and
- “when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.”⁴

Prior to approving the previous registrations and registration amendments for this product and others containing cyantraniliprole, EPA considered risks and benefits of approving the registrations and registration amendments. To determine the risks and benefits, the Agency reviews a large body of information to determine the effects of using these products. In assessing the risks from use of products containing cyantraniliprole, EPA has conducted both human health risk assessments⁵ and ecological and environment fate risk assessments.⁶ EPA also updated its ecological and environmental fate risk assessments in support of the 2023 draft biological evaluation (BE).⁷ EPA believes that that these risk assessments (and the benefits discussed below) are also applicable to the action to approve this amended registration.

³ FIFRA § 3(c)(5)(C), 7 U.S.C. § 136a(c)(5)(C).

⁴ FIFRA § 3(c)(5)(D), 7 U.S.C. § 136a(c)(5)(D).

⁵ Summary of Analytical Chemistry and Residue Data (Jan. 25, 2013) ([EPA-HQ-OPP-2011-0668-0009](#)); Dietary Exposure and Risk Assessment (Jan. 29, 2013) ([EPA-HQ-OPP-2011-0668-0010](#)); Occupational and Residential Exposure and Risk Assessment for the Proposed New Uses of the New Active Insecticide Cyantraniliprole (Feb. 28, 2013) ([EPA-HQ-OPP-2011-0668-0011](#)); Aggregate Human Health Risk Assessment for the Proposed New Uses of the New Active Insecticide Cyantraniliprole (Mar. 7, 2013) ([EPA-HQ-OPP-2011-0668-0012](#)); Chronic Aggregate Dietary Exposure and Risk Assessments in Support of a Section 3 Registration Action (Sept. 7, 2016) ([EPA-HQ-OPP-2014-0357-0009](#)); Human Health Risk Assessment for Various Proposed Uses and Several Tolerance Requests without U.S. Registration (Jan. 12, 2017) ([EPA-HQ-OPP-2014-0357-0011](#)); Summary of Analytical Chemistry and Residue Data (Apr. 21, 2016) ([EPA-HQ-OPP-2014-0357-0012](#)); Summary of Analytical Chemistry and Residue Data (Aug. 8, 2016) ([EPA-HQ-OPP-2014-0357-0013](#)); Human Health Risk Assessment for Proposed Uses and Tolerance Requests on Coffee; Caneberry Subgroup 13-07A; Low Growing Berry Subgroup 13-07H, Except Strawberry, Lowbush Blueberry and Lingonberry; Brassica Leafy Greens Subgroup 4-16A; Leafy Greens Subgroup 4-16B (June 20, 2018) ([EPA-HQ-OPP-2017-0694-0011](#)); Chronic Aggregate Dietary Exposure and Risk Assessments for Proposed Uses and Tolerance Requests on Coffee; Caneberry Subgroup 13-07A; Low Growing Berry Subgroup 13-07H, Except Strawberry, Lowbush Blueberry and Lingonberry; Brassica Leafy Greens Subgroup 4-16A (May 30, 2018) ([EPA-HQ-OPP-2017-0694-0012](#)); Human Health Risk Assessment for an Inadvertent Tolerance on Sugarcane (Feb. 28, 2022) ([EPA-HQ-OPP-2021-0154-0007](#)); Highly Refined Chronic Aggregate Dietary Exposure and Risk Assessments for Proposed Inadvertent Use and Tolerance Request on Sugarcane (Feb. 28, 2022) ([EPA-HQ-OPP-2021-0154-0008](#)).

⁶ Environmental Fate and Ecological Risk Assessment for the Registration of the New Chemical Cyantraniliprole – Amended (April 30, 2013) ([EPA-HQ-OPP-2011-0668-0008](#)); Environmental Risk Assessment of Proposed New Global Chemical Cyantraniliprole – Addendum (Jan. 24, 2014) ([EPA-HQ-OPP-2011-0668-0055](#)); Revised Drinking Water Assessment including Ground Water Exposure Refinements for Proposed New Uses on Leafy, Bulb, Fruiting, and Cucurbit Vegetables with Two Seasons of Applications (June 9, 2016) ([EPA-HQ-OPP-2014-0357-0010](#)); Ecological Risk Assessment and Drinking Water Assessment for the IR-4 New Use Petition for Pronamide on Low Growing Berry Subgroup except Strawberry, Subgroup 13-07H; Stone Fruit Crop group 12-12; Pome Crop Group 11-10; Caneberry subgroup 13-07A; Bushberry subgroup 13-07B; and Small Fruit Vine Climbing Subgroup (except Fuzzy Kiwifruit Subgroup 13-07F) (May 14, 2018) ([EPA-HQ-OPP-2017-0694-0013](#)).

⁷ See EPA’s Draft Biological Evaluation for Cyantraniliprole and supporting documentation, available at [EPA-HQ-OPP-2011-0668](#), Document ID Nos. 71-72, 75-87.

In the human health risk assessments, EPA did not select an acute dietary toxicity endpoint because the Agency did not identify any effect attributed to a single dose (*i.e.*, CTP is not expected to pose an acute risk to humans). In general, CTP produces both adverse and adaptive changes in the liver, thyroid gland, and adrenal cortex. With repeat dosing, consistent findings of mild to moderate increases in liver weights are observed across multiple species (rats, mice, dogs). CTP was classified as “not likely to be carcinogenic to humans” based upon data demonstrating lack of treatment-related increase in tumor incidence in rats and mice. No cumulative effects were identified. CTP presents no mutagenicity, neurotoxicity, immunotoxicity, developmental reproductive toxicity.

In the environmental risk assessments, EPA identified risks of concern for both aquatic and terrestrial invertebrates. Overall, however, the major risks of concerns are for direct effects to freshwater, estuarine/marine, and benthic invertebrates. EPA did not identify direct risks of concerns for birds, reptiles, amphibians, freshwater fish, terrestrial plants, or aquatic plants.

EPA also considered the benefits of products containing cyantraniliprole, including CTP’s activity on a wide variety of target insects on a variety of crops. CTP is effective for controlling aphids, weevils and thrips—all major agricultural pests. CTP is not expected to pose any acute risk to humans and was registered in 2013 as a reduced risk pesticide due to it posing lower relative risk to alternative chemicals available at that time. CTP also poses lower risk to non-target organisms relative to alternatives and is compatible with IPM practices.

This amended registration includes additional mitigation measures to address effects to listed species, including the following:

- Requirement that applicators use coarse/coarser droplets for ground and aerial applications to reduce spray drift
- Requirement that aerial applications abide by wind-directional buffers, as identified in Bulletins Live Two (BLT), also to reduce spray drift
- Increase in distance of vegetative filter strips from 25 to 30 feet to mitigate the potential for runoff to aquatic habitats
- Use of a 25’ buffer for airblast applications to dormant, non-bearing and/or vegetation that is not yet fully leafed out
- Requirement that treated seeds be immediately covered or collected if spilled during loading

After consideration, EPA has determined that approving this amended registration will not cause unreasonable adverse effects because the amended registrations are not expected to result in increased exposures⁸ and because EPA continues to believe that—consistent with the 2014 registration decision⁹

⁸ While the mitigations in the amended registrations are intended to reduce exposures to listed species, EPA expects that the mitigations will (1) not increase exposures to other non-listed non-target organisms, and (2) will generally reduce exposures to all non-target organisms (both listed and non-listed).

⁹ For EPA’s full risk-benefit analysis, *see* Registration of New Active Ingredient Cyantraniliprole, at 13-14 (Jan. 24, 2014) ([EPA-HQ-OPP-2011-0668-0057](#)).

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and other previous registration decision for products contain cyantraniliprole—the benefits of these registrations outweigh any remaining risks of concern from its use and there are no human dietary risks from uses of cyantraniliprole that are inconsistent with the FFDCA safety standard.¹⁰ Accordingly, EPA is approving these registration amendments because the FIFRA registration standard is met.

Conclusion

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. Consistent with Terms 2-5 above, and notwithstanding 40 C.F.R. § 152.130(c), you may only distribute or sell¹¹ this product under either the final stamped label associated with this approval letter or with accompanying labeling that incorporates the mitigations in this registration amendment.

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 C.F.R. § 156.10(a)(5) lists 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 product will be referred to EPA's Office of Enforcement and Compliance.

If you have any questions, please contact Gene Benbow at 703-712-9669 or at benbow.gene@epa.gov.

Sincerely,



Deanna (Dee) Colby, Chief
Invertebrate & Vertebrate Branch 3
Registration Division
Office of Pesticide Programs

Enclosure

¹⁰ See FIFRA § 2(bb) (defining “unreasonable adverse effects on the environment” as, in relevant part, “any unreasonable risk to [humans] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide” or any “human dietary risks” from pesticidal residues in or on food).

¹¹ See FIFRA § 2(gg), 7 U.S.C. § 136(gg); 40 C.F.R. § 152.3.

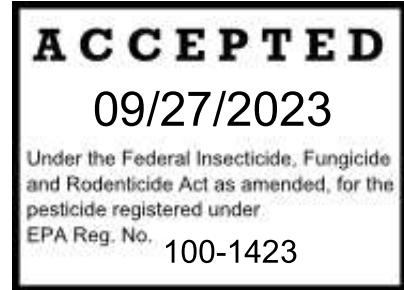
[MASTER]

Sale, use, and distribution of this product in Nassau and Suffolk Counties in the State of New York is prohibited.

A16901B Residential

Insecticide

For Outdoor Applications to Residential Landscape Plants



Active Ingredient:

Thiamethoxam¹ 20.0%

Cyantraniliprole² 20.0%

Other Ingredients: 60.0%

Total: 100.0%

¹CAS No. 153719-23-4

²CAS No. 736994-63-1

A16901B Residential is a water-dispersible granule.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1423

EPA Est.

Net Weight

Non-refillable container

FIRST AID	
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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOTLINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372 <i>[alternate phone number]</i>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling, and before drinking, eating, chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt, long pants, socks, shoes, and chemical-resistant gloves (such as natural rubber, Selection Category A).

Environmental Hazards

This pesticide is toxic to wildlife and highly toxic to aquatic invertebrates, oysters and shrimp. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high-water mark. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment wash waters.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds and may cause possible effects to pollinators from exposure to translocated residues in blooming crops. Do not apply this product or allow it to drift to blooming crops or weeds while bees are foraging in/or adjacent to the treatment area.

PROTECTION OF POLLINATORS



APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.



Look for the bee hazard icon in the Directions for Use for each application site for specific use restrictions and instructions to protect bees and other insect pollinators.

This product can kill bees and other insect pollinators.

Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:

- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen when the pesticide is applied as a seed treatment, soil, tree injection, as well as foliar applications.

When Using This Product Take Steps To:

- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants around the application site.
- Minimize drift of this product on to beehives or to off-site pollinator attractive habitat. Drift of this product onto beehives or off-site to pollinator attractive habitat can result in bee kills.

Information on protecting bees and other insect pollinators may be found at the Pesticide Environmental Stewardship website at:

<http://pesticidestewardship.org/PollinatorProtection/Pages/default.aspx>.

Pesticide incidents (for example, bee kills) should immediately be reported to the state/tribal lead agency. For contact information for your state, go to:

www.aapco.org/officials.html. Pesticide incidents should also be reported to the National Pesticide Information Center at: www.npic.orst.edu or directly to EPA at:

beekill@epa.gov

- **Surface Water Advisory**

This product may impact surface water quality due to spray drift and runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several months after application. Avoid accidental or intentional application of this product to ditches, swales, drainage ways or impervious surfaces such as driveways. Runoff of this product will be reduced by avoiding applications when rainfall is forecast to occur within 48 hours. (See manual at the following internet address:

<http://www.wsi.nrcs.usda.gov/products/W2Q/pest/core4.html>.)

- **Groundwater Advisory**

This product has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into the groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

- **Spray Drift Advisory**

Do not allow this product to drift.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label before using this product.

SURFACE WATER PROTECTION STATEMENT

For foliar applications: Do not apply during rain.

- Do not apply A16901B Residential while bees are foraging. Do not apply A16901B Residential to plants that are flowering. Only apply after all flower petals have fallen off.
- Do not allow people and pets to re-enter until the treated area has been allowed to dry.
- Do not use kitchen utensils such as measuring cups and spoons for food purposes after use with pesticides.
- Do not make applications during rain.
- Do not apply within 50 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams, wetlands or natural ponds, estuaries, and commercial fish farm ponds).
- Do not cultivate within 30 feet of the aquatic area to allow growth of a vegetative filter strip.
- Sale, use, and distribution of this product in Nassau and Suffolk Counties in the State of New York is prohibited.

HOW TO APPLY

- **Determine size of spraying job.** For application to landscape ornamental plants, determine the area to be sprayed.
- **Carefully measure and mix** the amount of product and water as indicated in the use directions. Always wear water-resistant gloves when handling pesticides.
- **Spray as directed.** Thorough coverage is important. Do not over wet.
- **Flush sprayer** with clean water after each use.

ORNAMENTAL TREES, SHRUBS AND FLOWERS

Plant Safety

A16901B Residential is safe on most ornamental plants. However, applications of A16901B Residential to yellow varieties of Honey Locust (*Gleditsia triacanthos*) may result in leaf chlorosis and abscission (yellowing and dropping). The effects are temporary.

Pests controlled

- Aphids
- Whiteflies
- Leafminers



How to apply [logo optional]

- Measure 1 teaspoon of A16001B Residential and add to a 1-gallon size (or larger) pump-style sprayer.
- Add 1 gallon of water to the sprayer.
- Close the sprayer and shake well.
- Pressurize the sprayer.
- Adjust nozzle to achieve a medium to coarse spray pattern and apply as a thorough cover spray.
- Re-pressurize the sprayer as needed to maintain a good spray pattern.
- 1 gallon treats plants in a 400 square feet area.

Use Tips for Ornamentals

- Apply before insect populations are high.
- Apply to both sides of plant leaves and all plant surfaces where insects are present.
- A second application may be made 7 days after the initial application if insects are still present.
- Do not make more than 2 applications per growing season.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place.

Pesticide Disposal and Container Handling (*consumer products*)

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or [1-800-888-8372] [Alternate phone number] for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Product name], the ALLIANCE FRAME, the SYNGENTA logo, and the PURPOSE ICON are trademarks of a Syngenta Group Company

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For non-emergency (e.g., current product information) call
Syngenta Crop Protection at 1-866-796-4368.

Manufactured for:

Syngenta Crop Protection, LLC

P.O. Box 18300

Greensboro, North Carolina 27419-8300