

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 10, 2010

Jane Rothwell
The Scotts Company
d/b/a The Ortho Group
P.O. Box 190
Marysville, OH 43040

Subject:

Amendment – Add Efficacy Claims

Home Defense Max® Perimeter Insect Killer Aerosol¹

EPA Reg. No. 239-2695

Your submission dated June 15, 2010

Dear Ms. Rothwell:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

- 1. Delete all claims listed under the "Spreading Characteristics" in the Optional Marketing Claims section. These claims are unacceptable, no data was submitted demonstrating the movement of active ingredient into cracks, crevices, harborage, etc., and efficacy in those areas was not assessed.
- 2. Delete all claims against bedbugs. See attached November 4, 2010 Efficacy Review.
- 3. Delete "Controls Ticks (including ticks that may transmit Lyme disease)" as residual control data was not submitted or cited for ticks. See attached November 4, 2010 Efficacy Review
- 4. Replace "To control Fleas & Ticks [including ticks that may transmit Lyme Disease]" with "To Kill Fleas & Ticks [including ticks that may transmit Lyme Disease]"
- 5. Delete all outdoor claims against roaches/palmetto bugs/water bug, scorpions and fleas. See attached November 4, 2010 Efficacy Review
- 6. Revise the following Optional Marketing Claims as follows:

- a. Delete "New!"
- b. Delete "[New] Barrier Technology" from "[New] Barrier Technology keeps bugs out of your home" and "[New] Barrier Technology keeps bugs from coming in".
- c. Delete "Long lasting Barrier technology"
- d. Replace "Kills [listed] bugs inside all year*" with "Kills listed bugs inside all year*"
- e. Replace "Kills [listed] home invading bugs all year*" with "Kills listed home invading bugs all year*"
- f. Replace "Kills [listed] indoor bugs all year*" with "Kills listed indoor bugs all year*"
- g. Replace all "Kills [listed] bugs" with "Kills listed bugs"
- h. Delete "Immediately" from "Immediately [quickly] forms [creates] [establishes] ...etc"

The company's website referenced on your label becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the websites are false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. 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. Should the Agency find or if it is brought to our attentions 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this action, please contact BeWanda Alexander at <u>Alexander.bewanda@epa.gov</u> or (703) 305-7460.

Sincerely,

Product Manager

Insecticide Branch

Registration Division (7505P)

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Enclosure

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text]. Text separated by / denotes and/or options.

Home Defense Max® Perimeter Insect Killer Aerosol 1

For Residential Use Only

Alternate Brand Names

Ortho® Home Defense Max® Ant & Roach Killer
Ortho® Home Defense Max® Ant, Roach & Spider Killer6
Ortho® Home Defense Max® Indoor & Perimeter Insect Killer

Ortho® Home Defense Max® Perimeter and Indoor Insect Killer 6

Ortho® Home Defense Max® Insect Killer

Ortho® Home Defense Max® Insect Killer Aerosol ¹
Ortho® Home Defense ® Ant & Roach Killer
Ortho® Home Defense ® Ant, Roach & Spider Killer

Ortho® Home Defense® Indoor & Perimeter Insect Killer

Ortho® Home Defense® Perimeter and Indoor Insect Killer 6
Ortho® Home Defense® Insect Killer
Ortho® Home Defense® Insect Killer
Ortho® Home Defense® Insect Killer Aerosol 1

ACTIVE INGREDIENTS:

Bifenthrin*......0.05% OTHER INGREDIENTS......99.92% TOTAL......100.00%

*Cis isomers 97% minimum, Trans isomers 3% maximum [US Patent No. 4,223,505]

KEEP OUT OF REACH OF CHILDREN

See back panel for additional precautionary statements.

NET WT X oz/XXX g

ACCEPTED with COMMENTS In EPA Letter Dated NOV 1 0 2010 Under the Federal Insecticide. Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Reg. No.

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID

[icon]

If on skin:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call a Poison Control Center for treatment advice

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-225-2883 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms. Drift and run-off from treated areas may be hazardous to aquatic organisms in neighboring areas. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Care should be used when spraying to avoid fish and reptile pets in and around ornamental ponds. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not apply this product around electrical equipment due to the possibility of shock hazard.

NOTICE: To the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.

DIRECTIONS FOR USE

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

Before you apply:

- Cover or remove exposed food [including pet food]
- Cover all food processing surfaces and utensils. Thoroughly wash with soap and water before re-use.

To apply:

- Shake well before using.
- Hold can about 18" from surface being sprayed.
- Apply a 4" wide band in areas where insects are a recurring problem.
- Spray until surfaces are wet.
- Indoors: Apply along baseboards, beneath and behind appliances, sinks, cabinets, in pantries, on floor coverings [including carpet, tile, linoleum and wood floors], around plumbing and garbage cans, in cracks and crevices in walls, around window frames and doorways, and in attics and basements. In pantries: Remove all items and clean thoroughly before applying.

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Outdoors: Apply along the foundation, around window frames and doorways, on porches and patios, in garages, [and] along eaves and exterior siding.

Do not use as a room spray. Do not spray animals or animal bedding [or resting quarters].

After you apply:

People and pets may re-enter treated areas after spray has dried.

[icon]

 For long lasting residual control, leave spray undisturbed so that the product will keep killing for up to 12 months.* Re-apply every 12 months indoors. Re-apply every 6 months outdoors.

STORAGE AND DISPOSAL

ficon1

PESTICIDE STORAGE: Store in a cool, dry place.

PESTICIDE DISPOSAL: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

[NO CFCs icon]

ICONTAINS NO CFCs WHICH DEPLETE THE OZONE LAYER

Federal regulations prohibit CFC propellants in aerosols.]

[phone icon]

Questions, Comments or Medical Information? ¿Preguntas, Comentarios o Información Médica? 1-800-225-2883

www.ortho.com [computer icon]

Ortho & Your Environment – Your home and yard are places for family and pets to enjoy. That's why Ortho® products are designed with care to provide effective solutions to insect problems inside and outside your home. Follow instructions for appropriate usage, storage and disposal.

[†]The ORTHO Guarantee

If for any reason you, the consumer are not satisfied with this product, mail us your original proof of purchase to obtain a full refund of your purchase price.

© 2010, Licensed by The ORTHO Group. World rights reserved. [Patent Pending.] note to PM: patent is for the unique applicator design

[Manufactured for][Sold by]
The ORTHO Group
P.O. Box 190, Marysville, OH 43040
EPA Reg. No. 239-2695
EPA Est. 58996-MO-1^A
239-IA-3 (1)
84064-IA-001 (P)
085652-OH-1 (W)

Superscript is first letter of lot number

Part Number TBD UPC CODE TBD [STEEL] Symbol DOT 2Q ITF Code TBD

Made in USA

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OPTIONAL MARKETING CLAIMS Non-Residual Claims

Kills (any or all of the following insects) Annual bluegrass weevil, Ants(including Argentine, Carpenter, Foraging Fire Ants, Lawn, Pavement, Pharaoh, Pyramid, and Red/Western Harvester), Aphids (including Apple, Black cherry, Buckhorn, Greenbug, Pea, Pecan, Rose, Rosy Apple and Walnut), Apple maggot, Armyworms, Beet Armyworm, Artichoke plume moth, Bagworms, Bedbugs, Bees, Beetles (including Asian Lady, Carpet, Colorado potato, Elm leaf, Flea, Japanese (adults), Mexican bean, Sap, Spotted Cucumber and Striped Cucumber), Billbugs, Biting Flies, Black Turfgrass Ataenius, Black vine weevil, Blueberry spanworm, Borers (including American plum, European corn, Lesser peach tree, Peach tree, Peach twig, Southwestern corn, Squash vine and Stalk), Boxelder bugs, Budworms, Caterpillars (including Alfalfa, Painted Lady, Saltmarsh, Tent and Velvetbean), Centipedes, Cherry fruit fly, Chiggers, Chinch bug (including Hairy and Southern), Cockroaches (including American/ Palmetto bug / Water bug, Asian (Oriental) and German), Codling moth, Comearworm, Corn rootworm (Adults), Corn silkfly, Cranberry fruitworm, Crickets, Curculio (including Cow pea and Plum), Cutworms, Diamondback moth, Earwigs, Eastern Sprucegall adelgade, European Crane Fly, Filbert worm, Firebrats/ Bristletails, Fleas (including Cat and Dog), Fungus Gnats, Grasshoppers, Green Cloverworm, Green fruitworm, Gypsy moth, Hickory shuckworm, Hornets/Yellow Jackets, Hornworm (including Tobacco and Tomato), House fly, Imported cabbageworm, Lacebugs, Lady Beetles, Leafhoppers, Leafminers (including Alder, Tentiform, Vegetable), Leafrollers (including Oblique banded, Red-banded and Variegated), Loopers (including Alfalfa, Cabbage and Celery), Lygus bug, Mealy bug, Midges, Millipedes, Mites (including Broad, Carmine, Clover, Spruce, Two spotted spider, European red and Pecan scorch), Mole crickets, Mosquitoes, Navel orangeworm, pantry pests, Pear psylla, Pecan leaf phylloxera, Pecan nut casebearer, Pecan spittlebug, Pecan stem phylloxera, Periodical cicada, Pickleworm, Pine chafer (grub), Pine Shoot beetle, Plantbugs, Psyllids, Rindworms, Sawflies (including European and Redheaded), Scales (including San Jose, Euonymus, Brown Soft and California Red), Scorpions, Silverfish, Sod webworms, Sowbua/ Pillbua/ Rollie Pollie, Spiders (including Black widow, Brown recluse, Hobo and Wolf), Silverfish, Spittlebug, Springtails, Squash bug, Stink bugs, Stored product pests (Moths and Beetles), Tarnished plant bug, Thrips, Ticks, Termites, Wasps/Yellow Jackets and Whiteflies.

Also Controls Ticks (including ticks that may Transmit Lyme Disease) Also Kills Ticks (including ticks that may Transmit Lyme Disease)

General

- New! (to be used for six months following commercial introduction of product)
- Continuous Spray!
- Kills by contact!
- [ICON] Water based
- [ICON] People and pets may re-enter treated areas after spray has dried
- Non-staining
- Dries fast

Water based product claims

- Water based [formula]
- Non-flammable
- Dries clean
- Dries clear
- Dries fast
- No oily residue
- No mess
- Does not stain [fabrics, floors, wood, surfaces]

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- Non-staining
- Unscented
- Fragrance-Free
- Leaves no odor
- No sticky mess
- No lingering [chemical] odor
- Odor Free
- Odorless
- No odor
- No greasy residue [mess]

Residual Control claims

- Kills bugs inside. Keeps bugs out.
- Forms [creates] [establishes] a perimeter treatment
- [Creates] [Establishes] a perimeter treatment
- Kills and prevents [listed insects] [inside your home] [outside your home]
- Provides residual control against listed home invading insects
- Keeps [on] killing with residual action, even after you spray
- Keeps [on] killing with residual action, even after spray has dried
- Keeps on killing after spray has dried
- Use in [kitchens], [garages], [basements], [attics] to keep listed bugs [listed insects] from entering your home
- Use in [kitchens], [garages], [basements], [attics] to kill listed bugs [listed insects]
- Long-lasting control
- Long-lasting insect control
- Long-lasting residual control
- Kills [two] [2] ways [Dual Action]: 1) Kills listed insects fast [by contact] and 2) Keeps killing even after spray has dried
- Immediately [quickly] forms [creates] [establishes] a perimeter treatment
- Immediately [quickly] forms [creates] [establishes] a [bug] [insect] barrier
- [Creates] [Establishes] a [bug] [insect] barrier
- Create a bug barrier
- Create bug barriers
- Creates a barrier that [will kill] [kills] the bugs you have and prevent[s] new bugs from coming [in] [inside your home] [all season]
- Kills the bugs you have and creates a barrier that prevents new bugs from coming inside your home all season.
- [New] Barrier Technology keeps bugs out of your home
- [New] Barrier Technology keeps bugs from coming in
- Long lasting Barrier technology
- Guards against bugs so you don't have to
- Guards against the bugs you can't (don't) see

12-Month Claims

- Up to 12 month control [protection]*
- Kills [Controls] [Protects] [for] up to 12 months*
- Kills [listed] bugs inside all year*
- Kills [listed] home invading bugs all year*
- Kills [listed] indoor bugs all year*

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Qualifier Option 1: * [applies to] [for] Ants, Roaches / palmetto bug / water bug, & Spiders indoors on nonporous surfaces

Qualifier Option 2: * [applies to] [for] American Cockroach / palmetto bug / water bug, carpenter ant, pharaoh ant, striped tail scorpion, black widow spider, brown recluse spider indoors on treated nonporous surfaces within minutes of exposure.

Qualifier Option 3: * [applies to] [for] American Cockroach / palmetto bug / water bug, German cockroach, carpenter ant, pharaoh ant, striped tail scorpion, black widow spider, brown recluse spider indoors on treated nonporous surfaces after 2 hour continuous exposure.

Qualifier Option 4: * [applies to] [for] American Cockroach / palmetto bug / water bug, German cockroach, carpenter ant, pharaoh ant, striped tail scorpion, black widow spider, brown recluse spider, centipedes indoors on treated nonporous surfaces after 24 hour continuous exposure.

6-Month Claims

- Up to 6 month control [protection] outdoors*
- Kills [Controls] [Protects] [for] up to 6 months outdoors*
- Kills [listed] bugs outdoors for 6 months*
- Kills [listed] bugs [indoors] [and] [outdoors] for 6 months*
 - * Applies to [for] spiders (excluding black widow, brown recluse, hobo)

5-Month Claims

- Keeps bugs away for up to 5 months indoors on listed insects[†]
- [One application provides] up to 5 month control indoors of listed insects[†]
- [One application] kills [bugs] [insects] up to 5 months indoors on listed insects[†]
- [One application] kills ants, roaches [and spiders] for up to 5 months indoors[†]
- Keeps ants, roaches [and spiders] away for up to 5 months indoors[†]
- Kills bugs inside, keeps bugs out for up to 5 months[†]
- Provides up to 5 months protection indoors[†]

[†]Up to 5 month control indoors on: Ants (including Western Harvester), Carpet Beetles, Crickets, Firebrats, Moths, Silverfish and Spiders on treated non-porous surfaces after 5 minutes continuous exposure to residues. Five (5) month control indoors on German Cockroaches after 30 minutes continuous exposure to residues.

4-Month Claims

- Up to 4 months control [protection] outdoors*
- Kills [Controls][Protects] [for] up to 4 months outdoors*
- Kills [listed] bugs outdoors for 4 months
- Kills [listed] bugs [indoors] [and] [outdoors] for 4 months*
- *Applies to [for] spiders (excluding black widow brown recluse, hobo)

3-Month Claims

- Up to 3 month control [protection] outdoors*
- Kills [Controls] [Protects] [for] up to 3 months outdoors*
- Kills [listed] bugs outdoors for 3 months*
- Kills [listed] bugs [indoors][and][outdoors] for 3 months*
- *Applies to [for] spiders (excluding black widow, brown recluse, hobo) harvester ants, roaches/palmetto bugs/water bugs, striped scorpians, fleas, crickets, grasshoppers
- Keeps listed [bugs] [insects] away for up to 3 months [indoors] ^
- Keeps [bugs][insects] away for up to 3 months [indoors] on listed insects ^
- [Provides] up to 3 month control of listed insects [indoors] ^
- [One application] kills ants, roaches [and spiders] for up to 3 months [indoors][^]
- [One application] kills listed [bugs] [insects] up to 3 months [indoors] ^

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- Keeps ants, roaches [and spiders] away [out] for up to 3 months [indoors]^
- [One application] kills roaches [and spiders] for up to 3 months [indoors]^
- Keeps ants, roaches [and spiders] away [out] for up to 3 months [indoors]^
- Kills bugs inside, keeps bugs out for up to 3 months^

^Up to 3 month control [indoors] on: Ants (including Western Harvester), Carpet Beetles, German Cockroaches, Crickets, Firebrats, Moths, Silverfish and Spiders on treated non-porous surfaces after 5 minutes continuous exposure to residues. 3 month control indoors on German Cockroaches after 30 minutes exposure to residues.

Egg Killing Claims

Kills beet armyworm, two spotted spider mites, Asian Lady Beetles and their eggs [Plus] kills insects and their eggs**
[Now] [new formula] kills insect eggs**
Prevents insect eggs from hatching!**
Up to 12 month control* plus kills insect eggs**

**Applies to [for] beet armyworm, two spotted spider mites, Asian Lady Beetles

Knockdown claims:

- Fast acting [formula]
- Quick knockdown
- Fast knockdown
- Kills [bugs] in seconds
- Kills [bugs] fast
- Starts killing [bugs] in seconds
- Starts killing [bugs] fast
- Kills by contact [Guaranteed]
- Quick [Fast] Kill

Area-related claims

- Consistent spray for maximum accuracy
- Consistent/even coverage
- Ideal for small/smaller areas [spaces] [rooms]
- Use inside and outside your home!
- 16 oz treats [covers] 151 linear feet
- 16.5 oz treats [covers] 156 linear feet
- 17 oz treats [covers] 161 linear feet
- 17.5 treats [covers] 166 linear feet
- Treats [142] [146] [151] [156] [161] [166] linear feet!
- Enough to create [an] [one] entire bug [treatment] for the average 1800 sq. ft. home!
- Use in [kitchens], [garages], [basements] [and] [attics].
- Use with confidence in [bathrooms], [kitchens], [family rooms], [pantry], [attics], [garages], [basements], [closets], [storage areas], and [bedrooms]
- [Illustrations of kitchen, bathroom, home perimeter/foundation, garage, windows and doorways, basement, attic, porches and patios]

Where to use/How to use claims

- Apply along [and behind] baseboards
- Apply along [behind] [and] [between] appliances
- Apply beneath [and behind] sinks
- Apply in other areas where insects [are often found] [often appear]
- Gets into cracks and crevices
- Gets to the places bugs hide
- Reaches where bugs hide
- Ready to Use

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- Easy to use
- 1[One] touch spray
- Continuous [aerosol] spray
- Easy Spray [Applicator]
- The easy way to spray [Home Defense Max]
- Use [Can be used] in [bathrooms], [kitchens], [family rooms], [pantry], [attics], [garages], [basements], [closets], [storage areas], and [bedrooms]
- Change the way you spray
- [Formulated][For] Indoor Use
- Indoor Formula
- Indoor/Outdoor [Formula]
- [Formulated][For] Indoor/Outdoor Use
- [Formulated] [For] Outdoor Use
- Outdoor Formula

Other claims

- Guaranteed [results] †
- Kills listed home invading insects
- Kills ants [and many other listed pests/listed insects!]
- Kills ants [and] roaches [and many other listed pests/listed insects!]
- Kills ants, roaches [and] spiders [and many other listed pests/listed insects!]
- No [more] tired hands
- No [more] hand fatigue
- Reduces hand fatigue
- Precise control for maximum accuracy
- Look inside [label] for special offer information!
- Also try Ortho Home Defense Max Perimeter & Indoor Insect Killer liquids [to kill home invading insects!] [to treat larger areas!]
- Go to [URL] now for a special offer! Offer subject to change or expiration.
- www.orthohomedefense.com

Spreading Characteristics

- Specially formulated to get into cracks and crevices
- Specially formulated to spread into cracks and crevices
- Specially formulated to get behind baseboards where bugs hide
- Spreads into spaces you [can't see] [can't reach]
- Advanced spreading technology
- Spreads fast
- [Get's into][Reaches] gaps behind baseboards and walls

Note to PM: the term cockroach can be interchanged with any and all instances of roaches and vice versa.

Note to PM: the term insects can be interchanged with any and all instances of bugs, pests, and vice versa.

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