71227-5

## 5-31-2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 3 1 2001

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

Mailed To: Erin Tesch (Agent for Sinanen's US Agent-HealthShield Technologies LLC) 1101 17<sup>th</sup> Street, N.W., Suite 500 Washington, D.C. 20036

RE: Zeomic Type AW Silver Zeolite A EPA Reg. No. 71227-5 Your Amendment Dated 2/26/2001 Your Submission Dated 3/20/2001 (Corrected labels)

The amendment and submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide a revised "Confidential Statement of Formula" with widened certified limits, and to provide updated labels (dated 2/26/2001) with the only change being the revision of the primary brand name from "Zeomic Type AW10D Silver Zeolite A", to "Zeomic Type AW Silver Zeolite A", is acceptable.

The submitted Confidential Statement of Formula dated 2/26/2001 is acceptable, and the revised primary brand name is also acceptable.

A stamped copy of the accepted label with the revised primary brand name is attached for your records. The only change to the label contents is the global change in primary brand name.

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)

CONCURRENCES									
SYMBOL									
DATE									

OFFICIAL FILE COPY

## Zeomic<sup>®</sup> Type AW 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	0.59 %
Other Ingredients	99.41 %
Total	100.0 %

## KEEP OUT OF REACH OF CHILDREN CAUTION

### SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured by:

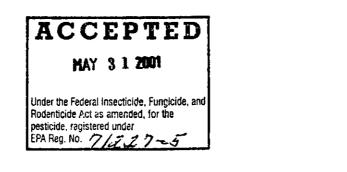
EPA Registration No.

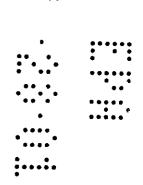
(File Symbol 71227-5) EPA Establishment No. 71227-JP-001

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

Net Wt. XXXX

### Lot No. XXXXXXXXX





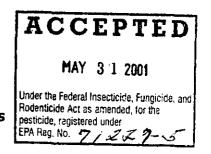
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## **Directions for Use**

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." Any incorporation of this product into an approved and listed food contact polymer. Any incorporation of this product 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



\* 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 AW 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 AW 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 AW 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 20.0% by weight or at least 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic<sup>®</sup> Type AW10D Silver Zeolite A for individual finished products.

#### Food contact\* and non-food contact uses:

packaging gaskets general purpose containers food and drink containers food travs and covers sponges plastic film food wrap (including coated deli paper, coated meat interleavers and plastic wrap) tubina brush bristles liners non-woven fabrics appliances and equipment kitchen and food processing utensils and supplies cutting boards countertops sinks tiles dishes CUDS 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)

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 31 2001

Under the Federal Insectorize, Fungicide, and Rodennoide Act as amended, for the pesucide, registered under EPA Reg. No.

71227-5

# pilet bowl seats)

Zeomic® Type AW10D Silver Zeolite A (EPA Reg. No. [File Symbol 71227-L]) Label amendment (food contact uses)-last revision October 20, 2000 - apr rev. 2 Page 3 of 7

### **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 AW 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 helmets 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

ACCEPTED
MAY 312001
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. $7/227-5$

### **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 AW 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 ACCEPTED concrete siding roofina MAY 3 1 2001 shingles industrial equipment Under the Federal Insecticide, Fungicide, and furniture Rodenticide Act as amended, for the pesticide, registered under automotive and vehicular parts EPA Reg. No. 71227packaging paper products (including wall coverings, towels, book covers) barrier fabrics alazing for cement tile glazing for vitreous china used in plumbing fixtures (including toilets, sinks, countertops)

### **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 AW 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:

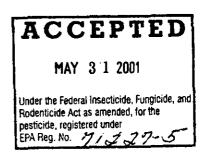
adhesives used in the manufacture of wood and plastic composites adhesives for ceramic tile, wood, paper, cardboard, rubber and plastic glazing for windows grout sealants for pipes adhesives, sealants and insulating materials for; appliances, bathrooms, showers, kitchens and construction

### **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 AW Silver Zeolite A for individual finished products.

### Non-food contact uses only:

toilets	
sinks	
tile	
flooring	
stucco	
plaster	
cat litter	
drainage and s	ewerage pipe



### 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.

