239-2695

08/10/2009 ()



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 10, 2009

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

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Subject: Amendment – Adding additional Residual and Marketing Language & alternate formula Home Defense Max Perimeter Insect Killer Aerosol¹ EPA Reg. No. 239-2695 Your submission dated March 23, 2009

Dear Mr. Wallace:

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. Move "For residential use only" to front panel.
- 2. On page 2, replace "To the extent allowed by law" with "To the extent consistent with applicable law" following NOTICE.
- 3. Delete "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 4 months outdoors". The 12 month control claims are not supported by submitted or cited data.
- 4. Delete all references to Pharaoh's Ants, Foraging Fire Ants, Oriental Cockroaches, Centipedes and Scorpion from the label. Data submitted or cited don't support claims for these public health pests.

5. Add the following footnote to the five (5) months control claims: "*Ants (including Harvester Ants, but excluding Carpenter, Pharaoh's Ant, and Foraging Fire Ants), Carpet Beetles, Crickets, Firebrats, Moths, Silverfish, and Spiders on treated non-porous surfaces after 5 minutes continuous exposure to residues. Five (5) months control indoors on German Cockroaches after 30 minutes continuous exposure to residues."

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- 6. Delete three (3) months claims for outdoor and/or "season-long" efficacy. The submitted and cited data do not support three (3) months claims and the length of seasons can vary in different geographical areas.
- 7. Under the *Optional Marketing claims*, *Non-Residual Claims* either delete all claims for Carpenter Ant and Flea or qualify by adding the statement "after 2 hours continuous exposure".
- 8. Delete the following *Optional Marketing Claims*:
 - a. [Creates] {Establishes] a [bug][insect] barrier:
 - b. Creates a bug barrier:
 - c. Creates bug barriers:
 - d. [New] InvisiShield[™] Brand Barrier Technology:
 - e. [Contains] [With] InvisiShield[™] Brand Technology:
 - f. InvisiShieldTM Brand Barrier:
 - g. InvisiShield Barrier[™] Brand:
 - h. Guards against bugs so you don't have to:
 - i. Guards against the bugs you can't (don't) see:
 - j. All 12 month claims:
 - k. Starts killing [bugs] on contact:
 - l. Kills on contact:
 - m. QuickKill[™] Brand [Technology]:
 - n. Immediately forms [creates][establishes] a [bug][insect] barrier:
 - o. Creates a barrier that [will kill] the bugs you have and prevent[s] new bugs from coming [in][inside your home]:
 - p. Enough to create [an][one] entire bug barrier for the average 1800 sq, ft. home!:
 - q. [New] Barrier Technology [keeps bugs out [of your home]]:
 - r. [New] Barrier Technology keeps bugs from coming in:
 - s. Long-lasting Barrier Technology:
- 9. Revise the following Optional Marketing Claims to read as follows:
 - a. Replace "Immediately forms [creates][establishes] a perimeter treatment" with "Forms [creates][establishes] a perimeter treatment"
 - b. Replace "Kills and prevents [insects][inside your home][outside your home]"

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- c. Replace "Provides residual control against home invading insects" with "Provides residual control against home invading listed insects"
- d. Replace "Use in [kitchens], [garages], [basements], [attics] to keep bugs [insects] from entering your home" with "Use in [kitchens], [garages], [basements], [attics] to keep listed bugs [listed insects] from entering your home".
- e. Replace "Use in [kitchens], [garages], [basements], [attics] to kill bugs [insects]" with "Use in [kitchens], [garages], [basements], [attics] to kill listed bugs [listed insects]".
- f. Replace "Kills [two][2] ways [Dual Action]: 1) Kills insects fast [on contact][by contact] and 2) Keeps killing even after spray has dried" with "Kills [two][2] ways [Dual Action]: 1) Kills listed insects fast [by contact] and 2) Keeps killing even after spray has dried".
- g. Replace "Kills [all][most][many][several] major home invading insects" with "Kills listed home invading insects".
- h. Replace "Kills [all][most][many][several] common home invading insects" with "Kills listed home invading insects".
- i. Replace "Kills ants [and many other listed pests [insects]!]" with "Kills ants [and many other listed pests [listed insects]!]".
- j. Replace "Kills ants, roaches [and] spiders [and many other listed pests [insects]!]" with "Kills ants, roaches [and] spiders [and many other listed pests [listed insects]!]"
- 10. Reminder, the two company's websites 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.

We have no objection to the use of the alternate formulation (dated March 23, 2009) requested in your letter of the above date. The alternate Confidential Statements of Formula (CSF) is acceptable and has been inserted in the file for the subject product.

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

Sincerely,

branda Alexander for chard Gebken

Interim Product Manager 13 Insecticide Branch Registration Division (7505P)

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Enclosure

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Home Defense Max[®] Perimeter Insect Killer Aerosol¹

Alternate Brand Names

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Ortho[®] Home Defense Max[®] Ant & Roach Killer Ortho[®] Home Defense Max[®] Ant, Roach & Spider Killer Ortho[®] Home Defense Max[®] Indoor & Perimeter Insect Killer Ortho[®] Home Defense Max[®] Perimeter and Indoor Insect Killer Ortho[®] Home Defense Max[®] Insect Killer Ortho[®] Home Defense Max[®] Insect Killer Aerosol ¹

ACTIVE INGREDIENTS:

Bifenthrin*	0.05%
ETOC	0.03%
OTHER INGREDIENTS	
TOTAL	

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements.

NET WT X oz/XXX g

ACCEPTED with COMMENTS PA Letter Dated In EPA Letter Da AUG TO 2009 Under the Federal Insecticide, Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Reg. No.



NOTE: 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.

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.

If on skin:

FIRST AID

[icon]

- 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 allowed by law, buyer assumes all responsibility for safety and use not in accordance with directions.

For residential use only

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 4 months outdoors.

STORAGE AND DISPOSAL

[icon]

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] [CONTAINS 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. For best results please follow instructions for appropriate usage, storage and disposal.

The ORTHO Guarantee

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

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[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^B 84064-IA-001^C 085652-OH-1^D Superscript is first letter of lot number

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

Made in USA

OPTIONAL MARKETING CLAIMS

Non-Residual Claims

 Kills (any or all of the following insects) Ants (including Carpenter, Western Harvester, Pharaoh and Foraging Fire), Beetles (including Asian Lady and Carpet), Centipedes, Cockroaches (including American, German and Oriental), Crickets, Earwigs, Firebrats, Fleas, Moths, Pantry Pests, Scorpions (including Dune and Striped Tail), Spiders (including Black Widow, Hobo and Wolf) and Silverfish.

General

- New! (to be used for six months following commercial introduction of product)
- Continuous Spray!
- Kills on contact!
- 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]
- 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.
- Immediately forms [creates] [establishes] a perimeter treatment
- [Creates] [Establishes] a perimeter treatment
- Immediately 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]

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.

- Enough to create [an] [one] entire bug barrier for the average 1800 sq. ft. home!
- [New] Barrier Technology [keeps bugs out [of your home]]
- [New] Barrier Technology keeps bugs from coming in
- Long-lasting Barrier technology
- [New] InvisiShield[™] Brand Barrier Technology
- [Contains] [With] InvisiShield™ Brand Technology
- InvisiShield™ Brand Barrier
- InvisiShield Barrier™ Brand
- Guards against bugs so you don't have to
- Guards against the bugs you can't (don't) see
- Kills and prevents [insects] [inside your home] [outside your home]
- Provides residual control against 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 bugs [insects] from entering your home
- Use in [kitchens], [garages], [basements], [attics] to kill bugs [insects]
- Long-lasting control
- Long-lasting insect control
- Long-lasting residual control
- Kills [two] [2] ways [Dual Action]: 1) Kills insects fast [on contact] [by contact] and 2) Keeps killing even after spray has dried

12-Month Claims

- Provides residual control for up to 12 months indoors [against listed home invading insects] [of listed insects]*
- Kills Two [2] ways [Dual Action]: 1) Kills insects fast [on contact] [by contact] and 2) Keeps killing [insects] [bugs] [pests] with residual action even after [you spray] [spray has dried], for up to 12 months indoors on listed insects*
- [One application] kills [bugs] [insects] up to 12 months indoors on listed insects*
- [One application provides] up to 12 month control indoors of listed insects
- Keeps [bugs] [insects] away for up to 12 months indoors on listed insects*
- [Provides] up to year-long control indoors on listed insects*
- Keeps killing insects for up to [1] [one] year indoors on listed insects*
- *Up to 12 month control indoors on: Ants (including Carpenter, Western Harvester and Foraging Fire), Carpet Beetles, Crickets, Firebrats, Moths, Scorpions (including Dune and Striped Tail), Silverfish and Wolf Spiders on treated tile, glass and steel household surfaces with 24 hours continuous exposure.

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[†]
 [†]Up to 5 month control indoors on: Ants (including Carpenter, Western Harvester and Foraging Fire), Carpet Beetles, Crickets, Firebrats, Moths, Scorpions (including Dune and Striped Tail), Silverfish and Spiders on treated common household surfaces after 5 minutes exposure. 5 month control indoors on Cockroaches (including American, German and Oriental) after 30 minutes exposure.

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3-Month Claims

- [One application] [provides] season long control [indoors] [and] [outdoors] on listed insects ^
- Keeps [bugs] [insects] away for up to 3 months [indoors] [and] [outdoors] on listed insects^
- [Provides] up to 3 month control of insects [indoors] [and] [outdoors] on listed insects^
- [One application] kills ants, roaches [and spiders] for up to 3 months [indoors] [and] [outdoors]^
- [One application] kills [bugs] [insects] up to 3 months [indoors] [and] [outdoors] on listed insects[^]
- Keeps ants, roaches [and spiders] away [out] for up to 3 months [indoors] [and] [outdoors]^
- [One application] kills roaches [and spiders] for up to 3 months [indoors] [and] [outdoors]^
- Keeps ants, roaches [and spiders] away [out] for up to 3 months [indoors] [and] [outdoors]^ ^Up to 3 month control [indoors] [and] [outdoors] on: Ants (including Carpenter, Western Harvester and Foraging Fire), Carpet Beetles, Cockroaches (including American, German and Oriental), Crickets, Firebrats, Moths, Scorpions (including Dune and Striped Tail), Silverfish and Spiders on treated tile, glass and steel household surfaces with 24 hours continuous exposure.

Knockdown claims:

- Fast acting [formula]
- Quick knockdown
- Fast knockdown
- Kills [bugs] in seconds
- Kills [bugs] fast
- Starts killing [bugs] in seconds
- Starts killing [bugs] on contact
- Starts killing [bugs] fast
- Kills on contact [Guaranteed]
- Kills by contact [Guaranteed]
- Quick [Fast] Kill
- QuickKill[™] Brand [Technology]

Area-related claims

- Consistent spray for maximum accuracy
- Consistent/even coverage
- Ideal for small areas [spaces]
- 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 in [kitchens], [garages], [basements] [and] [attics] to kill [bugs] [insects].

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

EPA Reg. No. 239-2695

NOTE:

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- Gets to the places bugs hide
- Reaches where bugs hide
- Ready to Use
- 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]

Other claims

- Guaranteed [results]
- Kills [all] [most] [many] [several] major home invading insects
- Kills [all] [most] [many] [several] common home invading insects
- Kills ants [and many other listed pests [insects]!]
- Kills scorpions [and many other listed pests [insects]!]
- Kills ants [and] roaches [and many other listed pests [insects]!]
- Kills ants, roaches [and] spiders [and many other listed pests [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