

5741-2

8-18-2003

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 18 2003

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

Subject: Sterigent
EPA Registration No. 5741-2
Amendment dated: May 20, 2003
EPA Received date: May 21, 2003

Dear: Mr. Ronald T. Cook,

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

Proposed Amendment

- Response to PR Notice 2001-1 Update First Aid Statement

Conditions

Revise the label as follows:

1. Revise the Precautionary Language

"Corrosive, Causes irreversible eye damage and skin burns. Harmful if absorbed through the skin and if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, safety glasses) rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse."

CONCURRENCES

SYMBOL	7510(c)						
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2. Add the following Environmental Hazards Statement for product packages in containers equal to or greater than 5 gallons.

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water 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.

3. Storage and Disposal (five gallon or larger containers) add the following statement

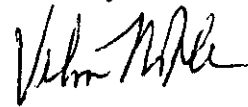
"Pesticide Storage: Store in original container in a cool, dry place"

General Comments

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (7510c)

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Sterigent Germicidal Cleaner

EPA Reg. No. 5741-2

Spartan Chemical Company, Inc. (Submitted 5/20/2003)

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Front Label Copy

Block "S" logo

Sterigent
Germicidal Cleaner

A Heavy Duty Cleaner and Disinfectant
for Hospital and Institutional Use

(Note to EPA: *This statement is optional*)

Original Fragrance

(Note to EPA: *This statement to be used with alternate perfume*)

Fresh Scent!

Staphylocidal / Pseudomonocidal / Salmonellacidal / Deodorizer

ACTIVE INGREDIENTS:

n-Alkyl (C₁₄ - 50%, C₁₂ - 40%, C₁₆ - 10%)
dimethyl benzyl ammonium chlorides 4.5%

INERT INGREDIENTS: 95.5%

Total 100.0%

EPA Reg. No. 5741-2

EPA Est. No. 5741-OH-1

DANGER: KEEP OUT OF REACH OF CHILDREN
See back panel for additional precautionary statements.

FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY

Spartan Chemical Company, Inc., 1110 Spartan Drive,
Maumee, Ohio 43537

NET CONTENTS: 1 U.S. Gallon/3.79 Liters (gallon screen only)

NET CONTENTS: 5 U.S. Gallons/18.95 Liters (pail screen only)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 18 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 5741-2

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Sterigent Germicidal Cleaner

EPA Reg. No. 5741-2

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Back Label Copy:

Sterigent Germicidal Cleaner

A proven one-step cleaner disinfectant in the presence of moderate amounts of organic soil, Sterigent is a quaternary based germicidal cleaner designed for use on a wide range of surfaces such as floors, walls, countertops, sinks and showers.

Sterigent has been specially formulated with low alkalinity so that when used as directed, it will not harm non-porous environmental surfaces.

Sterigent is effective against the pathogenic bacteria *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella choleraesuis* even in the presence of organic soil!

Sterigent is recommended for use in hospitals, nursing homes, restaurants, schools, hotels...and other commercial, institutional or industrial facilities 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 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.

DISINFECTION:

For one-step cleaning and disinfecting of walls, floors and other hard non-porous surfaces, use Sterigent at 3 oz. per gallon of water (1:43). Apply with a mop, cloth or spray device.

Treated surfaces 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.

Prepare fresh solution for each application. For heavily soiled surfaces, a preliminary cleaning is required.

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Sterigent Germicidal Cleaner

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Deodorization:

When used as directed for cleaning and disinfecting (3 oz. Sterigent per gallon of water), this solution will effectively eliminate noxious odors.

PRECAUTIONARY STATEMENTS

Hazard 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.

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 five 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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Sterigent Germicidal Cleaner

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(Note to EPA: The following text will be used on five gallon pails and larger containers only.)

STORAGE AND DISPOSAL

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

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.

(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.

(Note to EPA: The following is an optional phrase)

Guarantee: Spartan's modern manufacturing and laboratory control insure uniform quality. If dissatisfied with performance of product, any unused portion may be returned for credit within one year of the date of manufacture. Use product as directed and read all precautionary statements.

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

(Note to EPA: The following is an optional phrase)

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