

11/17/2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

56782-1

1/6

Carol Chapin
Environmental & Regulatory Coordinator
Sunshine Makers, Inc.
15922 Pacific Coast Hwy.
Huntington Beach, CA 92649

NOV 17 2003

Subject: Simple Green d
EPA Registration Number 56782-1
Application Date: August 15, 2003
Receipt Date: August 20, 2003

Dear Ms. Chapin,

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

- Revision of Master Label as per PR Notice 2001-1

Conditions

Revise the label as follows:

Make the following corrections to the third page of the label:

1. Revise the first frame to read: "...washable *hard* non-porous surfaces...stainless steel, chrome, *bedframes, bedpans, gurneys, wheelchairs*, glazed tile and porcelain, aluminum, glass..." such that your surfaces are in agreement with other text on your label and to delete "fiberglass" which is a porous surface.

In a future submission you may add fiberglass to the label by associating it with specific surfaces which are made of fiberglass and are by their nature hard non-porous such as shower stalls and bathtubs.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	J. Lopez						
DATE	11/17/03						

2. Revise the heading for the second frame to read: "The following statement is required if label lists use on medical equipment: bedframes, bedpans, gurneys, wheelchairs, or hospitals and stainless steel, chrome, or aluminum surfaces."

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy 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, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510C)

Enclosure: Stamped Label
 7510C:T.Lantz:11/14/03:56782-1d

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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MASTER LABEL FOR SIMPLE GREEN d® EPA REGISTRATION 56782-1

[FRONT PANEL - Only text inside frames would be printed on label.]

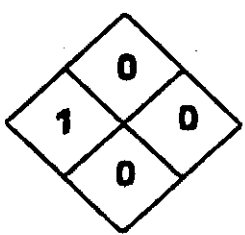
SIMPLE GREEN d® DISINFECTANT / VIRUCIDAL* CLEANER / DEODORIZER

When used according to label instructions, this product kills *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *HIV-1 on hard, nonporous surfaces.

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chloride	0.30%
Dioctyl dimethyl ammonium chloride	0.12%
Didecyl dimethyl ammonium chloride	0.18%
Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	0.40%
INERT INGREDIENTS	99.00%
TOTAL	100.00%

EPA Reg. No. 56782-1
EPA EST. No. 40873-CA-01
EPA EST. No. 40873-GA-01



Health = 1, REACTED
*Mild eye irritant
with butyl alcohol
in EPA Letter D-0001
Reactivity = 0, Special = 0
mutagenic, non-carcinogenic

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Under the Federal Insecticide,
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amended, for the pesticide,
registered under EPA Reg. No. 56782-1

KEEP OUT OF REACH OF CHILDREN.

CAUTION:
See back panel for additional precautionary statements.

OUNCES/MILLILITERS GALLONS/LITERS

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[BACK PANEL - only text inside frames would be printed on label.]

DISINFECTANT • VIRUCIDAL* • CLEANER • DEODORIZER

EFFICACY STATEMENT

*Kills HIV-1 (AIDS virus) on the precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare or other settings in which there is a 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 transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

DIRECTIONS FOR USE

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Clean up should always be done wearing protective latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

CONTACT TIME: Leave surface wet for 10 minutes.

DISPOSAL OF CONTAMINATED MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

For disinfecting & deodorizing: From full-strength to 10:1 solution – the maximum dilution ratio which can be used for disinfecting purposes is 10:1; Example: 1 gallon of water to 13 ounces of Simple Green d. 1. Pre-clean area to be disinfected and deodorized as instructed by the general cleaning directions below. 2. Apply Simple Green d with sponge, mop or coarse spray. 3. Wait for 10 minutes. 4. Rinse or wipe off. 5. When used on food contact surfaces, follow with potable water rinse. Cover or remove food if present. Do not use on drinking glasses, dishes, and eating utensils.

For general cleaning: 1. Mix 1:20 solution:
2. Apply to surface with sponge, mop or coarse spray.
3. Rinse or wipe off.

Simple Green d	
¼ Cup	5 Cups
6.5 ozs.	(1-gallon) 128 ozs.

For glass cleaning: Mix 1:150 solution (1 teaspoon of Simple Green d to 24 oz. spray bottle filled with water). Apply. Wipe dry.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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[BACK PANEL - continued]

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USES STATEMENT

Simple Green d can be used on washable, non-porous surfaces: floors, walls, counters, bathroom fixtures, rehabilitation, exercise and playground equipment, vehicle interiors and exteriors, linoleum, stainless steel, chrome, glazed tile and porcelain, ~~stainless steel~~, aluminum, glass, rubber, plastic and concrete in hospitals, clinics, convalescent facilities, locker rooms, athletic centers, hotels, motels, schools, garages, offices, homes, cafeterias and kitchens when food is not present.

[THE FOLLOWING STATEMENT IS REQUIRED IF LABEL LISTS USE ON MEDICAL EQUIPMENT: BEDFRAMES, BEDPANS, GURNEYS, OR WHEELCHAIRS]

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfecting.

STORAGE & DISPOSAL (For containers ≤ 1 gallon)

STORAGE AND DISPOSAL:

Store in original container in areas inaccessible to children and persons unfamiliar with the product. Do not reuse container. Discard in the trash.

STORAGE & DISPOSAL (For all containers > 1 gallon)

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage or disposal.
Pesticide Storage: Store in original container in areas inaccessible to children and persons unfamiliar with the product.
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 Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
Container Disposal: Do not reuse container. Triple rinse (or equivalent). Then offer for recycling or conditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

PRECAUTIONARY STATEMENTS & FIRST AID STATEMENTS

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals:
CAUTION. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

FIRST AID:

HAVE THE PRODUCT CONTAINER OR LABEL WITH YOU WHEN CALLING A POISON CONTROL CENTER OR DOCTOR, OR GOING FOR TREATMENT.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING: 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.

[BACK PANEL - continued]

ENVIRONMENTAL HAZARDS STATEMENT (For all containers)

ENVIRONMENTAL HAZARDS STATEMENT:

This product is toxic to fish. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment wash-water. Do not use on boats or other structures that come into direct contact with aquatic environments. 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.

COMPANY CONTACT INFO

Questions? Call toll free in the U.S. and Canada 1-800-228-0709
Made in the U.S.A.

©2003 Sunshine Makers, Inc., P.O. Box 2708, Huntington Beach, CA 92647
www.simplegreen.com

-END-

It is our intent to offer this label in two forms: English/Spanish and English/French. All verbiage would be directly translated and would be located side-by-side with its English equivalent. (11/06/03)

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