

71227-1

10-12-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 12 2000

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

**Mailed To: HealthShield Technologies LLC  
60 Audubon Road  
Wakefield, MA 01880**

**RE: Zeomic Type AJ10D Silver Zeolite A  
EPA Reg. No. 71227-1  
Your Amendment Dated 8/2/2000**

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 a preservative and bacteriostatic agent 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".

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

1. The following outstanding data must be submitted by **April 1, 2002** to support the **new food contact uses** on the attached stamped label. We note that in your two letter of commitment dated 8/2/2000 and 8/30/2000, you state that you intend to fulfill all outstanding data requirements, in the time frame allowed, to support the addition of food contact uses to the above referenced product 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 April 1, 2003. Sale or distribution of the subject product bearing labeling for these food contact uses after April 1, 2003 will be illegal.

**A. Sub-chronic rodent feeding study (830.3100)**

**B. Sub-chronic non-rodent feeding study (830.3150)**

**C. Developmental toxicity study (830.3700) CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

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D. Mammalian cells in culture forward gene mutation assay (870.5300)

E. In-vivo cytogenetics via metaphase analysis (870.5385), or micronucleus assay (870.5395)

F. Two-generation reproductive study (870.3800)

G. Copy of your FDA Petition package

This amendment for new food contact uses automatically expires on 4/1/2003. In order for the registration of the use of this product, for incorporation into approved food contact polymers, to continue, the data and information described in items A through G above, must be submitted, reviewed, and found acceptable. In addition, the Agency must make a 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 will expire.

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,

*Tony Kish for*

Marshall Swindell,  
Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

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# Zeomic® Type AJ10D 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	2.5%
Other Ingredients	97.5%
Total	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS**

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**Manufactured by:**

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

EPA Registration No. 71227-1

EPA Establishment No. 71227-JP-001

**Net Wt. XXXX**

**Lot No. XXXXXXXXXX**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 12 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
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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 AJ10D 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 AJ10D 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 AJ10D 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.

# 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 5.0% by weight or at least 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AJ10D 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)

### **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 5.0% by weight or at least 0.5% for fibers. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AJ10D 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

*Apparel -*

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

*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

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**Coatings, Films and Laminates**

The additive may be incorporated into the finished product at up to 5.0% 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 AJ10D 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
- natural and synthetic fibers and fabrics
- 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 5.0% 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 AJ10D 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 5.0% by weight. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AJ10D 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.

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### 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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