

5741-23

2/12/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 12 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ronald T. Cook, Manager -- Regulatory Affairs
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, Ohio 43537

Subject: Foamy Q & A
EPA Registration Number: 5741-23
Application Date: November 10, 2009
Receipt Date: November 17, 2009

Dear Mr. Cook:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions listed below.

Proposed Amendment:

- Label revisions per PR Notice 2007-4
- Add Pandemic 2009 H1N1Influenza claims and other minor formatting revisions.

Conditions

Revise the label as follows:

- 1.) Revise the claim "For Institutional and Industrial Only" on page 2 to read "*For Institutional, and Industrial Use.*"
- 2.) Qualify ceramic tile and quarry tile as hard nonporous surfaces on page 2 by stating "*glazed*" ceramic tile and "*glazed*" quarry tile.
- 3.) The 2nd claim under "Back Label Copy" on page 2 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.
- 4.) The "Personal Protection" and "Disposal of Infectious Materials" statements under HIV-1 directions on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "*must.*"
- 5.) Revise the 10th statement under "Precautionary Statements" on page 3 by stating "*Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.*"

6.) According to PR Notice 2001-1, First Aid Statements, the first aid statements must be reorganized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first. Therefore, reorganize the "First Aid" statements on page 4 to read "If In Eyes, IF On Skin or Clothing, If Swallowed, If Inhaled."

CONCURRENCES

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SURNAME							
DATE							

7.) The Agency has concerns regarding the efficaciousness of a public health product if the container is rinsed, and the rinsate is added to the application equipment or stored for later use. Therefore, alternative rinsate instructions have been developed specifically for public health products. Revise your Container Disposal/Handling statements to reflect the following:

Container Disposal: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsates). Offer for recycling if available. If not, puncture and dispose of in a sanitary landfill.

RESIDUE REMOVAL INSTRUCTIONS: *(For containers less than 5 gallons)*
Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

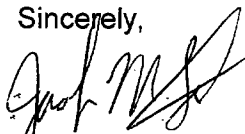
RESIDUE REMOVAL INSTRUCTIONS: *(For containers greater than 5 gallons)*
Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

General Comments:

A stamped label acceptable with conditions is enclosed for your records. . Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline McFarlane
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE	Enclosure: Stamped label						

Front Label Copy



Foamy Q & A
Acid Disinfectant Cleaner
Ready To Use
Foaming Clinging Action Kills Many Germs in Five Minutes!

ACCEPTED
with COMMENTS
in EPA Letter Dated:
FEB 12 2010

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

5741-23

Staphylocidal, Pseudomonicidal, Salmonellacidal, Virucidal*
Effective Against Antibiotic-Resistant Bacteria**

*Kills HIV-1 (AIDS Virus), Kills Herpes Simplex Type 2 and Influenza A₂/Hong Kong viruses.
**Kills Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant Enterococcus faecalis (VRE).

(Note to EPA -The use of the following phrases are optional :)

-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 A₂/Hong Kong 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 A₂/Hong Kong and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus

ACTIVE INGREDIENTS:

Phosphoric acid 12.00%
Alkyl (C₁₄-50%, C₁₂-40%, C₁₆-10%)
dimethyl benzyl ammonium chlorides..... 0.50%

INERT INGREDIENTS: 87.50%

TOTAL: 100.00%

E.P.A. Reg. No. 5741-23 E.P.A. Est. No. 5741-OH-1

KEEP OUT OF REACH OF CHILDREN
DANGER
See back panel for additional precautionary and first aid statements.

FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY

Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537
1-800-537-8990 / www.spartanchemical.com

NET CONTENTS:

Back Label Copy

Foamy Q & A is a ready-to-use acid-based cleaner disinfectant with special foaming action for fast and efficient maintenance of shower stalls, tubs, sinks, floors, walls, toilet bowls, urinals and other similar surfaces. Use only on acid-resistant surfaces such as ceramic tile, fiberglass, quarry tile, chrome and stainless steel. Foamy Q & A is effective against the pathogenic bacteria *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica* even in the presence of organic soil! In addition, Foamy Q & A has been tested and found effective against the antibiotic-resistant bacteria Methicillin-resistant *Staphylococcus aureus* (MRSA) and Vancomycin-resistant *Enterococcus faecalis* (VRE). Foamy Q & A is also effective against the pathogenic viruses HIV-1 (AIDS Virus), Herpes Simplex Type 2 and Influenza A₂/Hong Kong on hard non-porous inanimate surfaces.

Foamy Q & A is ~~recommended~~ for use in schools, hotels, hospitals or any other commercial, industrial and institutional facility where a clean and sanitary environment is important.

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

This product is not for use on medical device surfaces.

Five-Minute Disinfection Action: For 5-minute disinfectant activity against **bacteria and *viruses in the presence of organic soil:

1. Spray directly on soiled surface.
2. Allow foam to wet surface for 5 minutes.
3. Wipe off with a damp cloth or sponge.
4. Rinse surfaces thoroughly with water.

Preliminary cleaning is required for heavily soiled areas. Extremely heavy soils may require agitation with a mild scrubbing pad or brush.

***FOAMY Q & A KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Exposure to blood or body fluids ~~should~~ be avoided by use of barrier protection such as latex or other impervious gloves. Face shields and impervious gowns ~~should~~ also be worn if splashing of blood or body fluids may occur.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Foamy Q & A.

Contact Time: Leave surfaces wet for 5 minutes.

Disposal of Infectious Material: Gross contamination of blood or body fluids ~~should~~ be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

General Cleaning and Deodorizing: Dilute Foamy Q & A 1:10 (12 oz./gal. of water) for general cleaning and deodorizing of hard non-porous surfaces.

NOTE: Foamy Q & A contains phosphoric acid. Do not use with ammonia or bleach, or any other chemicals. Use of Foamy Q & A on older sinks and tubs, polished marble or aluminum, galvanized metal, resilient flooring, terrazzo or carpeting may cause etching or other damage. Some fiberglass such as Sterling's Vikrell is not acid-resistant. Consult manufacturer's warranty. Test in inconspicuous area before use.

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals
DANGER

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

(NOTE TO EPA –The following text will be used on containers of 5 gallons or larger)

ENVIRONMENTAL HAZARDS:

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 the 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.

FIRST AID

IF SWALLOWED: 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 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 mouth to mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

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 further treatment advice.

IF IN EYES: Hold eyes 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.

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

24 HOUR MEDICAL EMERGENCY NUMBER: 888-314-6171

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

(NOTE TO EPA: The following text will be used on containers of 5 gallons or less)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be 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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill container 1/4 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 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(NOTE TO EPA: The following text will be used on containers of greater than 5 gallons)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be 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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill container 1/4 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

SPARTAN CHEMICAL COMPANY, INC.
1110 Spartan Drive
Maumee, Ohio 43537
1-800-537-8990 / www.spartanchemical.com