

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

FEB 27 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

William F. Salminen
Ciba Specialty Chemicals Corporation
4090 Premier Drive
P.O. Box 2444
High Point, N.C. 27261

SUBJECT: November 21, 2002 amendment application
Irgaguard B 1000
EPA Registration 70404-5

Dear Mr. Salminen:

The Agency has reviewed the data submitted in response to our November 1, 2002 letter and is satisfied that the deficiencies we cited for product chemistry (GDLNs 61-2(b) and 62-2), acute toxicology (GDLN 81-5), and oncogenicity (GDLN 83-2(b)) have been resolved. The amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is conditionally acceptable provided that the upper limit of the percentage of the active ingredient is changed from 1% to 2% in the Textiles and Fabrics section of the Technical Bulletin. A copy of your stamped label is enclosed.

Two copies of the finished labeling must be submitted to the Agency for our files. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "for Tom Luminello".

Robert S. Brennis
Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510-C)

Enclosure



Ciba

Irgaguard® B1000

Bacteriostat

ACTIVE INGREDIENT:

5-chloro-2-(2,4-dichlorophenoxy)-phenol.....	99.0%
INERT INGREDIENTS.....	1.0%
Total:	100.0%

EPA Reg. No. 70404-5 EPA Est. 70404-DEU-001

Keep Out of Reach of Children

CAUTION

See additional precautionary statements and directions for use on the side panel.

Irgaguard® B1000 Trademarks of
Ciba Specialty Chemicals Corporation
© 2002 Ciba Specialty Chemicals Corporation

Net Weight 55 LBS 25 Kg

Ciba Specialty Chemicals Corporation
24-Hr Emergency Phone: 800-873-1138

IMPORTANT: Read the entire directions for use before using this product

DIRECTIONS FOR USE

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

USE DIRECTIONS: Irgaguard B1000 is an end-use (EP) bacteriostatic agent for the manufacture of polymer/plastic and textile products only. Not for Diaper Laundry Application.

Please refer to the Technical Bulletin for information concerning uses.

STORAGE AND DISPOSAL

Store below 130°F. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste facility. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration by state and local authorities. If burned stay out of smoke. Drum cannot be reused, dispose of in same manner

For minor spills, shovel into an approved disposal container, vacuum contaminated areas. Avoid creating dusty conditions. Take special precaution to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire or other emergency, call 1-800-873-1138 day or night.

Batch / Lot Number:

ACCEPTED
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Precautionary Statements HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if inhaled. Do not breathe dust, vapor or spray mist. Wear a mask or a pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Remove contaminated clothing. Wash thoroughly with soap and water after handling

ENVIRONMENTAL HAZARDS:

This product is toxic to fish and aquatic vertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID:

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

If swallowed: Call a physician or Poison Control Center. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. Have the product label or container with you when call a Poison Control Center or Doctor for treatment advice.

You may also contact 1-800-873-1138 for emergency medical treatment.

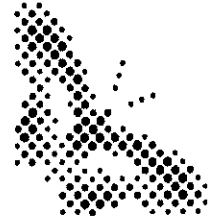
July 8, 2002

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A. COERTZ
DANK. CONSTATITS

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Ciba

Ciba Specialty Chemicals Corporation
Plastic Additives

70404-5

IRGAGUARD[®] B 1000

EPA Reg. 70404-5

Broad-spectrum bacteriostat for use in the manufacture of polymer / plastic and textile products.

IRGAGUARD B 1000 is an end-use (EP) bacteriostatic agent for the manufacture of polymer / plastic and textile products. IRGAGUARD B 1000 is effective against non-health related organisms which contribute to the deterioration, discoloration and production of unpleasant odors in polymeric materials.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use only under an agreement with Ciba Specialty Chemicals Corporation. Irgaguard B 1000 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 antibacterial and antifungal activity in manufactured materials and finished products. Irgaguard B 1000 inhibits the growth of non-health related microorganisms such as bacteria, mold, mildew, and fungus that may cause odor, stain, discoloration, unsightly texture, decay, or deterioration of physical properties of the material and finished product. Distributors of products containing the additive may not make claims of antimicrobial activity other than the protection of the product against the growth of bacteria, mold, mildew and fungi in or on the treated product. For further guidance on treated article label claims, please refer to 40 C.F.R. §152.25(a) and any additional guidance or policies issued by the U.S. Environmental Protection Agency.

TYPES OF MATERIALS:

Plastics (including films, foams, molded parts, pellets, sheets), fibers/fabrics (including multi-fiber blends and synthetic blends with natural fibers) composed of: Acetate, Acrylic, Acrylonitrile butadiene styrene, Epoxy, Fluoropolymers, Latex, Nitrile copolymers, Nylon, Polychlorophene, Polyester, Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride, Rayon, Rubber (natural & synthetic derivatives), Silicone, Urethane, & Vinyl and coating/finishes applied to such materials.

Currency
 Cushions
 Cutting boards
 Door & Floor mats
 Exercise & gym equipment
 Floor coverings (wax, sealers, and coatings)
 Flooring (concrete, epoxy, component fibers, & coatings of urethane, epoxy etc.)
 Floral containers
 Food distribution carts
 Food service trays
 Furniture coverings
 Furniture foam cushions
 Garbage bags and trash can liners
 Garbage cans
 Grease traps
 Medical & dental trays
 Menu materials
 Metallic coatings for plumbing fixtures, door handles, serving utensils, bed pans, and floor drains

Mop buckets
 Mops & mop components
 Pallets
 Paper and paperboard products
 Personnel cards (credit cards, driver's license, etc.)
 Playground equipment & furniture
 Portable toilets
 Shoe inner soles
 Storage containers (for clothing, instruments, electronics, food & condiments)
 Tile (wall & floor) & grout
 Toilet seats
 Toilets and urinals
 Tooth brush handles
 Toys
 Tray liners
 Waste bins
 Wheel for medical carts
 X-ray holders

Chemical and Physical Properties

Chemical name: 2,4,4'- trichloro-2'-hydroxy-diphenyl-ether
 Generic name: triclosan
 CAS number: 3380-34-5
 Molecular weight: 289.5
 Melting point: 57±1°C
 Odor: Slightly, faintly aromatic
 Appearance: Whitish fine crystalline powder
 Purity: 99% minimum
 Ash content: 0.1% maximum
 Bulk Density: 0.55 - 0.61 kg/l
 Specific Gravity: 1.58±0.03 g/cm³

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Solubility:
 IRGAGUARD B 1000 is sparingly soluble in water, moderately soluble in dilute alkaline solutions, and readily soluble in most organic solvents. Clear concentrated solutions can be prepared with water-miscible solvents or surfactants.

Thermal Stability:
 IRGAGUARD B 1000 does not decompose under normal storage conditions. It shows good stability when heated at 200°C for up to 2 hours. Differential scanning calorimetry studies have shown no rapid decomposition of the powder at temperatures below 300°C.

Light stability:
 In powder form, IRGAGUARD B 1000 is highly stable to intense radiation, but solutions may show instabilities when exposed to intense UV-light radiation.

Volatility:
 The vapor pressure of IRGAGUARD B 1000 is 4 x 10⁻⁶ mm Hg at 20°C and 2 x 10⁻² mm Hg at 100°C.



Features

Bacteriostat for textile treatment:
IRGAGUARD B 1000 can be used to control odor-causing and spoilage/deterioration microorganisms on or in textiles and textile fibers.

Bacteriostat for polymer/plastic treatment:
IRGAGUARD B 1000 can be added to polymers / plastics to protect the material against direct or indirect effects by microorganisms which can cause deterioration of the physical properties, appearance or odor of the material.

APPLICATIONS

1. Textiles and Fabrics:

(two)

Manufactured materials may be used in the following applications such that the finished product contains 0.10% to 2.0% by weight of the active ingredient. The additive may be incorporated directly into the fiber or as a finish for the fabric/product.

- Apparel trimmings and linings
- Aprons (food service, home)
- Athletic Wear
- Awnings (Indoor and outdoor)
- Bibs
- Blanket bags
- Blankets
- Brushes
- Carpets and Rugs
- Conveyor belts
- Covers for counter tops
- Covers for table tops
- Cubicle curtains
- Door and floor mats
- Dresses
- Exercise equipment
- Floor coverings
- Food Services wipes (towels)
- Furniture fabrics
- Garment bags
- Gloves (non-medical)
- Gowns (medical & consumer)
- Hair brushes
- Hosiery and socks

- Incontinence care products (diapers and underpads)
- Intimate Apparel (Underwear)
- Janitorial brushes and brooms
- Linens (towels, sheets, pillowcases, mattress covers, etc.)
- Mattress and pillow ticking
- Medical and Dental clothing
- Mops
- Paper mulch
- Pillow and mattress stuffing
- Quilt fabric
- Running apparel
- Service Uniforms
- Shoes, shoe inner soles and linings
- Shower curtains
- Silage wraps
- Sporting team uniforms
- Sportswear
- Sweatshirts/t-shirts
- Table clothes, napkins
- Tooth brush bristles
- Uniforms
- Wall covering
- Wet suits
- Window curtain and draperies

2. Polymers and plastics

Manufactured materials may be used in the following applications such that the finished product contains 0.10% to 1.0% by weight of the active ingredient. The additive may be incorporated directly into the polymer or as a coating on the final product.

- Adhesives
- Agricultural & mulch films
- Combs & brushes

- Containers for cosmetics
- Conveyor belts
- Counter and Table tops

ACCEPTED
DATE COMMENTS
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Conditions of Sale and Warranty

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Ineffectiveness, or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application all of which are beyond the control of Ciba Specialty Chemicals Corporation ("Ciba") or the Seller. All such risks shall be assumed by the Buyer.

Ciba warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions for Use subject to the inherent risks referred to above. **Ciba makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Ciba or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** Ciba and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing Conditions of Sale and Warranty, which may be varied only by agreement in writing signed by a duly authorized representative of Ciba.

No end-use of this product other than as described above is intended or implied by the above conditions of sale and warranty.

ACCEPTED
BY THE BUYER

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