

MAR 22 2005

Amy Roberts, Agent for Sinanen Company, Ltd.  
c/o Technology Sciences Group, Inc.  
1101 17<sup>th</sup> Street, N.W. Suite 500  
Washington, D.C. 20036

**Subject: Zeomic Type AK Silver Zeolite A (4.93% silver)**  
**EPA Reg. No. 71227-4**  
**Agency Initiated Action (Extends expiring time-limited approvals)**

This letter conditionally extends the expiration date to **4/1/06**, for the following label use categories which received time-limited approval until 4/1/05, in the letter dated 3/18/04:

**Indirect/direct food contact (limited to specific uses listed on stamped label)**

**Drinking water contact (limited to specific uses listed on stamped label)**

**HVAC (limited to specific uses listed on stamped label)**

These uses are all during original manufacture of treated articles, and do not include post-manufacturing upgrade uses (ie., while in-use). This approval extension is conditionally granted providing:

1. The data you recently submitted or cited, to satisfy the following time limited data listed in the EPA letter dated 6/13/02, 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, or micronucleus assay

Two-generation reproductive study

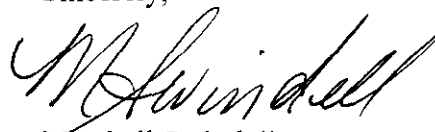
Copy of your FDA Petition package

2. An aggregate risk assessment 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 4/1/06 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 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)

3/15

# Zeomic® Type AK 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	4.93 %
Other Ingredients	95.07 %
Total	100.00 %

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS**

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

EPA Registration No. 71227-4  
EPA Establishment No. 71227-JP-001

**Net Wt. XXXX**

**Lot No. XXXXXXXXXXX**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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

**71227-4**

4/15

## Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**This product may not be used for any applications involving food contact, food packaging, or drinking water.**

***Zeomic® Type AK 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 AK 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 AK 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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71227-4

5/15

## 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. Do not exceed a 2.5% by weight maximum incorporation rate for all HVAC applications. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AK Silver Zeolite A for individual finished products.

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

- 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 (including toilet bowl seats)
- siding for housing
- liners
- non-woven fabrics
- kitchen and bathroom hardware
- appliances and equipment
- countertops
- sinks
- flooring
- floor covering
- tiles
- conveyor belts
- footwear (including boots, sports equipment and tools)
- † drain pan liners

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71227-4

† For HVAC and related uses, refer to Zeomic® AK Technical Bulletin No. 1 – Technical Bulletin for Zeomic Type AK Silver Zeolite Polymeric Coating for Heating, Ventilation and Air Condition Applications.

6/15

**Fibers**

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.5% for fibers. Do not exceed a 2.5% by weight maximum incorporation rate for all HVAC applications. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AK Silver Zeolite A for individual finished products.

**Non-food contact uses only:**

*Interior furnishings -*

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

*Industrial and Other Household Items -*

- brush bristles
- artificial leather
- filters
- book covers
- mops
- cloth for sails
- ropes
- tents and other outdoor equipment
- tarps
- awnings
- † drain pan liners

*Apparel -*

- umbrellas
- outerwear
- uniforms
- coats
- aprons
- sportswear
- sleepwear
- stockings
- socks and hosiery
- caps
- undergarments
- inner liners for jackets
- shoes
- gloves
- helmets
- trim for outerwear and garments

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71227-4

*Transportation -*

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

† For HVAC and related uses, refer to Zeomic® AK Technical Bulletin No. 1 – Technical Bulletin for Zeomic Type AK Silver Zeolite Polymeric Coating for Heating, Ventilation and Air Condition Applications.

**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. Do not exceed a 2.5% by weight maximum incorporation rate for all HVAC applications. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AK Silver Zeolite A for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder.

**Non-food contact uses only:**

- 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)
- † 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)

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71227-4

**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 AK Silver Zeolite A for individual finished products.

**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

† For HVAC and related uses, refer to Zeomic® AK Technical Bulletin No. 1 – Technical Bulletin for Zeomic Type AK Silver Zeolite Polymeric Coating for Heating, Ventilation and Air Condition Applications.

8/15

**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 AK 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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71227-4



9/15

### PRECAUTIONARY STATEMENTS

**Hazards to Humans: DANGER. Corrosive.** Causes irreversible eye damage and severe skin irritation. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and gloves. 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 of 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.

REGISTERED  
with COMMISSION  
in EPA Label

MAR 22 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act

Zeomic® Type AK Silver Zeolite A (EPA Reg. No. 71227-4)  
last revision May 29, 2002 – apr rev. 5

10/15

## Zeomic® AK Technical Bulletin No. 1

### TECHNICAL BULLETIN FOR ZEOMIC TYPE AK SILVER ZEOLITE POLYMERIC COATING FOR HEATING, VENTILATION AND AIR CONDITIONING APPLICATIONS

**Read the product label first.** Refer to the product label and MSDS for complete directions on safety precautions, storage and handling.

#### Product Description:

Zeomic® Type AK Silver Zeolite (Zeomic) contains 4.93% by weight silver in a natural zeolite carrier. Zeomic is registered by the U.S. Environmental Protection Agency for use in plastics, fibers, coatings, films, laminates, adhesives and sealants. In coatings applied to Heating, Ventilation and Air Conditioning (HVAC) systems and components thereof, the antimicrobial additive is incorporated into a coating to preserve, keep odor-free and operational the components of the HVAC system. The active ingredient provides residual activity against odor, discoloration, staining, deterioration or corrosion caused by bacteria, mold and mildew. This product is compatible with the substrates and products listed under "Approved Uses."

#### Features:

Good durability – Zeomic imparts a durable antimicrobial activity to the surface of a wide variety of substrates.

Antimicrobial activity – Effective against odor, discoloration, staining, deterioration or corrosion caused by bacteria, mold, mildew, fungi, algae and yeasts; antimicrobial action is exhibited on contact and in the presence of moisture.

#### Claims:

- Zeomic preserves treated articles.
- Zeomic is an EPA registered antimicrobial agent that will effectively prevent the growth of mold, mildew, fungus and bacteria that cause odor, discoloration, staining, deterioration or corrosion on the surface of a treated article.
- Zeomic prevents odor, discoloration, staining, deterioration or corrosion caused by bacteria, fungi, mold and mildew.
- Zeomic provides protection from odor, discoloration, staining, deterioration or corrosion caused by bacteria, fungi, mold and mildew.
- Zeomic controls bacteria, mold and mildew, which cause corrosion.

**Important:** Zeomic does not protect building occupants from airborne disease-causing bacteria, viruses, mold or mildew or airborne allergens. Always clean and

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11/15

maintain the heating, ventilation and air conditioning system in accordance with the manufacturer's directions.

**Technical Data:**

Active Ingredient: 4.93% Silver  
 Color: White  
 Physical State: Dry Powder  
 Flammability: Not Flammable  
 Specific Gravity: 2.15 ± 0.1 g/cm<sup>3</sup>  
 pH: 7-9 (1g Zeomic/100 ml water)  
 Thermal Stability: 800 °C

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**Approved Uses:**

For use in polymeric coatings and adhesives, including aqueous, aqueous/solvent solutions, protectorant wax or silicone technology to treat –

- Heating, Ventilation and Air Conditioning systems and related materials (including insulation, air handlers, ducts, heat exchangers, drain pans and liners thereof, air filters, air purifiers, diffusers, humidifiers and parts and components thereof),
- Automobile air conditioning systems.

**How to Use Zeomic:**

**Surface Preparation:**

**Metal Surfaces:** Apply only to clean dry surfaces free of all dirt, grease or impurities. Abrade all surfaces to remove all surface rust and corrosion products, and wash the intended surface with the appropriate cleaner, rinse and allow to dry thoroughly. Use surface pretreatments or primer coatings as required.

**Painted Surfaces:** Apply only to clean dry surfaces free of all dirt, grease or impurities. Wire brush painted surfaces removing all flaking, loose or chalking material. Sand all glossy surfaces to roughen the entire area. Use surface pretreatments or primer coatings as required.

**Mixing:**

Incorporate Zeomic directly into formulations developed for the coating of heating, ventilation and air conditioning system applications. Maintain constant agitation of the coating during the application process.

12/15

**Application:**

Following the surface preparation steps, various coating technologies may be used to apply the Zeomic compound, including automated dip, flow, roll or electro-deposition coating and manual brush, roller or spray coating.

Automated Processes:

Circulate Zeomic and coating via a closed system maintaining agitation. Ensure excess coating applied via dip, flow or roll coating technologies is collected and returned to the system. Maintain constant solids concentration by the addition of fresh, properly mixed coating to make up for usage. Minimize evaporation of the coating by maintaining covers on storage vessels. Utilize appropriate drying conditions, including infrared or conventional ovens to properly cure coating incorporating the Zeomic compound. These processes must be conducted in accordance with federal, state and local air pollution laws and regulations.

Apply coating to all surfaces at a rate to achieve a dry film thickness of approximately five (5) to twenty five (25) microns.

See handling instructions below for operator exposure requirements.

Manual Processes:

Zeomic may be incorporated into polymer adhesives and coatings and applied manually by brush, roller, spray or other coating technology. These products may be easily applied by high volume low-pressure (HVLP) spray equipment commonly used throughout the industry. These processes must be conducted within a downdraft spray booth permitted and operating in accordance with federal, state and local air pollution laws and regulations.

Apply coating to all surfaces at a rate to achieve a dry film thickness of approximately five (5) to twenty five (25) microns.

See handling instructions below for operator exposure requirements.

**Contact Sinanen Zeomic Co., LTD to confirm optimum application technology and drying conditions, such as time and temperature, for each application before use in a commercial process.**

**Clean up:**

Use fresh water or solvent to clean brushes and equipment before product dries.

**Handling Instructions:**

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13  
15

Wear goggles or face shield and rubber gloves when handling the dry powder.

Airborne Exposure Limits pursuant to OSHA 1910.1000 Table Z-3 for Mineral Dust:

<u>Permissible Exposure Limit (PEL)</u>	
Respirable fraction:	5 mg/m3
Total dust:	15 mg/m3

As with any fine powder, avoid generating dust.

**Ventilation System:**

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is preferred to help control the emissions of the contaminant at the source, preventing its dispersion through the work area.

**Personal Respirators (NIOSH Approved):**

If the exposure limit is exceeded, a half-face respirator with filter appropriate for 1-micron dust may be worn per appropriate guidelines.

**Storage, Shelf Life and Disposal:**

Do not contaminate water, food or feed by storage and disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep containers covered during storage; store below 130°F.

**Shelf Life:** Zeomic has a minimum shelf life of 12 months from date of shipment.

**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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**PRECAUTIONARY STATEMENTS**

MAR 22 2005

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71427-4

141  
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**Hazards to Humans: DANGER. Corrosive.** Causes irreversible eye damage and severe skin irritation. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

<b>FIRST AID</b>	
<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 of 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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<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.	

**MSDS Information:**

Refer to the Material Safety Data Sheet for this product for complete handling and safety information.

**Transportation Information:**

Zeomic is not regulated as a hazardous material under DOT.

**Regulatory Information:**

Zeomic Type AK is registered by the U.S. Environmental Protection Agency as EPA Reg. No. 71227-4.

**For technical assistance or questions contact:**

Sinanen Zeomic Co., LTD.  
4-22, Kaigan 1-Chome, Minato-ku

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15  
/15

Tokyo 105-8525, Japan

Questions? 011-81-3-5470-7125

**Important: Warranty and Disclaimer Information**

Sinanen Zeomic Co., LTD warrants that each of its products will be manufactured in accordance with Sinanen's specifications in effect on the date of manufacture. **SINANEN MAKES NO OTHER WARRANTIES AND EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** If a product fails to meet this limited warranty purchaser's sole and exclusive remedy is replacement of the product or, at Sinanen's option, refund of the purchase price. **SINANEN'S ACCEPTANCE OF ANY ORDERS FOR THIS PRODUCT IS EXPRESSLY CONDITIONAL UPON PURCHASERS' ASSENT TO THE TERMS ON THE APPLICABLE INVOICE.**

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