

11631-2

05/22/2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401

"M" St., S.W.

Washington, D.C. 20460

EPA Reg. Number:

11631-2

Date of Issuance:

MAY 22 2000

Term of Issuance:

Time-Limited:**Expires November 15, 2001**

Name of Pesticide Product:

**"Antimicrobial AlphaSan
RC 5000"**

NOTICE OF PESTICIDE:

☒ Registration
☐ Re-registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Milliken Chemical, M-400
920 Milliken Road
P.O. Box 1927,
Spartanburg, SC 29304-1927

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number:

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Add the new EPA Registration Number phrase: "EPA Reg. No. "11631-2".
3. The following fish and daphnia studies must be submitted by November 1, 2000:

Signature of Approving Official:

Marshall Swindell
Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

MAY 22 2000

A. Acute toxicity testing using one species of freshwater fish (preferably rainbow trout), and a freshwater invertebrate (daphnia) must be submitted, and found acceptable, using Guideline 850.1075 and 850.1010, respectively. If the test material used is the current formulation in our files for AlphaSan RC 5000 containing 3.8% silver, any acceptable results will apply only to AlphaSan RC 5000. They will neither apply to AlphaSan RC 2000 containing 10% silver, nor to AlphaSan RC 7000 containing 3.1% silver (because this also uses AlphaSan RC 2000). If you use the current formulation in our files for AlphaSan RC 2000 (containing 10% silver), any acceptable results can apply to AlphaSan RC 2000, 5000, and 7000.

B. On May 2, 2000 you submitted individual animal data in an attempt to upgrade the acute oral and acute dermal studies. EPA will review this data to verify clinical observations and necropsy statements made in the original reports. This information must also be found acceptable by **November 15, 2001**.

C. As per 40 CFR, you must submit samples of your new active ingredient to the Pesticide Repository at EPA's "Environmental Science Center", 701 Mapes Road, Ft. Meade, MD. You can call Dick Griffith at 410-305-2905, or Chuck Stafford at 410-305-2914 for specific requirements. You must submit these reference samples **prior to shipment of any product**.

4. You must make the following label changes prior to release for shipment of the product. You must submit two copies of the revised final printed label for the record.

A. You must include a minimum dose level for each application listed on the label. Your current label states only using "...up to 2% by weight".

B. As per the EPA "Label Review Manual" and the acute toxicity categories established for this product, the "Precautionary Statements" must be revised to read as follows:

"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". (Optional - "Do not breathe dust").

C. As per the EPA "Label Review Manual" and the acute toxicity categories established for this product, the "First Aid" statement must be revised to read as follows:

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

Your "If Inhaled " statement is optional but must conform to the following:

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

D. You must delete the uses "dishes", and "china"(you can use "vitreous china"), and any other uses which are used mainly, or exclusively, for food, or drinking water contact. We have blacked out these two particular uses on the stamped label.

E. The following restriction statement must be **boldfaced** and placed in several places on your

label. It must be placed on page 1 of the label, as well as directly after "The additive may be incorporated into the finished product at up to 2.0% by weight", in each of the five places it currently appears.

"This product is not approved for any food contact or human drinking water contact uses".

F. You must add the exact following "Environmental Hazards" section and box it.

"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."

5. This product has been registered as an antimicrobial additive for materials preservation only. Neither this product nor articles treated with this product may state or imply any public health claims.

6. Articles or substances treated with this product will be exempt from FIFRA registration pursuant to 40 CFR 152.25 (a), **only** if the intended use for incorporating this material into the treated article or substance is for protection of the treated article or substance itself. Please refer to PR Notice 2000-1 for further guidance on treated articles.

7. We will not accept/stamp the "Technical Bulletin" until you make the following changes and submit five copies of a revised bulletin via an Amendment.

First, delete the bulletin co-title "Antimicrobial AlphaSan RC 7000", and all identical or related wording wherever it appears.

Second, delete the claim, "Antimicrobial AlphaSan products kill and inhibit microorganisms known to generate odor" ("products" is unspecific; "kill" claims not allowed since your main claim is that the product "suppresses the growth").

Third, delete the repeating phrase, "AlphaSan products..." (unspecified "products" not allowed).

Fourth, in the "Safety Information" section, delete items #1, 2, 3, 7, 10 (all are too broad/unspecific, and involve unspecified "Antimicrobial AlphaSan products").

This conditional registration will **expire automatically on 11/15/2001**. The registration requirements listed herein must be fully satisfied in order for EPA to change the "Terms of Issuance". If you fail to satisfy the conditions imposed in this registration, EPA may issue a Notice of Registration to Cancel under Section 6(e) of FIFRA. Your release for shipment of the product constitutes acceptance of these conditions.

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A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell
Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

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Antimicrobial

AlphaSanTM RC 5000

An antimicrobial additive especially designed to withstand high temperatures in the manufacture of plastics, films, fibers, polymeric materials and ceramics.
Not for food contact or drinking water contact uses.

* * * * *

Active Ingredient:	
Silver sodium hydrogen zirconium phosphate*	99.9%
Other ingredients	0.1%
TOTAL:	100.00%

*Contains 3.8% silver, weight/weight

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans

Do not breathe dust. Do not get in eyes.

FIRST AID

IF INHALED: Remove victim to fresh air.

IF IN EYES: Flush with plenty of water.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 22 2000

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

11631-2

EPA Registration No. 11631-
EPA Establishment No. 11631-SC-001

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

Net Weight 10 Kg

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 the materials listed below during the manufacturing process to impart antimicrobial activity to the manufactured products. *Antimicrobial AlphaSan™ RC 5000* suppresses the growth of bacteria, algae, fungus, mold and mildew.

This product is not approved for food contact or drinking water contact uses.

If growth of bacteria and mold in the finished product could lead to unpleasant odors and discoloration of the product, then such a claim may be made. Finished products containing *Antimicrobial AlphaSan™ RC 5000* may not make public health claims relating to antimicrobial activity without EPA pesticide registration.

1) Plastics, including films, sheets, slabs, and molded plastic parts.

Resins: Including polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH), polyvinylacetate (PVA), ethylene-vinylacetate (EVA), polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), epoxy, phenolic, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylics, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile-styrene-acrylic copolymers (ASA), acetals, polyketones, polyphenylene ether, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymers and fluoropolymers, and blends and copolymers thereof.

Applications: Including automobile parts, shower curtains, mats, protective covers, tape, packaging, gaskets, waste containers, general purpose containers, brush handles, sponges, mops, vacuum cleaner bags, insulators, plastic film, indoor and outdoor furniture, tubing, insulation for wire and cable, plumbing supplies and fixtures, siding for housing, liners, non-woven fabrics, kitchen and bathroom hardware, appliances and equipment, countertops, sinks, flooring, floor covering, conveyor belts, footwear including boots, sports equipment and tools.

ACCEPTED
WITH COMMENTS
in EPA Letter Dated:

The additive may be incorporated into the finished product at up to 2.0% by weight.

MAY 22 2000

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2) Fibers.

Resins: Including acetate, polyester (PET and PTT), polyolefins, polyethylene, polypropylene, polyamide including "Nylon", acrylics, viscose, polyurethane, and "Rayon." and copolymers and blends thereof.

Applications: Interior furnishings: 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, and brush bristles.

Transportation: Automotive and truck upholstery, carpeting, rear decks, trunk liners, convertible tops and interior liners.

Apparel: Umbrellas, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, and undergarments and inner liners for jackets, shoes, gloves and helmets.

Industrial and other Household Items: Brush bristles, artificial leather, filters, book covers, mops, cloth for sails, ropes, tents and other outdoor equipment, tarps, and awnings.

The additive may be incorporated into the finished product at up to 2.0% by weight.

3) Coatings, films and laminates.

Resins: Including alkyds, amino resins (melamine formaldehyde and urea formaldehyde) polyester (unsaturated polyester, PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH), polyvinylacetate (PVA), ethylene-vinylacetate (EVA), polyvinyl chloride (PVC, including plastisol), polyvinylidene chloride (PVDC), epoxy, phenolic, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylics, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile-styrene-acrylic copolymers (ASA), acetals, polyketones, polyphenylene ether, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymers and fluoropolymers, and blends and copolymers thereof.

Types of coatings: water-borne, solvent-borne, 100% solids, radiation cure, and liquid and powder coatings.

Applications: Including walls, wallboard, floors, concrete, siding, roofing shingles, industrial equipment, natural and synthetic fibers and fabrics, furniture, automotive and vehicular parts, packaging, paper products (wall coverings, towels, book covers), barrier fabrics, and glazing for cement tile and for vitreous china used in plumbing fixtures such as toilets, sinks, and countertops, including kitchen countertops and other countertops.

The additive may be incorporated into the finished product at up to 2.0% by weight.

4) Adhesives and sealants.

Resins: Including alkyds, amino resins (melamine formaldehyde and urea formaldehyde) polyester (Unsaturated polyester, PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH), polyvinylacetate (PVA), ethylene-vinylacetate (EVA), polyvinyl chloride (PVC, including plastisol), polyvinylidene chloride (PVDC), epoxy, phenolic, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylics, cyanoacrylates, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile-styrene-acrylic copolymers (ASA), acetals, polyketones, polyphenylene ether, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymers and fluoropolymers, and blends and copolymers thereof.

Methods of application: hot-melt, aqueous, solvent borne, 100% solids, radiation cure

Applications: 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, and adhesives for packaging.

The additive may be incorporated into the finished product at up to 2.0% by weight.

5) Miscellaneous Applications.

Materials: Clay, [REDACTED] ceramics, concrete, sand, and grout.

Applications: Toilets, sinks, tile, flooring, stucco, plaster, cat litter, drainage and sewerage pipe.

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amended, for the pesticide,
registered under EPA Reg. No.
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See additional information in the technical bulletin.

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.

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