



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

SEP 12 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Sunshine Makers, Inc
15922 Pacific Coast Highway
Huntington Harbour, CA 92649

Attention: Bruce P. Fabrizio, President
John A. Todhunter, Agent

Subject: Simple Green d
EPA Registration No. 56782-1
Your Amendment Dated June 28, 1995

The amendment (adding packet, container labels) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Master Label).
 - a. Revise the heading: Federal EPA Reg No. to read: EPA Reg No.
 - b. Revise "Manufacturers EPA Reg No. 40873-CA-01" to read: "EPA Establishment No. 40873-CA-01"
 - c. Revise "Net" to read: "Net Contents".
 - d. Revise " Hazardous to Humans..." to read: "Hazards to Humans..."
 - e. Add the Heading: Directions for Use.
 - f. Place the following statements directly below the ingredient section:

KEEP OUT OF REACH OF CHILDREN
CAUTION

See back panel for additional precautionary statements

- g. The Storage and Disposal section are use directions and should be moved to another location on the label. The current location under the precautionary statements section is incorrect.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

h. The HIV use directions section is incomplete. Add the following subheading and statement:

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

i. Revise the statement "...surfaces sould be free of filth or heavy soil" to read: "...surfaces must be free of filth or heavy soil."

j. Revise the statement "... non-porous surfaces such as floors, wall..." to read: "...hard inanimate environmental nonporous surfaces such as floors, walls..."

k. Clearly indicate that the dilution for the section "Glass Surfaces" is for cleaning only.

2. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Container Label)

a. Delete "Packaged for and distributed by Marietta Corp". Since "Sunshine Makers" is the legal owner of this registration, only your company name can appear on these master file labels. Marietta is a distributor and their name must only appear on distributor labels, not on the labels for Sunshine Makers.

b. Revise "Establishment No. 046229-NY-001" to read: "EPA Establishment No. 46229-NY-1".

c. For consistency, revise the Inert Ingredients percentage to read: 99.00%

d. Add the following subheading: Container Disposal. Note that you can now place the following containers under this heading: empty packets, sealed packets, empty carton cases.

e. Add the following subheading: "Pesticide Disposal" to appear directly above the section titled: disposal of unused solutions.

f. Place the following statements directly below the ingredient section:

KEEP OUT OF REACH OF CHILDREN
CAUTION

See back panel for additional precautionary statements

g. Since not all the ingredients are biodegradable, delete the claim. The only claim which is permitted: Detergents within this product are biodegradable.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

h. The HIV use directions section is incomplete. Add the following subheading and statement:

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

i. Revise the statement "...surfaces sould be free of filth or heavy soil" to read: "...surfaces must be free of filth or heavy soil."

j. Revise the statement "... non-porous surfaces such as floors, wall..." to read: "...hard inanimate environmental nonporous surfaces such as floors, walls..."

k. The headings: Active Ingredients and Inert Ingredients must be of the same type size and be given equal prominence.

l. According to the data you submitted with your original application and based upon our calculations, in order to achieve the recommended dilution, the product must be adjusted accordingly.

Option # 1: Revise the Net contents of packet to read: 2.5 FL. Oz.

or

Option # 2: Revise the spray bottle size to read: 23 oz.

3. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Packet Label)

a. Delete "Packaged for and distributed by Marietta Corp". Since "Sunshine Makers" is the legal owner of this registration, only your company name can appear on these master file labels. Marietta is a distributor and their name must only appear on distributor labels, not on the labels for Sunshine Makers.

b. Revise "Establishment No. 046229-NY-001" to read: "EPA Establishment No. 46229-NY-1".

c. For consistency, revise the Inert Ingredients percentage to read: 99.00%

d. Revise "Net" to read: "Net Contents".

e. Add the Heading: Directions for Use.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

f. Place the following statements directly below the ingredient section:

KEEP OUT OF REACH OF CHILDREN
CAUTION

See back panel for additional precautionary statements

g. The Storage and Disposal section are use directions and should be moved to another location on the label. The current location under the precautionary statements section is incorrect.

h. Delete: Saves time and money. NOTE: Comparative claims are not permitted.

i. Revise the statement: "...in for detailed instructions for use..." to read: in for detailed directions for use..."

j. Delete the reference to "Case insert". NOTE: No case insert was provided with the labeling for review.

k. The headings: Active Ingredients and Inert Ingredients must be of the same type size and be given equal prominence.

l. According to the data you submitted with your original application and based upon our calculations, in order to achieve the recommended dilution, the product must be adjusted accordingly.

Option # 1: Revise the Net contents of packet to read: 2.5 FL. Oz.

or

Option # 2: Revise the spray bottle size to read: 23 oz.

4. Our records have been adjusted to reflect your product name change:

OLD PRODUCT NAME: Simple Green d Disinfectant

NEW PRODUCT NAME: Simple Green d

5. It has been noted that currently this company: SRS International is not an authorized agent of record for your company therefore this letter will only be sent to your attention and not to the author of this amendment.

If SRS International is to be Agent of Record, submit a copy of an Agent letter from your company designating SRS International as the Agent for this amendment.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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6. A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

7. A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

Marion Johnson
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Current d. label

simple green d[®]

Disinfectant • Virucidal* • Cleaner • Deodorizer

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

Kills HIV-1 (AIDS Virus) on the pretreated 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 human immunodeficiency virus Type 1 (HIV-1) (as associated with AIDS).

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

Personal Protection: Use barrier protection methods suitable for handling items soiled with blood or body fluids. Disposable latex gloves, masks, or eye coverings may be appropriate.
Cleaning Procedure: Surfaces for disinfection should be thoroughly cleaned of gross dirt, heavy soil, and blood and body fluids per the directions below, **FOR DISINFECTING**.
Decontaminate: Follow directions below, **FOR DISINFECTING**.

FOR DISINFECTING: From full strength up to 10:1 solution -- the maximum dilution ratio which can be used for disinfecting purposes is 10:1; example: 1 gallon of water to 10 ounces of Simple Green d. Simple Green d. as a disinfectant is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and Human Immunodeficiency Virus Type 1 (HIV-1 as associated with AIDS). Surface should be free of dirt or heavy soil. Apply Simple Green d. with sponge, mop or coarse spray, wet surface first if using full strength. Allow solution to remain 10 minutes. Rinse thoroughly. Prepare fresh mixture daily, or more often if solution becomes diluted or soiled.

GENERAL CLEANING: Mix 20:1 or greater for effective, economical general cleaning. Apply with sponge, mop, or coarse spray. Rinse.

GLASS SURFACES: Mix 150:1 solution. Apply. Rinse. Wipe dry.

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

PRECAUTIONARY STATEMENTS

HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS: CAUTION. Avoid contact with skin, eyes, or clothing. In case of contact, immediately flush eyes and skin with plenty of water. Get medical attention if irritation persists.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

STORAGE AND DISPOSAL: Rinse empty container thoroughly with water and recycle or discard. Do not contain/reuse water, food or feed by storage or disposal.

DISINFECTING SOLUTION
Fill to this line with Simple Green d.
Fill to bottom of bottle neck with tap water



REFILL BOTTLE
See bottom of back panel for instructions



CAUTION: KEEP OUT OF REACH OF CHILDREN

See back panel for additional precautionary statements.

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chloride	0.30%
Diocetyl dimethyl ammonium chloride	0.16%
Didecyl dimethyl ammonium chloride	0.15%
Alkyl (C ₁₄ 50%; C ₁₂ 40%; C ₁₆ 10%) dimethyl benzyl ammonium chloride	0.40%
INERT INGREDIENTS	99.00%

Federal EPA Reg. No. 56782-1

Manufacturer's EPA Reg. No. 40873-CA-01

40873-GA-01



Health - 1, Fire - 1, Reactivity - 1, Environment - 1
*Not applicable to this product.

Net 16 FL. OZ. (473 ml)

ACCEPTED
SEP 12 1995

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Health = 1* Fire = 0 Reactivity = 0 Special = 0
 *Mild eye irritant, non-mutagenic, non-carcinogenic

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

Active Ingredients

Octyl decyl dimethyl ammonium chloride.....	0.30%
Diocetyl dimethyl ammonium chloride.....	0.15%
Didecyl dimethyl ammonium chloride.....	0.15%
Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%)	
dimethyl benzyl ammonium chloride.....	0.40%
INERT INGREDIENTS:.....	99%

EPA Reg No. 56782-1 Establishment No. 046229-NY-001

Disinfectant • Virucidal • Cleaner • Deodorizer**
Institutional Use Pre-measured-Packets:
NOT FOR RESALE

**Kills HIV-1 (AIDS Virus) on the pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare 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 human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

NET CONTENTS: 250 Pre-measured Packets,
 each 2.4 Fl. Oz (70.97 mL)
TOTAL 2.69 gal. (17.74L)

A product of
 ©1995 Sunshine Makers, Inc.
 Huntington Beach, CA 92649
 Packaged for and distributed by Marietta Corp.
 Registered trademark of Sunshine Makers, Inc.

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals
CAUTION Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes and skin with plenty of water. Get medical attention if irritation develops or persists.

Statement of Practical Treatment
 In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

STORAGE AND DISPOSAL
Do Not Contaminate Water, Food, or Feed
by Storage or Disposal

PRODUCT STORAGE: Store the unopened case in a cool place, away from sources of heat. After the case is opened, close case when stored to protect contents.

STORAGE OF DILUTED SOLUTION OF SIMPLE GREEN d: Simple Green d, after dilution, is not intended for storage for later use. Use all of contents of spray bottle for cleaning within same day the solution is prepared in the bottle. See DISPOSAL instructions, below, for disposal of unused solution in the spray bottle.

DISPOSAL OF EMPTY PACKETS: The empty packets should be rinsed out and may then be disposed as non-hazardous solid waste in accordance with applicable Federal, State and local provisions. Contact your local authorities for information on applicable regulations in your locality.

DISPOSAL OF SEALED PACKETS: Packets which have not been opened and which are to be discarded (example: out of date, etc.) must be disposed of in accordance with applicable Federal, State and local regulations. Contact your local authorities for information on applicable regulations in your locality.

CASE DISPOSAL: The empty case (carton) may be offered for recycling if such programs exist in your locality.

DISPOSAL OF UNUSED DISINFECTING/CLEANING SOLUTION: The unused contents of the spray bottle may be disposed by sewerage and flushing with water. This product contains ingredients which are biodegradable in waste water treatment plants and sewerage to waste water treatment is the disposal method of choice for unused or spent solutions of Simple Green d

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DIRECTIONS FOR USE

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

SI USTED NO ENTIENDE BIEN LAS INSTRUCCIONES DE USO, REFIERASE A SU SUPERVISOR ANTES DE USAR ESTE PRODUCTO. ES CONTRA LA LEY USAR ESTE PRODUCTO EN CONTRA DE LAS INSTRUCCIONES DE USO

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV SURFACE/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: use barrier protection methods suitable for handling items soiled with blood or body fluids; disposable latex gloves, masks, or eye coverings may be appropriate.

Cleaning Procedure: Surfaces for disinfection should be thoroughly cleaned of gross filth, heavy soil, and blood and body fluids per the directions below, "FOR DISINFECTING."
Contact Time: Follow directions below, "FOR DISINFECTING."

FOR DISINFECTING: The maximum dilution ratio which can be used for disinfecting purposes is 10:1. At this dilution, Simple Green d is effective as a disinfectant against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and human immunodeficiency virus Type 1 (HIV-1 associated with AIDS). Surface should be free of filth or heavy soil.

This case/box contains pre-measured packets which will give a 10:1 dilution when their contents are mixed with 24 ounces of water and are designed to be used with a 24 ounce spray bottle equipped with a sprayhead which will deliver a coarse spray. To use these pre-measured packets, simply open the packet by tearing the corner at the notch, completely empty the packet contents into a 24 ounce spray bottle, add water to "fill line" or bottom of bottle neck. Replace the sprayhead and firmly screw it tight. Shake to mix. Simple Green d may then be applied as a coarse spray to the surfaces/objects to be disinfected. Allow the solution to remain on the surfaces/objects for at least 10 minutes, then rinse thoroughly.

GENERAL CLEANING (NO DISINFECTION): Apply as a coarse spray to the surfaces/objects to be cleaned. Rinse. Wipe dry. For general cleaning of glass surfaces, be sure to rinse thoroughly after application.

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

CONTAINER LABEL

7 2 8

**SIMPLE GREEN d[®]
DISINFECTANT CLEANER DEODORIZER**

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. SEE CASE THIS PACKET WAS SHIPPED IN FOR DETAILED INSTRUCTIONS FOR USE.

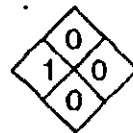
Contents of this packet are premeasured to provide an effective disinfecting dilution (10:1) in a 24 oz. spray bottle. Unscrew and remove sprayhead. Open this packet by tearing upper corner at notch. Completely empty contents into bottle and add water to "fill line" or to bottom of bottle neck of a 24 oz. spray bottle. Replace sprayhead and firmly screw tight. Shake to mix product. Apply Simple Green d by spraying surface to be cleaned. Allow solution to remain 10 minutes, then rinse thoroughly. Use mixture on same day it is prepared.

SI USTED NO ENTIENDE LAS INSTRUCCIONES DE USO, REFERASE A SU SUPERVISOR, ANTES DE USAR ESTER PRODUCTO.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: CAUTION. Avoid contact with skin, eyes, or clothing. In case of contact, immediately flush with plenty of water. Get medical attention if irritation persists. **STATEMENT OF PRACTICAL TREATMENT:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. **STORAGE AND DISPOSAL:** Refer to case label and case insert.

EPA Reg.No. 56782-1
Establishment No.
046229-NY-001



Health = 1* Fire = 0 Reactivity = 0 Special = 0
*Mild eye irritant, non-mutagenic, non-carcinogenic

**SAVES
TIME & MONEY**

"Together For A Cleaner World"

MARIETTA[®]

PROUDLY
OFFERS YOU

simple green d[®]

**CLEANER
DISINFECTANT
& DEODORIZER**

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

Active ingredients
Octyl decyl dimethyl ammonium chloride 0.30%
Dioctyl dimethyl ammonium chloride 0.15%
Didecyl dimethyl ammonium chloride 0.15%
Alkyl (C₁₄ 50%; C₁₂ 40%; C₁₆ 10%)
dimethyl benzyl ammonium chloride 0.40%
INERT INGREDIENTS: 99%

A product of ©1995 Sunshine Makers, Inc
Huntington Harbour, CA 92649
Packaged for and distributed by Marietta Corp
*A registered trademark of Sunshine Makers, Inc.

NET. 2.4 Fl. Oz. (70.97 mL)

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