

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

71227-12

EPA Reg. Number:

Date of Issuance:

5/18/2015

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Zeomic Type XLJ50D Silver Zeolite A

Name and Address of Registrant (include ZIP Code):

Sinanen Zeomic Company, LTD 1-1 Nakagawa-honmachi, Minato-ku Nagoya, Japan 455-0051

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Elizabeth & Wathins for

Date:

5/18/2015

John Hebert, Chief

Regulatory Management Branch I, Antimicrobials Division

(7510P)

- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Silver GDCI-072501-1129

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 71227-12."
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. 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) list 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. 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 Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

• Basic CSF dated 4/29/2015

If you have any questions, please contact Elizabeth Watkins by phone at 703-347-0241, or via email at Watkins.Elizabeth@epa.gov.

Enclosure

Zeomic Type XLJ50D 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
 0.50 %

 Other Ingredients
 99.50 %

 Total
 100.00 %

ACCEPTED

05/18/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 71227-12

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-TBD EPA Establishment No. 71227-JPN-001

Net Wt. XXXX

Lot No. XXXXXXXXX

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 XLJ50D 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:
 - o Water filter components and housing units
 - Water bottle dispensers and components
 - Water dispensers
 - o Ice machine trays
 - o Ice machine bins
 - Ice machine water hoses
 - o Ice dispensers and other ice machine components
 - Water bottles
 - o 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.

Zeomic Type XLJ50D 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 XLJ50D 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 XLJ50D 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 XLJ50D 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 supplies

Gaskets Cutting boards
General purpose containers Countertops
Food and drink containers Sinks

Food trays and covers

Sponges

Tiles

Dishes

Plastic film Cups
Food wrap (including coated deli paper, coated Bottles

meat interleavers and plastic wrap) Conveyor belts

Tubing Food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)

(claims allowed: *odor*, *discoloration*, *staining*))

Beverage processing equipment (including mixers, transfer equipment, pumps, bottlers,

Non-woven fabrics canners, dispensers and fermenters)
Appliances and equipment Garbage bags and garbage cans
Kitchen and food processing utensils and

Non-food contact uses only:

Automobile parts mouthguards (claims allowed: *odor*,

Shower curtains discoloration, staining))
Mats Siding for housing

Protective covers Kitchen and bathroom hardware

Tape Flooring
Waste containers Floor coverings

Brush handles Footwear (including boots, sports equipment

Mops and tools)
Vacuum cleaner bags Insulation for wire and cable

Plumbing supplies and fixtures (including toilet Insulators

bowl seats)

Indoor and outdoor furniture

Drain pan liners

Toys (claims allowed: odor, disco

Drain pan liners

Toys (claims allowed: *odor, discoloration,*Office equipment and supplies (including staining, deterioration)

binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, components thereof

desk accessories, computers, keyboards, mice, Telephones, mobile devices, head phones,

scanners, and printers) headsets and accessories

Personal care items (including grooming items, toothbrushes (claims allowed: *odor*, Electrical wiring devices and wall plates

toothbrushes (claims allowed: *odor*, Electrical wiring devices and wall plate *discoloration*, *staining*), sports and dental

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 XLJ50D 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

Charleta

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 liners

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 XLJ50D 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

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:

Walls Roofing Wallboard Shingles

Floors Industrial equipment

Concrete Furniture

Siding 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)

Spas, bathtubs, showers, and filters and components thereof

Electrical wiring devices and wall plates

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. 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):

Food collection, conveyance and storage equipment (including conveyor belts, 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 and ice machine equipment (including mixers, transfer equipment, pumps, bottlers, canners, fermenters and dispensers and other components)

Food and chemical transportation equipment including railcars, tankers, trailers and components thereof

Building materials and components (including walls, ceilings and floors consisting of concrete, gypsum board, and cellulose ceiling tile)

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 XLJ50D 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 Zeomic Company Ltd. to determine the appropriate amount of Zeomic Type XLJ50D 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

Slurries and intermediates

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: 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 and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of E.P.A.

FIRST AID	
If on skin or clothing	 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	 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	 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	 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	

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.