

71227-6

4-1-2003

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:
71227-6

Date of Issuance:
APR 01 2003

NOTICE OF PESTICIDE:

Registration
 Re-registration

(under FIFRA, as amended)

Term of Issuance:
Expires on 4/1/04 and
supercedes prior
Registration Notice
dated 2/6/01.

Name of Pesticide Product:
"Zeomic Type AV Silver
Zeolite A"

Name and Address of Registrant (include ZIP code):

Sinanen Company, Limited
4-22, Kaigan 1-Chome, Minato-ku
Tokyo 105, Japan

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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, as amended.

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:

1. You 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. The data you recently submitted or cited to satisfy the following time limited data listed in the last Registration Notice dated 2/6/01, must be found fully acceptable:

Signature of Approving Official:

Marshall Swindell,
Product Manager, Team 33,
Regulatory Management Branch I,
Antimicrobials Division

Date:

APR 01 2003

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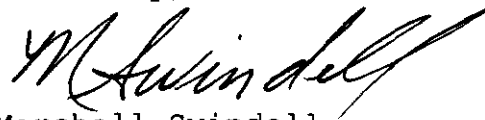
- A. Sub-chronic rodent feeding study
- B. Sub-chronic non-rodent feeding study
- C. Developmental toxicity study
- D. Mammalian cells in culture forward gene mutation assay
- E. In-vivo cytogenetics via metaphase analysis, or micronucleus assay
- F. Two-generation reproductive study
- G. Copy of your FDA Petition package

3. An aggregate risk determination under FIFRA Section 2 (bb), using all data submitted/cited, must result in a determination by the Agency that the food, drinking water, HVAC, and all other non-food/water uses listed on the label will not result in un-reasonable adverse effects to humans or the environment. If the Agency is unable to make this determination for each label use, then label uses which are found to pose an unreasonable risk will expire on 4/1/04 and must be deleted.

Your release for shipment of the product constitutes acceptance of these conditions. 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
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division(7510C)

Enclosure

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Zeomic® Type AV Silver Zeolite A

A preservative and bacteriostatic agent for use in the
manufacture of polymer, plastic and latex products.
For commercial and industrial use only.

Active Ingredient:

Silver	0.3 %
Other Ingredients	99.7 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured by:

Sinanen Company, Ltd.
4-22, Kaigan 1-Chome, Minato-ku
Tokyo 105, Japan

EPA Registration No.

(File Symbol 71227-6)
EPA Establishment No. 71227-JP-001

Net Wt. XXXX

Lot No. XXXXXXXXXXXX

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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amended, for the pesticide,
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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.

For all uses listed*:

* Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System." Any incorporation of this product into an approved and listed food contact polymer must comply with the specific use conditions listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System," for such food contact polymer. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited.

* This product may be used for the following human drinking water contact uses:

- water filter components and housing units
- water bottle dispensers and components
- water dispensers
- ice machine trays
- ice machine bins
- ice machine water hoses
- ice dispensers and other ice machine components
- water bottles
- cups
- water storage vessels

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* This product may be incorporated into food 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.

Zeomic® Type AV Silver Zeolite A is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during the manufacturing process to impart antimicrobial activity to the manufactured products. ***Zeomic® Type AV Silver Zeolite A*** suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining or deterioration only. No finished product incorporating ***Zeomic® Type AV Silver Zeolite A*** may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the finished product which permits such claims, and without a tolerance or exemption from the requirement of a tolerance. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

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Types of Finished Products

Plastics - including films, sheets, slabs, and molded plastic parts

The additive may be incorporated into the finished product at up to 20.0% by weight or at least 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products.

Food contact* and non-food contact uses:

- packaging
- gaskets
- general purpose containers
- food and drink containers
- food trays and covers
- sponges
- plastic film
- food wrap (including coated deli paper, coated meat interleavers and plastic wrap)
- tubing
- brush bristles
- liners
- non-woven fabrics
- appliances and equipment
- kitchen and food processing utensils and supplies
- cutting boards
- countertops
- sinks
- tiles
- dishes
- cups
- bottles
- conveyor belts
- food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
- beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners, dispensers and fermenters)

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Non-food contact uses only:

- automobile parts
- shower curtains
- mats
- protective covers
- tape
- waste containers
- brush handles
- mops
- vacuum cleaner bags
- insulators
- indoor and outdoor furniture
- insulation for wire and cable
- plumbing supplies and fixtures (including toilet bowl seats)
- siding for housing
- kitchen and bathroom hardware
- flooring
- floor coverings
- footwear (including boots, sports equipment and tools)

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Fibers

The additive may be incorporated into the finished product at up to 20.0% by weight or at least 0.5% for fibers. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products.

Food contact* and non-food contact uses (in all cases, when the article itself is an approved polymer, or as an approved polymer coating on an article):

- napkins, tablecloths and wiping cloths
- bags
- brush bristles
- filters
- clothing apparel (including uniforms, outerwear, gloves, aprons, coats and shoes)
- sponges
- packaging (including bags, sacks, wraps, cushion and absorbent materials, and containers)
- conveyor belts
- kitchen, commercial and industrial wipes and fabrics

Non-food contact uses only (in all cases, when the article itself is an approved polymer, or as an approved polymer coating on an article):

Interior furnishings -

- mattress cover pads and filling
- pillow covers
- sheets
- blankets
- fiberfill for quilts and pillows
- curtains
- draperies
- carpet and carpet underlay
- rugs
- upholstery
- mops
- towels
- wall covering fabrics
- cushion pads
- sleeping bags

Transportation -

- automotive and truck upholstery
- carpeting
- rear decks
- trunk liners
- convertible tops
- interior liners

Industrial and Other Household Items -

- artificial leather
- filters
- book covers
- mops
- cloth for sails
- ropes
- tents and other outdoor equipment
- tarps
- awnings

Apparel -

- umbrellas
- outerwear
- sportswear
- sleepwear
- stockings
- socks and hosiery
- caps
- undergarments
- inner liners for jackets
- helmets
- trim for outerwear and garments

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Coatings, Films and Laminates

The additive may be incorporated into the finished product at up to 20.0% by weight, or at least 0.05% for paper or 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder.

Food contact* and non-food contact uses (in all cases, as an approved polymer coating for the article):

- packaging
- paper products (including wipes and tissues)
- food wrap (including coated deli paper, coated meat interleavers and plastic wrap)
- natural and synthetic fibers and fabrics
- sinks
- countertops
- cutting boards
- dishes
- cookware
- general purpose containers
- kitchen, commercial and industrial utensils and supplies
- collection and storage equipment (including conveyor belts, piping systems, silos, tanks and process vessels)
- appliances and food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
- beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners and fermenters and dispensers)
- building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only (in all cases, as an approved polymer coating for the article):

- walls
- wallboard
- floors
- concrete
- siding
- roofing
- shingles
- industrial equipment
- furniture
- automotive and vehicular parts
- packaging
- paper products (including wall coverings, towels, book covers)
- barrier fabrics
- glazing for cement tile
- glazing for vitreous china used in plumbing fixtures (including toilets, sinks, countertops)

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Adhesives and Sealants

The additive may be incorporated into the finished product at up to 20.0% by weight, or at least 0.05% for paper or 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products.

Food contact* and non-food contact uses (in all cases, when used in approved polymers incorporated into adhesives or sealants):

- plumbing adhesives
- pipe sealants and insulating materials
- grout and joint compound for; countertops, architectural elements and food and beverage related equipment

Non-food contact uses only:

- 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

Miscellaneous Applications

The additive may be incorporated into the finished product at up to 20.0% by weight. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products.

Non-food contact uses only:

- toilets
- sinks
- tile
- flooring
- stucco
- plaster
- cat litter
- drainage and sewerage pipe

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PRECAUTIONARY STATEMENTS

Hazards to Humans: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid:

If on skin: Wash with plenty of soap and water.

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

If in eyes: Flush with plenty of water. Call a physician if irritation persists.

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 product dry and containers covered during storage; store below 130°F.

Container Disposal: Inner Plastic Bag: Completely empty plastic bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. **Outer Steel Can:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

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