

71227-6

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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 A V Silver Zeolite A  
EPA Registration Number 71227-6  
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

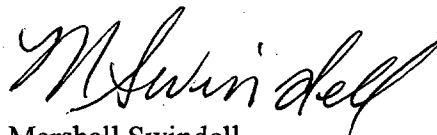
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2. An aggregate risk assessment under FIFRA Section 2(bb), using all data submitted/cited, must result in determination by the Agency that all indirect food, drinking water, HVAC, and all other non-food/water uses listed on the label will not result 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.

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)

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# Zeomic® Type AV 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	0.3 %
Other Ingredients	99.7 %
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. 71227-6  
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, for the purposes,  
registered under EPA Reg. No.

71227-6

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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 AV 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 AV 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 AV 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 20.0% by weight or at least 0.3% for bulk plastics. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV 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
- 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)
- shower curtains
- 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 20.0% by weight or at least 0.5% for fibers. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AV Silver Zeolite A for individual finished products.

**Food contact\* and non-food contact uses (in all cases, when the article itself is an a FDA-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

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Under the Federal Insecticide,  
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**ACCEPTED**  
**with COMMENTS**  
**in EPA Letter Dated:**  
**MAR 25 2009**

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**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 AV 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
- 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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to EPA Label Draft:

MAR 25 2009

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**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 AV 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



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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 AV 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.

### 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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