

71227-4

4/4/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 04 2006

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Erin M. Tesh
Regulatory Consultant for,
Sinanen Company, Ltd.
c/o Technology Sciences Group, Inc.
Suite 500
Washington, D.C. 20036

Subject: Zeomic Type AK Silver Zeolite (4.93% silver)
EPA Registration Number 71227-4
Your Amendment Dated February 16th, 2006
EPA Received Date February 17th, 2006

This letter conditionally extend the expiration date to 4/1/07, for the following label use categories which received time-limited approval until 4/1/07 in the letter of that same date:

Indirect/direct food contact (limited to specific uses listed on stamped label)
Drinking water contact (limited to specific uses on stamped label)
HVAC (limited to specific uses listed on stamped label)

1. The data you recently submitted or cited, to satisfy the following time limited data listed in EPA letter dated 6/13/02, must be found fully accepted:

- Subchronic rodent feeding study
- Subchronic non-rodent feeding study
- Developmental toxicity study
- Mammalian cells in culture forward gene mutation assay
- In-vivo cytogenetics via metaphase analysis, microbucleus assay
- Two generation reproductive study

2. An aggregate risk assessment under FIFRA Section 2(b), using all submitted/cited, must result in a determination by the Agency that 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 an unreasonable risk will expire on 4/1/07 and must be deleted.

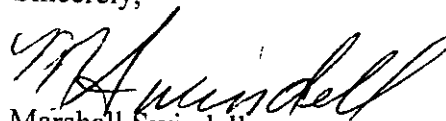
The revised labeling submitted to lower the minimum loading rate from 0.5% to 0.1% has been reviewed and found to be acceptable.

A stamped copy of the labeling is enclosed for your records.

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If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6273.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

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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

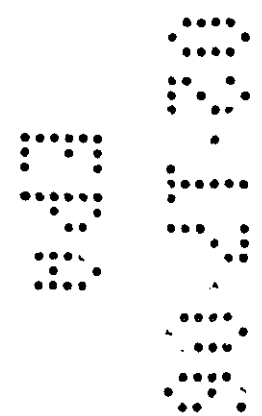
Lot No. XXXXXXXXXXX

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Under the Federal Insecticide,
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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.
- * 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.

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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 the manufacturing process to impart antimicrobial activity to the manufactured products. ***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
- 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)

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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*))
- siding for housing
- kitchen and bathroom hardware
- flooring
- floor coverings
- footwear (including boots, sports equipment 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.

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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 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

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

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Apparel -

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

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.

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
 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

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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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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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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.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

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Storage and Disposal

Do not contaminate water, food or feed by storage and disposal. 71227-4

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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Zeomic® AK Technical Bulletin No. 1

TECHNICAL BULLETIN FOR ZEOMIC TYPE AK SILVER ZEOLITE POLYMERIC COATING FOR HEATING, VENTILATION AND AIR CONDITIONING APPLICATIONS

Read the product label first. Refer to the product label and MSDS for complete directions on safety precautions, storage and handling.

Zeomic® Type AK Silver Zeolite (Zeomic) contains 4.93% by weight silver in a natural zeolite carrier. Zeomic is registered by the U.S. Environmental Protection Agency for use in plastics, fibers, coatings, films, laminates, adhesives and sealants. In coatings applied to Heating, Ventilation and Air Conditioning (HVAC) systems and components thereof, the antimicrobial additive is incorporated into a coating to preserve, keep odor-free and operational the components of the HVAC system. These applications apply only during the original manufacture of HVAC systems and components, and are not for use on existing or in place HVAC systems and components. This product is compatible with the substrates and products listed under "Approved Uses."

Incorporate this product into coatings that are intended for application to the surface of articles. The purpose of the coating is to preserve, keep odor-free and operational the components of the HVAC system. 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.

Product Description:

Zeomic® Type AK Silver Zeolite (Zeomic) contains 4.93% by weight silver in a natural zeolite carrier.

Claims:

When incorporated into a coating, the Zeomic will 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.

Important for HVAC Articles: Zeomic does not protect building occupants from disease-causing bacteria, viruses, mold or mildew or airborne allergens. Always clean and maintain the heating, ventilation and air conditioning system in accordance with the manufacturer's directions.

Technical Data:

Active Ingredient:	4.93% Silver
Color:	White
Physical State:	Dry Powder
Flammability:	Not Flammable
Specific Gravity:	2.15 ± 0.1 g/cm ³

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pH: 7-9 (1g Zeomic/100 ml water)
Thermal Stability: 800 °C

Approved Uses:

For use in polymeric coatings and adhesives, including aqueous, aqueous/solvent solutions, protectorant wax or silicone technology to treat –

- Heating, Ventilation and Air Conditioning systems and related materials (including insulation, air handlers, ducts, heat exchangers, drain pans and liners thereof, air filters, air purifiers, diffusers, humidifiers and parts and components thereof),
- Automobile air conditioning systems.

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How to Use Zeomic:

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Surface Preparation:

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Metal Surfaces: Apply only to clean dry surfaces free of all dirt, grease or impurities. Abrade all surfaces to remove all surface rust and corrosion products, and wash the intended surface with the appropriate cleaner, rinse and allow to dry thoroughly. Use surface pretreatments or primer coatings as required.

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Painted Surfaces: Apply only to clean dry surfaces free of all dirt, grease or impurities. Wire brush painted surfaces removing all flaking, loose or chalking material. Sand all glossy surfaces to roughen the entire area. Use surface pretreatments or primer coatings as required.

Mixing:

Incorporate Zeomic directly into formulations developed for the coating of heating, ventilation and air conditioning system applications. Maintain constant agitation of the coating during the application process.

Application:

Following the surface preparation steps, various coating technologies may be used to apply the Zeomic compound, including automated dip, flow, roll or electro-deposition coating and manual brush, roller or spray coating.

Automated Processes:

Circulate Zeomic and coating via a closed system maintaining agitation. Ensure excess coating applied via dip, flow or roll coating technologies is collected and returned to the system. Maintain constant solids concentration by the addition of fresh, properly mixed coating to make up for usage. Minimize evaporation of the coating by maintaining covers on storage vessels. Utilize appropriate drying conditions, including infrared or conventional ovens to properly cure coating incorporating the Zeomic compound. These processes must be conducted in accordance with federal, state and local air pollution laws and regulations.

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Apply coating to all surfaces at a rate to achieve a dry film thickness of approximately five (5) to twenty five (25) microns.

See handling instructions below for operator exposure requirements.

Manual Processes:

Zeomic may be incorporated into polymer adhesives and coatings and applied manually by brush, roller, spray or other coating technology. These products may be easily applied by high volume low-pressure (HVLP) spray equipment commonly used throughout the industry. These processes must be conducted within a downdraft spray booth permitted and operating in accordance with federal, state and local air pollution laws and regulations.

Apply coating to all surfaces at a rate to achieve a dry film thickness of approximately five (5) to twenty five (25) microns.

See handling instructions below for operator exposure requirements.

Contact Sinanen Zeomic Co., LTD to confirm optimum application technology and drying conditions, such as time and temperature, for each application before use in a commercial process.

Clean up:

Use fresh water or solvent to clean brushes and equipment before product dries.

Handling Instructions:

Wear goggles or face shield and rubber gloves when handling the dry powder.

Airborne Exposure Limits pursuant to OSHA 1910.1000 Table Z-3 for Mineral Dust

<u>Permissible Exposure Limit (PEL)</u>	
Respirable fraction:	5 mg/m3
Total dust:	15 mg/m3

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As with any fine powder, avoid generating dust.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is preferred to help control the emissions of the contaminant at the source, preventing its dispersion through the work area.

Personal Respirators (NIOSH Approved):

If the exposure limit is exceeded, a half-face respirator with filter appropriate for 1-micron dust may be worn per appropriate guidelines.

Storage and Disposal:

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Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Do not store in areas accessible to children. Keep 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.

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: 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.

MSDS Information:

Refer to the Material Safety Data Sheet for this product for complete handling and safety information.

Transportation Information:

Zeomic is not regulated as a hazardous material under DOT.

Regulatory Information:

Zeomic is registered by the U.S. Environmental Protection Agency as EPA Reg. No. 71227-4.

For technical assistance or questions contact:

Sinanen Zeomic Co., LTD.
4-22, Kaigan 1-Chome, Minato-ku
Tokyo 105-8525, Japan

Questions? 011-81-3-5470-7125

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Important: Warranty and Disclaimer Information

Sinanen Zeomic Co., LTD warrants that each of its products will be manufactured in accordance with Sinanen's specifications in effect on the date of manufacture. **SINANEN MAKES NO OTHER WARRANTIES AND EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** If a product fails to meet this limited warranty purchaser's sole and exclusive remedy is replacement of the product or, at Sinanen's option, refund of the purchase price. **SINANEN'S ACCEPTANCE OF ANY ORDERS FOR THIS PRODUCT IS EXPRESSLY CONDITIONAL UPON PURCHASERS' ASSENT TO THE TERMS ON THE APPLICABLE INVOICE.**

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