

JUN 08 2005

Connie Welch  
Agent for Ciba Specialty Chemicals Corporation  
c/o ChemReg International  
1990 Old Bridge Road, Suite 201  
Lake Ridge, VA 22192

**Subject: Irgaguard B 5000  
EPA Reg. No. 40810-18  
Your Amendment Dated 6/2/03**

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 to HVAC and indirect human drinking water contact uses, is acceptable under a time-limited restriction with the following conditions.

The primary basis for granting a conditional time-limited approval at this time is the recent FDA indirect food contact approval (FDA Notification #193; product must be first incorporated into food contact approved FDA polymers). The FDA approval can be read at [www.cfsan.fda.gov/](http://www.cfsan.fda.gov/).

1. The following outstanding data for both silver and zinc must be submitted and found acceptable by **6/8/06**. For guidance on the correct test substance to use for satisfying these data requirements, contact the Agency.

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

2. All the indirect food/drinking water, and HVAC uses listed on the proposed draft label dated 5/20/03 have a time-limited approval which automatically expires on **6/8/06**.

3. If the outstanding data listed above is fully satisfied by **6/8/06**, 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.

4. 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

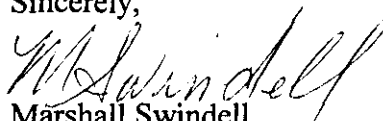
products to submit such data. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product constitutes acceptance of these conditions.

5. All subsequent amendments that are approved for this product will also be time-limited to expire on **6/8/06**.

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 Tony Kish at 703-308-9443.

Sincerely,



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

# IRGAGUARD® B5000

Silver-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) .....	0.44%
Zinc (as elemental) .....	1.36%
Other ingredients.....	98.20%
Total.....	100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

<b>FIRST AID:</b> Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>

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

EPA Establishment No. 70404-AL-002

EPA Registration No. 40810-18

Net Weight

Lot No.

Ciba Specialty Chemicals Corp.  
Plastic Additives  
540 White Plains Road  
Tarrytown, NY 10591

**ACCEPTED**  
with **COMMENTS**  
in EPA Letter Dated:

**JUN 08 2005**

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

**40810-18**

4/10

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS**

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

**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\*\***

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46810-18

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® 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 Specialty Chemicals Corporation to determine the appropriate amount of IRGAGUARD® B5000 for individual finished products.

**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.

**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 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. 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 Specialty Chemicals Corporation

Revisions, NOT EPA APPROVED 5-20-2003



**NON-FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS**

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>Automobile parts</td> <td>Mops</td> </tr> <tr> <td>Brush bristles</td> <td>Non-woven fabrics</td> </tr> <tr> <td>Brush handles</td> <td>Plastic film</td> </tr> <tr> <td>Building materials (such as hardware, handles)</td> <td>Plumbing supplies and fixtures (including toilet bowl seats)</td> </tr> <tr> <td>Conveyor belts</td> <td>Protective covers</td> </tr> <tr> <td>Countertops</td> <td>Shower curtains</td> </tr> <tr> <td>Floor coverings</td> <td>Siding for housing</td> </tr> <tr> <td>Flooring</td> <td>Sinks</td> </tr> <tr> <td>Footwear (including boots, sports equipment and tools)</td> <td>Sponges</td> </tr> <tr> <td>Gaskets</td> <td>Tape</td> </tr> <tr> <td>General purpose containers</td> <td>Tiles</td> </tr> <tr> <td>Indoor and outdoor furniture</td> <td>Tubing</td> </tr> <tr> <td>Insulation for wire and cable</td> <td>Vacuum cleaner bags</td> </tr> <tr> <td>Insulators</td> <td>Waste containers</td> </tr> <tr> <td>Kitchen and bathroom hardware</td> <td></td> </tr> <tr> <td>Liners</td> <td></td> </tr> </table>	Appliances and equipment	Mats	Automobile parts	Mops	Brush bristles	Non-woven fabrics	Brush handles	Plastic film	Building materials (such as hardware, handles)	Plumbing supplies and fixtures (including toilet bowl seats)	Conveyor belts	Protective covers	Countertops	Shower curtains	Floor coverings	Siding for housing	Flooring	Sinks	Footwear (including boots, sports equipment and tools)	Sponges	Gaskets	Tape	General purpose containers	Tiles	Indoor and outdoor furniture	Tubing	Insulation for wire and cable	Vacuum cleaner bags	Insulators	Waste containers	Kitchen and bathroom hardware		Liners	
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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)

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40810-18

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

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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."

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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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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended by the FIFRA Act of 1990,  
registered under FIFRA Section 24(b)

**DRINKING WATER CONTACT USES**

*Iraguard 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/cm<sup>3</sup> @ 25° C

Revisions, NOT EPA APPROVED 5-20-2003

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40816-18