

70258-4

4-14-2008

FILE COPY

115



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

70258-4

Date of Issuance:

APR 14 2008

Term of Issuance:

Unconditional

Name of Pesticide Product:

Sani-Pure Sanitizer and Cleaner

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Urnex Brands
170 Ludlow Street
Yonkers, NY 10705

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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 (OPP Decision No. D-389990) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA File Symbol to read, "EPA Reg. No. 70258-4".

Signature of Approving Official:

Emily Mitchell
Emily Mitchell
Product Manager Team-32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

APR 14 2008

EPA Registration No. 70258-4
Page 2

- b. This product is "For Use As A Sanitizing Agent In Food Service Establishments" which has been added to the label.
- c. Revise the Ingredient Statement as follows:

Active Ingredient:	
Sodium Hypochlorite	12.5%
Other Ingredients.	<u>87.5%</u>
Total	100.0%
Available Chlorine: XX%	

The amount of available chlorine must be declared on the label.

- d. The Heading "For Use On Food Processing Equipment and Utensils" has been added to the label.
 - e. The "Food Wares" use site is not recognized by the Agency. Please identify what is meant by **Food Wares**.
 - f. The unsupported claim that this product is for "All Equipment Vulnerable To Dangerous Bacteria Build-Up" has been removed.
3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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.

Sincerely,

Emily Mitchell
 Emily Mitchell
 Product Manager 32
 Regulatory Branch II
 Antimicrobials Division (7510C)

Enclosures: (Stamped Label)

3/5

7lb Pail Label

Left Panel on Label

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles, or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS:

This product is toxic to fish and aquatic organisms. Do not discharge into lakes, streams, ponds or public waterways unless in accordance with a NPDES permit. For guidance, contact the regional office of the U.S. Environmental Protection Agency.

PHYSICAL OR CHEMICAL HAZARDS

STRONG OXIDIZING AGENT:

MIX ONLY WITH WATER, according to label instructions ("Directions"). Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces, etc.) will release chlorine gas which is irritating to eyes, lungs and mucous membranes.

STORAGE AND DISPOSAL:

PESTICIDE STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

PESTICIDE DISPOSAL: Product or residues that cannot be used should be diluted with water before disposal in a sanitary sewer.

CONTAINER DISPOSAL Rinse empty container thoroughly with water to dissolve all material before discarding. Place in trash collection or dispose in approved landfill area. Do not contaminate food or feed by storage, disposal or cleaning of equipment.

FOR RINSE OR IMMERSION METHODS OF SANITIZING:

Prepare 100 ppm sanitizing solution by thoroughly mixing ½ ounce of this product (1 ounce = 2 tablespoons) with 1 gallon of water. If no test kit is available, prepare a sanitizing solution by thoroughly mixing 1 ounce of this product with one gallon of water to provide approximately 200 ppm available chlorine by weight. Clean equipment in the normal manner. Prior to use, rinse all surfaces thoroughly with the sanitizing solution for a least 2 minutes and allow the sanitizer to drain. If solution contains less than 50 ppm available chlorine, as determined by a suitable test kit, either discard the solution or add sufficient product to establish a 200 ppm residual. Do not rinse equipment with water after treatment and do not soak equipment overnight. Sanitizers used in automated systems may be used for general cleaning but may not be re-used for sanitizing purposes.

Tel: 800-222-2826 www.urnex.com

MANUFACTURED IN U.S.A. BY: Urnex Brands, Inc.

170 Ludlow Street Yonkers, New York 10705 - Fax:914-963-2145

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 14 2008

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

70258-4

4/5

FOR USE AS A SANITIZING AGENT IN FOOD SERVICE ESTABLISHMENTS
Center Panel on Label

**Sani-Pure™
SANITIZER & CLEANER**

FOR USE ON FOOD PROCESSING EQUIPMENT & UTENSILS

FOR SOFT SERVE ICE CREAM & YOGURT
MACHINES, ICED TEA DISPENSERS,
GRANITA & ICED CAPPUCCINO MACHINES,
DISHES, GLASSWARE, STEAM KETTLES,
PLASTIC WARE, ~~FOOD WARES, STEAMERS &
ALL EQUIPMENT VULNERABLE
TO DANGEROUS BACTERIA BUILD-UP.~~

ACTIVE INGREDIENT:		
SODIUM HYPOCHLORITE.....	4.0%*	
OTHER INERT INERT INGREDIENTS.....	96.0%	
TOTAL.....	100.0%	

*Derived from Trisodium Phosphate Chlorinated

Available Chlorine xx%

DANGER:
KEEP OUT OF REACH OF CHILDREN
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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. Call a poison control center or doctor for treatment advice.
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 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 by a poison control center or doctor. ▪ Do not give anything to an unconscious person
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicates the use of gastric gavage.	
Have the product container or label with you when calling a Poison Control Center or doctor, or when going for treatment.	

(See additional precautions on left side panel)

EPA REG. NO. 70258-__

CONTENTS: 7 LBS.

EPA EST. NO. 70258-NY-001

Right Panel on Label

DIRECTIONS FOR USE:

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

CLEANING PRIOR TO SANITIZING:

Equipment must be cleaned prior to sanitizing with a good detergent, followed by a potable water rinse. Gross food particles and soil must be removed by a pre-flush, or pre-scrape and, when necessary, pre-soak treatment. Sanitizing: (For manual operations, fresh sanitizing solution should be prepared at least daily or more if the solution becomes diluted or soiled.)

TEA & COFFEE VESSELS, ICED CAPPUCCINO & GRANITA MACHINES:

Use 2 tablespoons (1 oz.) of SANI-PURE for each 1 gallon of water (liquid) capacity to provide approximately 200 ppm. available chlorine. Immerse and allow solution to soak in warm water for 2 minutes. Brush vessel surfaces. (If applicable, run a "cycle" of any machine being sanitized so that lines, valves and faucets are also sanitized.) Then drain thoroughly. ALLOW TO AIR DRY ONLY. DO NOT WIPE.

SOFT SERVE MACHINES:

Use 1 oz. (2 tablespoons) of SANI-PURE added to each gallon of water in mix hopper. Pump into freezer and operate for about five minutes drain. for sanitizing, repeat process with a 2 minute cycle of mixing, then drain. Air dry only.

FOR RINSE OR IMMERSION METHODS OF SANITIZING:

Prepare 100 ppm sanitizing solution by thoroughly mixing ½ ounce of this product (1 ounce = 2 tablespoons) with 1 gallon of water. If no test kit is available, prepare a sanitizing solution by thoroughly mixing 1 ounce of this product with one gallon of water to provide approximately 200 ppm available chlorine by weight. Clean equipment in the normal manner. Prior to use, rinse all surfaces thoroughly with the sanitizing solution for at least 2 minutes and allow the sanitizer to drain. If solution contains less than 50 ppm available chlorine, as determined by a suitable test kit, either discard the solution or add sufficient product to establish a 200 ppm residual. Do not rinse equipment with water after treatment and do not soak equipment overnight. Sanitizers used in automated systems may be used for general cleaning but may not be re-used for sanitizing purposes.

ALL OTHER VESSELS & UTENSILS:

Use 1 oz. (2 tablespoons) of sanitizer for each gallon of liquid capacity. Allow to soak for 2-3 minutes. Drain and allow to air dry.