

11631-2

11-9-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 09 2000

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

**Mailed To: Bob Sielaty, Agent for Milliken
ChemReg International
2239-H Tacketts Mill Drive
Lake Ridge, VA 22192**

**RE: Antimicrobial AlphaSan RC 5000
EPA Reg. No. 11631-2
Your Submissions Dated 8/14/2000, and 10/27/2000**

The Agency is conditionally approving your amendment to the registration of the product referenced above under authority of FIFRA Section 3(c)(7)(B). This amendment allows use of the subject product as an antimicrobial additive when incorporated into the specific food contact polymers listed in 21 CFR Parts 174 through 186 inclusive, or in FDA's "Food Contact Substance Notification System", and also allows incorporation of the product into certain human and animal drinking water contact treated articles.

This amendment, and the approved uses, will expire automatically on **May 1, 2003**. In addition, during the period that this amendment is effective (approximately 2.5 years), it will be subject to the conditions in this letter listed below:

1. The following outstanding data must be submitted by **May 1, 2002** to support **both the new food and drinking water contact uses** on the attached stamped label. Failure to satisfy the data requirements listed below may result in EPA issuing a notice to cancel this amendment under FIFRA section 6(e). This conditional registration will expire automatically on **May 1, 2003**. Sale or distribution of the subject product bearing labeling for these food contact uses after **May 1, 2003** will be illegal.

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

B. Two-generation reproductive study (870.3800)

2. Label Changes: You must submit five copies of a final printed label which makes the following changes.

CONCURRENCES							
SYMBOL							
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A. We received your submission dated 10/31/2000 containing the outstanding rainbow trout (MRID 45252301), and daphnia study (MRID 45252302). These studies have not been reviewed yet and were a requirement listed in the time-limited registration (dated 5/22/2000) for this product. Because this product is considered indoor use, and indoor end-use registrations do not usually require and "Environmental Hazards" statement", you can now remove the "Environmental Hazards" statement. However, if these studies are found not acceptable, you may be asked to put the statement back on this label.

B. On page 2 of the label, in the food contact use section, delete the redundant "conveyor belts" and "food packaging" which are listed elsewhere (as "direct food packaging", and as "including conveyor belts").

This amendment for new food and drinking water contact uses automatically expires on 5/1/2003. In order for the registration of the use of this product, for incorporation into approved food contact polymers, and into certain drinking water treated articles, to continue, the outstanding data described above, must be submitted, reviewed, and found acceptable. In addition, the Agency must make a risk assessment determination under FIFRA Section 2 (bb)(2) that these uses will not result in unreasonable adverse effects. If the Agency is unable to make this determination, then the registration of these uses for incorporation into approved food contact polymers and drinking water treated articles will expire.

Note that under the proposed rule which amends 40 CFR Parts 152 and 156 (ie., 156.444), for non-public health products, the word "Antimicrobial" will not be permitted in the product name, and the word "antimicrobial" will only be allowed if "clearly and properly" qualified by a statement in close proximity to the word "antimicrobial". Also note that you must have efficacy data on file which justifies the various claims and use sites on this label. You do not need to submit this data until the Agency requests it.

A stamped copy of the accepted label is attached 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 5000

An antimicrobial additive especially designed to withstand high temperatures in the manufacture of plastics, films, fibers, polymeric materials and ceramics.

* * * * *

Active Ingredient:

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

*Contains 3.8% 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

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and other aquatic invertebrates. Do not discharge effluent containing this product into lakes, rivers, streams, ponds, estuaries, marshes, oceans, or other 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

EPA Reg. No. 11631-2
EPA Est. 070231-JPN-002

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

Net Weight 10 Kg (22 Lbs)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

11631-2

DIRECTIONS FOR USE:

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

Antimicrobial AlphaSan® RC 5000 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 5000** 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 5000** 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 5000** 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 5000 may be incorporated into manufactured products listed below from 0.1% to 2.0% by weight.

Food Contact Uses

Antimicrobial AlphaSan® RC 5000 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 5000** 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 5000** 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 conveyor belts, piping systems, silos, tanks and processing vessels); conveyor belts; cookware; countertops, including kitchen countertops and other countertops; cups; cutting boards; direct food packaging; dishes; filters; food and drink containers; food handling equipment; food packaging; food processing equipment; 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 5000 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 5000 may be incorporated into manufactured products listed below for non-food contact uses. *Antimicrobial AlphaSan® RC 5000* 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 conveyor belts, 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.

Storage: Do not store in areas accessible to children. Keep containers covered during storage and away from water and excessive moisture or humidity.

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.

Draft Label Revision: 10-27-2000

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