

11631-3

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FEB 26 2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Elizabeth Brown, Agent for Milliken Chemicals, Inc.
 c/o ChemReg International, LLC
 2239-H Tacketts Mill Drive
 Lake Ridge, VA 22192

Subject: Antimicrobial AlphaSan RC 5000 EPA Reg. No. 11631-2
Antimicrobial AlphaSan RC 2000 EPA Reg. No. 11631-3 ✓
Antimicrobial AlphaSan RC 7000 EPA Reg. No. 11631-4
Your Three Submissions, All Dated 12/5/2001

The three submissions referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, requesting that the Agency re-classify these registered products from their current designation as end use products (EP's), to manufacturing use products (MUP's), and providing three revised labels reflecting the new MUP designation, is acceptable with the following conditions:

(1) you must make and submit five copies of the "final printed master label" with the changes listed below within 30 days from the date stamped on this letter, and

(2) you must comply with the existing time limited data requirements re-iterated below which were listed in previous registration notices and amendment letters.

EXISTING TIME LIMITED REQUIREMENTS

The following outstanding data listed below must be submitted by **October 1, 2002**, and found acceptable, to support the existing food and drinking water contact uses on the attached stamped labels. These two approved uses will expire automatically on **May 1, 2003**. Failure to satisfy these data will result in EPA issuing a new Notice of Registration and label with these uses deleted.

A. Sub-chronic, non-rodent feeding study (830.3150)

B. Two-generation reproductive study (870.3800)

REQUIRED LABEL CHANGES

EPA Reg. No.s 11631-3 and 11631-4

1. Your submission contained a revised label for EPA Reg. No. 11631-4 dated 12/5/01. The product was registered on 12/7/01 with label changes listed in the Registration Notice which must be reflected in the 12/5/01 version. You must make all (1a,b,c,d) the following labeling

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changes for EPA Reg. No. 11631-4, as well as changes 1b, 1c and 1d for EPA Reg. No. 11631-3 (10% silver):

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 11631-4."
- b. The product has an acute toxicity category of II for dermal because you are relying on a study from the 10% silver variant. Therefore, you must add the following "First Aid" statement:

"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 treatment advice."
- c. As per the revised acute toxicity categories, you must change the "Precautionary Statements" to the following:

"Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling."
- d. You must make the following changes. Change "Storage" to "Pesticide Storage". Change "Disposal" to "Pesticide Disposal". Boldface "Container Disposal" to match the other subheadings.

2. For EPA Reg. No. 11631-4, we note that on page 2, the directions state "The final article may contain from 0.3% to 6.5% by weight". As per the FDA food contact approval for the active ingredient, all Milliken products with the silver sodium hydrogen zirconium phosphate active ingredient are approved for use only at levels not to exceed 2% by weight of the polymer into which they are incorporated. Because this product contains 31% of the active ingredient which itself can be at up to 2% by weight of the polymer, the stated maximum application rate of 6.5% by weight of AlphaSan RC 7000 does not exceed the allowable 2% by weight of the active ingredient ($6.5\% \times 31\% = 2\%$). The other two products (EPA Reg. No.s 11631-2 and 11631-3 have a correct maximum use rate of 2%.

For All Three Labels (EPA Reg. No.s 11631-2/-3/-4)

- 1. On page 1 of each label, you must change, "For Formulation and Manufacturing/Fabrication Use Only" to "For Use In Formulating, Manufacturing, and Fabricating of Treated Article Products Specified in the Use Directions".
- 2. On page 2 of each label, you must delete the three lines beginning with, "2) Uses for which USEPA has approved...", and ending with "...compliance with USEPA requirements". These words are not needed on the label.

MANUFACTURING USE PRODUCT DECISION

Based on the written information you submitted, and on subsequent meetings and telephone conversations, your request to change the product designation from an EP to an MUP is

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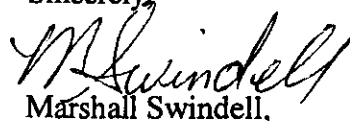
approved. This new MUP designation is only applicable to the general type of manufacturing based uses on the attached stamped labels. Certain new or additional uses proposed in the future might be considered as end uses (eg., involving post-manufacturing applications to existing treated articles, etc.). These EP uses and associated use directions would then have to be placed on a separate EP label.

These three revised conditional registrations will expire automatically on May 1, 2003. The registration requirements listed herein must be fully satisfied in order for EPA to change the "Terms of Issuance". Your release for shipment of the product constitutes acceptance of these conditions.

A stamped revised label (accepted with comments) for each of the three registered product 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, or myself at 703-308-6341.

Sincerely,



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

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Antimicrobial AlphaSan® RC 2000

An antimicrobial additive especially designed to withstand high temperatures in the manufacture of plastics, films, fibers, polymeric materials and ceramics.
For formulation and Manufacturing/Fabrication Use Only

* * * * *

Active Ingredient:	
Silver sodium hydrogen zirconium phosphate*	99.9%
Other ingredients	0.1%
TOTAL:	100.0%

*Contains 10% silver, weight/weight

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans

Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling. Do not breathe dust.

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.
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EPA File Symbol No. 11631-3
EPA Est. 11631-SC-001

Milliken Chemical
P.O. Box 1927
Spartanburg, S.C. 29304

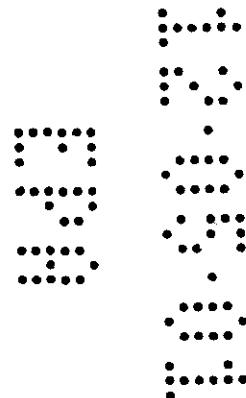
Net Weight 10 Kg (22 Lbs)

ACCEPTED
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registered under EPA Reg. No.

11631-3



DIRECTIONS FOR USE:

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

Only for manufacture of or fabrication into antimicrobial pesticides for 1) the uses listed on this label; 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.

Antimicrobial AlphaSan® RC 2000 is an antimicrobial powder for commercial use. It is designed to be incorporated into materials during the manufacturing process to impart antimicrobial activity to manufactured products. **Antimicrobial AlphaSan® RC 2000** suppresses the growth of bacteria, algae, fungus, mold and mildew. If microbial activity in the manufactured product could lead to unpleasant odors, discoloration or deterioration of the product, then such a claim may be made for the manufactured product. Manufactured products incorporating **Antimicrobial AlphaSan® RC 2000** may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product which permits such claims. When incorporated into manufactured products, **Antimicrobial AlphaSan® RC 2000** does not protect users of any such manufactured product or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

Antimicrobial AlphaSan® RC 2000 may be used in materials that may be incorporated into manufactured products listed below. The final article may contain from 0.1% to 2.0% by weight.

Food Contact Uses

Antimicrobial AlphaSan® RC 2000 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 **Antimicrobial AlphaSan® RC 2000** into any food contact polymer unless that food contact polymer and use conditions 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." Any incorporation of **Antimicrobial AlphaSan® RC 2000** into any food contact substance other than an approved and listed food contact polymer is prohibited.

Plastics, coatings, films and laminates: Including appliances and equipment; barrier fabrics; beverage dispensing equipment; beverage processing equipment; bottles; brush bristles; building materials and components; collection and storage equipment (including piping systems, silos, tanks and processing vessels); conveyor belts; cookware; countertops, including kitchen countertops and other countertops; cups; cutting boards; dishes; filters; food and drink containers; food handling equipment; food packaging; food processing equipment; food storage containers and bags; food trays and covers; food wrap (including coated deli paper, coated meat interleavers and plastic wrap); gaskets; general purpose containers; glazing for cement tile and for vitreous china used in plumbing fixtures such as sinks; industrial equipment; insulators; kitchen and bathroom hardware; kitchen and food processing utensils and supplies; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; packaging; paper products (wipes and tissues, towels); plastic film; plumbing supplies and fixtures; protective covers; sinks; sponges; tape; tiles; tubing; waste containers.

Fibers: Including table cloths; napkins; wiping cloths; mops; towels; bags; brush bristles; filters; sponges; packaging (including bags, sacks, wraps, cushion and absorbent materials, containers); conveyor belts; clothing apparel (including uniforms, outerwear, gloves, aprons, coats); kitchen, commercial and industrial wipes and fabrics; food packaging (containers and bags).

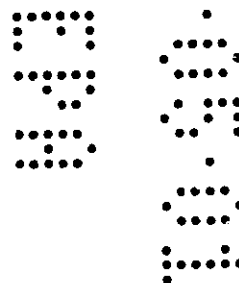
Adhesives and sealants: Including adhesives used in the manufacture of wood and plastic composites; adhesives for ceramic tile, wood, paper, cardboard, rubber and plastic; grout and joint compound; sealants for pipes; adhesives, sealants and insulating materials for appliances; plumbing adhesives; adhesives for packaging.

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Drinking Water Contact Uses

Antimicrobial AlphaSan® RC 2000 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.

Plastics; Fibers; Coatings, films, and laminates; Adhesives and sealants: Including ice making equipment (water pans, piping, tubing, guards, ice storage bins, ice scoops, buckets, valves, and gaskets); drinking water contact materials (water bottles, cups, gaskets, plumbing fixtures, storage tanks, water piping, tubing, valves, spigots, coolers, water dispensing components, housing units, and water filter components).

Non-Food Contact Uses

Antimicrobial AlphaSan® RC 2000 may be incorporated into manufactured products listed below for non-food contact uses. **Antimicrobial AlphaSan® RC 2000** also may be used for *non-food contact uses* in any manufactured product listed above for Food Contact Uses or Drinking Water Contact Uses.

Plastics, coatings, films and laminates: Including appliances and equipment; automotive and vehicular parts; barrier fabrics; brush handles; building materials and components; collection and storage equipment (including piping systems, silos, tanks and processing vessels); concrete; conveyor belts; countertops; floor covering; flooring; footwear including boots; furniture; gaskets; general purpose containers; glazing for cement tile and for vitreous china used in plumbing fixtures such as toilets, sinks, countertops; indoor and outdoor furniture; industrial equipment; insulation for wire and cable; insulators; kitchen and bathroom hardware; liners; mats; mops; natural and synthetic fibers and fabrics; non-woven fabrics; packaging; paper products (wipes and tissues, wall coverings, towels, book covers); plastic film; plumbing supplies and fixtures; protective covers; roofing shingles; shower curtains; siding; sinks; sponges; sports equipment; tape; tiles; tools; tubing; vacuum cleaner bags; wallboard; walls; waste containers.

Fibers: Including Mattress cover pads and filling; pillow covers; sheets; blankets; fiberfill for quilts and pillows; curtains; draperies; carpet and carpet underlay; rugs; upholstery; table cloths; napkins; wiping cloths; mops; towels; bags; wall covering fabrics; cushion pads; sleeping bags; brush bristles; filters; sponges; packaging; conveyor belts; automotive and truck upholstery; carpeting; rear decks; trunk liners; convertible tops and interior liners; umbrellas; outerwear; uniforms; coats; aprons; sportswear; sleepwear; stockings; socks; hosiery; caps; undergarments; inner liners for jackets; shoes; gloves and helmets; artificial leather; book covers; cloth for sails; ropes; tents and other outdoor equipment; tarps; awnings.

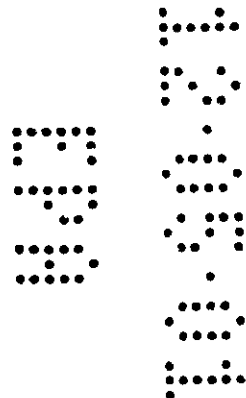
Adhesives and sealants: Including adhesives used in the manufacture of wood and plastic composites; adhesives for ceramic tile, wood, paper, cardboard, rubber and plastic; glazing for windows; grout; sealants for pipes; adhesives; sealants and insulating materials for appliances, bathrooms, showers, kitchens, and construction; plumbing adhesives; adhesives for packaging.

Miscellaneous Manufactured Products: Toilets; sinks; tile; flooring; stucco; plaster; cat litter; drainage and sewerage pipe.

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Questions: 1-800-345-0372 (8:00 a.m. to 5:00 p.m., Eastern time)

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 containers covered during storage and away from water and excessive moisture or humidity.

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.

WARRANTY STATEMENT

MILLIKEN CHEMICAL warrants that this product conforms to the chemical description on the label. MILLIKEN CHEMICAL makes no warranties of merchantability or fitness for a particular purpose or any other expressed or implied warranty except as stated above.

Not EPA Approved. Draft 12-5-2001

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