

73148-4

07-14-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 14 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dr. Keith A. Hostetler, Ph.D.
Agent for,
Ishizuka Glass Co. Ltd.
1880 Kawai-cho, Iwakura-shi
Aichi-ken, 482-8510 Japan

Mail to: Dr. Keith A. Hostetler, Ph.D.
11400 Van Story Drive
Huntersville, NC 28078

Subject: Ionpure IPM
EPA Registration Number 73148-4
Your Amendment Dated February 26th, 2009
EPA Received Date February 27th, 2009

The Agency is conditionally approving your amendment to the registration of the product referenced above under the authority of FIFRA Section 3(c)(7)(B). This amendment allows use of the subject product as an antimicrobial additive when incorporated into the specific food contact polymers listed in 21 CFR Parts 174 through 186 inclusive, or in FDA's "Food Contact Substance Notification System", and also allows incorporation of the product into certain human and animal drinking water contact treated articles.

This amendment, and the approved uses, will expire automatically within 2.5 years after the Agency notifies you to submit the 2 studies listed below. In addition, during the period that this amendment is effective, it will be subject to the conditions in this letter listed below:

1. The following outstanding data must be submitted within 2 years to support both the new food and drinking water contact uses on the attached stamped label. Failure to satisfy the data requirements listed below may result in EPA issuing a notice to cancel this amendment under FIFRA section 6(e). This conditional registration will expire automatically within 2.5 years. Sale or distribution of the subject product bearing labeling for these food contact uses after the Agency notifies you that you have failed to satisfy these data requirements will be illegal.

A. Sub-chronic, non-rodent feeding study (830.3150)

B. Two-generation reproductive study (870.3800)

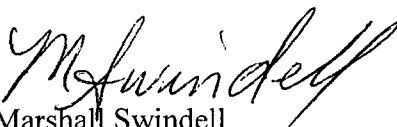
In order for the registration of the use of this product, for incorporation into approved food contact polymers, and into certain drinking water treated articles, to continue, the outstanding data described above, must be submitted, reviewed, and found to be acceptable. In addition, the Agency must make a risk assessment determination under FIFRA Section 2 (bb)(2) that these uses will not result in unreasonable adverse effects. If the Agency is unable to make this determination, then the registration of these uses for incorporation into approved food contact polymers and drinking water treated articles will expire.

Note that under the proposed rule which amends 40 CFR Parts 152 and 156 (ie., 156.444), for Non-public health products, the word "Antimicrobial" will only be allowed if "clearly and properly" qualified by a statement in close proximity to the word "antimicrobial". Also note that you must have efficacy data on file which justifies the various claims and use sites on this label. You do not need to submit this data until the Agency requests it.

A stamped copy of the accepted label is attached for your records.

If you have any questions concerning this letter, please contact Karen Leavy at (703)-308-6237.

Sincerely,


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

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IONPURE IPM
Silver Glass

A material preservative and antimicrobial agent for use in the
manufacture of polymer, plastic, paint, and textile products.
For Manufacturing/Fabrication Use Only.

Active ingredient:	
Silver (as elemental)	2.5%
Other ingredients	97.5%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

**PRECAUTIONARY STATEMENT
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

FIRST AID: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
IF SWALLOWED	<ul style="list-style-type: none"> • 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 do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.

EPA Establishment No. 73148-JPN-001

EPA Registration No. 73148-4

Net Weight

Lot No. _____

Ishizuka Glass Co., Ltd.
1880 Kawai-cho, Iwakura-shi
Aichi-ken, 482-8510
Japan
Telephone +81 (0) 587 37 3251

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 73148-4

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**PRECAUTIONARY STATEMENT
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

CAUTION. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**** See Supplemental Label for detailed use information****

Only for manufacture of or fabrication into antimicrobial pesticides for 1) the uses listed on this label and supplemental label; 2) Uses for which US EPA has approved the required data and/or citations of data that the formulator has submitted in support of registration; and 3) Uses for experimental purposes that are in compliance with USEPA requirements.

IONPURE IPM is an antimicrobial powder for the manufacture of polymeric, plastic, and paint products only. It is designed to be used in materials that are incorporated into the products indicated on the supplemental labeling for **IONPURE IPM** during the manufacturing process to impart antimicrobial activity to the manufactured products. **IONPURE IPM** suppresses the growth of bacteria, algae, fungus, mold and mildew which cause unpleasant odors, discoloration, staining, deterioration or corrosion of those manufactured products.

Finished products containing **IONPURE IPM** may not make public health claims relating to antimicrobial activity without EPA pesticide registration. 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.

Incorporate **IONPURE IPM** into permitted materials in the finished product at 0.1 to 1.5% **IONPURE IPM** by weight. Contact Ishizuka Glass Co., Ltd. to determine the appropriate amount of **IONPURE IPM** for individual finished products.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

Pesticide Storage: Do not store in areas accessible to children. Keep away from direct sunlight.

Pesticide Disposal: Dispose wastes from the use of this product on site or at an approved waste disposal facility.

Container Disposal: Completely empty bags into processing equipment where the pesticide is used. Then dispose of empty bag and box in sanitary landfill or by incineration, if allowed by state and local authorities.

EPA Approval Date:

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Supplemental Product Label

IONPURE IPM

EPA Reg. 73148-4

Material preservative and antimicrobial agent for use in the manufacture of polymer, plastic, paint, and textile products.

For Manufacturing/Fabrication Use Only

IONPURE IPM is an antimicrobial pesticide for the manufacture of polymeric, plastic, and paint products only. It is designed to be incorporated into the materials for manufacture into final products listed below during the manufacturing process to impart antimicrobial activity to the manufactured products. IONPURE IPM suppresses the growth of bacteria, algae, fungus, mold and mildew which cause unpleasant odors, discoloration, staining, deterioration or corrosion of those manufactured products.

Finished products containing IONPURE IPM may not make public health claims relating to antimicrobial activity without EPA pesticide registration. 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.

Incorporate IONPURE IPM in permitted materials for finished products at 0.1 to 1.5% of IONPURE IPM by weight. Contact Ishizuka Glass Co., Ltd. to determine the appropriate amount of IONPURE IPM for individual finished products.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use only under agreement with Ishizuka Glass Co., Ltd. IONPURE IPM is intended for use as an additive into the following materials and substances as part of the manufacturing process in order to provide built-in antimicrobial activity in manufactured and finished products.

APPLICATIONS AND TYPES OF MATERIALS:

APPLICATION	TYPES OF FINISHED PRODUCTS
Plastics, including films, sheets, slabs, and molded plastic parts	Appliances and equipment, automobile parts, brush bristles, brush handles, containers, floor coverings, flooring, foam containers, footwear (including boots, sports equipment and tools), furniture, gaskets, general purpose containers, gloves, insulation for wire and cable, insulators, kitchen and bathroom hardware, liners, mats, mops, non-woven fabrics, plastic film, plumbing supplies and fixtures (including toilet bowl seats), protective covers, shower curtains, sinks, tape, tiles, tubing vacuum cleaner bags, waste containers.

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APPLICATIONS AND TYPES OF MATERIALS, continued

APPLICATION	TYPES OF FINISHED PRODUCTS
Fibers	<p>Apparel (such as umbrellas, outerwear, sportswear, sleepwear, socks and hosiery, caps, undergarments, inner liners for jackets, trim for outerwear and garments, uniforms, outerwear, gloves, aprons, coats, and shoes.)</p> <p>Industrial and other household items (such as artificial leather, filters, book covers, mops, cloth for sails, ropes, tents and other outdoor equipment, tarps, awnings, bags, brush bristles, commercial and industrial wipes and fabrics, sponges, wiping cloths)</p> <p>Interior furnishings (such as mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, curtains, draperies, carpet and carpet underlay, rugs, upholstery, towels, wall covering fabrics, cushion pads, sleeping bags)</p> <p>Packaging</p> <p>Textile finishing (various surface resins for coating textiles)</p> <p>Transportation items (such as automotive and truck upholstery, carpeting, rear decks, trunk liners, convertible tops, interior liners)</p>

APPLICATION	TYPES OF FINISHED PRODUCTS
Coatings, Films, and Laminates	<p>Appliances, automotive and vehicle parts, barrier fabrics, building materials and components (such as walls, wallboard, floors, concrete, siding, roofing, shingles, hardware, floors, ceilings, commercial and industrial applications),</p> <p>Collection and storage equipment (such as conveyor belts, piping systems, silos, tanks, and process vessels), countertops, furniture, general purpose containers, glazing for cement tile, glazing for vitreous china used in plumbing fixtures (such as toilets, sinks, countertops)</p> <p>Industrial equipment, natural and synthetic fibers and fabrics, packaging, paper products (such as wipes, tissues, wall coverings, towels, book covers, corrugated paper filters), sinks.</p>

APPLICATION	TYPES OF FINISHED PRODUCTS
Adhesives and Sealants	<p>Appliances, bathrooms, cardboard, ceramic tile, construction materials, glazing for windows, grout and joint compound, paper, pipe sealant and insulating materials, plastic, plumbing adhesives, plywood rubber, sealants for pipes showers, wood, wood and plastic composites</p>

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APPLICATIONS AND TYPES OF MATERIALS, continued

APPLICATION	TYPES OF FINISHED PRODUCTS
Paints (Indoor use only)	Solvent-based paints Water-based paints

FOOD CONTACT USES for IONPURE IPM

IONPURE IPM is permitted to be incorporated at the specified Maximum Concentrations (MC) on a dry weight basis of finished polymeric products listed below that are used for manufacturing, packing, packaging, transporting, handling and /or holding food if such use is not intended to have any antimicrobial effect in the food itself. Do not incorporate IONPURE IPM into any food or drinking water contact application listed on this label without first incorporating IONPURE IPM into a polymer which is approved, with associated use conditions, for food contact in 21 CFR 174-186 (inclusive) as amended, or in the United States Food and Drug Administration's Food Contact Substance Notification System, as amended.

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Plastics, including films, sheets, slabs, and molded plastic parts	Appliances and equipment, beverage dispensing equipment, beverage processing equipment, bottles, brush bristles, brush handles, containers, conveyor belts, countertops, food handling equipment, food processing equipment, food storage containers, food trays and covers, food packaging, food processing utensils, gaskets, general purpose containers, kitchen and bathroom hardware, liners, mats, non-woven fabrics, plastic film, plumbing suppliers and fixtures, protective covers, sinks, sponges, tape, tiles, tubing.	1.0%
Fibers	, containers, conveyor belts, table cloths, napkins, wiping cloths, mops, sponges, brush bristles, filters, packaging (including bags, sacks, wraps, cushions, absorbent materials and containers), commercial and industrial wipes and fabrics for kitchen use, food packaging.	1.0%
Coatings, Films, and Laminates	Appliances and equipment, barrier fabrics, building materials and components, collection and storage equipment (such as conveyor belts, piping systems, silos, tanks and process vessels), cookware, countertops, food wrap (including coated deli paper, coated meat interleavers and plastic wrap), general purpose containers, glazing for cement tile, glazing for vitreous china used in plumbing fixtures (such as sinks and countertops), industrial equipment, natural and synthetic fibers and fabrics, packaging, paper products (such as wipes, tissues, wall coverings, towels), plastic film, sinks.	1.0%
Adhesives and Sealants	Appliances, cardboard, ceramic tile, grout and joint compound, paper, pipe sealant, and insulating materials, plastic, plumbing adhesives, rubber, sealants for pipes, wood, wood and plastic composites.	1.0%

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DRINKING WATER CONTACT Uses for IONPURE IPM

IONPURE IPM is permitted for the human drinking water contact uses listed below. The additive is permitted at the specified maximum Concentrations (MC) on a dry weight basis of finished products for use in food bowls 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.

DRINKING WATER CONTACT Uses for IONPURE IPM, continued

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Plastics; Fibers; Coatings, films and laminates; adhesives and sealants	Including ice making equipment (water pans, piping, tubing, guards, ice storage bins, trays, ice scoops, buckets, valves and gaskets); drinking water contact materials (water bottles, cups, gaskets, plumbing fixtures, storage tanks and vessels, water piping, tubing valves, spigots, coolers, water dispensing components, housing units, and water filter components.	1.0%

CHEMICAL AND PHYSICAL PROPERTIES

Appearance: White powder

Odor: None detectable

Density: 2.58 g/cm³ at 20°C

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