

42182-1

11-16-2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 16 2001

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Kevin Drake  
Microban Products Company  
11515 Vanstory Drive, Suite 110  
Huntersville, N.C. 28078

SUBJECT: February 28, 2001 Amendment  
Microban Additive "B"  
EPA File Symbol 42182-1

Dear Mr. Drake:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the conditions listed below:

- addition of **servicing utensils, water dispensers and components** to the Housewares section with a caveat that the use rate for the water dispensers and components are limited to 0.5%.
- addition of **water filter components and housing units, water dispensers and components** to the Industrial section with a caveat that the use rate is limited to 0.5%.
- revised First Aid Statement per PR Notice 2001-1.

**Conditions**

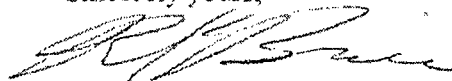
1. A new hydrolysis study, conducted in accordance with guideline requirement 161-1, is required and must be submitted by November 30, 2002.
2. Additional information for the 2 studies entitled "A Risk Analysis for Microban Additive "B" Water Filtration Components" and "A Risk Analysis for Microban Additive "B" Water Storage Components" is required. See enclosed review for additional information regarding deficiencies in these 2 studies.
3. Additional information on the migration of residues into food from countertops, cutting boards, table tops and serving utensils is required. See enclosed review for additional information regarding this data deficiency.
4. The signal word **caution** must be placed under "Hazard to Humans and Domestic Animals" in front of Harmful if Swallowed.

**General Comments**

In accordance with 40 CFR § 152.115, the conditions stated above in items 1, 2, and 3 are required since the Agency is agreeing to a time-limited addition of these uses. The required data cited above must be submitted by November 30, 2002 as a condition of temporary approval of the additional uses. If these data are not submitted by November 30, 2002 and the Agency has not agreed to a time extension, then the approval of the label will be withdrawn. Final approval of the label is dependent on Agency acceptance of the data. If you do not agree to these conditions, you must advise the Agency within 30 days of your receipt of this letter and the conditional approval of these uses will be withdrawn.

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,



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

Enclosure

**PRECAUTIONARY STATEMENTS**

**HAZARD TO HUMANS AND DOMESTIC ANIMALS**

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

**ENVIRONMENTAL HAZARD**

Do not contaminate irrigation water, lakes, streams, or ponds by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of 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.

**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 Microban Products Company. Microban Additive "B" 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. Microban Additive "B" inhibits the growth of non-health related microorganisms such as bacteria, mold, mildew, & 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.

**APPLICATIONS**

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:

**Microban Additive "B"**  
*A bacteriostatic and fungistatic additive for use in the manufacture and preservation of commodity products*

**ACTIVE INGREDIENT:**

5-CHLORO-2(2,4-DICHLOROPHENOXY)PHENOL.....99%

**INERT INGREDIENTS:**..... 1%

**TOTAL:**..... 100%

**KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL**

**CAUTION**

FIRST AID	
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 a poison control center or doctor. Do not give anything by mouth and do not induce vomiting.
If Inhaled	Move person to fresh air. If not breathing, call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth. Call a poison control center or doctor for further advice.
If on Skin	Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further advice.
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 for further advice.

**Directions for Use (continued)**

**Apparel:** aprons, athletic shirts, bibs, dresses, footwear (including socks & innersoles), general wear, gloves (consumer), gowns (medical & consumer), hosiery, intimate apparel, linings, running gear, sports apparel, trimmings, uniforms (service, medical, dental, sports), wet suits.

**Construction & building materials:** adhesives, awnings, bathtubs and bathtub enclosures, caulking (tub & tile), coatings (aqueous, solvent based; liquid, powder; metallic coating for plumbing fixtures, door handles, bed pans, floor drains, grease traps), concrete, flooring (concrete, epoxy, component fibers, & coatings), grout, handles & knobs, paint (aqueous & solvent based), shower stalls, tile, wall coverings, whirlpools.

**Films:** agricultural and mulch films, bags (blanket, garbage, garment, vacuum), curtains (window, shower, cubicle), liners (garbage, trays), wraps (silage).

**Floor coverings:** carpets, rugs, mats, sealer/wax components.

**Home furnishings:** blankets, cloths, countertops, curtains, draperies, furniture & fabrics, linens (towels, sheets, pillowcases, etc.) mat & pillow ticking, mattress pads, napkins, shower curtains.

**Housewares:** cutting boards, humidifier components, storage containers (for clothing, cosmetics, flowers, instruments, electronics, food & condiments), vacuum cleaner components, serving utensils, water dispensers and components\*.

**Industrial:** air filters, air filtration media, appliance housings, automotive interiors, brooms, brushes, buckets, carts, closure gaskets, conveyor belts, countertops (& covers), earplugs, garbage cans, hoses (non food; non-potable water transfer), ice making equipment\* (water pans, piping, tubing, guards), water filter components and housing units\*, water dispensers and components\*, janitorial supplies, mops, respirator mask components, tabletops, trays, wipes.

**Miscellaneous:** cards, currency, paper & paperboard (including menu materials & mulch), phones, toilets & toilet components/accessories, toys, wheels.

**Personal care products:** bristles & handles of brushes (tooth, hair), combs, incontinence care products, razors.

**Sporting goods:** boating/marine equipment, exercise & gym equipment, playground equipment.

Specific manufacturing directions for a given application will be provided by consultation with Microban Products Company. \*Active concentration is limited to 0.5% in these applications.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**1. PESTICIDE STORAGE**

Keep in original container during storage. Store in cool, dry, well ventilated place. Keep away from fire or open flame, or other source of heat.

**2. PESTICIDE DISPOSAL**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**3. CONTAINER DISPOSAL**

Completely empty liner by shaking or tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

EPA Registration Number: 42182-1  
 EPA Establishment No.: 42182-NC-6

**MICROBAN PRODUCTS COMPANY**

11515 Vanstory Drive  
 Huntersville, NC 28078

Phone: (704) 875-0806 Fax: (704) 875-0810

Net Contents: Marked on container

Lot Number:

with COMMENTS  
 in EPA Letter Dated:  
 NOV 16 2001

is a Federal Insecticide,  
 and Rodenticide Act as  
 for the pesticides,  
 registered under EPA Reg. No.

42182-1

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