

84890-1

9/30/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 30 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FILE COPY

Ben Schroeder
Manager, Regulatory
PureLabs LLC
1919 Stoughton Road
Madison, WI 53716

Subject: Lonza Formulation I-1.75
EPA Registration No. 84890-1
Application Date: July 23, 2010
EPA Receipt Date: August 2, 2010

Dear Mr. Schroeder:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

Proposed Amendment:

- Label amendment to change primary brand name to "IO Purge 5065"

Conditions:

1. Qualify that "tile" is a hard nonporous surface under Disinfection-Hospitals, Veterinary Clinics...Schools" directions on page 2 by stating "glazed" tile.
2. Revise the "Shoe Bath Sanitizer" directions on page 2 by deleting the phrase, "tracking harmful organisms" and stating "cross contamination".
3. Revise the "Sanitizing-Meat and Food Processing Equipment and Utensil" directions on page 2 to be in compliance with DIS/TSS by stating:

Remove gross filth and soil by preflush, prescrape, or when necessary presoak. Wash surfaces with a compatible detergent or 1 oz per gallon of water and rinse with potable water prior to sanitizing. Sanitize surfaces with 1 oz per 5 gallons of water (25 ppm titratable iodine). Articles that can be immersed such as silverware, glasses, and dishes must remain in solution for 1-2 minutes. Articles too large for immersion must be thoroughly wetted or flooded by rinsing, spraying, or swabbing for 1-2 minutes. Allow sanitized surfaces to drain thoroughly and air dry. Prepare a fresh solution daily or more often if solution becomes visibly diluted, clouded, or soiled.

For mechanical application, use-solution may not be reused for sanitizing applications but may be reused for cleaning.

- 4. Delete the "Hand Sanitizing" directions on page 2 because this use is not under the jurisdiction of EPA but the Food and Drug Administration.
- 5. The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Therefore, delete the "Storage and Disposal" statements for containers one gallon or less.
- 6. Revise the "Container Disposal" statements to read:

Container Disposal: Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying.

(Containers 5 gallons or less [please note that the statements are the same for plastic and metal containers])

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Container greater than 5 gallons [please note that the statements are the same for plastic and metal containers])

Triple rinse as follows: Fill container ¼ full with water. 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. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

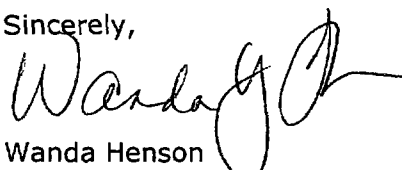
(Fiber drums with liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration, if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

General Comments:

A stamped copy of the accepted labeling is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,



Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and protective gloves (rubber, chemical resistant) when handling. Harmful or fatal if swallowed. Do not breathe spray. Avoid contamination of food.

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

Emergency Information: *(insert telephone number here)*

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer: For containers that are 5 gallons or larger, the following Environmental Hazards statements will be used:)

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. 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 the EPA.

IO Purge 5065

Disinfectant – Cleaner – Sanitizer - Deodorizer
With Organic Soil and 400 ppm
Hard Water Tolerance

For Hospital, Institutional, Industrial,
School, Dairy, and Other Farm Use

Active Ingredient:

Iodine* 1.75%
Other Ingredients 98.25%
Total: 100.00%

* from Nonylphenyloxypolyethoxyethanol-Iodine Complex

KEEP OUT OF REACH OF CHILDREN

DANGER

See (left) (right) (side) (back) panel for Precautionary
Statements and First Aid.

EPA Reg. No. 84890-1

EPA Est. No. *(insert EPA Est. No. here)*

Net Contents *(insert size of container here)*

Purelabs, LLC.

1919 South Stoughton Rd

Madison, Wisconsin 53716

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 30 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 84890-1

(Note to reviewer: Language in () is optional or interchangeable)



IO PURGE 5065 is a proven "one-step" cleaner - disinfectant - sanitizer - deodorizer in the presence of moderate amounts of organic soil and 400 ppm hard water.

DIRECTIONS FOR USE

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

Apply **IO PURGE 5065** with a cloth, mop, sponge or coarse mechanical spray device until surfaces are thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. Prepare fresh solution daily or more often if the use solution becomes visibly diluted or dirty.

Disinfection - Hospitals, Veterinary Clinics, Other Health Care Institutions, Institutions, Industry, Schools,

Apply a use solution of 1/2 oz. of **IO PURGE 5065** per gallon of water to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, countertop laminates, tile, glazed porcelain, and sinks. For heavily soiled areas, a preliminary cleaning is required.

Disinfection - Farm Premises and Poultry Houses:

Remove all animals and feed from premises, vehicles and enclosures such as coops and crates. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1/2 oz. of **IO PURGE 5065** per gallon of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use 1/2 oz. of **IO PURGE 5065** per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard nonporous surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Shoe Bath Sanitizer - To prevent tracking harmful organisms into animal areas, scrape shoes and place in a 3 oz. of **IO PURGE 5065** per gallon of water solution for 30 seconds prior to entering area.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [optional: This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

(or)

This product is not for use on medical device surfaces.

Sanitizing - Meat and food processing equipment and utensils:

Remove heavy soils by flushing, scraping, or mopping. Wash with 1 oz. per gallon of **IO PURGE 5065** (or other good cleaner). Rinse with clean water and sanitize surfaces with 1 oz. **IO PURGE 5065** per 5 gallons of water (25 ppm titratable iodine). Surface should remain in contact with solution for 1 - 2 minutes. Drain well and air dry. Do not rinse.

Hand Sanitizing - In food handling and meat cutting operations:

Rinse hands and immerse in a 1 oz. of **IO PURGE 5065** per 5 gallons of water solution (25 ppm titratable iodine).

Retort Cooling Water - For canning operations.

Add 1 oz. **IO PURGE 5065** per 5 - 10 gallons of retort water prior to starting up operation to control slime and odor causing bacteria.

Poultry Drinking Water Sanitization - Use 1 oz. of **IO PURGE 5065** per 10 gallons of drinking water.

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(Note to reviewer: If the container size is 1 gallon or less, the following Storage and Disposal Statements will be used:)

Storage and Disposal

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If the container size is greater than 1 gallon, the following Storage and Disposal Statements will be used:)

Storage and Disposal

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

Pesticide Storage:

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container. Do not store on side. Avoid creasing or impacting of side walls.

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 according to label instructions, contact your State Pesticide, Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

(Plastic containers): Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Fiber drums with liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill or by incineration, if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(Metal containers): 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.

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