

71227-4

03/25/2009

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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 18th Street, N.W., Suite 1000
Washington, D.C. 20036

Subject: Zeomic Type AKSilver Zeolite (4.93% silver)
EPA Registration Number 71227-4
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 2/3/2009. 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)
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 time limited data listed in EPA letter dated 6/13/02, must be found fully accepted:

- 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
- Two generation reproductive study
- Copy of your FDA Petition package

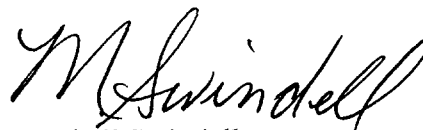
2. An aggregate risk assessment under FIFRA Section 2(b), using all data submitted/cited, must result in determination by the Agency the food, drinking water, HVAC, and all other non-food/water uses listed on the label will not result in unreasonable adverse effects to humans or the environment. If the Agency is unable to make this determination for each label use, then the label uses which are found to pose unreasonable risk will expire on 4/1/09 and must be deleted.
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.

The revised labeling submitted to lower the minimum rate from 0.5% to 0.1% has been reviewed and found to be acceptable.

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 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:

MAR 25 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, and the corresponding
regulations under 40 CFR, this No.

71227-4

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 AK 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, the pesticide registered under EPA Reg. No. 71227-4

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 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 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.

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.

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

Packaging (for repeat use only)

gaskets

general purpose containers

food and drink containers

food trays and covers

sponges

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)

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 liners¹

office equipment

personal care items (including grooming items, sports and

dental mouthguards (Claims allowed: *odor, discoloration, staining*)

ACCEPTED
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to EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended in the products
registered under EPA Reg. No. 71227-4

siding for housing

kitchen and bathroom hardware

flooring

floor coverings

footwear (including boots, sports equip-
ment and tools)

insulation for wire and cable

insulators

indoor and outdoor furniture

spas, bathtubs, showers and filters and
components thereof.

garbage bags and garbage cans

¹ For HVAC and related uses, refer to Zeomic® AK Technical Bulletin No. 1 – Technical Bulletin for Zeomic® Type AK 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 0.5% for fibers. Contact Sinanen Company Ltd. to determine the appropriate amount of Zeomic® Type AK 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 liners¹

ACCEPTED
 with COMMENTS
 in EPA latest Draft:
 MAR 25 2009

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, see the pesticide
 registration number EPA Reg. No.

71227-4

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

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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 AK 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 (for repeat use only)
- paper products (including wipes and tissues)
- 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)¹
- spas, bathtubs, showers, and filters and components thereof

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 25 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the amendments
recommended under FIFRA Reg. No.

71227-4

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

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.

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 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
- interior paints and coatings

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in EPA Letter Dated:
MAR 25 2009
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended by the FIFRA Act of
 1990, and under EPA Reg. No.
 71227-4

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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. 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	
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 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.

ACCEPTED
with COMMENTS
in EPA Letter Docket

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