1677-216

9/29/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

SEP 29 2014

Nicole Damon Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102

Subject: Exposure Base Concentrate EPA Registration Number 1677-216 Application Date: June 27, 2014 Receipt Date: June 30, 2014

Dear Ms. Damon:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7(A) as amended, is acceptable.

Label Amendment:

• Add container handling and disposal directions for additional sizes.

General Comments

A stamped label is enclosed for your records. Please submit a final printed label before selling or distributing the product bearing the revised labeling. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, you may contact R. Cromwell at (703) 347-0169 or by email at <u>cromwell.rame@epa.gov</u>. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

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-PSEUDOMONACIDAL-SPORICIDAL

DISINFECTING LEVEL – Kills bacteria, including *Pseudomonas aeruginosa* 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	
Total	

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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. Do not get in eyes, on skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, the wing gum, using tobacco or using the restroom.

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 clenses, 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.

6/27/2014

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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. 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.

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, animal care facilities, animal housing facilities, farms, livestock quarters, poultry premises, and poultry hatcheries.

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, animal care areas, animal housing and feeding and watering equipment. In addition **Exspor** will deodorize those areas that are generally hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas that are prone to odors caused by microorganisms. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

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 instruction that (1) is introduced directly into the human body, either into or in contact with the bloodstream or $e_{c,e,c}$ normally sterile areas of the body or (2) contacts intact mucous membranes but which does not or dirarly 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 $e_{c,e,c}$ 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 $CaCO_3$).

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 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. Rinse treated surfaces with potable water, and wipe or air dry.

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 eyec 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.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with EXSPOR Sterilant-Disinfectant Solution (EXSPOR Solution), which will inactivate bacteria and fungi in 3 minutes at 20°C. Viruses are inactivated in 5 minutes at 20°C. Rinse treated surfaces with water, then thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent, rinse with potable water and drain (air dry) before reusing the facility. Facility and treated equipment can be reused after final potable water rinse is drained (air dried).

POULTRY HATCHERY DISINFECTION

Clean out any remaining eggs and chicks. Remove gross soils, such as litter, down, shell fragments or other hatching related debris. Empty all racks and other equipment. Thoroughly wash all surfaces, including floors, walls, conveyors, trays and water systems with a recommended detergent. Rinse thoroughly with water. Apply EXSPOR Solution with a mop, cloth, brush or coarse spray, which will inactivate bacteria and fungi in 3 minutes at 20°C. Viruses are inactivated in 5 minutes at 20 °C. Rinse treated surfaces with water, then thoroughly scrub treated surfaces with a detergent, rinse with potable water and drain (air dry) before reusing the facility. Facility can be reused after final potable water rinse is drained (air dried).

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNS, KENNELS, HUTCHES)

Remove animals and feed from facilities. Remove litter, waste matter and gross soils. Empty all troughs, rack and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply EXSPOR Solution with a mop, cloth, brush or coarse spray, which will inactivate bacteria and fungi in 3 minutes at 20°C. Viruses are inactivated in 5 minutes at 20 °C. Rinse treated surfaces with water, then thoroughly scrub treated surfaces with a detergent, rinse with potable water and drain (air dry) before reusing the facility. Facility can be reused after final potable water rinse is drained (air dried).

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.

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:

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

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

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

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) 300 U.S. Gals (1135.6 L)

Optional Marketing Language:

- Respiratory illnesses attributable to Pandemic 2009 H1N1are 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 c_{c} inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swife 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.