

71227-1

03/25/2009

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAR 25 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Erin Tesch  
Agent for Sinanen  
c/o Technology Sciences Group, Inc.  
1150 18<sup>th</sup> Street, N.W., Suite 1000  
Washington, D.C. 20036

Subject: Zeomic Type AJ Silver Zeolite A  
EPA Registration Number 71227-1  
Agency Initiated Action (Extends expiring time-limited approvals)

This letter conditionally extends the approval date to 4/1/2011, for the following label use categories which received time-limited approval until 4/1/2011, in the letter dated 2/3/09. This includes uses involving incorporation of the product during original manufacture and during post-manufacture of listed articles:

Indirect/direct food contact (limited to specific uses listed on stamped label)  
Drinking water contact (limited to specific uses listed on stamped label)  
Non-food/non-drinking water contact (limited to specific uses listed on stamped label)  
HVAC (limited to specific uses listed on stamped label)

This approval extension is conditionally granted providing:

1. The data recently submitted or cited to satisfy the following required data for this product must be found fully acceptable:

Sub-chronic rodent feeding study  
Sub-chronic non-rodent feeding study  
Developmental toxicity study  
Mammalian cells in culture forward gene mutation assay  
In-vivo cytogenetics via metaphase analysis, micronucleus assay  
Copy of your FDA Petition package

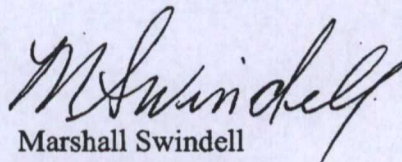


2. An aggregate risk assessment under FIFRA Section 2(bb), using all data submitted/cited, must result in determination by the Agency that all indirect food, drinking water, HVAC, and all other non-food/water uses listed on the label will not result in un-reasonable adverse effects to humans or environment. If the Agency is unable to make this determination for each label use, then label uses which are found to pose unreasonable risk will expire on 4/1/09 and must be deleted at that time.
3. The official "Master Label" for this product is now considered the main label; Technical Bulletin # 1,2,3; and six product Information Bulletins Z-100 through Z-006 inclusive. All labeling and related marketing/sales and website information about this product must be in harmony with this revised label.

Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the accepted label is attached for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510P)



3  
10

# Zeomic® Type AJ 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	100.0 %

**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. 71227-1  
EPA Establishment No. 71227-JP-001

**Net Wt. XXXX**

**Lot No. XXXXXXXXXX**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 25 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the Administrator hereby certifies that the pesticide is registered under the Act.

71227-1



4  
10

## 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.
- \* For applications involving direct or indirect food or human drinking water contact, Zeomic® Type AJ must be used with an FDA approved polymer or coating. Non-food and non-drinking water contact applications can use either FDA or non-FDA approved coatings.
- \* 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 25 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended by the pesticides  
reform act of 1990, EPA Reg. No.

71227-1

**Zeomic® Type AJ Silver Zeolite A** is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during and after the manufacturing process to impart antimicrobial activity to the manufactured products. Approved post manufactured product upgrade applications are detailed in the label section titled "Coatings for Upgrade Applications." **Zeomic® Type AJ Silver Zeolite A** suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only. No finished product incorporating **Zeomic® Type AJ 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 AJ Silver Zeolite A for individual finished products.

### **Food contact\* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer):**

- 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 (including personal care grooming items, toothbrushes (Claims allowed: *odor, discoloration, staining*), and cosmetic brushes (Claims allowed: *odor, discoloration, staining*))
- 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)
- garbage bags and garbage cans

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 25 2009  
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended by the FIFRA Act, registration of this product is required under EPA Reg. No. 71227-1

### **Non-food contact uses only:**

- automobile parts
- shower curtains
- mats
- protective covers
- tape
- waste containers
- brush handles
- mops
- vacuum cleaner bags
- plumbing supplies and fixtures (including toilet bowl seats)
- drain pan liners<sup>1</sup>
- office equipment and supplies (including binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, desk accessories, computers, keyboards, mice, scanners, and printers)
- personal care items (including grooming items, toothbrushes (Claims allowed: *odor, discoloration, staining*), sports and dental mouthguards (Claims allowed: *odor, discoloration, staining*))
- siding for housing
- kitchen and bathroom hardware
- flooring
- floor coverings
- footwear (including boots, sports equipment and tools)
- insulation for wire and cable
- insulators
- indoor and outdoor furniture
- toys (Claims allowed: *odor, discoloration, staining, deterioration*)
- spas, bathtubs, showers and filters and components thereof
- Telephones, mobile devices, head phones, headsets and accessories
- Cameras and imaging equipment

<sup>1</sup> For HVAC and related uses, refer to Zeomic® AJ Technical Bulletin No. 1 – Technical Bulletin for Zeomic® Type AJ Silver Zeolite A Polymeric Coating for Heating, Ventilation and Air Conditioning Applications.



**Fibers**

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.1% for fibers. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AJ Silver Zeolite A for individual finished products.

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

- napkins, tablecloths and wiping cloths
- bags
- brush bristles (including personal care grooming items, toothbrushes (Claims allowed: *odor, discoloration, staining*), and cosmetic brushes (Claims allowed: *odor, discoloration, staining*))
- 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:**

*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
- drain pan liners<sup>1</sup>

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 25 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended by the FIFRA Act of 1990,  
registration of this pesticide is required.  
EPA Reg. No. 71227-1

71227-1

<sup>1</sup> For HVAC and related uses, refer to Zeomic® AJ Technical Bulletin No. 1 – Technical Bulletin for Zeomic® Type AJ Silver Zeolite A Polymeric Coating for Heating, Ventilation and Air Conditioning Applications.



**Coatings, Films and Laminates**

The additive may be incorporated into the coating, film or laminate applied to 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 AJ 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 food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating, film or laminate on an 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:**

- 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)
- Heating, Ventilation and Air Conditioning equipment and related materials (including insulation, ducts, heat exchangers, drain pans, air filters, air purifiers, diffusers, and parts and components thereof)<sup>1</sup>
- spas, bathtubs, showers, and filters and components thereof

ACCEPTED  
with COMMENTS  
in EPA Letter Docket:  
**MAR 25 2009**  
Under the Federal Insecticide,  
Fungicide and Rodenticide Act as  
amended by the FIFRA  
Reauthorization Act of 2002, Reg. No.  
71227-1

<sup>1</sup> For HVAC and related uses, refer to Zeomic® AJ Technical Bulletin No. 1 – Technical Bulletin for Zeomic® Type AJ Silver Zeolite A Polymeric Coating for Heating, Ventilation and Air Conditioning Applications.



## Coatings for Upgrade Applications

Upgrade Applications are defined as the incorporation of Zeomic into polymeric coatings that are applied to articles onsite (after the article has been manufactured and is in the place of use). Coatings may be used on articles that have not previously incorporated the antimicrobial compound. Zeomic may be incorporated into the finished coating at up to 5.0% by weight, or at least 0.5% of the coating. Types of coatings include waterborne coatings/adhesives, solvent borne coatings and two part reactive coatings consisting of a resin and curing agent. Upgrade Applications are for onsite application at Commercial, Industrial or Institutional Establishments. Unless otherwise specified in the technical bulletin, the coating is applied to the entire article. Contact Sinanen Company Ltd. or refer to Zeomic AJ Technical Bulletin No. 2 and No. 3 to determine the appropriate application technique and amount of Zeomic for individual products.

### **Food contact\* and non-food contact articles (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating on an article)<sup>2</sup>:**

- food collection, conveyance and storage equipment (including conveyor belts, 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 and ice machine equipment (including mixers, transfer equipment, pumps, bottlers, canners, fermenters and dispensers and other components)
- food and chemical transportation equipment including railcars, tankers, trailers and components thereof
- building materials and components (including walls, ceilings and floors consisting of concrete, gypsum board, and cellulose ceiling tile)

Incorporate this product into coatings that are intended for application to the surface of articles. The purpose of the coating is to seal the article from moisture and corrosion. The purpose of Zeomic® in the coating is to inhibit the growth of mold, mildew, fungus and bacteria that cause odor, discoloration, staining, deterioration or corrosion on the surface of the coating film. The product protects the applied coating itself from microorganism attack, not the underlying substrate. This product is not intended for remediation, prevention or control of existing or anticipated public health related microorganisms. Refer to Zeomic® AJ Technical Bulletin No. 2 for complete application directions.

### **HVAC articles<sup>3</sup>:**

Heating, ventilation and air conditioning systems and related materials including air handlers, drain pans, heat exchangers, distribution lines, flexible ductwork, diffusers, and insulation lined porous ductwork.

Incorporate this product into coatings that are intended for application to HVAC systems. The purpose of the coating is to seal the HVAC system from moisture and corrosion. The purpose of Zeomic® in the coating is to inhibit the growth of mold, mildew, fungus and bacteria that cause odor, discoloration, staining, deterioration or corrosion on the surface of the coating film. The product protects the applied coating itself from microorganism attack, not the underlying substrate. This product is not intended for remediation, prevention or control of existing or anticipated public health related microorganisms. Refer to Zeomic® AJ Technical Bulletin No. 3 for complete application directions.

<sup>2</sup> For these listed applications, refer to Zeomic® AJ Technical Bulletin No. 2 – Technical Bulletin for Zeomic® Type AJ Silver Zeolite A Polymeric Coating for Non-Residential, Non-HVAC Upgrade Applications.

<sup>3</sup> For these listed HVAC Applications, refer to Zeomic® AJ Technical Bulletin No. 3 – Technical Bulletin for Zeomic® Type AJ Silver Zeolite A Polymeric Coating for Non-Residential, HVAC Upgrade Applications.

ACCEPTED  
in EPA Laboratory  
MAR 25 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended by the FIFRA Act of 1990,  
EPA Reg. No. 71227-1



9/10

**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 AJ Silver Zeolite A for individual finished products.

**Food contact\* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer incorporated into FDA-approved adhesives or sealants):**

- plumbing adhesives
- pipe sealants and insulating materials
- grout and joint compound for; countertops, building materials and components, 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 AJ Silver Zeolite A for individual finished products.

**Non-food contact uses only:**

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

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:  
 MAR 25 2009

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, and the related  
 regulations, EPA Reg. No.

71227-1



10  
10

### 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. Wear goggles or face shield and rubber gloves when handling the dry powder. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

### 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAR 25 2009

Under the Federal Insecticide,  
Fungicide and Rodenticide Act as  
amended, and the related  
regulations, EPA Reg. No. 71227-1

Zeomic® Type AJ Silver Zeolite A (EPA Reg. No. 71227-1)  
Page 8 of 8

71227-1