

40810-18

04/21/2006

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APR 21 2006

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
Agency Initiated Action: Extension of Time Limited Approval
For Certain Uses

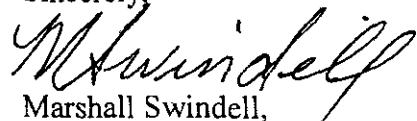
This product currently has time-limited approval until 6/8/06 for all the indirect food, drinking water, and HVAC uses listed on the last stamped label. The other uses on the labels are not time-limited. This letter represents an Agency initiated action which hereby extends the time-limited approvals for these uses until 6/8/07. This will permit the Agency time to complete the review of the 90-day dog, and two-generation reproduction data you submitted, and to complete the final risk assessment for all uses on the label. The two submitted studies referenced above must be found valid and the final risk assessment of all label uses must be found acceptable.

Failure to find the data valid and the risk assessment acceptable may result in EPA issuing a notice to cancel one or more of the indirect food, drinking water, HVAC or other uses, under FIFRA Section 6(e). This time-limited approval will expire automatically on 6/8/07. Sale or distribution of the subject product bearing labeling for these food contact uses after 6/8/07 will be illegal.

A copy of the applicable label, stamped "Accepted with comments" is attached for your records.

If you have any questions about the comments in this letter, please feel free to contact Portia Jenkins at 703-308-6230, or myself at 703-308-6341.

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

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:

APR 21 2006

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

40810-18

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****

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 21 2006

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

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Ciba Specialty Chemicals 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 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 21 2006

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
40810-18

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Irgaguard® B 5000

NON-FOOD CONTACT USES: APPLICATIONS AND TYPES OF MATERIALS

APPLICATION	TYPES OF FINISHED PRODUCTS
Plastics Including films, sheets, slabs, and molded plastic parts.	<ul style="list-style-type: none"> 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

APPLICATION	TYPES OF FINISHED PRODUCTS
Fibers	<ul style="list-style-type: none"> 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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in EPA Letter Dated:

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

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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

with OCCASIONAL TRENDS
in EPA Letter Dated:

APR 21 2006

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

40810-18

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Irgaguard® B 5000

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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ACCEPTED
with COMMENTS
in EPA Letter D-123

APR 21 2006

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

40810-18

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Irgaguard® B 5000

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

ACCEPTED
with COMMENTS
in EPA Label Draft

APR 21 2006

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by ...
registered under ...

40810-18

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Irgaguard® B 5000

DRINKING WATER CONTACT USES

Irguard 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

Revisions, NOT EPA APPROVED 5-20-2003

ACCEPTED
with COMMENTS
in EPA Lower Data:

APR 21 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg No.

40816-18