



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 18, 2024

Manuela Petrisor
Regulatory Consultant
Sinanen Zeomic Company, Ltd.
c/o Technology Sciences Group
Electronic Transmittal: Manuela.Petrisor@tsgconsulting.com

Subject: Label and CSF Amendment – Response to Silver GDCI Reclassification Letter including updates to label and the Basic CSF and Alternate #1 CSF; inquiry regarding previously submitted Alternate CSF #2
Product Name: ZEOMIC TYPE AJ SILVER ZEOLITE A
EPA Registration Number: 71227-1
Received Date: 12/10/2019
Action Case Number: 00220528

Dear Manuela Petrisor:

The amended label, basic Confidential Statement of Formula (CSF), and alternate CSF #1, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, are acceptable. In your cover letter you asked for clarification on the approval status of Alternate Formulation #2 from a previous submission. The Agency determined that alternate CSF #2 is not acceptable due to the formulation not being similar enough to the basic formulation. The product chemistry review is attached.

This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved

labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 12/15/2020
- Alternate CSF #1 dated 12/09/2019

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2) If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact me via email at garvie.heather@epa.gov.

Sincerely,



Heather A. Garvie
Senior Regulatory Advisor
Regulatory Management Branch 2
Antimicrobials Division
Office of Pesticide Programs

Attachment: Product Chemistry Review dated 2/1/2022; submission # 1044396

ACCEPTED

06/18/2024

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 71227-1

**Zeomic® Type AJ
Silver Zeolite A**

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

Active Ingredient:	
Silver ion	2.5 %
Other Ingredients	97.5 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

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

EPA Registration No. 71227-1
EPA Establishment No. 71227-JPN-001

Net Wt. XXXX

Lot No. XXXXXXXXXX



Standard 51 Listed

**Nonfood Compounds
Program Listed PX**

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 AJ 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:**

**Cups
Ice machine trays
Ice machine bins
Ice machine water hoses
Ice dispensers and other ice machine components
Water filter components and housing units
Water bottle dispensers and components
Water dispensers
Water bottles
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.**

Zeomic® Type AJ 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 AJ 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 AJ 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 0.1% for bulk plastics. Contact Sinanen Zeomic Company Ltd. to determine the appropriate amount of Zeomic® Type AJ 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):

- Appliances and equipment
- Beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners, dispensers and fermenters)
- Bottles
- Brush bristles (including personal care grooming items, toothbrushes (claims allowed: odor, discoloration, staining), and cosmetic brushes (claims allowed: odor, discoloration, staining))
- Conveyor belts
- Countertops
- Cups
- Cutting boards
- Dishes
- Packaging
- Food and drink containers
- Food drip sheet
- Food trays and covers
- Food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
- Food wrap (including coated deli paper, coated meat interleavers and plastic wrap)
- Garbage bags and garbage cans
- Gaskets
- General purpose containers
- Kitchen and food processing utensils and supplies
- Liners
- Non-woven fabrics
- Plastic film
- Sinks
- Sponges
- Tiles
- Tubing

Non-food contact uses only:

- Automobile parts
- Brush handles
- Cameras and imaging equipment
- Drain pan liners
- Electrical wiring devices and wall plates
- Flooring
- Floor coverings
- Footwear (including boots, sports equipment and tools)
- Insulation for wire and cable
 - Water blocking tape for domestic and industrial cable (power cable, optical fiber cable)
- Insulators
- Indoor and outdoor furniture
- Kitchen and bathroom hardware
- Mats
- Mops
- Office equipment and supplies (including binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, desk accessories, computers, keyboards, mice, scanners, and printers)
- Personal care items (including grooming items, toothbrushes (claims allowed: odor, discoloration, staining), sports and dental mouthguards (claims allowed: odor, discoloration, staining))
- Plumbing supplies and fixtures (including toilet bowl seats)
- Protective covers
- Shower curtains
- Siding for housing
- Spas, bathtubs, showers and filters and components thereof
- Tape
- Toys (claims allowed: odor, discoloration, staining, deterioration)

- Telephones, mobile devices, head phones, headsets and accessories
- Waste containers
- Vacuum cleaner bags

Fibers

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.1% for fibers. Contact Sinanen Zeomic Company Ltd. to determine the appropriate amount of Zeomic® Type AJ 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):

- Bags
- Brush bristles (including personal care grooming items, toothbrushes (claims allowed: odor, discoloration, staining), and cosmetic brushes (claims allowed: odor, discoloration, staining))
- Conveyor belts
- Clothing apparel (including uniforms, outerwear, gloves, aprons, coats and shoes)
- Filters
- Kitchen, commercial and industrial wipes and fabrics
- Napkins, tablecloths and wiping cloths
- Packaging (including bags, sacks, wraps, cushion and absorbent materials, and containers)
- Sponges

Non-food contact uses only:

- *Interior furnishings*
 - Blankets
 - Carpet and carpet underlay
 - Curtains
 - Cushion pads
 - Draperies
 - Fiberfill for quilts and pillows
 - Mattress cover pads and filling
 - Mops
 - Pillow covers
 - Rugs
 - Sheets
 - Sleeping bags
 - Upholstry
 - Towels
 - Wall covering fabrics
- *Automotive and truck upholstery*
 - Carpeting
 - Convertible tops
 - Interior liners
 - Rear decks
 - Trunk liners
- *Industrial and Other Household Items*
 - Artificial leather
 - Awnings
 - Book covers
 - Cloth for sails
 - Drain pan liners
 - Filters
 - Mops
 - Ropes
 - Tents and other outdoor equipment
 - Tarps
- *Apparel*
 - Caps
 - Inner liners for jackets
 - Outerwear
 - Sportswear
 - Sleepwear
 - Stockings
 - Socks and hosiery
 - Trim for outerwear and garments
 - Umbrellas
 - Undergarments
- *Luggage*
 - Cosmetic bags
 - Duffel bags
 - Luggage
 - Laundry bags
 - Luggage Lining
 - Packing Organizers
 - Sports bags
 - Shoe bags
 - Sports bag accessories
- *Transportation*

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 0.1% for bulk plastics. Contact Sinanen Zeomic Company Ltd. to determine the appropriate amount of Zeomic® Type AJ 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):

- 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)
- Cookware
- Countertops
- Cutting boards
- Collection and storage equipment (including conveyor belts, piping systems, silos, tanks and process vessels)
- Dishes
- Food wrap (including coated deli paper, coated meat interleavers and plastic wrap)
- General purpose containers
- Kitchen, commercial and industrial utensils and supplies
- Natural and synthetic fibers and fabrics
- Packaging
- Paper products (including wipes and tissues)
- Sinks

Non-food contact uses only:

- Automotive and vehicular parts
- Barrier fabrics
- Concrete
- Floors
- Furniture
- Electrical wiring devices and wall plates
- 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)
- Spas, bathtubs, showers, and filters and components thereof
- Industrial equipment
- Packaging
- Paper products (including wall coverings, towels, book covers)
- Roofing
- Shingles
- Siding
- Walls
- Wallboard
- Luggage
 - Cosmetic bags
 - Duffel bags
 - Luggage
 - Laundry bags
 - Luggage Lining
 - Packing Organizers
 - Sports bags
 - Shoe bags
 - Sports bag accessories

Coatings for Upgrade Applications

Upgrade Applications are defined as the incorporation of Zeomic into polymeric coatings that are applied to articles onsite (after the article has been manufactured and is in the place of use). Coatings may be used on articles that have not previously incorporated the antimicrobial compound. Zeomic may be incorporated into the finished coating at up to 5.0% by weight, or at least 0.1% of the coating. Types of coatings include waterborne coatings/adhesives, solvent borne coatings and two part reactive coatings consisting of a resin and curing agent. Upgrade Applications are for onsite application at Commercial, Industrial or Institutional Establishments. Unless otherwise specified, the coating is applied to the entire article. Contact Sinanen Zeomic Company Ltd. to determine the appropriate application technique and amount of Zeomic for individual products.

Food contact* and non-food contact articles (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating on an article):

- Appliances and food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers, and countertops)
- Beverage processing and ice machine equipment (including mixers, transfer equipment, pumps, bottlers, canners, fermenters and dispensers and other components)
- Building materials and components (including walls, ceilings and floors consisting of concrete, gypsum board, and cellulose ceiling tile)
- Food collection, conveyance and storage equipment (including conveyor belts, silos, tanks and process vessels)
- Food and chemical transportation equipment including railcars, tankers, trailers and components thereof

Incorporate this product into coatings that are intended for application to the surface of articles. The purpose of the coating is to seal the article from moisture and corrosion. The purpose of Zeomic® in the coating is to inhibit the growth of mold, mildew, fungus and bacteria that cause odor, discoloration, staining, deterioration or corrosion on the surface of the coating film. The product protects the applied coating itself from microorganism attack, not the underlying substrate. This product is not intended for remediation, prevention or control of existing or anticipated public health related microorganisms.

HVAC articles:

Heating, ventilation and air conditioning systems and related materials including air handlers, drain pans, heat exchangers, distribution lines, flexible ductwork, diffusers, and insulation lined porous ductwork.

Incorporate this product into coatings that are intended for application to HVAC systems. The purpose of the coating is to seal the HVAC system from moisture and corrosion. The purpose of Zeomic® in the coating is to inhibit the growth of mold, mildew, fungus and bacteria that cause odor, discoloration, staining, deterioration or corrosion on the surface of the coating film. The product protects the applied coating itself from microorganism attack, not the underlying substrate. This product is not intended for remediation, prevention or control of existing or anticipated public health related microorganisms.

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 0.1% for bulk plastics. Contact Sinanen Zeomic Company Ltd. to determine the appropriate amount of Zeomic® Type AJ 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):

- Grout and joint compound for; countertops, building materials and components, and food and beverage related equipment
- Pipe sealants and insulating materials
- Plumbing adhesives

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
- Adhesives, sealants and insulating materials for; appliances, bathrooms, showers, kitchens and construction
- Glazing for windows
- Grout
- Sealants for pipes

Hygiene products

The additive may be incorporated into the finished product at between 0.001% and 1.0% by weight.

Non-food contact uses only:

- Adult incontinence pads
- Baby diaper
- Bed pads
- Bladder control pads
- Disposable breast pads
- Feminine care pads
- Protective underwears
- Sanitary napkin
- Sheets for treating corpse

Miscellaneous Applications

The additive may be incorporated into the finished product at up to 5.0% by weight. Contact Sinanen Zeomic Company Ltd. to determine the appropriate amount of Zeomic® Type AJ Silver Zeolite A for individual finished products.

Non-food contact uses only:

- Cat litter
- Drainage and sewerage pipe
- Flooring
- Interior paints and coatings
- Plaster
- Puppy pads
- Sinks
- Stucco
- Slurries and intermediates
- Toilets
- Tile
- Waste liquids/substances: Control of spill and waste aqueous fluid, spilt blood and biological waste.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. CAUTION: Harmful if swallowed, 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 and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear goggles or face shield and rubber gloves. Remove and wash contaminated 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 or 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.