

US EPA ARCHIVE DOCUMENT

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW

ANTIMICROBIAL PROGRAM BRANCH

IN 09/29/95 OUT 10/30/95

EPA Reg. No. or File Symbol 8383-3

LAN Code 8383-3.125

Date Division Received 06-15-95

Type Product Hospital Disinfectant

MRID No (s) None

Product Manager PM 31 (Douglas)

Product Name Sporicidin Brand Disinfectant Solution

Company Name Sporicidin International

Submission Purpose Amendment to delete the previously accepted "TO CLEAN AIR DUCTS" language and substitute an air duct sanitizing claim. No other changes have been made to the previously accepted label except that "lensed instruments" has been added to the indications for use on the back panel as requested in amendment submitted September 19, 1994, and "Directions for Use" replaced "Directions" per your comments in the June 5, 1995 acceptance letter.

Type Formulation Liquid

Active Ingredient (s): %

Phenol.....1.56

Sodium Phenate.....0.06

Recommendations (see next page)

Labeling:

1. Delete the term "lensed instruments". It is too general. It includes endoscopy equipment. Only FDA approved liquid sterilants may be used to disinfect endoscopy equipment.
2. The request to include an air duct sanitizing claim cannot be accepted. It is currently accepted only for volatile products that leave no residue. Prior to approval of this use pattern for a phenolic product, OPP's Health Effects Division must make a hazard assessment on building occupants from prolonged inhalation of dried phenolic residues remaining in the air ducts after treatment.

Z.Vaituzis 12-26-95

Reviewed by Srinivas Gowda Date 10/30/95

SPORICIDIN BULLETIN NO. 302
(EPA Reg. No. 8383-3)

FOR SANITIZING AIR DUCTS
with
SPORICIDIN BRAND DISINFECTANT SOLUTION

Directions for Use:

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

Recommended for professional application by trained individuals.

Sporicidin Brand Disinfectant Solution has been shown to be an effective hospital disinfectant when tested by AOAC and EPA test methods. In air duct systems, disinfectants may not totally eliminate all vegetative microorganisms due to the construction and/or design of the ducts. Sporicidin Brand Disinfectant Solution can sanitize air ducts by reducing the number of microorganisms to acceptable levels when used as directed.

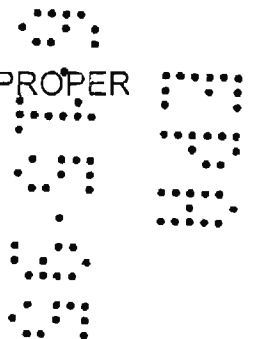
The surfaces of the ducts must be cleaned and allowed to dry prior to the application of the product. When the size or configuration of the ducts do not permit regular surface application, the sanitizing solution may be applied by "fogging" or atomizing the solution thru the duct system. Exhaust for the process should always be from the interior of the structure to the outside environment.

Allow to dry after application.

Precautions:

- Avoid skin contact: Prolonged contact may cause skin irritation. Flush thoroughly with water after contact.
- Avoid eye contact. Causes eye irritation. In case of contact, flush with water immediately. Consult a physician if necessary.
- Avoid food contamination.

RINSE EMPTY CONTAINER THOROUGHLY WITH WATER. DISPOSE OF IN PROPER RECEPTACLE.



FRONT PANEL

DISINFECTANT SOLUTION (PUMP SPRAY)

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant Solution

Continuous Residual Activity
for Over 6 Months*

ACTIVE INGREDIENTS:

Phenol 1.56%
Sodium Phenate 0.06%

INERT INGREDIENTS: 98.38%

Solution is alkaline, pH 7.9-8.6

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL
- ELIMINATES ODORS*
- PREVENTS MOLD AND MILDEW

Keep Out of Reach of Children

CAUTION:

See additional precautions on back panel

EPA Reg. No. 8383-3

Net Wt. 22 fl. oz. (651 ml)

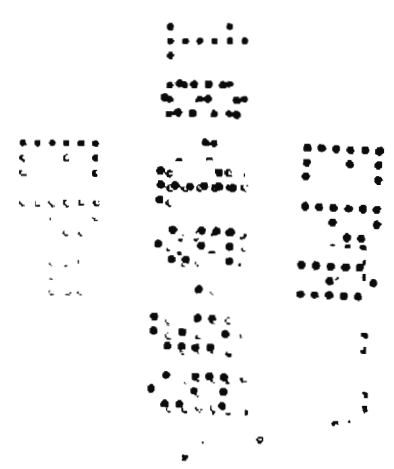
ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 5 1995

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

8383-3

~~NO CHANGE~~



HOSPITAL DISINFECTION

An effective disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT. Acts effectively on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on lensed instruments, medical equipment and beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers, damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on environmental surfaces.

ACTIVE DEODORIZER. *It provides continuous residual bacteriostatic activity against odor-causing organisms, for over 6 months in the presence of adequate moisture if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- ◆ Kills Athlete's Foot fungus on bathroom, shower, and pool surfaces.
- ◆ Self-sanitizes surfaces against odor-causing bacteria.
- ◆ Penetrates cracks.
- ◆ Non-staining
- ◆ Contains no harmful abrasives.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporicidin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION. Tested against *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli*. **Herpes simplex types 1 and 2 (oral and genital), Influenza A₂ (Japan 305/57 Asian strain), Vaccinia, and Polio type 1 viruses. HIV-1 (AIDS virus) on environmental surfaces, Trichophyton mentagrophytes (Athlete's Foot fungus) and *Mycobacterium tuberculosis* on environmental surfaces.

DIRECTIONS FOR USE:

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

PRECLEAN surface to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Ensure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above).

NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

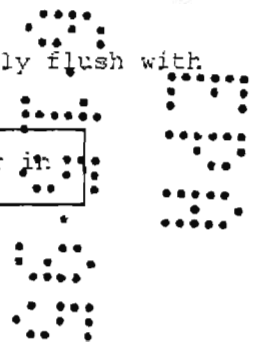
FOR FOGGING CLEAN ROOMS: See Sporicidin Bulletin No. 301.

TO SANITIZE AIR DUCTS: See Sporicidin Bulletin No. 302.

NOTE: 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.

CAUTION: Avoid direct contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.



OLD LABEL

BACK PANEL

DISINFECTANT SOLUTION (PUMP SPRAY)

HOSPITAL DISINFECTION

An effective disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

lensed instruments,
DISINFECTANT. Acts effectively on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical equipment and beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers, damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on environmental surfaces.

ACTIVE DEODORIZER. *It provides continuous residual bacteriostatic activity against odor-causing organisms, for over 6 months in the presence of adequate moisture if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- ♦Kills Athlete's Foot fungus on bathroom, shower, and pool surfaces.
- ♦Self-sanitizes surfaces against odor-causing bacteria.
- ♦Penetrates cracks.
- ♦Non-staining.
- ♦Contains no harmful abrasives.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporidicin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION. Tested against Staphylococcus aureus, Streptococcus pyogenes, Streptococcus salivarius, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli, **Herpes simplex types 1 and 2 (oral and genital), Influenza A₂ (Japan 305/57 Asian strain), Vaccinia, and Polio type 1 viruses. HIV-1 (AIDS virus) on environmental surfaces, Trichophyton mentagrophytes (Athlete's Foot fungus) and Mycobacterium tuberculosis on environmental surfaces.

for use:
DIRECTIONS

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

PRECLEAN surface to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Ensure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above).
NOTE: See Sporidicin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporidicin Bulletin No. 301.

TO CLEAN AIR DUCTS: Manually apply to hard non-porous precleaned duct surfaces. Rinse surfaces after application.

deleted added
TO SANITIZE AIR DUCTS: See Sporidicin Bulletin No. 302.

NOTE: 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.

CAUTION: Avoid direct contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL; Store at room temperature. Discard empty container in regular trash.

with COMMENTS
in EPA Letter Dated:

SPORICIDIN INTERNATIONAL

JUN 5 1995

5901 Montrose Road
Rockville, MD 20850

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

9383-3

FRONT PANEL

DISINFECTANT SOLUTION (PUMP SPRAY)

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant Solution

Continuous Residual Activity
for Over 6 Months*

ACTIVE INGREDIENTS:

Phenol 1.56%
Sodium Phenate 0.06%

INERT INGREDIENTS: 98.38%

Solution is alkaline, pH 7.9-8.6

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL
- ELIMINATES ODORS*
- PREVENTS MOLD AND MILDEW

Keep Out of Reach of Children

CAUTION:

See additional precautions on back panel

EPA Reg. No. 8383-3

Net Wt. 22 fl. oz. (651 ml)

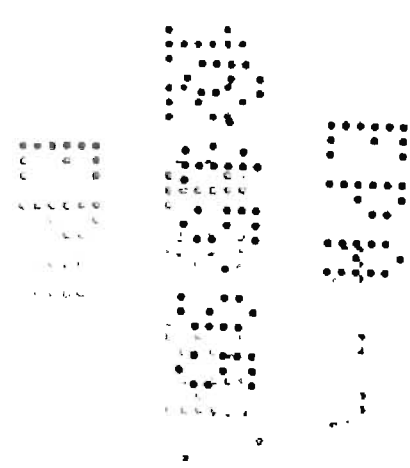
ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 5 1995

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

8383-3

NO CHANGE



HOSPITAL DISINFECTION

An effective disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT. Acts effectively on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on lensed instruments, medical equipment and beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers, damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on environmental surfaces.

ACTIVE DEODORIZER. *It provides continuous residual bacteriostatic activity against odor-causing organisms, for over 6 months in the presence of adequate moisture if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- ◆ Kills Athlete's Foot fungus on bathroom, shower, and pool surfaces.
- ◆ Self-sanitizes surfaces against odor-causing bacteria.
- ◆ Penetrates cracks.
- ◆ Non-staining
- ◆ Contains no harmful abrasives.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporcidin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION. Tested against *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli*. **Herpes simplex types 1 and 2 (oral and genital), Influenza A₁ (Japan 305/57 Asian strain), Vaccinia, and Polio type 1 viruses. HIV-1 (AIDS virus) on environmental surfaces, Trichophyton mentagrophytes (Athlete's Foot fungus) and *Mycobacterium tuberculosis* on environmental surfaces.

DIRECTIONS FOR USE:

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

PRECLEAN surface to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Ensure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above).
NOTE: See Sporcidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

FOR FOGGING CLEAN ROOMS: See Sporcidin Bulletin No. 301.

TO SANITIZE AIR DUCTS: See Sporcidin Bulletin No. 302.

NOTE: 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.

CAUTION: Avoid direct contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

Sporcidin International

5901 Montrose Road
Rockville, MD 20852

SPORICIDIN BULLETIN NO. 302
(EPA Reg. No. 8383-3)

FOR SANITIZING AIR DUCTS
with
SPORICIDIN BRAND DISINFECTANT SOLUTION

Directions for Use:

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

Recommended for professional application by trained individuals.

Sporicidin Brand Disinfectant Solution has been shown to be an effective hospital disinfectant when tested by AOAC and EPA test methods. In air duct systems, disinfectants may not totally eliminate all vegetative microorganisms due to the construction and/or design of the ducts. Sporicidin Brand Disinfectant Solution can sanitize air ducts by reducing the number of microorganisms to acceptable levels when used as directed.

The surfaces of the ducts must be cleaned and allowed to dry prior to the application of the product. When the size or configuration of the ducts do not permit regular surface application, the sanitizing solution may be applied by "fogging" or atomizing the solution thru the duct system. Exhaust for the process should always be from the interior of the structure to the outside environment.

Allow to dry after application.

Precautions:

- Avoid skin contact: Prolonged contact may cause skin irritation. Flush thoroughly with water after contact.
- Avoid eye contact. Causes eye irritation. In case of contact, flush with water immediately. Consult a physician if necessary.
- Avoid food contamination.

RINSE EMPTY CONTAINER THOROUGHLY WITH WATER. DISPOSE OF IN PROPER RECEPTACLE.

