



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 4, 2016

Nicole Listner
Associate Regulatory Affairs II
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: Notification per PRN 98-10 – To update label language
Product Name: OXY-PAK
EPA Registration Number: 1677-228
Application Date: April 11, 2016
Decision Number: 516825

Dear Ms. Listner:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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 have any questions, you may please contact Emilia Oiguenblik by phone at 703-347-0199, or via email at Oiguenblik.emilia@epa.gov, or Julie Chao by phone at 703-308-8735, or via email at Chao.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

OXY-PAK

COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF FOODS

COMMERCIAL STERILANT FOR ASEPTIC MANUFACTURING AND
PACKAGING EQUIPMENT FOR FOOD PROCESSING

**CLEANER ADDITIVE COMPATIBLE WITH ALKALINE OR ACID
DETERGENTS USED FOR CLEANING FOOD PROCESSING EQUIPMENT**

Active Ingredients:

Hydrogen Peroxide	35%
Inert Ingredient.....	<u>65%</u>
Total.....	100.0%

NOTIFICATION

1677-228

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

5/4/2016

KEEP OUT OF REACH OF CHILDREN
DANGER

(See [back], [side], [other] label for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid])

(Refer to (MSDS) (SDS) for additional product hazard information)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

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 ON SKIN OR CLOTHING: Take off contaminate clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor for treatment advice. Have a 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

**FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHSYCIAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Contact with combustibles may cause fire. Contamination may cause rapid decomposition and generation of large quantities of oxygen and heat.

ENVIRONMENTAL HAZARDS: This product is toxic to birds, fish and aquatic invertebrates. 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 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.

DIRECTIONS FOR USE:

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

COMMERCIAL STERILIZATION

OXY-PAK can be used to achieve commercial sterility of food-packaging materials and food processing equipment.

COMMERCIAL STERILIZATION OF FOOD PACKAGING MATERIALS

Commercially sterilize food packaging materials with undiluted solution **OXY-PAK**. Apply **OXY-PAK** by immersion, coarse spray, mist or circulation techniques **in a closed system**, as appropriate, to food packaging material. Surfaces must be exposed to **OXY-PAK** for a period of 20 seconds at 75° C. This product when used per label directions is effective against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584).

OXY-PAK may be used to sterilize containers for aseptic food packaging of low acid foods that has a schedule process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including, but not limited to 21 CFR parts 108, 110, and 113 and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

COMMERCIAL STERILIZATION OF CLOSED SYSTEM MANUFACTURING FILLING AND PACKAGING EQUIPMENT FOR FOOD PROCESSING

Prior to use of this product, remove gross soil particles from equipment surfaces, thoroughly clean surfaces, and follow with a potable water rinse. Commercially sterilize pre-cleaned manufacturing, filling and packaging equipment with undiluted **OXY-PAK** by immersion, coarse spray or circulation techniques, as appropriate. Surfaces must be exposed to **OXY-PAK** at a temperature of 75° C for 20 seconds, unless a longer time is specified by the governing food processing authority. This product when used per label directions is effective against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584).

This product may be used for Aseptic Packaging of Low Acid Foods that has a scheduled process by FDA. The aseptic food processing operations must comply with the all applicable FDA regulations, including, but not limited to 21 CFR parts 108, 110, 113 and /or 114. Use in an aseptic food processing operation includes testing required for the process validation.

This product is not for use as a sterilant on medical devices.

CLEANER ADDITIVE COMPATIBLE WITH ALKALINE DETERGENTS USED FOR CLEANING FOOD PROCESSING EQUIPMENT: *Oxy-Pak* can also be used as a cleaner additive compatible with alkaline detergents to aid in the removal of soils. Remove gross filth then use 0.25-1.5% v/v in detergent use solution (0.32 - 1.92 oz. per gallon of detergent use solution). All hard non-porous food contact surfaces treated with this solution must be rinsed thoroughly with a potable water rinse followed by sanitizing with an approved food contact surface sanitizer.

CLEANER ADDITIVE COMPATIBLE WITH ACID DETERGENTS USED FOR CLEANING FOOD PROCESSING EQUIPMENT: *Oxy-Pak* can also be used as a cleaner additive compatible with acidic detergents to aid in the removal of soils. Remove gross filth then use 0.25-1.5% v/v in detergent use solution (0.32 - 1.92 oz. per gallon of detergent use solution). All hard non-porous food contact surfaces treated with this solution must be rinsed thoroughly with a potable water rinse followed by sanitizing with an approved food contact surface sanitizer.

STORAGE & DISPOSAL:

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE AND DISPOSAL.

STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration and in a vented container to avoid any explosion hazard. Keep this product in a tightly close container, when not in use. In case of spill, flood the area with large quantities of water. Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

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 or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL:

(≤ 5 gallons) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a 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. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(>5-55 gallons) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the 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 application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(Tote) Verify the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

(Bulk) Refill the container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

**FOR COMMERCIAL USE
STRONG OXIDIZING AGENT**

Manufactured by:

Ecolab Inc.

370 N. Wabasha Street

St. Paul, MN 55102

(Made in United States of America) (Made in USA)

<p>Net Contents: 32 ounces, 96 ounces, 1 U.S. Gal. (3.78 L), 2.5 U.S. Gal. (9.45 L), 4 U.S. Gal (15.2 L), 5 U.S. Gal (18.9 L), 30 U.S. Gal (113.5 L), 50 U.S. Gal (189 L), 300 Gal (1135 L) tote, bulk</p>

EPA Reg. No. 1677 –228

EPA Est.:1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TC-1 (D),

1677-IL-2 (J), 1677-CA-1 (S), 1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code

Optional marketing language:

PRODUCT DESCRIPTION

- ▲ <product name> is an EPA-registered sterilant for package and filler equipment (21 CFR 178.1005).
- ▲ <product name> is specifically formulated at high purity to be used in aseptic fillers with spray application methods.
- ▲ <product name> is specifically formulated to be used in aseptic bath application methods.

BENEFITS

Saves Money

- ▲ Eliminates need for multiple hydrogen peroxide formulations.

Promotes Quality Assurance

- ▲ Rapid action to promote quality assurance.
- ▲ High purity:
 - Helps minimize cleaning frequency
 - Helps decrease nozzle plugging in spray applications
 - Meets low residue requirement for vaporized hydrogen peroxide filler application
- ▲ Part of a complete Ecolab product and professional services program.

Environmental Implications *(using only for Basic or Alternate #2 CSF)*

- ▲ No phosphate.

- “See side/back panel for First Aid...”



Sterilant
Esterilizante