

73148-3

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 IPL
EPA Registration Number 73148-3
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 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 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)

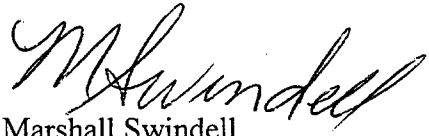
In order for the registration of the use of this product, for incorporation into approved food contact polymers, and into certain drinking water treated articles, to continue, the outstanding data described above, must be submitted, reviewed, and found to be acceptable. In addition, the Agency must make 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)

(Front Panel Label)

IONPURE IPL
Silver-Glass

IONPURE IPL is an antimicrobial powder for commercial and industrial use designed to be incorporated into various materials during varying stages of the manufacturing process to preserve the integrity of the manufactured materials. A preservative for use in the manufacture of plastic films, interior paint, paper coatings, adhesives, and synthetic fibers. For more details of the various materials, refer to the supplemental labeling for uses of **IONPURE IPL**.

ACTIVE INGREDIENT:
Silver*as elemental:1.8%
OTHER INGREDIENTS:98.2%
Total:100%

*from silver-magnesium-calcium-phosphate-borate complex.

KEEP OUT OF REACH OF CHILDREN
CAUTION

PRECAUTIONARY STATEMENT
HAZARD TO HUMAN AND DOMESTIC ANIMALS

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

FIRST AID	
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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.
HOT LINE NUMBER	
For medical questions, emergencies or accidents involving this product call: 1-800-858-7378. Have the product container or label with you when calling a poison control center or doctor.	

ENVIRONMENTAL HAZARD: This pesticide is toxic to fish. 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 Pollution 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 the EPA.

STORAGE AND DISPOSAL: Do not store in areas accessible to children. Do not store in places where food or feed may come in contact with the product. Keep away from direct sunlight or humidity. Do not contaminate water, food or feed by storage or disposal. **PESTICIDE DISPOSAL:** Unused material should be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** Empty container thoroughly and rinse with water. Dispose in regular trash collection.

EPA Reg. No. 73148-3

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

Net Contents: 22 lbs/10 kg, 33 lbs/15 kg or 44 lbs/20 kg

EPA ~~ACCEPTED~~ 73148-JPN-001
with **COMMENTS**
EPA Letter Dated:

JUL 14 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 73148-3

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(Back Panel)
IONPURE IPL

DIRECTIONS FOR USE:

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

BLENDING AND FORMULATING INSTRUCTION FOR THE LISTED MATERIALS

IONPURE IPL is a silver glass antimicrobial powder designed to be incorporated into various materials at various stages of their manufacturing process to preserve the integrity of the manufactured materials. The powder can be incorporated into the materials as an integral part of the finished products throughout their entire thickness, or as a film over the surfaces of the manufactured materials, depending upon the particular method of manufacture of the finished materials and need of the manufacturer.

Incorporate **IONPURE IPL** into the following materials at or below the specified Maximum Concentrations (MC) on a dry weight basis of finished products, or on a weight by weight basis for liquid products such as paints.

	APPLICATION	MC
Plastics and films	For non-food contact applications in polyethylene, polypropylene, polyvinyl chloride, polyacetate, and polyester.	1.5%
Paint	Water base and solvent base-interior only.	1.5%
Paper coating	For non-food packaging paper, not for paper production use.	1.5%
Adhesive	For non-food contact, including plywood adhesives.	2.0%
Fibers	Polyester, Nylon, Polypropylene, Acrylic and Rayon	2.0%
Textile finishing		0.75%

For details on blending **IONPURE IPL** with these materials, refer to supplemental labeling. For detailed use information on food contact and water contact applications, refer to supplemental labeling.

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(SUPPLEMENTAL LABELING)

**IONPURE IPL – EPA Reg. No. 73148-3
(Silver-Glass)**

Claims: **IONPURE IPL** is to be incorporated into the following materials at the specified maximum Concentrations (MC) on a dry weight basis of finished products, or on a weight by weight basis for liquid products such as paints. Incorporate **IONPURE IPL** at suitable stages of the manufacturing process to preserve the integrity of the manufactured/treated materials, and thus make them suppress the growth of bacteria and mold.

APPLICATIONS AND TYPES OF MATERIALS:

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Plastics, including films, sheets, slabs, and molded plastic parts. Polymers including polyester, polyamide, polypropylene, polyethylene, polysiloxane, polyethylene copolymer, polyvinyl alcohol, epoxy resin, phenol resin, polycarbonate, cellulose acetate, polystyrene, polyurethane, acrylic resin, methyl methacrylate, acrylonitrile butadiene styrene copolymer, etc.	Gloves, shower curtains, cable wraps, protective covers, foam containers, brush handles, sponges, insulators, gaskets, tubing, containers, films, furniture, etc.	1.5%

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Paint – Indoor use only	Water-based paint, solvent-based paint	1.5%

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Paper coatings - Cellulosic, synthetic, specialty, reinforced papers, etc. Not for paper production use.	Wallpaper, wiping towels, book covers, corrugated paper filters, etc.	1.5%

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Adhesives	Adhesives for plywood manufacture, adhesive for cement tile and sealants, etc.	1.5%

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(SUPPLEMENTAL LABELING, continued)

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Fibers - polyester polypropylene, nylon, polyethylene, acrylic, rayon, etc.	Home furnishings, including mattress cover pads, sheets, blankets, quilt and pillow fiber fill, curtain and drapery, carpet and its underlay, upholstery, wiping cloth, towels, bags, wall cover fabrics, cushion pads, etc. Apparel, including inner lining, industrial uniforms, coats and aprons, sportswear, sleepwear, stockings, socks, helmets, caps, gloves, etc. Industrial products, including brush bristles, shoe linings, artificial leather, filters, book covers, sail cloth, ropes, etc	2.0%

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Textile finishing	Various surface resin coatings	0.75%

DRINKING WATER CONTACT Uses for IONPURE IPL

IONPURE IPL is permitted for the human drinking water contact uses listed below. The additive is permitted for used 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.

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%

FOOD CONTACT USES for IONPURE IPL

IONPURE IPL is permitted for use as an antimicrobial additive in the polymeric manufactured 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 IPL into any food or drinking water contact application listed on this label without first incorporating IONPURE IPL 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%

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FOOD CONTACT USES for IONPURE IPL, continued

APPLICATION	TYPES OF FINISHED PRODUCTS	MC
Fibers	Apparel (such as outerwear, uniforms, gloves, aprons, coats), bags, 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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