

70585-10

2/5/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

FEB - 5 2014

Ms. Rebecca Barnes
Novartis Animal Health US, Inc.
3200 Northline Avenue
Greensboro, NC 27408

Subject: Amended label to update the Environmental Hazards and add a pollinator restriction to the spot spray treatment directions
Product Name: Agita 10 WG
EPA Reg. No. 70585-10
EPA Decision No. 487383
Submission dated January 30, 2014

Dear Ms. Barnes:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable. A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. See 40 CFR 156.10(a)(6).

Under 40 CFR 152.130(d), EPA may establish dates by which all product distributed or sold by the registrant must bear revised labeling. The following paragraphs set forth the schedule for ensuring that that your product bears revised labeling within a reasonable time period:

- Any product released for shipment after 2/28/14 must bear the new label.

If these conditions are not complied with, EPA will take appropriate action against this registration. If you have any questions please contact Julie Chao at 703-308-8735 or chao.julie@epa.gov.

Regards,

A handwritten signature in black ink that reads "Venus Eagle".

Venus Eagle, Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

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GROUP 4A INSECTICIDE

AGITA® 10 WG

- *Reduces housefly populations in and around the outside perimeter of animal housing*
- *With fly sex attractant, Z-9-Tricosene*
- *Attracts and kills houseflies (Musca domestica)*
- *For control of Litter Beetles (Darkling Beetles)*
- *Thiamethoxam Spot Spray Fly Bait*
- *Water Dispersible Granule Insecticide for Control of Houseflies and Litter Beetles*

Active Ingredients:

Thiamethoxam (CAS No. 153719-23-4)	10.00%
(Z)-9-Tricosene (CAS No. 27519-02-4)	0.05%
Other Ingredients:	89.95%
Total:	100.00%

EPA Reg. No. 70585-10
EPA Est. 71637-AUT-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements and direction for use on back of container.

Net Weight: 2.2 lbs (1 kg) or 0.88 lbs (400 g) or 0.55 lbs (250 g)

Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

Product of Austria

® Trademark of Novartis AG

ACCEPTED
FEB - 5 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 70585-10

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 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 15-20 minutes. • 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.	
USA HOT LINE NUMBERS	
For Medical Emergency Assistance (Human or Animal) Call 1-800-637-0281	
For Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-424-9300	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt, long pants, socks, shoes, chemical-resistant gloves, and protective eyewear. Remove and wash contaminated clothing before reuse.

Environmental Hazards

This product is highly toxic to bees exposed to direct treatment or residues on blooming plants or weeds. Do not apply this product or allow it to drift to blooming plants or weeds if bees are foraging in the treatment area. This pesticide is toxic to birds and other wildlife and is highly toxic to aquatic 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. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water.

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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. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS 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. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS 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 NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

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

DIRECTIONS FOR USE

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

FAILURE TO FOLLOW DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN INJURY, INADEQUATE FLY CONTROL, AND/OR ILLEGAL RESIDUES.

Use Information

AGITA® 10 WG is a water dispersible insecticidal bait formulation for the reduction of housefly (*Musca domestica*) populations in and around the outside perimeter animal housing. The combination of a neonicotinoid insecticide, with both contact and stomach modes of action, with a housefly attractant provides an effective fly bait formula which encourages both male and female houseflies to remain in treated areas and consume a contact lethal dose of the bait.

In addition, AGITA® 10 WG has been shown to be highly effective in controlling Litter beetle (*Alphitobius diaperinus*) infestations in broiler houses.

Use AGITA® 10 WG as part of an integrated pest management program for houseflies.

AGITA® 10 WG is a formulation suitable for application as a spot spray insecticidal bait.

Use any AGITA® 10 WG suspension on the day of mixing, preferably immediately after preparation. Do not treat dirty, highly porous or newly whitewashed walls to prevent loss of long term efficacy. Do not apply on metal and glass surfaces to avoid run-off.

New litter and fresh bedding must be put into poultry houses prior to restocking.

Areas of Use:

Apply ONLY in locations not accessible to children, pets, domestic animals or wildlife. Protect from direct sunlight, water and rainfall. Do not apply bait where animals can lick the product. Do not apply directly to livestock or livestock feed as illegal residues may result.

Restriction: For commercial animal housing facilities only.

Insecticide Resistance Management

For resistance management, thiamethoxam is a Group 4A insecticide. Any housefly population may contain individuals naturally resistant to thiamethoxam and Group 4A insecticides. To delay insecticide resistance, avoid exclusive, repeated use of AGITA® 10 WG or other Group 4A insecticides. Keep accurate records of insecticides used in your operation. Keep the housefly population as low as possible by manure management.

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“Spot Spray” Application:

As indicated in the Table below, thoroughly mix the appropriate quantity of AGITA® 10 WG in the corresponding volume of lukewarm water to obtain a mixture with the consistency of a sprayable suspension. Apply the spray, using a standard liquid spray applicator, to approximately one-third (1/3) of the total intended surface area to be treated. Surfaces on which flies are particularly likely to settle should be sprayed. Such areas may include window sills, door frames, warm wall areas and areas near animal pens, provided the applied product is kept out of reach of animals. Stir occasionally during application. Re-agitate before use if spraying is interrupted for longer than 30 minutes. Do not allow product to contact plants in bloom if bees are foraging in the treatment area. Do not use on walkways used by animals. See mixing and surface area examples in the Table below:

**TABLE
AGITA® 10 WG “Spot Spray”**

[NOTE TO EPA REVIEWER: This table is for the 0.55 lb. and 0.88 lb. presentations.]

Quantity of AGITA® 10 WG:	2 oz.	4 oz.	8 oz.
Quantity of lukewarm water:	15 fl. oz.	30 fl. oz.	60 fl. oz.
Approximate Building Size:	125 sq. ft.	250 sq. ft.	500 sq. ft.
Corresponding approximate wall / ceiling surface area:	250-375 sq. ft.	500-750 sq. ft.	1000-1500 sq. ft.

[NOTE TO EPA REVIEWER: This table is for the 2.2 lbs. presentation.]

Quantity of AGITA® 10 WG:	4 oz.	8 oz.	16 oz.	2.2 lbs.
Quantity of lukewarm water:	30 fl. oz.	60 fl. oz.	120 fl. oz.	2 gallons
Approximate Building Size:	250 sq. ft.	500 sq. ft.	1000 sq. ft.	2250 sq. ft.
Corresponding approximate wall / ceiling surface area:	500-750 sq. ft.	1000-1500 sq. ft.	2000-3000 sq. ft.	4500-6500 sq. ft.

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Directions for Litter Beetle Control in Broiler Houses (“Spot Spray” Method)

AGITA[®] 10 WG is highly effective in controlling Litter Beetle (*Alphitobius diaperinus*) infestations in broiler houses. Under each feeder apply 2 fl oz of the mixed spray suspension (i.e., 2 oz of AGITA[®] 10 WG mixed in 32 fl oz of lukewarm water) per square foot of 1.5-inch thick bedding material. Treatments to bedding must be made using a low pressure applicator.

STORAGE AND DISPOSAL

Do not discharge leftover product into ponds, streams or sewage systems. Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed container and away from children, preferably in a locked storage area. Store in a cool, dry place and away from direct sunlight.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

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

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(internal label code)