

71227-4

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 16 2002

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

Subject: Zeomic Type AK Silver Zeolite A (4.93% silver)
EPA Reg. No. 71227-4
Your Submission Dated 7/18/2001

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add certain HVAC uses (product applied during manufacture), is acceptable on an interim time limited basis, and with the following required label changes, data requirements, and conditions.

Time Limited Approval Rationale

1. The proposed HVAC uses are being approved on an interim time-limited basis until a final risk assessment is completed. The determination of whether the Agency has adequate information to conduct this final risk assessment cannot be ascertained until after the Agency completes its reviews of the time limited submitted and cited data sent on 1/10/2002 for EPA Reg. No. 71227-1 (2.5% silver). We note that you are relying on these same data to support the proposed HVAC uses for this 4.93% silver product.
2. Our initial risk assessment and time limited approval of these identical HVAC uses for EPA Reg. No. 71227-1 was based on your migration study which used the 2.5 % silver product incorporated at a maximum rate of 5% in plastic. This would result in a treated article containing 0.125% silver by weight.
3. You did not submit migration data using this 4.93% silver product at a maximum 5% incorporation rate which would result in a treated article containing 0.25% silver by weight. You have not submitted any data or justification showing that the risk is unchanged and still acceptable with a doubling of the silver concentration in a treated article. Therefore, a migration study using this 5% silver product may be required in the future. Until you submit these data or justification, the label must be restricted to a maximum of 0.125% silver in HVAC uses.

Label and Technical Bulletin Changes

1. Because of items #1, #2, and #3 listed above, you must add the restriction statement listed below, in the HVAC sections.

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Agency must make a determination under FIFRA Section 2 (bb)(2) that these HVAC uses will not result in unreasonable adverse effects. If the Agency is unable to make this determination, then the approval of these uses will expire and you must delete them from the label via amendment.

A copy of the label stamped "accepted with comments", 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,

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

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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

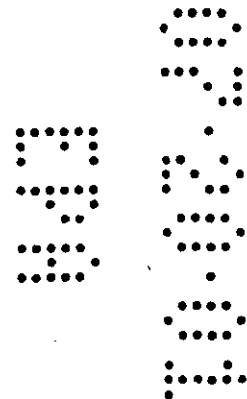
Lot No. XXXXXXXXXXX

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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.

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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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 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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† 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.

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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 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

Transportation -

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

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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 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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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.

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

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Zeomic® Type AK Silver Zeolite A (EPA Reg. No. 71227-4)
Label Amendment to add HVAC use site
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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 long-term residual activity and lasting protection 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; it is leach resistant and non-migrating. Salt spray, water soak and humidity testing has indicated that the antimicrobial benefit will be present as long as the coating or treatment remains on the substrate.

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 and spread 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 caused by bacteria, fungi, mold and mildew.
- Zeomic provides long-lasting protection from odor, discoloration, staining, deterioration or corrosion caused by bacteria, fungi, mold and mildew.
- Zeomic controls bacteria, mold and mildew, which cause corrosion.

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Important: Zeomic does not protect building occupants from airborne disease-causing bacteria, viruses, mold or mildew or airborne allergens. Always clean and 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/cm³
pH: 7-9 (1g Zeomic/100 ml water)
Thermal Stability: 800 °C

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.

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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.

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.

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Clean up:

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

Handling Instructions:

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

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

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For technical assistance or questions contact:

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