

5741-18

12/2/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ronald T. Cook
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

DEC -2 2009

Subject: NABC Non-Acid Disinfectant Bathroom Cleaner
EPA Reg. No.: 5741-18
Notification Date: October 26, 2009
EPA Receipt Date: November 2, 2009

Dear Mr. Cook,

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

Proposed Notification

Adding 2009 H1N1 Marketing Claims

General Comments

Based on a review of the submitted materials, your notification to add 2009 H1N1 Marketing Claims in accordance with the Agency guidance for testing labeling claims against Pandemic 2009 H1N1 Influenza A (Formerly called Swine Flu) is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)

Regulatory Management Branch I
Antimicrobial Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other (checked)

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 5741-18
2. EPA Product Manager: Velma Noble
3. Proposed Classification: None (checked), Restricted
4. Company/Product (Name): NABC Non-Acid Disinfectant Bathroom Cleaner
PM#: 31
5. Name and Address of Applicant: Spartan Chemical Company, Inc.
6. Expedited Review: EPA Reg. No., Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. 'Me Too' Application. Other - Explain below.

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

Notification of Additional Influenza A virus per PR Notice 95-2. Addition of Pandemic 2009 H1N1 Influenza A Claim. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product.

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container: Metal, Plastic, Glass, Paper, Other. 3. Location of Net Contents Information: Label, Container. 4. Size(s) Retail Container. 5. Location of Label Directions: On Label, On Labeling accompanying product. 6. Manner in Which Label is Affixed to Product: Lithograph, Paper glued, Stenciled, Other.

Section - IV

1. Contact Point: Name: Ronald T. Cook, Title: Mgr, Regulatory Affairs, Telephone No.: 800-537-8900. Certification: I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. 2. Signature: Ronald T. Cook, 3. Title: Mgr, Regulatory Affairs, 4. Typed Name: Ronald T. Cook, 5. Date: 10/26/2009, 6. Date Application Received (Stamped):



Spartan Chemical Company, Inc.
Manufacturer of Guaranteed Specialty Maintenance Products

October 26, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Attn: Velma Noble PM/31

Subject: NABC Non-Acid Disinfectant Bathroom Cleaner
EPA Reg. No. 5741-18
**Notification of Additional Influenza A virus per PR Notice 95-2
Addition of Pandemic 2009 H1N1 Influenza A Claim**

Dear Ms. Noble,

Spartan Chemical Company, Inc. would like to amend the registration of the above product as follows:

- Addition of Pandemic 2009 H1N1 Influenza A Claims by notification per "Guidance for Testing and Labeling Claims Against Pandemic 2009 H1N1 Influenza A Virus" (10-22-2009)

Please note: This product currently has an efficacy claim against Influenza A2/ Hong Kong. The MRID Number for the study is 00128866.

To support this action, the following items are being submitted:

- One (1) copy of the Application for Pesticide Amendment
- One (1) copy of the revised label with the 2009 H1N1 Influenza A claims highlighted.

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions regarding this submission, please contact me at 800-537-8990.
Thank you for your assistance.

Sincerely,
SPARTAN CHEMICAL COMPANY, INC.

Ronald T. Cook
Manager, Regulatory Affairs

cc: William Schalitz



Front Copy:

NABC

Non-Acid Disinfectant Bathroom Cleaner

Ready-To-Use

Disinfects, Cleans, Deodorizes

Effective against Antibiotic-Resistant Bacteria*

Staphylocidal/Pseudomonicidal/Salmonellacidal/Virucidal**

Virucidal** Disinfectant Cleaner

Cleans as it Disinfects

RTU Handi Spray

Kills Staphylococcus aureus, Pseudomonas aeruginosa and Salmonella choleraesuis

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 (formerly called swine flu).

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

Kills Pandemic 2009 H1N1 influenza A virus.

ACTIVE INGREDIENTS:

Alkyl (C₁₄-50%, C₁₂-40%, C₁₆-10%)

dimethyl benzyl ammonium chloride..... 0.16%

Octyl decyl dimethyl ammonium chloride..... 0.12%

Diocetyl dimethyl ammonium chloride..... 0.06%

Didecyl dimethyl ammonium chloride..... 0.06%

INERT INGREDIENTS: 99.60%

(Includes compatible cleaning agents, solvent and deodorizer)

*Kills Methicillin resistant Staphylococcus aureus (MRSA) and Vancomycin resistant Enterococcus faecalis (VRE)

**Kills Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), kills Herpes simplex Type 2 and Influenza A₂/Hong Kong viruses on hard, inanimate nonporous environmental surfaces.

Keep Out of Reach of Children

CAUTION

See rear panel for additional precautionary statements.

(Note to EPA: Optional Graphics)



(Avoid Contact With Eyes) (Keep Out of Reach of Children)

FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, OH 43537

NET CONTENTS: 5 U.S. Gallons/18.95 Liters (5-gallon pail copy)

NET CONTENTS: 1 U.S. Gallon/3.79 Liters (gallon jug copy)

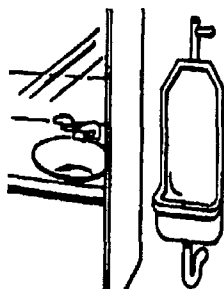
NET CONTENTS: 32 Fl. Oz. (One Quart)/0.946 Liters

Back Side Copy:

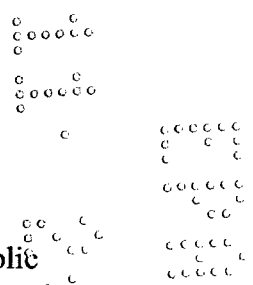
NABC is a ready-to-use, non-acid formulation designed to disinfect, clean and deodorize toilet bowls, urinals, and similar hard, nonporous bathroom surfaces. Formulated for use in daily maintenance programs, NABC is a proven one-step cleaner-disinfectant in the presence of moderate amounts of organic soil.

NABC is recommended for use in hotels and motels, hospitals, office buildings, schools, public buildings, restaurants...any commercial, institutional or industrial building with lavatory facilities.

(Note to EPA: Optional Graphic of Urinal and Bathroom Surfaces)



NABC is designed for use in hotels and motels, hospitals, office buildings, schools, public buildings, restaurants...any commercial, institutional or industrial facility where a clean and sanitary environment is important. Use NABC to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, countertops, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets.



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.

One-Step Disinfecting and Cleaning Toilet Bowls and Urinals:

Remove gross filth before disinfection. Empty toilet bowl or urinal and apply product to exposed surfaces with a brush or swab mop. Brush or swab thoroughly, especially under the rim. Let stand for 10 minutes, then flush.

One-Step Disinfecting Ceramic Tile, Porcelain, Shower Walls, Floors and Other Hard Nonporous Surfaces:

Remove gross filth before disinfection. Apply NABC with a cloth, mop, sponge or coarse sprayer. Treated surfaces must remain wet for 10 minutes. Rinse thoroughly with water.

General Deodorizing and Cleaning:

Dilute NABC 1:10 (12 oz./gal. of water) for general deodorizing and cleaning of hard, nonporous bathroom surfaces.

Disinfection and Cleaning: Remove gross filth before disinfection. Apply NABC with a cloth, mop, sponge or coarse sprayer. Treated surfaces must remain wet for 10 minutes. Wipe off with a damp cloth or rinse with water. This product will not leave grit or soap scum.

****KILLS HCV, HBV AND HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care 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 Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

Special Instructions for Cleaning and Decontamination Against HCV, HBV and HIV on Surfaces or Objects Soiled with Blood or 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 the disinfectant.

Contact Time: Leave surfaces wet for 10 minutes.

Disposal of Infectious Material: Contaminated cleaning materials, blood and other body fluids should be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

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

(NOTE TO EPA -The following text will be used on five gallon pails and larger containers only)

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 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 contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.

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 one gallon and smaller containers only)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in a cool, dry place.

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

