

71227-7

11/24/2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Sinanen Co., Ltd.
4-27, Kaigan 1-Chome, Minato-ku
Tokyo 105, Japan

NOV 24 2010

U.S. Agent:
1150 18th Street, NW
Suite 1000
Washington, DC 20036

Attention: Erin M. Tesch
Regulatory Consultant

Subject: Zeomic Type AC Silver Copper Zeolite A
EPA Reg. No. 71227-7
Amendment Letter Dated May 1, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the following:

- The addition of various food contact applications to the label.

The justification for this decision is based on the Agency decision that the silver and copper ions in the product are to be considered separately and not as a joint silver-copper zeolite compound at this time. A complete assessment is provided in an accompanying science review, the highlights of which are summarized below.

The human health risks to silver of this product are supported by the existing registration of Zeomic Type AK Silver Zeolite A, Registration Number 71227-4, 4.93% Silver. 71227-4 is registered for use as a materials preservative for the same use sites and at a higher application rate than 71227-7.

As to the issue of a copper assessment, as there is not human toxicity endpoints associated with Copper, there are no risks concerns anticipated from copper exposures that may result from the proposed amended uses on this label.

Due to the fact that silver ion is present, and Agency requires a notice to be placed on the labeling advising users that prolonged contact with this product may cause skin discoloration.

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A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,



Marshall Swindell

Product Manager (33)

Regulatory Management Branch I

Antimicrobials Division (7510P)

3049

Zeomic® Type AC Silver Copper Zeolite A

A preservative and bacteriostatic agent for use in the manufacture of polymer, plastic, latex products.
For commercial and industrial use only.

Active Ingredient:

Silver	3.5 %
Copper	6.1 %
Other Ingredients	90.4 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured by:
Sinanen Zeomic Co., Ltd.
1-1, Nakagawa honmachi
Minato-ku
Nagoya, Japan
455-0051

EPA Registration No. 71227-7
EPA Establishment No. 71227-JP-001

Net Wt. XXXX

Lot No. XXXXXXXXXX

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 24 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the use as a preservative
registered under the
71227-7

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 AC 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.

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registered under EPA Reg. No
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Zeomic® Type AC Silver Copper 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 AC Silver Copper 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 AC Silver Copper 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. 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 AC Silver Copper 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
- gaskets
- general purpose containers
- food and drink containers
- food trays and covers
- sponges
- tubing
- brush bristles (including personal care grooming items, toothbrushes), and cosmetic brushes
- liners
- non-woven fabrics,
- plastic sheeting for construction and agricultural applications
- 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)
- building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

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Non-food contact uses only:

- | | |
|--|--|
| <ul style="list-style-type: none"> Automobile Parts Mats Waste containers Mops Plumbing supplies and fixtures Siding for housing Flooring Insulation for wire and cable Indoor and outdoor furniture Spas, bathtubs, showers, filters and components thereof Office equipment and supplies (including binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, desk accessories, computers, keyboards, mice | <ul style="list-style-type: none"> Shower curtains Protective Covers Brush handles Vacuum cleaner bags Drain pan liners Kitchen and bathroom hardware Floor coverings Insulators Plastic building materials Garbage bags and garbage cans Telephones, mobile devices, head phones, head sets and accessories Cameras and imaging equipment |
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scanners, and printers).
Medical devices, equipment and supplies

Fibers – including cotton, rayon and synthetically derived 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 AC Silver Copper 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):

- Synthetic and Natural Fibers
- napkins, tablecloths and wiping cloths
- bags
- brush bristles (including personal care grooming items, toothbrushes and cosmetic brushes)
- 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

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Non-food contact uses only:

- Synthetic and Natural Fibers
- Paper for gypsum board.
- Paper, paperboard, composite building materials
- 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
- drain pan liners¹

- Apparel –*
- umbrellas
- outerwear
- sportswear
- sleepwear
- stockings
- socks and hosiery
- caps

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undergarments
inner liners for jackets
trim for outerwear and garments
medical devices, equipment and supplies

Coatings, Films and Laminates

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for coatings. Contact Sinanen Company, Ltd. to determine the appropriate amount of **Zeomic® Type AC Silver Copper Zeolite A** for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder emulsion, starch, cellulosic, lacquer, thermoset, thermoplastic, thermal spray coatings including pre-dispersions and components thereof.

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
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)

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Non-food contact uses only:

Building Materials (including gypsum board, insulation, cellulose or fiberglass ceiling tile, and polymer flooring.)
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
Industrial equipment
Furniture
Automotive and vehicular parts
Packaging
Siding
Roofing
Shingles

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

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Industrial equipment
Medical devices, equipment and supplies

Adhesives and Sealants

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for adhesives and sealants. Contact Sinanen Company, Ltd. to determine the appropriate amount of ***Zeomic® Type AC Silver Copper 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, joint compound and grout for gypsum board, ceramic tile, wood, paper, cardboard, rubber and plastic.
Medical devices, equipment and supplies

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 AC Silver Copper 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 coating.

Interior paints and coatings
Stucco
Plaster
Leather
Medical devices, equipment and supplies

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PRECAUTIONARY STATEMENTS

Hazards to Humans: Caution. Causes moderate eye irritation. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling.

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: Nonrefillable container. Do not reuse or refill inner plastic bag or outer steel can. **Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then offer for recycling if available or 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:** Offer for recycling if available or reconditioning if appropriate, 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 AC Silver Copper Zeolite A (EPA Reg. No.71227-7)
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