

40810-18

10/01/2008

1/11



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Elizabeth Brown
Steptoe & Johnson
Agent for Ciba Corporation
1330 Connecticut Ave., NW
Washington, D.C. 20036

OCT 1 2008

**Subject: Irgaguard B 5000; EPA Reg. No. 40810-18
Amendment Letter dated August 4, 2008**

The amendment referred to above, submitted in connection with registration under section 3 (c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add new label uses for applications involving indirect food, human drinking water, and HVAC contact, 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 Notification #248. The product must be first incorporated into food contact approved FDA polymers, and can be added up to a maximum of 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 slightly higher than the declared nominal concentration of this product at 17.90%.

2. The following outstanding generic data for both silver and zinc must be submitted (ie., four studies total, two per active ingredient) and found acceptable by 10/1/10. You are responsible for using the correct Technical Grade Active Ingredient test substance to satisfy these data.

870.3150 Subchronic oral toxicity (90 day feeding, non-rodent)
870.3800 Two generation reproduction and fertility effects, rat

The rest of the tier-one generic data set required to support these new uses is listed on the submitted data matrix. The Agency has the following comments on this matrix. On page 4/9, the listed 90 day oral toxicity study, subchronic nonrodent study, and reproduction study for silver are

listed as being submitted by "Ciba" and "own". These designations are incorrect and must be revised to reflect the data gaps for the two silver studies required above, and that only one 90-day rodent study is required. On pages 2/9 and 3/9, delete the 24 listings for "Product Specific Data for Source Product" which are not needed. You must submit a signed and dated revised data matrix that reflects these changes with your final printed labels.

3. All the indirect food/drinking water, and HVAC uses listed on the proposed draft label have a time-limited approval that automatically expires on 10/1/10.

4. If the outstanding data listed above is fully satisfied by 10/1/10, and an aggregate risk assessment is found acceptable for all uses, the time-limited restriction will be lifted. If the data is not satisfied, and/or if the risk assessment is not found acceptable, the Agency will require you to delete all or certain affected uses.

5. You must submit/cite all data required for registration and/or re-registration of your product under FIFRA section 3 (c) (5) and section 4 when the Agency requires all registrants of similar products to submit such data. If these 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 constitutes acceptance of these conditions.

6. All subsequent amendments that are approved for this product will also be time-limited to expire on 10/1/10.

7. Submit three copies of a final printed label that makes the following clarification so that the product is used in harmony with the FDA approval, and other changes:

A. On page 4/6, change "Do not incorporate Irgaguard B7000 into any food contact polymer intended for commercial food packaging uses unless that food contact polymer and use condition are approved and listed in 21 CFR 174-186 (inclusive), or in the United states Food and Drug Administration's Food Contact Substance Notification System", to the following statement,

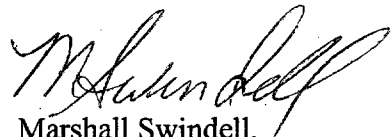
"Do not incorporate Irgaguard B7000 into any food or drinking water contact application listed on this label without first incorporating Irgaguard B7000 into a polymer which is approved, with associated use conditions, for food contact in 21 CFR 174-186 (inclusive) as amended, or in the United States Food and Drug Administration's Food Contact Substance Notification System, as amended"

B. On the main label and last page of the Technical Bulletin, delete "EPA Approval Date: Not EPA approved". Keep the "Draft 10-13-2003" label date.

A stamped copy of the approved time-limited label is enclosed for your records.

If you have any questions about the comments in this letter, please feel free to contact Demson Fuller at 703-308-8062.

Sincerely,



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

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IRGAGUARD® B5000

Silver-Zinc Zeolite

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

DIRECTIONS FOR USE

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

See Technical Bulletin for detailed use information

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.

Active ingredient:

Silver (as elemental)	0.44%
Zinc (as elemental)	1.36%
Other ingredients	98.20%
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.:

IRGAGUARD® B5000 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® B5000 during the manufacturing process to impart antimicrobial activity to the manufactured products. IRGAGUARD® B5000 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® B5000 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® B5000 may be incorporated into materials that may be used in the finished product at 0.1 to 3.0% of Irgaguard® B5000 by weight. Contact Ciba Corporation to determine the appropriate amount of IRGAGUARD® B5000 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 resulting 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.

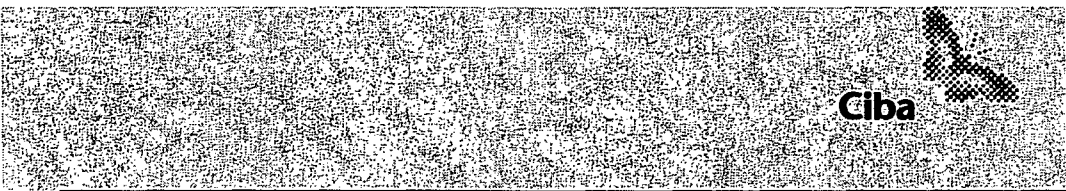
CIBA CORPORATION
PLASTIC ADDITIVES
540 WHITE PLAINS RD.,
TARRYTOWN, NY 10591

IRGAGUARD® is a trademark of Ciba Corporation
EPA Registration No. 40810-18

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 1 2008

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

40810-18



**PRECAUTIONARY STATEMENTS
KEEP OUT OF REACH OF CHILDREN
CAUTION**

HAZARDS TO HUMANS

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 lakes, 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 label or container 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 immediately for treatment advice.

ACCEPTED
with COMMENTS
in EEF Letter Dates:
OCT 1 2008

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

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

40810-18

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Ciba Corporation

Plastics Additives



Technical Bulletin

Irgaguard® B5000

EPA Reg. 40810-18

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

For Manufacturing/Fabrication Use Only

IRGAGUARD® B5000 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® B5000 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® B5000 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® B5000 may be used in material that may be incorporated into the finished product at 0.1 to 3.0% of IRGAGUARD® B5000 by weight. Contact Ciba Corporation to determine the appropriate amount of IRGAGUARD® B5000 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. Use only under agreement with Ciba Specialty Chemicals Corporation. IRGAGUARD® B5000 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.

REGISTERED
MAY 10 2008
U.S. PATENT & TRADEMARK OFFICE
OCT 1 2008
antimicrobial biocide,
antimicrobial preservative Act 29
antimicrobial preservative,
antimicrobial preservative EPA Reg. No.

40810-18

NON-FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS

APPLICATION	TYPES OF FINISHED PRODUCTS
<p>Plastics Including films, sheets, slabs, and molded plastic parts</p>	<p>Appliances and equipment Automobile parts Brush bristles Brush handles Building materials (such as hardware, 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>

APPLICATION	TYPES OF FINISHED PRODUCTS
<p>Fibers</p>	<p>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>

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with COMMENTS
in EPA Letter Dated
OCT 1 2008
Under the Federal Insecticide,
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amended, for the pesticide,
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Irgaguard® B 5000

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 Automotive and vehicle parts 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

ACCEPTED
 WITH COMMENTS
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 40810-18

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

Irgaguard B5000 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 B5000** into any food contact polymer intended for commercial food packaging uses unless that food contact polymer and use condition are approved and listed in 21 CFR 174-186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System."

APPLICATION	TYPES OF FINISHED PRODUCTS																																						
Plastics Including films, sheets, slabs, and molded plastic parts	<table border="0"> <tr> <td>Appliances and equipment</td> <td>Mats</td> </tr> <tr> <td>Beverage dispensing equipment</td> <td>Non-woven fabrics</td> </tr> <tr> <td>Beverage processing equipment</td> <td>Plastic film</td> </tr> <tr> <td>Bottles</td> <td>Plumbing supplies and fixtures</td> </tr> <tr> <td>Brush bristles</td> <td>Protective covers</td> </tr> <tr> <td>Brush handles</td> <td>Sinks</td> </tr> <tr> <td>Containers</td> <td>Sponges</td> </tr> <tr> <td>Conveyor belts</td> <td>Tape</td> </tr> <tr> <td>Countertops</td> <td>Tiles</td> </tr> <tr> <td>Food handling equipment</td> <td>Tubing</td> </tr> <tr> <td>Food processing equipment</td> <td></td> </tr> <tr> <td>Food storage containers</td> <td></td> </tr> <tr> <td>Food trays and covers</td> <td></td> </tr> <tr> <td>Food packaging</td> <td></td> </tr> <tr> <td>Food processing utensils</td> <td></td> </tr> <tr> <td>Gaskets</td> <td></td> </tr> <tr> <td>General purpose containers</td> <td></td> </tr> <tr> <td>Kitchen and bathroom hardware</td> <td></td> </tr> <tr> <td>Liners</td> <td></td> </tr> </table>	Appliances and equipment	Mats	Beverage dispensing equipment	Non-woven fabrics	Beverage processing equipment	Plastic film	Bottles	Plumbing supplies and fixtures	Brush bristles	Protective covers	Brush handles	Sinks	Containers	Sponges	Conveyor belts	Tape	Countertops	Tiles	Food handling equipment	Tubing	Food processing equipment		Food storage containers		Food trays and covers		Food packaging		Food processing utensils		Gaskets		General purpose containers		Kitchen and bathroom hardware		Liners	
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40810-18

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 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

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as amended, for the pesticide,
Irgaguard B 5000, EPA Reg. No.
40810-18

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DRINKING WATER CONTACT USE

Irgaguard B5000 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: 3.35 g/cm³ @ 25° C

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with COMMENTS
in EPA Letter Dated:

OCT 1 2008

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

40816-18