

40810-27

10/2/2008

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

OCT 2 2008



Office of Pesticide Programs

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

Attention: Thomas Barber

Subject: Irguard B6000
EPA Registration No. 40810-27
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 B6000

The Notification dated February 26, 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,

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

3/a

 United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number 40810-27	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Irgasiva Gard B6000	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 B6000 (Primary brand name) EPA Reg No. <u>40810-27</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	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.	No. per container	<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>	
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 checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

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
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 (Stamped)
2. Signature 		
3. Title Head Regulatory Services, Compliance & EPA Notifications		
4. Typed Name Thomas Barber		
5. Date <u>9/4/08</u>		

3/9

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 B6000, Alternate Brand Name for Irgaguard B6000, EPA Reg. No. 40810-27

Dear Mr. Swindell:

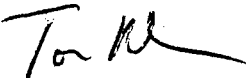
The purpose of this submission is to file a label Notification pursuant to PR Notice 98-10. This Notification is for the addition of an alternate brand name for an existing antimicrobial product with exact formulation and use patterns.

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

4090 Premier Drive
High Point, NC 27265

Tel. 336-801-2603
Fax 336-801-2056



Technical Bulletin

Irgasiva Gard® B6000

EPA Reg. 40810-27

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

For Manufacturing/Fabrication Use Only

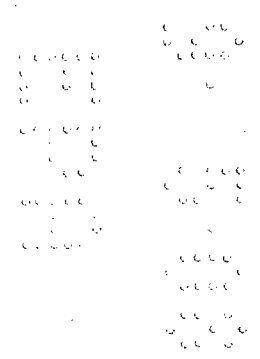
IRGASIVA GARD® B6000 is an antimicrobial pesticide for the manufacture of polymeric, plastic, and latex products only. It is designed to be incorporated into the materials for manufacture into final products listed below during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGASIVA GARD® B6000 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® B6000 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® B6000 may be used in material that may be incorporated into the finished product at 0.1 to 3.0% of IRGASIVA GARD® B6000 by weight. For use in Adhesives and Sealants, may be incorporated into the finished product at 0.1 to 5.0% by weight. Contact Ciba Corporation to determine the appropriate amount of IRGASIVA GARD® B6000 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® B6000 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 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
<p>USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States</p>		

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)	
<p>USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States</p>		

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
USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States	

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
USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States	

APPLICATION	TYPES OF FINISHED PRODUCTS
Miscellaneous applications	Cat litter Drainage and sewage pipe Flooring Plaster Sinks Stucco Tile Toilets
USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States	

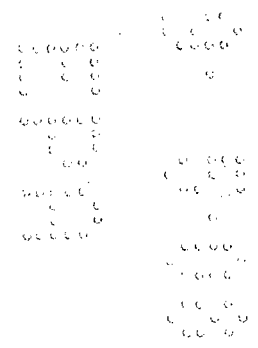
FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS

Irgasiva Gard B6000 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 B6000 into any food or drinking water contact application listed on this label without first incorporating Irgasiva Gard B6000 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

USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States

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 system, 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
USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States	

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
USE PRECAUTIONS: Do not use this product for any human drinking water contact uses in the United States	

CHEMICAL AND PHYSICAL PROPERTIES

Appearance: White to grayish-white powder

Odor: None detectable

Density: 2.44 g/cm³ @ 25° C

IRGASIVA GARD® B6000

Ciba
Silver Glass - Zinc Zeolite

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) 1.18%
Zinc (as elemental) 3.58%
Other ingredients 95.24%
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 its labeling.

Do not use this product for any human drinking water contact uses in the United States. Only for manufacture of or fabrication into antimicrobial pesticides for 1) the uses listed on this label and technical bulletin; 2) Uses for which USEPA has approved the required data and/or citations of data that the formulator has submitted in support of registration; and 3) Uses for experimental purposes that are in compliance with USEPA requirements.

IRGASIVA GARD® B6000 is an antimicrobial powder for the manufacture of polymeric, 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® B6000 during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGASIVA GARD® B6000 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® B6000 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® B6000 may be incorporated into materials that may be used in the finished product at 0.1 to 3.0% of Irgasiva Gard® B6000 by weight. For use in Adhesives and Sealants, may be incorporated into the finished product at 0.1 to 5.0% by weight. Contact Ciba Corporation to determine the appropriate amount of IRGASIVA GARD® B6000 for individual finished 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 direct sunlight.

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

Container Disposal: Completely empty bags into processing equipment where the pesticide is used. Offer for recycling, if available. Otherwise dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

IRGASIVA GARD® is a trademark of Ciba Corporation
EPA Registration No. 40810-27

**PRECAUTION
KEEP OUT OF REACH OF CHILDREN
CAUTION**

HAZARDS TO HUMANS

CAUTION. Causes moderate eye irritation. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge into streams, ponds, estuaries, oceans, or public water systems without previously notifying the appropriate authority. Do not discharge into sewer systems without previously notifying the sewer authority. For more information, contact your State Water Board or Regional Office.

FIRST AID:

Have the product container or label with you when you call a doctor, or going for treatment.

IF IN EYES

- Hold eye open for 15 minutes. Remove contact lenses, if present, after 5 minutes, then continue to irrigate with clean water for at least 15 minutes.
- Call a poison center or doctor for treatment.

FOR 24-HOUR EMERGENCY INFORMATION