5741-6

5/9/2003



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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

May 9, 2003

Mr. Robert MacDonald SRC Scientific & Regulatory Consultants, Inc. The agent for SPARTAN CHEMICAL COMPANY, INC. P. O. Box 1041 Columbia City; IN 46725

Subject:

PD-64 Phenolic Base Cleaner and Disinfectant EPA Registration Number 5741-6 Application Date: May 6, 2003 Receipt Date: May 6, 2003

Dear Mr. MacDonald:

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

Proposed Amendment:

- Add claims for control of odor causing bacteria
- Revised first aid statements per PR Notice 2001-1

General comment:

1. The first aid statement and the precautionary statement must be placed in separate boxes.

2. Since this product will be used in hospitals and other health facilities, the following statement must be added to the label. Refer to PR Notice 94-4 for detailed information:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surfaces 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." 3. Add the word "*Automotive*" prior to the subheading so that it reads:

"Automotive Air Conditioning Cooling Coils"

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,

Adam Heyward

Product Manager (34) Regulatory Management Branch II Antimicrobial Division (7510C)

enclosure:

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(PD-64 DRAFT MASTER LABEL COPY)

SRU

Block "S" Logo with [®] PD-64TM Phenolic Base Cleaner and Disinfectant Tuberculocide/Bactericide/Cleaner/Deodorizer

Active Ingredient: Ortho-phenylphenol......6.13% Other Ingredients:.......93.87% Total 100%

KEEP OUT OF REACH OF CHILDREN CAUTION

See rear panel [outer box] [enclosure] for [directions for use and] additional precautionary statements.

For Institutional, Industrial and Professional Service Technicians Use Only {optional statement if only air conditioning use pattern is on the marketing label}

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

EPA Reg. No. 5741-6 EPA Est. No. 5741-OH-1

Net Contents: [0.06 ounces]

[1 U.S. Gallon/3.79 Liters] [5 U.S. Gallons/18.95 Liters] [15 U.S. Gallons/15.85 Liters] [30 U.S. Gallons/113.7 Liters] [55 U.S. Gallons/208.45 Liters] ACCEPTED with COMMENTS

- EPA Lotter Dated:

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Under the Federal Insecticide, Fungicide, and Rocanticide Act as amended, for the pesticide, registered under EPA Reg. No. 5741-6

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PD-64TM

Phenolic Base Cleaner and Disinfectant

PD-64 is recommended to clean, disinfect and deodorize floors, walls, countertops and other hard, non-porous surfaces in hospitals, schools, hotels or any commercial, industrial or institutional facility where a clean and sanitary environment is important. Controls odors originating from air conditioning cooling coils.

SR.

Directions for Use:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Before disinfecting, the surface must be free of gross filth or heavy soil. Thoroughly clean the surface with a solution of PD-64 at 2 oz. per gallon of water.

General Disinfection:

Apply PD-64 at 2 oz. per gallon water to a pre-cleaned surface with a mop, cloth or coarse spray device.

Treated surface must remain wet for 10 minutes.

Tuberculocidal Activity:

PD-64 is tuberculocidal under the above conditions in 10 minutes at 68°F (20°C).

Air Conditioning Cooling Coils

Controls odor-causing bacteria associated with odors originating from cooling coils in air conditioning systems. Do not use in air ducts, ductwork, or associated portions of these systems.

FOR USE ONLY BY PROFESSIONAL SERVICE TECHNICIANS OR TRAINED INSTITUTIONAL MAINTENANCE STAFF.

INDIVIDUALS APPLYING PRODUCT MUST USE EYE PROTECTION, RUBBER GLOVES, AND PROTECTIVE CLOTHING

NO OCCUPANTS ARE ALLOWED IN THE VEHICLE DURING PRODUCT APPLICATION IN AUTOMOBILES (statement included ONLY on market labels with the automobile use pattern.)

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PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION

Harmful if swallowed. Causes moderate eye initation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

If swallowed

First Aid

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

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 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 1-888-314-6171. Have product container or label with you when seeking medical advice or treatment.

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STORAGE AND DISPOSAL

{For one gallon or less}

Do not reuse empty container. Wrap container and put in trash.

{For packaging > one gallon: }

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 instruction, 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.

{For sizes 5 gallons or more}

ENVIRONMENTAL HAZARD Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirments 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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Automotive { this heading is optional if no other use patterns are on the label }

1. Mix 1 part (0.06 ounces) of PD-64 concentrate with 64 parts (4 ounces) of water. (the ounces of product and water may vary depending on the final package size chosen but the ratio will remain 1:64}

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2. Screw the bottle of the above mixture on the applicator tool.

3. Connect the assembled applicator tool to the shop compressed air supply line.

4. Verify that the blower speed is on HIGH – AC, mode switch is on PANEL OUTLETS, temperature switch is on FULL COLD, recirculation switch is on FRESH AIR, all windows in vehicle are OPEN and ignition switch is set to RUN (do not start engine) to allow blower motor operation.

5. Insert the applicator tool into the cowl inlet.

6. Spray the full contents of the bottle into the air stream continuously until the bottle is empty.

7. Turn the ignition switch OFF.

8. Let the vehicle sit for a minimum of 30 minutes.

9. Turn the ignition switch ON (do not start engine), to allow blower motor operation.

10. Repeat steps 1-10 as needed until odor is no longer detected then proceed to next step.

11. Fill the applicator bottle with normal tap water.

12. Screw the bottle of water onto the applicator tool.

13. Turn the ignition switch ON (do not start engine), to allow blower motor operation.

14. Insert the applicator tool into the cowl inlet.

15. Inject all water in applicator bottle.

16. Turn the ignition switch off.

Industrial, Commercial and Residential {this heading is optional if no other use patterns are on the label }

Use as an intermittent flush treatment during regular maintenance/cleaning of air conditioning units. Before use shut off unit, then remove visible debris and built-up contamination using PD-64 (2 ounces per gallon water) or a suitable industrial cleaner and rinse according to directions with clean water.

1. Mix 2 ounces of PD-64 concentrate per gallon of water.

2. Apply by coarse spray so as to thoroughly flush cooling coil and other parts that are normally wet during operation of the system.

3. Let the unit sit idle for a minimum of 30 minutes.

4. Rinse unit thoroughly with normal tap water.

5. Turn unit back on.