

MAR 22 2005

Elizabeth Brown, Agent for Milliken Chemicals, Inc.
c/o ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

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

These products currently have time-limited approval until 5/1/05 for all the indirect food, drinking water, and HVAC uses listed on the last stamped labels. 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 5/1/06. 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 5/1/06. Sale or distribution of the subject product bearing labeling for these food contact uses after 5/1/06 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 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)

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 Use In Formulating, Manufacturing, and Fabricating of Treated Article Products Specified in the Use Directions.

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

*Contains 10.0% silver, weight/weight

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

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. 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: 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.

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.

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 ACCEPTED

MILLIKEN CHEMICAL warrants that the chemical described on the label. MILLIKEN CHEMICAL does not warrant the chemical's merchantability or fitness for a particular purpose or any other expressed or implied warranty except as stated above.

EPA Reg. No. 11631-3
EPA Est. 11631-SC-001
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide,
Net Weight 10.0 kg (22.0 lbs) No. 11631-3

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

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 (or finished coating, for all uses requiring coating type applications) 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 counterstops; 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.

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; rug decks; trunk liners; convertible tops and interior liners; umbrellas; outerwear uniforms; coats; aprons; sportswear; sleepwear; stockings; socks; hosiery; caps; undergarments; innerliners for jackets; shoes; gloves and helmets; artificial leather; boot 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: oil tanks; tile; flooring; stucco; plaster; cat litter; drainage and sewerage pipe.

Heating, Ventilation and Air Conditioning (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.

Question: 10-345-0372 (8:00 a.m. to 5:00 p.m., Eastern time)

Lab Revision: 09-26-2002