

S.C. Johnson Commercial Markets, Inc.  
 8310 16 th Street, MS 675  
 Sturtevant, WI 53177-0902

MAY 08 2000

ATTENTION: Lisa Amadio  
 SUBJECT: Disinfectant D.C. 100  
 EPA Registration Number 70627-2  
 Your Amendment Dated: November 3, 1999  
 EPA Received Date: November 10, 1999

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

The following comments apply to data submitted/cited in support of this application for amendment of the above referenced label.

**Efficacy**

The submitted efficacy study MRID# 449720-01 demonstrates the effectiveness of Disinfectant D.C. 100 against *Campylobacter fetus* (ATCC 27374) on hard, non-porous surfaces when sprayed undiluted (as packaged) at 22°C with a one minute contact time in the presence of 10 % serum. The submitted report MRID# 449720-02 demonstrates the ability of Disinfectant D.C. 100 to inactivate the F(1) strain of Herpes simplex virus type (HSV-1) (ATCC VR-733) after being sprayed undiluted with a one minute exposure time at room temperature (26°C) when tested on hard, non-porous surfaces.

**CONCURRENCES**

SYMBOL	75100						
SURNAME	S. Amadio						
DATE	5/8/00						

The following organisms were added to the label based on the cited study MRID# 447679-01: Methicillin-resistant *Staphylococcus aureus* (MRSA) (ATCC 33592), Vancomycin-resistant *Staphylococcus aureus* (VRSA) (HIP-5836), and Vancomycin-resistant *Enterococcus faecalis* (VRE) (ATCC 51299).

**Product Toxicity**

The submitted acute oral, eye irritation, dermal irritation, and dermal sensitization studies are acceptable. The requirements for product toxicity are supported as follows:

<u>Guideline Study</u>	<u>Tox Category</u>	<u>Method of Support</u>
Acute Oral	IV	449720-03 & 449720-07
Acute Dermal	IV	"Cite-all"
Acute Inhalation	IV	"Cite-all"
Primary Eye	III	449720-04
Primary Dermal	III	449720-05 & 449720-08
Dermal Sensitization	non-sensitizer	449720-06

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. The following statement, in addition to being included in the first paragraph on page two, must be repeated in the directions for "Disinfection, Deodorizing and Cleaning": "*A rinse with potable water is required for surfaces in direct contact with food.*"

B. Revise the following statement in the directions for "Disinfection, Deodorizing and Cleaning": "Allow product to penetrate and remain wet for..." to read as follows: "Allow product to *saturate the surface* and remain wet for..."

C. On page three revise the following statement in the section describing fungicidal activity: "This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus)..." to read as follows: "This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (*the fungus which causes Athlete's Foot*)..."

3. Submit two ( 2 ) copies of your final printed labeling before you release the product for shipment.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

If these conditions are not complied with, this registration will be subject to cancellation in accordance with FIFRA sec. 6 ( e ). Your release for shipment of this product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosures:  
Product Tox Review  
Stamped Label  
7510C:T.Lantz:5/4/00:70627-2c

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

# DISINFECTANT D.C. 100

READY-TO-USE DISINFECTANT DEODORIZING CLEANER

- Cleaner • Deodorizer • Disinfectant • Tuberculocidal •\*Virucide
- Fungicide (against pathogenic fungi) • Mildewstat (on hard non-porous surfaces)

<b>ACTIVE INGREDIENTS:</b>	
n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chlorides.....	0.105%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chlorides.....	0.105%
<b>INERT INGREDIENTS:</b> .....	<u>99.790%</u>
<b>TOTAL:</b> .....	100.000%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

MAY - 8 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 70627-2

See additional precautionary statements on back (side) (left) (right) (panel) label below.

NET CONTENTS 32 FL. OZ. (1 QT.) 946 ml

**DIRECTIONS FOR USE**

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

DISINFECTANT D.C. 100 is designed specifically as a general non-acid cleaner and disinfectant for use in hospitals, nursing homes, schools and hotels. It is formulated to disinfect hard non-porous environmental surfaces such as walls, metal surfaces, stainless steel surfaces, sink tops, tables, chairs, telephones, glazed ceramic tile in bathrooms, shower stalls, bathtubs, and cabinets. May be used in the kitchen on counters, sinks, appliances, and stove tops. A rinse with potable water is required for surfaces in direct contact with food. Do not use on eating utensils, plates or glasses. In addition, this product deodorizes those areas, which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.

**Disinfection, Deodorizing and Cleaning** - Remove gross filth or heavy soil prior to application of the product. Hold container six to eight inches from surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum.

**One-step cleaning and disinfection of toilet bowls and urinals:** Remove water from bowl by forcing water over trap with a swab mop application. Press swab mop against side of bowl to remove excess water from applicator. Apply 1 to 2 ounces of this product evenly, allowing sufficient time for product to cover entire surface of bowl for maximum cleaning. Swab bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand 10 minutes and flush.

**Bactericidal Activity** - When used as directed, this product exhibits effective disinfectant activity against the organisms: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli* 0157:H7, *Campylobacter fetus* (ATCC 27374), Methicillin resistant *Staphylococcus aureus* (MRSA) (ATCC 33592), Vancomycin resistant *Staphylococcus aureus* (VRSA) (HIP-5836), Vancomycin resistant *Enterococcus faecalis* (VRE) (ATCC 51299) and meets the requirements for hospital use.

**Tuberculocidal Activity** - This product exhibits disinfectant efficacy against *Mycobacterium tuberculosis* (BCG) in 10 minutes at 20° C when used as directed on previously cleaned hard non-porous environmental surfaces.

**\*Virucidal Activity** - This product, when used on hard non-porous environmental surfaces, exhibits effective virucidal activity against HIV-1 (associated with AIDS), Herpes simplex virus type 1 (ATCC VR-733, strain F(1)) and *Canine Parvovirus*.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY - 8 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 70627-2

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) 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).

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

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**Mildewstat** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

**Fungicidal Activity** - This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

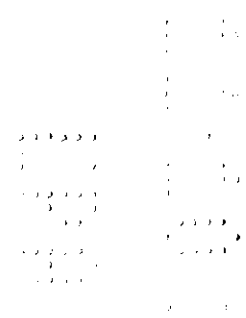
EFFICACY TEST HAVE DEMONSTRATED THAT DISINFECTANT D.C. 100, IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

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 contact with the blood stream 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 maybe used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY - 8 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 70627-2



ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY - 8 2000

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 70627-2

**CAUTION**

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

**FIRST AID**

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.  
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

(for use with containers larger than one gallon)

**STORAGE AND DISPOSAL**

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

Pesticide Storage - Store in original container and place in locked storage area. Store in a dry place no lower in temperature than 50°F or higher than 120°F.

Pesticide Disposal - Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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, by burning. If burned, stay out of smoke.

(for use with containers one gallon or less)

**STORAGE AND DISPOSAL**

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

Storage - Store in original container and place in locked storage area. Store in a dry place no lower in temperature than 50°F or higher than 120°F.

Container Disposal - Do not reuse container. -Wrap container and put in trash.

**ENVIRONMENTAL HAZARDS** (for containers of 5 gallons or 50 lbs. or more)

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 agency 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.

EPA Reg. No. 70627-2  
EPA Est. 0312-WI-1 (A) or 4822-WI-1 (B)  
Lot number suffix A or B indicates Manufacturing Site

©1999 S.C. Johnson Commercial Markets, Inc., Sturtevant, WI 53177-0902 U.S.A.

All Rights Reserved