

40810-24

10/2/2008

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

OCT 2 2008



United States
Environmental Protection
Agency

Office of Pesticide Programs

Ciba Corporation
4090 Premier Drive
High Point, N. C. 27265

Attention: Thomas Barber

Subject: Irgaguard B7000
EPA Registration No. 40810-24
Notification Dated September 4, 2008

This will acknowledge receipt of your notification for the addition of the following alternate brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

ADDITIONAL BRAND NAME

Irgasiva Gard B7000

The Notification dated September 4, 2008 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please feel free to contact Martha L. Terry at (703) 308-6217.


Sincerely,

A handwritten signature in black ink that reads 'M Swindell'.

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

| | | |
|---|--|-----------------------|
|  United States Environmental Protection Agency Washington, DC 20460 | <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other | OPP Identifier Number |
|---|--|-----------------------|

Application for Pesticide – Section I

| | | |
|--|---|---|
| 1. Company/Product Number 40810-24 | 2. EPA Product Manager Marshall Swindell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Irgasiva Gard B7000 | PM # 33 | |
| 5. Name and Address of Applicant (Include ZIP Code) Ciba Corporation 4090 Premier Drive High Point, NC 27265 <input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: Irgaguard B7000 (Primary brand name) EPA Reg No. <u>40810-24</u> Product Name _____ |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment – Explain below | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification – Explain below | <input type="checkbox"/> Other – Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)


Notification of Alternate Brand Name per PR Notice 98-10

This notification is consistent with the provisions of PR 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR 98-10 and 40 CFR 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Section III

| | | | | | |
|---|---|--|--|---|-------------------|
| 1. Material This Product Will be Packaged in: | | | | 2. Type of Container | |
| <input type="checkbox"/> Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="checkbox"/> Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>2X10 Kg bags in a cardboard box</u> | | |
| *Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 20 Kg | | 5. Location of label directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Label and technical bulletin | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | | | |

Section IV

| | | |
|---|--|--|
| 1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Thomas Barber | Title Head Regulatory Services, Compliance & EPA Notifications | Telephone No. (Include Area Code) (336) 801-2603 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law | | 6. Date Application Received <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: auto;"> (Stamped) </div> |
| 2. Signature  | 3. Title Head Regulatory Services, Compliance & EPA Notifications | |
| 4. Typed Name Thomas Barber | 5. Date <u>9/4/08</u> | |

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Ciba

September 4, 2008

via overnight courier

US Environmental Protection Agency
Document Processing Desk (**NOTIF**)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. Marshall Swindell (PM33)

Re: Label Notifications: Irgasiva Gard B7000, Alternate Brand Name for Irgaguard B7000, EPA Reg. No. 40810-24

Dear Mr. Swindell:

The purpose of this submission is to file a label Notification pursuant to PR Notice 98-10. This Notification is for the addition of an alternate brand name for an existing antimicrobial product with exact formulation and use patterns.

Enclosed with this cover letter are the following documents:

- EPA Form 8570-1
- Product label – 1 copy
- Technical bulletin – 1 copy

Should you have any questions or wish further information, do not hesitate to contact me directly at (336) 801-2603.

Respectfully,



Tom Barber
Head, Regulatory Services
Compliance & EPA Notifications

IRGASIVA GARD® B7000

Ciba
Silver - Zinc Glass

A material preservative and antimicrobial agent for use in the Manufacture of polymer, plastic, and textile products.
For Manufacturing/Fabrication Use Only

Active ingredient:
Silver (as elemental) 0.37%
Zinc (as elemental) 17.90%
Other ingredients 81.73%
Total 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Establishment No. 70404-AL-002
EPA Establishment No. 70404-DEU-002
EPA Establishment No. 040810-CHE-001
EPA Establishment No. 82415-JPN-001
EPA Establishment No. 84692-JPN-001
EPA Establishment No. 69829-IL-001

****See Technical Bulletin for detailed use information****

Net Weight:
Lot No.:
Ident. No.:

CIBA CORPORATION
PLASTIC ADDITIVES
540 WHITE PLAINS RD.,
TARRYTOWN, NY 10591

DIRECTIONS FOR USE

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

Only for manufacture of or fabrication into antimicrobial pesticides for 1) the use of which is described in the label and technical bulletin; 2) Uses for which USEPA has approved the requirements of data that the formulator has submitted in support of registration; or 3) experimental purposes that are in compliance with USEPA requirements.

IRGASIVA GARD® B7000 is an antimicrobial powder for the manufacture of plastic, and latex products only. It is designed to be used in materials that may be incorporated into the products on the technical bulletin for Irgasiva Gard® B7000. In the manufacturing process to impart antimicrobial activity to the manufactured product, IRGASIVA GARD® B7000 suppresses the growth of bacteria, algae, fungus, and mold which cause unpleasant odors, discoloration, staining, deterioration or corrosion of the manufactured products.

Finished products containing IRGASIVA GARD® B7000 may not make public statements relating to antimicrobial activity without EPA pesticide registration. When incorporated into treated articles, this product does not protect users of any such treated article against foodborne or disease causing bacteria, viruses, germs or other disease causing organisms.

IRGASIVA GARD® B7000 may be incorporated into materials that may be used as a product at 0.1 to 3.0% of Irgasiva Gard® B7000 by weight. Contact Ciba Corporation to determine the appropriate amount of IRGASIVA GARD® B7000 for individual products.

STORAGE AND DISPOSAL

Nonrefillable container. Do not reuse or refill this container.
Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Do not store in areas accessible to children. Keep away from sunlight.

Pesticide Disposal: Wastes from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal: Completely empty bags into processing equipment when used. Offer for recycling, if available. Otherwise dispose of empty bag and container at a landfill or by incineration, if allowed by state and local authorities.

IRGASIVA GARD® is a trademark of Ciba Corporation
EPA Registration No. 40810-24

40810



Technical Bulletin

Irgasiva Gard® B7000

EPA Reg. 40810-24

Material preservative and antimicrobial agent for use in the manufacture of polymer, plastic, and textile products

For Manufacturing/Fabrication Use Only

IRGASIVA GARD® B7000 is an antimicrobial pesticide for the manufacture of polymeric, plastic, and latex products only. It is designed to be incorporated into the materials for manufacture into final products listed below during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGASIVA GARD® B7000 suppresses the growth of bacteria, algae, fungus, mold and mildew which cause unpleasant odors, discoloration, staining, deterioration or corrosion of those manufactured products.

Finished products containing IRGASIVA GARD® B7000 may not make public health claims relating to antimicrobial activity without EPA pesticide registration. When incorporated into treated articles, this product does not protect users of any such treated article or others against foodborne or disease causing bacteria, viruses, germs or other disease causing organisms.

IRGASIVA GARD® B7000 may be used in material that may be incorporated into the finished product at 0.1 to 3.0% of IRGASIVA GARD® B7000 by weight. Contact Ciba Corporation to determine the appropriate amount of IRGASIVA GARD® B7000 for individual finished products.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. IRGASIVA GARD® B7000 is intended for use as an additive into the following materials and substances as part of the manufacturing process in order to provide built-in antimicrobial activity in manufactured and finished products.

APPLICATIONS AND TYPES OF MATERIALS

| APPLICATION | TYPES OF FINISHED PRODUCTS | |
|---|--|--|
| Plastics Including films, sheets, slabs, and molded plastic parts | Appliances and equipment Automobile parts Brush bristles Brush handles Conveyor belts Countertops Face gear (face masks, respirator filter media, goggles, etc.) Floor coverings Flooring Footwear (including boots, sports equipment and tools) Gaskets General purpose containers Indoor and outdoor furniture Insulation for wire and cable Insulators Kitchen and bathroom hardware | Liners Mats Mops Non-woven fabrics Plastic film Plumbing supplies and fixtures (including toilet bowl seats) Protective covers Shower curtains Siding for housing Sinks Sponges Tape Tiles Tubing Vacuum cleaner bags Waste containers |

| APPLICATION | TYPES OF FINISHED PRODUCTS | |
|-------------|---|--|
| Fibers | Apparel (such as umbrellas, outerwear, sportswear, sleepwear, socks and hosiery, caps, undergarments, inner liners for jackets, trim for outerwear and garments, uniforms, outerwear, gloves, aprons, coats, and shoes) Conveyor belts Industrial and other Household Items (such as artificial leather, filters, book covers, mops, cloth for sails, ropes, tents and other outdoor equipment, tarps, awnings, bags, brush bristles, commercial and industrial wipes and fabrics, sponges, wiping cloths) Interior furnishings (such as mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, curtains, draperies, carpet and carpet underlay, rugs, upholstery, towels, wall covering fabrics, cushion pads, sleeping bags) Packaging Transportation items (such as automotive and truck upholstery, carpeting, rear decks, trunk liners, convertible tops, interior liners) | |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|--------------------------------|---|
| Coatings, Films, and Laminates | Appliances Automotive and vehicle parts Barrier fabrics Building materials and components (such as walls, wallboard, floors, concrete, siding, roofing, shingles, hardware, floors, ceilings, commercial and industrial applications) Collection and storage equipment (such as conveyor belts, piping systems, silos, tanks, and process vessels) Countertops Furniture General purpose containers Glazing for cement tile Glazing for vitreous china used in plumbing fixtures (such as toilets, sinks, countertops) Industrial equipment Natural and synthetic fibers and fabrics Packaging Paper products (such as wipes, tissues, wall coverings, towels, book covers) Sinks |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|------------------------|--|
| Adhesives and Sealants | Appliances Bathrooms Cardboard Ceramic tile Construction materials Glazing for windows Grout and joint compound Paper Pipe sealant and insulating materials Plastic Plumbing adhesives Rubber Sealants for pipes Showers Wood Wood and plastic composites |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|----------------------------|---|
| Miscellaneous applications | Cat litter Drainage and sewage pipe Flooring Plaster Sinks Stucco Tile Toilets |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|--|---|
| Heating, Ventilation and Air Conditioning (HVAC) | HVAC equipment and related materials including air handlers, plenums, coils, fins, insulation, rigid or flexible ducts, drain pans, duct support mechanisms, diffusers, filters, heat exchangers, air purifiers, supplemental articles used in the assembly of HVAC systems such as gaskets, fixtures, sealants, adhesives, and HVAC reinforcing as well as parts and components thereof. These articles could be constructed of fibrous materials (textiles), non-woven, plastic or coated metal material. For use only during manufacture of the article. |

FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS

Irgasiva Gard B7000 may be used as an antimicrobial additive in the polymeric manufactured products listed below that are used for manufacturing, packing, packaging, transporting, handling and/or holding food if such use is not intended to have any microbial effect in the food itself. Do not incorporate *Irgasiva Gard B7000* into any food or drinking water contact application listed on this label without first incorporating *Irgasiva Gard B7000* into a polymer which is approved, with associated use conditions, for food contact in 21 CFR 174-186 (inclusive) as amended, or in the United States Food and Drug Administration's Food Contact Substance Notification System, as amended.

| APPLICATION | TYPES OF FINISHED PRODUCTS | |
|---|---|---|
| Plastics Including films, sheets, slabs, and molded plastic parts | Appliances and equipment Beverage dispensing equipment Beverage processing equipment Bottles Brush bristles Brush handles Conveyor belts Countertops Food handling equipment Food processing equipment Food storage containers Food trays and covers Food packaging Food processing utensils Gaskets General purpose containers Kitchen and bathroom hardware Liners | Mats Non-woven fabrics Plastic film Plumbing supplies and fixtures Protective covers Sinks Sponges Tape Tiles Tubing |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|-------------|---|
| Fibers | Apparel (such as outerwear, uniforms, gloves, aprons, coats) Bags Containers Conveyor belts Table cloths, napkins, wiping cloths Mops, sponges Brush bristles Filters Packaging (including bags, sacks, wraps, cushion, absorbent materials and containers) Kitchen: commercial and industrial wipes and fabrics Food packaging |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|--------------------------------|--|
| Coatings, Films, and Laminates | Appliances and equipment Barrier fabrics Building materials and components Collection and storage equipment (such as conveyor belts, piping systems, silos, tanks, and process vessels) Cookware Countertops Food wrap (including coated deli paper, coated meat interleavers and plastic wrap) General purpose containers Glazing for cement tile Glazing for vitreous china used in plumbing fixtures (such as sinks, countertops) Industrial equipment Natural and synthetic fibers and fabrics Packaging Paper products (such as wipes, tissues, wall coverings, towels) Plastic film Sinks |

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|------------------------|---|
| Adhesives and Sealants | Appliances Cardboard Ceramic tile Grout and joint compound Paper Pipe sealant and insulating materials Plastic Plumbing adhesives Rubber Sealants for pipes Wood Wood and plastic composites |

DRINKING WATER CONTACT USES

Irgasiva Gard B7000 may be used for the human drinking water contact uses listed below. The additive may be incorporated into food bowls and water bowls, dishes and other containers used by domestic animals. Do not use for any food or drinking water applications involving non-domestic animals.

| APPLICATION | TYPES OF FINISHED PRODUCTS |
|--|---|
| Plastics; Fibers, Coatings, films and laminates; Adhesives and sealants | Including ice making equipment (water pans, piping, tubing, guards, ice storage bins, trays, ice scoops, buckets, valves, and gaskets); drinking water contact materials (water bottles, cups, gaskets, plumbing fixtures, storage tanks and vessels, water piping, tubing, valves, spigots, coolers, water dispensing components, housing units, and water filter components). |

CHEMICAL AND PHYSICAL PROPERTIES

Appearance: White to grayish-white powder

Odor: None detectable

Density: 2.96 g/cm³ @ 25° C
