

5741-20

11-20-2002

47

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: DMQ
EPA Registration No. 5741-20
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. 456842-01 and -02) may be acceptable regarding the use of the product, DMQ, 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 and at a 1:64 dilution. Confirmatory testing was performed under a different study director and provided similar results with apparent product efficacy. Although the product demonstrated complete inactivation of the virus, 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 and titration..
3. Obtain a full description of the host cell line (MDBK) including its preparation, susceptibility to BVDV, and the rationale for its selection over other candidate cell lines.
4. 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.

CONCURRENCES

SYMBOL	7510C						
SURNAME	J. J. ...						
DATE	11-19-02						

5. Obtain a complete description of the infectivity assay using immunofluorescence.
6. Review the preparation of the data consistency control (Bardac 2280) to determine if sufficient independence was displayed between the two assays.

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 concerning this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



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

3/7

Master Label for DMQ: (DMQ Master Label 11)
EPA Reg. No. 5741-20
Spartan Chemical Company, Inc.
(Submitted to the EPA 5-23-2002)

Front Copy

DMQ®

Damp Mop Neutral Disinfectant Cleaner

Non-Acid Disinfectant Bathroom Cleaner

Clean on the Go® 1

For use only with Spartan Clean on the Go dispenser.

Non-alkaline germicidal cleaner concentrate specially designed to clean and disinfect high gloss floors!

Non-acid germicidal cleaner concentrate specially designed to clean and disinfect toilet bowls and restroom surfaces!

Bactericide/Virucide*

Effective against Antibiotic-Resistant Bacteria**

Kills Staphylococcus aureus, Pseudomonas aeruginosa and Salmonella choleraesuis.

*Kills Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Herpes simplex Type 2 and Influenza A₃/Hong Kong viruses on hard, nonporous inanimate surfaces.

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

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.

5741-20

ACTIVE INGREDIENT:	
Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%)	
dimethyl benzyl ammonium chlorides.....	4.50%
INERT INGREDIENTS:	95.50%

E.P.A. Reg. No. 5741-20
E.P.A. Est. No. 5741-OH-1

Keep Out of Reach of Children
DANGER
See side panel for additional precautionary statements.

FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY
SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 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: 2 Liters/67.6 Fl. Oz. (2 liter jug copy)

4/7

Back Side Copy

DMQ®

Damp Mop Neutral Disinfectant Cleaner

Non-Acid Disinfectant Bathroom Cleaner

DMQ retains the beauty of high gloss floors with the added effectiveness of a disinfectant!

DMQ is recommended to clean, disinfect and deodorize floors, walls, countertops and other hard, non-porous environmental surfaces in hospitals, schools, hotels, manufacturing sites/facilities, restaurants, bars, cafeterias and food processing plants.

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

DMQ provides 700 ppm of quaternary germicide at use-dilution.

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 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.

One-Step Cleaning and Disinfecting Toilet Bowls and Urinals

1. Remove water from the bowl by forcing it over the trap with a swab mop.
2. Liberally apply DMQ at 2 oz. per gallon of water to the exposed surfaces. Swab the exposed surfaces including under the rim.
3. Allow DMQ to remain wet on surfaces for 10 minutes.
4. Flush toilet or urinal and rinse swab mop thoroughly.

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5/7

Master Label for DMQ (DMQ Master Label 11)

EPA Reg. No. 5741-20

Spartan Chemical Company, Inc.

(Submitted to the EPA 5-23-2002)

Bactericidal and Virucidal* Activity

One-Step Cleaning and Disinfecting Hard, Non-Porous Surfaces:

For one-step cleaning and disinfecting in the presence of 5% organic soil use DMQ at 2 oz. per gallon of water.

Apply with a mop, cloth or spray device.

Treated surface must remain wet for 10 minutes.

Wipe off with a clean cloth or paper towel.

Rinsing of floors is not necessary except before application of a floor finish or polish.

Preliminary cleaning is required for heavily soiled areas.

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinsed with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes, or cookware.

***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/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 PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of DMQ.

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.

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6/7

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Harmful if absorbed through the skin. Harmful if swallowed. Do not get in eyes, skin or on clothing. Wear protective eye wear (goggles/face shield/safety glasses) 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 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:
-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 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 to do so by a poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

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 PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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7/7

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(NOTE TO EPA -The following text will be used on one gallon and smaller containers only)

<p>STORAGE AND DISPOSAL</p> <p>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.</p>
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(NOTE TO EPA -The following text will be used on five gallon pails and larger containers only)

<p>STORAGE AND DISPOSAL</p> <p>Do not contaminate water, food, or feed by storage or disposal. Pesticide Storage: Store in original container in a cool, dry place. 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: 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.</p>

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537
Questions? 800-537-8990/ 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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