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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 26 2002

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 6/13/2002**

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(7)(B), as amended, to add new uses for application to HVAC components during original manufacture, is acceptable with the following requirements and conditions:

Time Limited Approval

The Agency is granting an interim, time limited approval for your amendment pending submission of an outstanding sub-chronic non-rodent feeding study (830.3150), and a two-generation reproductive study (870.3800) by 10/1/02, and pending a final risk assessment for these HVAC uses conducted using all data, including these missing data.

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

Manufacturing Use Only

Use as a coating or incorporation for HVAC components is approved only during the original manufacture of the component. No approval is granted for application to "in-place" HVAC components which requires vastly expanded use directions.

Required Label Changes

You must submit two copies of a final printed label which changes, "The final article may contain from 0.1 to 2.0% by weight, except as noted", to the following, "The final article (or finished coating, for all uses requiring coating type applications), may contain from 0.1 to 2.0% by weight, except as noted.

This clarifies the dose difference between product incorporation throughout an entire treated article, from incorporation into just the coating on a treated article. For example, a polymeric

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treated article can incorporate no more than 2% AlphaSan by weight. Similarly, for a one ton HVAC plenum which is coated with AlphaSan, the coating (not the plenum total weight) can contain no more than 2% AlphaSan by weight. For treated articles requiring coatings, it is not the Agency's intent to approve use of the product up to 2% of the weight of the article itself (only of the applied coating).

Other

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 copy of the 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)

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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.
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 3.8% 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 | <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. |
| If on skin or clothing | <ul style="list-style-type: none"> • 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. |

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

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

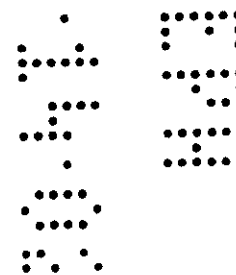
Net Weight 10 Kg (22 Lbs)

ACCEPTED
with **COMMENTS**
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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 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, except as specifically noted

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 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 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 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. For coatings used on the inside of fire system sprinkler pipes, Antimicrobial AlphaSan RC 5000 may be incorporated at levels up to 5% by weight.

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.

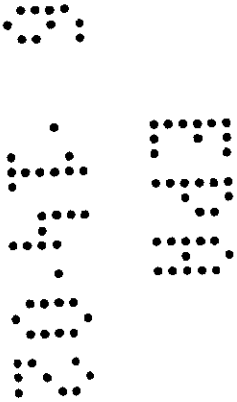
Heating, Ventilation and Air Conditioning (HVAC): equipment and related materials including air handlers, plenums, coils, fins, insulation, rigid or flexible ducts, drain pans, duct support mechanisms, diffusers, filters, heat exchangers, air purifiers, supplemental articles used in the assembly of HVAC 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.

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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.

DRAFT not EPA Approved 06-13-2002

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