

5741-18

11-20-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV 20 2002

Subject: NABC  
EPA Registration No. 5741-18  
Application Date: 5/23/02  
Receipt Date: 5/29/02

Dear Mr. Cook:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Add efficacy claim against Hepatitis C Virus (HCV)

GENERAL COMMENTS

The proposed label claims (as supported by MRID Nos. 456858-01 and -02) may be acceptable regarding the use of the product, NABC, as a virucide against Hepatitis C virus in the presence of a 5% organic soil load (serum) on hard, non-porous surfaces for a contact time of 10 minutes. Confirmatory testing was performed under a different study director and provided similiar results with apparent product efficacy. The confirmatory study used one lot of product, not the standard two. Although the product demonstrated at least a 3-log reduction beyond the cytotoxic level, a few minor modifications regarding specific procedural details must be submitted to the Agency:

1. Request information on the specific virus strain and specific cell culture line identification used in the two studies (only the source was identified).
2. Obtain a more detailed description of the challenge BVDV strain, concerning its virus stock preparation, susceptibility to BVDV, and the rationale for its selection over candidate cell lines.
3. Obtain an explanation why only 0.5 ml of the virus-disinfection mixture is neutralized when using a column instead of the full 2.0 ml recovered from the plate.

4. Obtain a complete description of the infectivity assay using immunofluorescence.

SYMBOL	7510C						
SURNAME	3. Jones						
DATE	11-19-02						

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A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments regarding this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble  
Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)



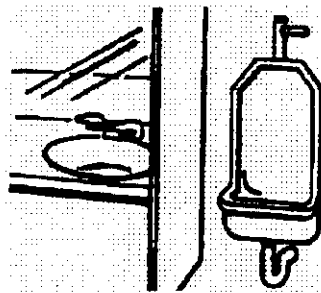
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**Back Side Copy:**

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)*



ACCEPTED  
with COMMENTS  
in 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. 5741-18

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 preclean 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.

Master Label for NABC  
EPA Reg. No. 5741-18  
Spartan Chemical Company, Inc.  
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Under the Federal Insecticide,  
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**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-1 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.

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<b>FIRST AID</b>	
<b>If in eyes:</b>	-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.
<b>If on skin or clothing:</b>	-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.
<b>24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171</b> 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)*

<b>STORAGE AND DISPOSAL</b>
Do not contaminate water, food, or feed by storage or disposal. <b>Pesticide Storage:</b> Store in original container in a cool, dry place. <b>Container Disposal:</b> Securely wrap original container in several layers of newspaper and discard in trash.

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

<b>STORAGE AND DISPOSAL</b>
Do not contaminate water, food, or feed by storage or disposal. <b>Pesticide Disposal:</b> Waste resulting from use of this product may be disposed of on site or at an approved waste disposal facility. <b>Container Disposal:</b> Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537  
Questions? 800-537-8990/ [www.spartanchemical.com](http://www.spartanchemical.com)

*(NOTE TO EPA: The following is an optional phrase)*

Fax On Demand Material Safety Data Sheet: 888-383-4666, No. (XXXX)

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