MAR 2008

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



## **⊕ EPA** United States Envisionmental Protection Office of Pesticide Programs Agency

Ciba Specialty Chemicals Corporation 540 White Plains Road P.O. Box 2005 Tarrytown, N. Y. 10591-9005

AGENT: Steptoe & Johnson

1330 Connecticut Avenue, N.W. Washington, D. C. 20036

Attention: Elizabeth Anne Brown, Ph.D.

**Technical & Regulatory Analyst** 

Subject: Irgaguard B6000

EPA Registration No. 40810-27

Amendment Dated December 7, 2007

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add new label uses for applications involving "Indirect Food", is acceptable under a time-limited restriction with the following conditions.

- 1. The primary basis for granting a time-limited approval at this time is that the product has FDA indirect food contact approval under FDA Notifications #275 and #294. The product must be first incorporated into food contact approved FDA polymers, and be added up to a 3% by weight into the various products. The FDA approval is recorded at www.cfsan.fda.gov/. Note that the FDA approval is for a zinc concentration range from 19-23% in the formula, which is higher than the declared nominal concentration of this at 3.58%.
- 2. All the indirect food/drinking water uses listed on the proposed draft label have a time-limited approval which automatically expires on March 4, 2009.

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- 3. An aggregate risk assessment under FIFRA Section 2(bb), using all data submitted/cited, must result in determination by the Agency that all indirect food, drinking water and all other non-food/water uses listed on the label will not result in un-reasonable adverse effects to humans or environment. If the Agency is unable to make this determination for each label use, then label uses which are found to pose unreasonable risk will expire on March 4, 2009 and must be deleted at that time. If the aggregate risk assessment data is found acceptable for all uses, the time-limited restriction will be lifted.
- 4. You must submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.
- 5. All subsequent amendments that are approved for this product will also be time-limited to expire on March 4, 2009.
- 6. Submit two (2) copies of your final printed labeling before you release the product for shipment.
- 7. If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the "accepted" labeling is enclosed for your record.

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)

**Enclosure** 

## **IRGAGUARD® B6000**

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 EPA Establishment No. 82415-JPN-001

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

Not 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.

IRGAGUARD <sup>®</sup> 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 Irgaguard® B6000 during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGAGUARD® 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 IRGAGUARD <sup>®</sup> 86000 may not make public health claims relating to antimicrobial activity without EPA posticide 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.

RGAGUARD <sup>®</sup> 86000 may be incorporated into materials that may be used in the finished product at 0.1 to 3.0% of Irgaguard® 86000 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 IRGAGUARD <sup>®</sup> 86000 for individual finished products.

#### STORAGE AND DISPOSAL

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 sunfight.

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. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

IRGAGUARD® is a trademark of Ciba Corporation EPA Registration No. 40810-27 ACCEPTED with COMMENTS

EPA Letter Dated

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Under the Federal însăcricide, Fungicide, and Rodenticide Act or amended, for the pesticide, registered under EFA Rog. To...



# PRECAUTIONARY STATEMENTS KEEP OUT OF REACH OF CHILDREN CAUTION

#### HAZARDS TO HUMANS

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### FIRST AID:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### IF IN EYES

- 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.

FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL 1-800-873-1138

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Cibe Corporation

Plastics Additives



#### **Technical Bulletin**

## Irgaguard® 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

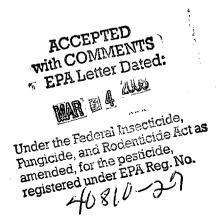
IRGAGUARD <sup>®</sup> B6000 is an antimicrobial pesticide for the manufacture of polymeric, plastic, and latex products only. It is designed to be incorporated into the materials for manufacture into final products listed below during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGAGUARD 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 IRGAGUARD 8 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.

IRGAGUARD® B6000 may be used in material that may be incorporated into the finished product at 0.1 to 3.0% of IRGAGUARD® 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 IRGAGUARD® 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. IRGAGUARD® 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	Appliances and equipment	Mats
Including films, sheets, slabs,	Automobile parts	Mops
and molded plastic parts	Brush bristles	Non-woven fabrics
• • • • • • • • • • • • • • • • • • • •	Brush handles	Plastic film
	Conveyor belts	Plumbing supplies and fixtures
	Countertops	(including toilet bowl seats)
	Floor coverings	Protective covers
	Flooring	Shower curtains
	Footwear (including boots, sports	Siding for housing
	equipment and tools)	Sinks
	Gaskets	Sponges
	General purpose containers	Tape
	Indoor and outdoor furniture	Tiles
•	Insulation for wire and cable	Tubing
·	Insulators	Vacuum cleaner bags
	Kitchen and bathroom hardware Liners	Waste containers

	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) of use this product for any human drinking water contact uses in the

With COMMENTS EPA Letter Dated:

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

HORIO-2-7

**United States** 

APPLICATION	TYPES OF FINISHED PRODUCTS
Coatings, Films, and	Appliances
Laminates	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 n	ot use this product for any human drinking water contact uses in the

APPLICATION	TYPES OF FINISHED PRODUCTS	
APPLICATION Adhesives and Sealants	TYPES OF FINISHED PRODUCTS  Appliances Bathrooms Cardboard Ceramic tile Construction materials Glazing for windows Grout and joint compound Paper Pipe sealant and insulating materials Plastic	ACCEPTED with COMMENTS EPA Letter Dated: MAR & 2006 Under the Federal Insecticide
USE PRECAUTIONS: Do not United States	Plumbing adhesives Rubber Sealants for pipes Showers Wood Wood and plastic composites use this product for any human drinki	Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 40810-27

APPLICATION	TYPES OF FINISHED PRODUCTS
Miscellaneous applications	Cat litter
•	Drainage and sewage pipe
	Flooring
	Plaster
	Sinks
	Stucco
	Tile
	Toilets
USE PRECAUTIONS: Do no United States	ot use this product for any human drinking water contact uses in the

# 7/9

#### FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS

Irgaguard 86000 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 Irgaguard 86000 into any food or drinking water contact application listed on this label without first incorporating Irgaguard 86000 into a polymer which is approved, with associated use conditions, for food contact in 2t CFR (74-186 (inclusive) as amended, or in the United States Food and Orug Administration's Food Contact Substance Notification System, as amended.

APPLICATION	TYPES OF FINISHED PRODUCT	TYPES OF FINISHED PRODUCTS	
Plastics Including films, sheets, slabs, and molded plastic parts	Appliances and equipment Beverage dispensing equipment Beverage processing equipment Bottles	Mats Non-woven fabrics Plastic film Plumbing supplies and fixtures	
	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	Protective covers Sinks Sponges Tape Tiles Tubing	

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ACCEPTED
with COMMENTS
EPA Letter Dated:

MAR = 4 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

40810-27

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
Coatings, Films, and	Appliances and equipment
Laminates	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
USE PRECAUTIONS: Do	not use this product for any human drinking water contact uses in the
United States	

APPLICATION	TYPES OF FINISHED PRODUCTS	700
Adhesives and Sealants	Appliances	ACCEPTED
	Cardboard	with COMMENTS
	Ceramic tile	EPA Letter Dated:
	Grout and joint compound	. }
	Paper	MAR = 4 200B
	Pipe sealant and insulating materials	
	Plastic	Under the Federal Insecticide
	Plumbing adhesives	- Muguido, and Rodondelas al
	Rubber	THE RUCEU. TOT the people is a little
	Sealants for pipes	registered under EPA Reg. No
	Wood	41010 27
	Wood and plastic composites	10310

### **CHEMICAL AND PHYSICAL PROPERTIES**

Appearance: White to grayish-white powder

Odor: None detectable

Density: 2.44 g/cm<sup>3</sup> @ 25° C

ACCEPTED with COMMENTS EPA Letter Dated:

MAR = 4 2008

Under the Foderal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

40810-27