

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE OF PESTICIDE: X Registration

___ Reregistration (under FIFRA, as amended)

89110-36

EPA Reg. Number:

Date of Issuance:

5/21/20

Term of Issuance
Conditional

Name of Pesticide Product: BIONIX PHMB20

Name and Address of Registrant (include ZIP Code):

Isomeric Industries 3400 Research Forest Drive, Suite B4 The Woodlands, TX 77381

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:	Date:
Jacque Hardy	5/21/20
Jacquie Hardy, Product Manager 34 RMBII, Antimicrobials Division (7510P)	

- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. PHMB GDCI-111801-1519

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. Be aware that proposed data requirements for PHMB, have been identified in a Work Plan. For more information on these proposed data requirements, you may obtain copies in the docket EPA-HQ-OPP-2012-0341 at www.regulations.gov or contact the contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division
 - 4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 89110-36."
 - 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 CSF:

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• Basic Confidential Statement of Formula CSF dated 12/30/2019

If you have any questions, please contact Lorena Rivas by phone at 703-305-5027, or via email at rivas.lorena@epa.gov.

Enclose: Stamped Label

BIONIX PHMB20

[SWIMMING POOL] [SPA] [AND] [HOT TUB] [SANITIZER] [AND] [ALGISTAT] [Chlorine Free] [Swimming pool sanitizer and algistat - Not a disinfectant] [Microbiocide]. [PHMB20 is a high activity microbiocide [and in-can preservative] for use In applications such as [oil-in- water and water-in-oil emulsions], [preservation of animal hides and skins], [industrial reagents], [silicone systems], [cellulose solutions], and [oil recovery systems].

Active Ingredient:

Poly (hexamethylenebiguanide hydrochloride)	
Other Ingredients:	
Total:	100.0%

WARNING

FIRST AID	
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 SWALLOWED	 Call a 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 by a poison control center or doctor. Do not give anything to an unconscious person.
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 INHALED:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth ifpossible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency endangering life or property involving this product, please call INFOTRAC: (800)-535-5053.	

SEE [BACK] [SIDE] PANEL[S] FOR ADDITIONAL PRECAUTIONARY STATEMENTS [and first aid].

EPA Reg. No. 89110-TBD **EPA Est. NET CONTENTS:** As Marked on Container

Manufactured for:
ISOMERIC INDUSTRIES
3400 Research Forest Drive, Suite B4,
The Woodlands, TX 77381
1-833-BIONIXX

ACCEPTED

05/21/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2014 2020

89110-36

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing vapor or mist. Wear goggles or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

[1. User Safety Recommendation section required only for products sold with occupational use:]

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

[2. The following statement required only for products sold with oil-field uses:]

Applications involving drilling muds and workover fluids must use metering pump systems.

[If container size is 5 gallons or greater, use the following statement:]

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water 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 notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

[If container size is less than 5 gallons, use the following statement:]

ENVIRONMENTAL HAZARDS

This product is toxic to fish.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Important – PHMB20 [sanitizer] is incompatible with chlorinating chemical products.

[[This product][PHMB20] [sanitizer] is registered as a swimming pool, spa and hot tub sanitizer, not as a disinfectant.] Consult your [authorized] [Dealer of PHMB20] [local pool supply store] for information on balancing your pool water.

[Start up] [Treating the pool]

[Pools Previously Treated with Chlorinating Chemicals

Check with chlorine test kit for free and combined chlorine prior to the beginning of neutralization. To destroy chlorine, add [STOP CHLORE] chlorine neutralizer per label directions. Filter overnight.

Check with chlorine test kit. If free chlorine is detected, repeat neutralizer treatment.

[Note to reviewer: Directions may be lettered or numbered on final printed labelling.]

Freshly Filled and Dechlorinated Pools Start up with PHMB20 [sanitizer]

Note: If the pool water contains algae or is hazy, consult [the problem-solving section of the "Pool [Owner's] [Care] Guide," available from] your [local pool supply store] [authorized] [Dealer of PHMB20].

- * Backwash or clean pool filter. Check pool pH; adjust to 7.0 7.8 if necessary.
- * Add PHMB20 [sanitizer] to give a content of 50 ppm (1/2 gallon product/10,000 gallons of [pool] water).
- * After 24 hours, check pH and PHMB20 [sanitizer] concentration with the test kit for PHMB [SANITIZER] and adjust if necessary.

[Maintenance] Normal Pool Routine

- * Every week, check PHMB [sanitizer] concentration and pH.
- * Maintain PHMB20 [sanitizer] concentration at about 50 ppm. If concentration falls 10 ppm or more, add a top-up dose. The level should not be allowed to drop below 30 ppm. For example, to raise the PHMB [sanitizer] level 10ppm, add [16 oz.] [1 pint] per 10,000 gallons of [pool] water. [Consult the booklet, "The Pool [Owner's] [Care] Guide for PHMB [sanitizer],"] [Consult your local pool supply store] for calculation instructions.

NOTE: PHMB20 [sanitizer] AND CHLORINE ARE INCOMPATIBLE.

[Refer to the Pool [Owner's] [Care] Guide for PHMB [sanitizer]] [Consult your local pool supply store] for information on how to deal with accidental chlorination.]

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Problem-Solving and Supplemental Pool Information.

Do not use in unpainted plaster pools previously exposed to metals which may cause staining.

PHMB20 [sanitizer] is not compatible with many detergents and some supplemental algaecides (such as those based on copper). Do not use in freestanding [spas] [hot tubs].

If algae development, cloudiness, or pool problems occur or additional information on water quality is desired, consult [your] ["The Pool [Owner's] [Care] Guide for PHMB"] [available from your] [Authorized Dealer of PHMB20 [sanitizer]] [PHMB [sanitizer] Authorized Dealer] [your local pool supply store].

[Initial Treatment for spa or hot tub]

Important – PHMB20 [sanitizer] is incompatible with chlorinating [and] [or] brominating chemical products.

- * Remove chlorine or bromine source and disconnect feeder. Discontinue use of ionizers and electrochlorinators if present.
- * Drain existing water in spa.
- * Clean [spa] [hot tub] [surface] [and filter] [with water].
- * Fill [spa] [hot tub] [surface] with water.
- * [Bring a sample of [spa] [hot tub] water to your [local pool supply store] [PHMB20 [sanitizer] Authorized dealer] [Authorized Dealer of PHMB [sanitizer]] to check it for proper water balance.] [Have your authorized dealer of PHMB20 [sanitizer] check your water for proper water balance.]
- * After [your] [spa] [hot tub] water has been balanced, add PHMB20 [sanitizer] to give a concentration of 50 ppm. (1 (fl.) oz. of product [for] [per] 150 gallon of [spa] [hot tub] water).
- * Circulate [water] [for] 30 minutes then check the PHMB [sanitizer] [level] [concentration] [with PHMB TEST STRIPS] [and]. Adjust if necessary.

[Normal] Spa/Hot Tub Maintenance

- * Every week, check PHMB [sanitizer] concentration and pH. Adjust if necessary.
- * The [level of] PHMB [sanitizer] [level] should be maintained between 30 and 50 ppm. [When the level of PHMB is 30 ppm or less, add enough PHMB20 to bring the level up to 50 ppm.]
- * The [PHMB level] [spa's level of PHMB20] should never [be allowed to] drop below 30 ppm.
- * To raise the [PHMB] sanitizer level 10 ppm, add 0.2 oz. per 150 gal. of [spa] water.]

[General Information]

[PHMB20 is an effective preservative in most aqueous compositions. The concentration required to give protection depends on factors such as the susceptibility of the system to microbiological degradation, the extent to which micro-organisms can gain access and the type of micro-organisms present.]

[PHMB20 is a highly effective preservative for use in a wide variety of applications including oil-in-water and water-in-oil emulsions, industrial reagents, silicone systems, cellulose solutions and oil recovery systems. PHMB20 can also be used for the preservation of animal hides and skins and certain textiles and cellulosic products.]

[Chemical Description]

[PHMB20 is an aqueous solution of PolyHexaMethylene Biguanide hydrochloride and is soluble in water and stable under all normal conditions of storage. The active ingredient, itself, is heat stable and nonvolatile.]

[Compatibility]

[PHMB20 is a mild cationic compound and is compatible with nonionic and cationic compounds. PHMB20 nonionics and cationics should be metered through separate pumps. PHMB20 is not compatible with oxidizing chemicals, most anionic compounds and copper or other divalent metals. PHMB20 is precipitated by strong alkalis and complex phosphates. When doubt exists as to the compatibility of PHMB20 with other compounds, bottle tests at the concentrations to be used should be made with the material in question.]

[Note to Reviewer: The following use directions will appear on product labels sold for industrial uses:] [Typical applications [of the industrial product PHMB20] and suggested dosages include:]

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Aqueous Paints and Coatings [Not for use in CA].

For the preservation of aqueous based Paints and Coatings such as paper and wood coatings, paints and coatings used for architectural product finishes, industrial finishes and special purpose coatings. Special purpose coatings include uses as a:

- -Preservative for electrodeposition paints or solutions,
- -Preservative for photo-plating solutions or coatings,
- -Preservative in fount (or fountain) solutions used in the printing process as a maintenance fluid/coating and as a special coating for printing plates, and
- Preservative in spin finish coatings for fibers.

Dosage: 5 lb. to 50 lb. PHMB20 per 10,000 lb of product (500 to 5000ppm).

Silicones such as silicone emulsions and silicone dispersions [Not for use in CA].

Dosage: 1 lb. to 50 lb. PHMB20 per 10,000 lb. of product (100 to 5000 ppm)

Tunnel Pasteurization Waters [Not for use in CA].

For the preservation of waters used in tunnel pasteurization and tunnel cooling of sealed packages of canned and bottled foodstuffs. Dosage: 13 fl. oz. to 1 gal. of PHMB20 per 1,000 gal. tunnel pasteurization water (100 to 1000 ppm).

Aqueous Industrial Chemicals [Not for use in CA].

For the preservation of aqueous industrial chemicals such as reagents, oil-in-water emulsions, water-in-oil emulsions, textile spin finish lubricants, wash water and cellulose solutions. Dosage: 1 lb. to 50 lb. of PHMB20 per 10,000 lb. of product (100 to 5000 ppm).

Leather Processing [Not for use in CA].

For the preservation of leather processing solutions.

Dosage: 1b. to 30 lb. of PHMB20 per 10,000 lb. of product (100 to 3000 ppm).

Aqueous Based Polymer Lattices [Not for use in CA].

For the preservation of aqueous based polymer lattices such as polyvinyl acetate and polyvinyl alcohol. Do not use to preserve lattices used for paper coating compositions that may contact food. Dosage: 5 lb. to 50 lb. of PHMB20 per 10,000 lb. of product (500 to 5000 ppm).

Aqueous Mineral Slurries [Not for use in CA].

For the preservation of aqueous mineral slurries such as calcium carbonate, titanium dioxide. Do not use to preserve slurries used for paper coating compositions that may contact food. Dosage: 5 lb. to 50 lb. of PHMB20 per 10,000 lb. of product (500 to 5000 ppm).

Aqueous Based Adhesives [Not for use in CA].

For the preservation of aqueous based adhesives such as animal glues, latex adhesives based on polyvinyl acetate, PVA, etc., starch, synthetic, dextrin, casein and other glues. Dosage: 5 lb. to 50 lb. of PHMB20 per 10,000 lb. of product (500 to 5000 ppm). Preserved water-based adhesives may be used for food-contact purposes at a maximum use level of 1,000 ppm.

Industrial Electrocoats [Not for use in CA].

For the preservation of aqueous solutions such as electrocoat resins and depositions systems. Dosage: 10 lb. to 50 lb. PHMB20 per 10,000 lb. of product (1000 to 5000 ppm).

Household Consumer Products [Not for use in CA].

For the preservation of liquid, solids and paste consumer products such as surface cleaners, floor cleaners, fabric stain removers, fabric softeners, fabric conditioners, laundry detergents, laundry additives, automotive care silicone emulsions, and automotive cleaning products.

Dosage: 2.5 lb. to 25 lb. of PHMB20 per 10,000 lb. of product (250 to 2500 ppm).

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Preservation of Fresh Animal Hides and Skins [Not for use in CA].

For the preservation of fresh animal hides and skins prior to use. During processing, use 15fl.oz. to 3Gal. Add the appropriate quantity of PHMB20 to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other portions of the processing operations. The specific use rate and contact time needed to control microbial attack will depend upon the degree of decomposition of the hides or skins prior to treatment.

Dosage: 1.0 to 2.6 lbs. of PHMB20 per 1,000 lb. of hides or skins.

Cellulosic Materials and Textiles [Not for use in CA].

PHMB20 can be used as an agent to control the growth and action of microorganisms, and control generation of odors, on textiles such as cotton, cotton blends, cellulosic materials, and synthetic fibers such as non-wovens, tissues, paper and pulps.

Dosage: PHMB20 is diluted and applied to give 0.025 to 2% on the dry weight of the substrate. Application is by conventional means such as padding, spraying, soaking or exhaustion. The optimum conditions for application of the dilute solution are pH 6.5 to 8 and temperature of 20 to 30°C.

The following are examples of products (substrates) suitable for antimicrobial finishing with PHMB20:

- -Textiles such as: Household products, for example, upholstery, carpet, curtains, wall covering, mops, dishcloths, yarns, cords, toweling and blankets.
- -Cellulosics such as: wipes, tissues, sponges, paper products (non-food contact) such as filters and cellulose pulp.
- -Apparel items includes: slacks, shirts, underwear, sweatshirts, sweatpants, socks, oven mitts, slippers, bathrobes, gloves, hats, scarves, jackets, sheets, pillowcases, incontinence pads cover stock, washable incontinence briefs and panties.

Oil Recovery [Not for use in CA].

Not for use in oil recovery systems that employ holding ponds for spent liquids. Do not apply in, over or near marine and/or estuarine oil fields.

Dosage: Specific rates for use of PHMB20 should be determined by bacteriological tests made prior to treatment. These tests should establish (a) the presence of microorganisms, (b) the severity of the problem, and (c) required treating ratio. The effectiveness of a treatment can be evaluated by similar bacteriological tests. The compatibility of PHMB20 with the water should be determined prior to treatment. Some suggested treatment methods and treating rates for water systems include:

Oil Field Injection Water

- 1. SLUG METHOD When the system is noticeably fouled, apply 4 gallons of PHMB20 per 1,000 barrels (42,000Gal) of water (95.2ppm of product). PHMB20 should be added to the system at a point where it will be uniformly mixed. Repeat on a weekly basis, or as needed to establish control. When microbial control is evident, the treating rate may be lowered to 2 gallons of PHMB20 per 1,000 barrels of water (47.6ppm of product) weekly, or as needed to maintain control. Badly fouled systems should be cleaned before treatment is begun.
- 2. CONTINUOUS METHOD Before beginning a continuous treatment, apply a slug treatment of 4 gallons of PHMB20 per 1,000 barrels of water (95.2 ppm of product). Continue treatment by applying 0.15 to 0.8 gallons (19 to 102 ounces) of PHMB20 per 1.000 barrels of water (4 to 20 ppm of product).

Drilling Muds

- 1. Calculate the total volume of drilling mud system, and using this volume calculate the number of gallons of PHMB20 needed to produce a concentration of approximately 3,000 ppm. For example, 126 gallons of PHMB20 per each 1,000 barrels of total volume will produce this concentration.
- 2. While the system is circulating, add the amount of PHMB20 calculated above in a thin stream.
- 3. As the well depth increases, increasing the total volume of the system, add additional PHMB20 as required to maintain the proper concentration.

Workover Fluids

- 1. Calculate the total volume of the workover fluid system and, using this volume, calculate the number of gallons of PHMB20 needed to produce a concentration of approximately 3,000 ppm. For example, 60 gallons of PHMB20 per each 20,000 Gal (476 barrels) of total volume will produce this concentration.
- Add PHMB20 into the system
- 3. Circulate the workover fluid system until the fluid returns clear.
- Shut the system down and idle for several hours. Remove the workover fluid. The well should be ready for productive use.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Keep container closed when not in use. Store in original container in an area inaccessible to children. Protect from freezing.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use in accordance with label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING

[For nonrefillable containers with capacities less than or equal to 5 gallons.]

[Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.]

[For nonrefillable containers with capacities greater than 5 gallons.]

[Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.]

[For nonrefillable containers - residential/household use only.]

[Pesticide] Storage and Disposal: Store in original container and in an area inaccessible to children. Keep container closed when not in use. Protect from freezing. In case of a leak or spill, soak up with absorbent, such as sand earth, or sawdust, and shovel into waste container. Remove waste to chemical waste area, and dispose in accordance with pesticide disposal instructions. Non-refillable container. Do not reuse or refill. Securely wrap original container in several layers of newspaper and discard in trash.

SPILLS

[For industrial use applications only.]

In case of a leak or spill, soak up with absorbent, such as sand earth, or sawdust, and shovel into waste container. Remove waste to chemical waste area, and dispose of in accordance with pesticide disposal instructions.

WARRANTIES AND WARRANTY DISCLAIMERS

Conditions of Sale: Isomeric Industries ("ISOMERIC") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to ISOMERIC. To the extent consistent with applicable law, ISOMERIC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. To the extent consistent with applicable law, ISOMERIC SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, and ISOMERIC's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. BUYER AND USER ACKNOWLEDGE AND ASSUME ALL RISKS AND LIABILITY RESULTING FROM HANDLING, STORAGE AND USE OF THIS PRODUCT. ISOMERIC DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.

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