

40810-18

5-8-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 08 2003

Elizabeth Brown
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 11/18/02, and Re-Submission Dated 5/1/03**

The amendment and re-submission 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 certain indirect food contact uses, and which provided a migration study (MRID 45803302), a toxicology review (MRID 45803301), and a copy of the FDA food contact approval notification #193, is acceptable under the following requirements and conditions.

1. The following outstanding indirect food contact data for silver and zinc must be satisfied by **6/8/05**. The Agency will provide guidance to you soon on the correct test substance to use for satisfying these data requirements. All tier one and other food data requirements for the actives have been satisfied by the revised matrix dated 4/30/03.

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

2. All the indirect food uses listed on the proposed draft label dated 4/30/03 have a time-limited approval which automatically expires on **6/8/05**. The basis for granting interim approval now with outstanding data, is that the product formula has FDA approval for indirect food contact use only when first incorporated into polymers, as stated in the FDA Food Contact Notification #193 (www.cfsan.fda.gov/). If these outstanding data are not fully satisfied by **6/8/05**, the Agency will require you to delete them from the label.

3. After you satisfy the outstanding data listed above, an aggregate risk assessment will be conducted for the new indirect food contact uses. If this risk assessment is not found acceptable, the Agency may require you to delete all or certain uses.

4. The submitted migration study was not reviewed because the aggregate risk assessment for

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these new uses could not be completed without the outstanding data. Therefore, your response to this letter should request that the migration study be reviewed in conjunction with satisfying the outstanding data.

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.

6. All subsequent amendments that are approved for this product will also be time-limited to expire on 6/8/05.

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.

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)

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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

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	<ul style="list-style-type: none"> • 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**

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:
MAY 08 2003

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

40810-18

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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****

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

EPA Approval Date: NOT EPA APPROVED. Draft 4-30-2003

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 08 2003

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

40810-18

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Ciba



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 Specialty Chemicals 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.

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in EPA Letter Dated:

MAY 08 2013

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

40810-18

NON-FOOD CONTACT USES: 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

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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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

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Under the Federal Insecticide,
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40810-18

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	Appliances and equipment Beverage dispensing equipment Beverage processing equipment Bottles Brush bristles Brush handles Containers 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

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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

CHEMICAL AND PHYSICAL PROPERTIES

Appearance: White to grayish-white powder

Odor: None detectable

Density: 3.35 g/cm³ @ 25° C

Draft: Not EPA-approved. 4-30-2003

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