

71227-6

4-1-2006

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

APR 1 2006

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Erin Tesch
Agent for Sinanen
c/o Technology Sciences Group, Inc.
1101 17th Street, N.W., Suite 500.
Washington, D.C. 20036

Subject: Zeomic Type AV Silver Zeolite A
EPA Registration Number 71227-6
Agency Initiated Action(Extends expiring time-limited approvals)

This letter conditionally extends the approval date to 4/1/07, for the following label use categories which received time-limited approval until 4/1/07, in the letter dated 3/16/04. 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:

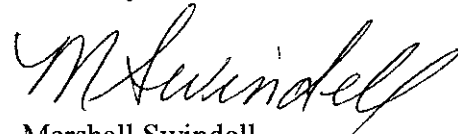
- Sub-chronic rodent feeding study
- Sub-chronic non-rodent feeding study
- Developmental toxicity study
- Mammalian cells in culture forward gene mutation assay
- In-vivo cytogenetics via metaphase analysis, micronucleus assay
- Two-generation reproductive study
- Copy of your FDA Petition package

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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 4/1/07 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(7510C)

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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:

Sinaren Company, Ltd.
4-22, Kaigan 1-Chome, Minato-ku
Tokyo 105, Japan

EPA Registration No.

(File Symbol 71227-6)

EPA Establishment No. 71227-JP-001

Net Wt. XXXX

Lot No. XXXXXXXXX

ACCEPTED
with COMMENTS
EPA Letter Dated:
APR 11 2006

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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 board
- countertops
- sinks
- tiles
- dishes
- cups
- bottles
- conveyor belt
- food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, toasters, grinders, choppers, peelers and countertops)
- beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners, dispenser and fermenters)

Non-food contact uses only:

- automobile parts
- shower curtains
- mats
- protective covers
- tape
- waste containers
- brush handle
- mops
- vacuum cleaner bags
- insulators
- indoor and outdoor furniture
- insulation for wire and cable
- plumbing supplies and fixtures (including toilet bowl seats)

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- 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 approved polymer, or as an approved polymer coating on an article):

napkins, table cloths 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 belt
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

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

Apparel -

umbrellas
outerwear
sportswear
sleepwear
stockings
socks and hosiery
caps
undergarments
inner liners for jackets
helmets
trim for outerwear and garments

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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 board
 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 fabric
 glazing for cement tile
 glazing for vitreous china used in plumbing fixtures (including toilets, sinks, countertops)

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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 11.05% 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
- 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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