

1677-216

12-28-2009

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

OFFICE OF
PREVENTION, PESTICID
AND TOXIC SUBSTANCES

December 28, 2009

**Theodore K. Head
Ecolab Inc.
370 Wabasha Street N.
St. Paul, MN. 55102**

**Subject: Exspor Base Concentrate
EPA Registration Number 1677-216
Application Date: November 20, 2009**

Dear Mr. Head:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

- **Addition of marketing claims relative to Pandemic 2009 H1N1.**

General Comments

Based on a review of the material submitted, the notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

A handwritten signature in cursive script that reads "Tom Luminello".

Handwritten initials "for" in cursive script.

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



United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number <p style="text-align: center;">1677-216</p>	2. EPA Product Manager <p style="text-align: center;">Emily Mitchell</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <p style="text-align: center;">Exspor Base Concentrate</p>	PM# <p style="text-align: center;">32</p>	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)

Adding optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-216 (Exspor Base Concentrate).

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <hr/> If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <hr/> If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1, 5, 55 gallons	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)		
Name Theodore D. Head	Title Product Registration Manager	Telephone No. (Include Area Code) (651) 293-2848
Certification I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Data Application Received (Stamped) <div style="border: 1px solid black; padding: 5px; text-align: center;"> RECEIVED NOV 20 2009 </div>
2. Signature 	3. Title Product Registration Manager	
4. Typed Name Theodore D. Head	5. Date November 20, 2009	



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THEODORE HEAD
 Manager, Product Registration
 Regulatory Affairs
 T 651.293.2848
 F 651.225.3122
 ted.head@ecolab.com

November 20, 2009

Document Processing Desk (E-SUB)
 Office of Pesticide Programs (7502P)
 U.S. Environmental Protection Agency
 2777 S. Crystal Drive
 Arlington, VA 22202

ATTN: Emily Mitchell, PM-32

Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-216 (Exspor Base Concentrate)

Dear Emily:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1.

Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8750-1.
- Certification with Respect to Label Integrity.
- Proposed Labeling (5 copies)
- Label CD

If you have any questions please contact me at the above phone, fax or email address.

Sincerely,

Theodore D. Head
 Product Registration Manager
 Regulatory Affairs
 Ecolab Inc.

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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%

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.

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.

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 wet 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/or 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 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

Net Contents:

1 U.S. Gal. (3.78 L)
5 U.S. Gals. (18.9 L)
55 U.S. Gals. (207.9 L)

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.