

1677-216

3/17/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAR 17 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Rhonda Schulz
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

FILE COPY

Subject: Exspor Base Concentrate
EPA Registration No. 1677-216
Application Dated: December 15, 2010
Receipt Dated: December 20, 2010

Dear Ms. Schulz:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to remove Tuberculocidal claims per November 9, 2010 Agency correspondence, is accepted with conditions.

Condition

Revise the "Hazards to Humans and Domestic Animals" statement as follows:

CAUTION: Harmful if absorbed through skin. Cause moderate eye irritation. Do not get in eyes, on skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the restroom.

And

Revise the "Additional Precautionary Language for Mixed Solution" as follows:

CAUTION: Use of mixed solutions or large volume area may lead to respiratory irritation. If irritation occurs, leave the area immediately and seek medical attention if irritation persists. Harmful if absorbed through skin. Cause moderate eye irritation. Do not get in eyes, on skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the restroom.

General Comments

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

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

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Y. Henson". The signature is fluid and cursive, with a large, stylized initial "W" and "H".

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

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EXSPOR BASE CONCENTRATE

Part 1 Base Concentrate

4:1:1 STERILANT-DISINFECTANT

A SYSTEM FOR CONTROLLING BACTERIAL CONTAMINATION IN 3 MINUTES AND VIRAL CONTAMINATION IN 5 MINUTES) ON HARD, NON-POROUS INANIMATE SURFACES

FOR USE WITH EXSPOR ACTIVATOR CONCENTRATE (PART 2)

BACTERICIDAL-VIRUCIDAL-FUNGICIDAL-TUBERCULOCIDAL-PSEUDOMONACIDAL-SPORICIDAL

DISINFECTING LEVEL – Kills bacteria, including *Pseudomonas aeruginosa* and *Mycobacterium bovis*, and pathogenic fungi on hard, non-porous environmental surfaces in 3 minutes (see directions for use).

Sterilizes laboratory equipment and other non-medical immersible items in 10 hours at 20°C. (See directions for use and precautionary information).

Effective against the following viruses on hard, non-porous environmental surfaces in 5 minutes:

- Influenza Virus Type A2 (Hong Kong) (ATCC VR-544)
- Herpes Simplex Virus Types 1 (ATCC VR-735) and 2 (ATCC VR-734)
- Poliovirus Type 1 (ATCC VR-58)
- Adenovirus Type 2 (ATCC VR-846)
- Vaccinia Virus (ATCC VR-119)
- Avian Influenza A Virus (ATCC VR-2072)
- Coxsackievirus (ATCC VR-28)
- Echovirus Type 2 (ATCC VR-32)
- Vesicular Stomatitis Virus (VSV) (ATCC VR-158)
- Norovirus (Feline Calicivirus surrogate ATCC VR-782)

Active Ingredients:

Sodium chlorite	1.52%
Other Ingredients	98.48%
Total	100.00%

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**KEEP OUT OF REACH OF CHILDREN
CAUTION**

This statement refers only to the unmixed EXSPOR BASE CONCENTRATE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

FIRST AID STATEMENTS

IF ON SKIN OR CLOTHING: 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: 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 eyes. 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 the product container or label with you when calling a poison control center or doctor, or going for treatment.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 1677-216

ADDITIONAL PRECAUTIONARY LANGUAGE FOR MIXED SOLUTION:

Use of mixed solutions in a confined or large volume area may lead to respiratory irritation. If irritation occurs, leave the area immediately and seek medical attention if irritation persists. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ADDITIONAL FIRST AID STATEMENTS FOR MIXED SOLUTION:

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

IF ON SKIN OR CLOTHING: 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: 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.

EXSPOR is recommended for use in schools, hospitals, medical, dental, industrials and institutional facilities, as well as animal hospitals, animal laboratories, kennels, pet shops, zoos. Exspor can be used for sterilizing laboratory and other non-medical immersible items. Exspor can be used to disinfect floors, walls, and other nonporous surfaces such as tables, chairs countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel or glass, cages, kennels, and animal housing.

EXSPOR solution may be safely used on most plastics, ceramic and glass. Never soak items in metal vessels. Prolonged or repeated exposure will oxidize metals, including aluminum and stainless steel. Do not use on copper, brass or bronze. Do not apply to surfaces containing residues from bleach, strong acids, or other chemicals, without first rinsing surface thoroughly with water.

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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR USE

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

USE IN A WELL-VENTILATED AREA. AVOID BREATHING FUMES. EXSPOR BASE CONCENTRATE must be diluted with water prior to adding EXSPOR ACTIVATOR CONCENTRATE. Improper preparation can result in excessive generation of chlorine dioxide fumes.

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. 1677-216

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PREPARATION OF EXSPOR STERILANT-DISINFECTANT SOLUTION (EXSPOR SOLUTION):

1. Measure 1 part EXSPOR BASE CONCENTRATE (Part 1) into a clean, empty NON-METALLIC container.
2. Add 4 parts cool tap water (at or below 25°C)
3. Add 1 part EXSPOR ACTIVATOR CONCENTRATE (Part 2) and stir.

The final solution should appear colorless or pale yellow. Variations in local water hardness may result in dark color and/or strong odor. Deionized or distilled water may be substituted to minimize these effects.

STERILIZATION OF LABORATORY AND OTHER NON-MEDICAL EQUIPMENT:

Prepare EXSPOR solution as described above. Moderate amounts of organic load, such as soil, will not lower the efficacy of EXSPOR solutions. However, to ensure best results, surfaces should be rinsed and, if possible, equipment dismantled and rinsed free of heavy soil and gross debris. Hollow objects must be flushed and filled.

Immerse equipment for a minimum of 10 hours at 20°C to destroy resistant pathogenic spores as represented by *Clostridium sporogenes* and *Bacillus subtilis*. Remove equipment from EXSPOR solution using sterile technique and rinse thoroughly with sterile water prior to drying. Mix and use right away. Discard solution after each use.

DISINFECTION:

Prepare EXSPOR solution as described above. Disinfection is not affected by water hardness up to 400 ppm (calculated as CaCO₃).

Mixed solution needs to be used within 24 hours of mixing. Discard used solution after each use. Although efficacy at 30-second contact time has shown to be adequate against HIV-1, this time would not be sufficient for other organisms.

EXSPOR solution will inactivate bacteria (including *M. tuberculosis*) and fungi in 3 minutes at 20°C. Viruses are inactivated in 5 minutes at 20 °C.

Soaking is the best method of application. However, the solution may be sprayed or wiped on by any convenient means (mop, cloth, sponge, etc.). The surface should be thoroughly wetted with solution. To minimize potential for oxidation or corrosion, a contact time of 5 minutes on metal surfaces or equipment should not be exceeded.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS POSSIBLY CONTAINING THE HUMAN IMMUNODEFICIENCY (AIDS) VIRUS:

- Wear protective barriers such as disposable latex gloves, gowns, face masks and eye covering when handling items soiled with blood or body fluids.
- Blood and other body fluids must be thoroughly cleaned from surfaces and objects before use of EXSPOR.
- Such fluids and contaminated cleaning materials should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Ventilation: Always use in a well-ventilated area. Avoid breathing fumes. When used in a confined or large-volume area, the quantity of chlorine dioxide in the air may exceed OSHA Permissible Exposure Limits (PEL's) and may require respirator protection. Limits are defined as 0.1 ppm for an 8-hour time weighted average, and 0.3 ppm for a 15-minute short term exposure limit (29 CFR Part 1910.134 and 1910.100, Air Contaminants, Table Z-1). Personnel

ACCEPTED FOR REGISTRATION
with COMMERCIAL USE
EPA Letter Dated:

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Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for the pesticide.

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should contact their resident safety officer or Ecolab Inc. for information on appropriate gear when such application is undertaken.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store unmixed concentrates in a cool, dark, dry place in the original containers. Always replace covers.

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 DISPOSAL:

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available, or discard in trash.

EPA Reg. No. 1677-216
EPA Est. No. 35347-CA-001

Manufactured for:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

<p>Net Contents:</p> <p>1 U.S. Gal. (3.78 L)</p> <p>5 U.S. Gals. (18.9 L)</p> <p>55 U.S. Gals. (207.9 L)</p>
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Optional Marketing Language:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

MAR 17 2011