

875-106

1/14/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 14 2004

Mr. Lisa M. Amadio
Senior Registration Specialist
JohnsonDiversey, Inc.
8310 16th Street, MS 486
Sturtevant, WI 53177-0902

Subject: Render II
EPA Registration No. 875-106
Application Date: 10/16/03
Receipt Date: 10/17/03

Dear Ms. Amadio:

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

Request to change directions for use to add instructions for dispensing device

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies 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 Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL	87510						
SURNAME	Velma Noble						
DATE	1/14/04						

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Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

RENDER® II

Detergent/Disinfectant

Cleaner • Detergent • Disinfectant • Sanitizer • Deodorizer • *Virucide
Fungicide (pathogenic fungi) • Mildewstat (on hard inanimate surfaces)

For Institutional Use (Only)

ACTIVE INGREDIENTS:	
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride.....	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride.....	2.25%
INERT (OTHER) INGREDIENTS:	95.50%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

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

(See reference sheet (enclosed in each case) for (a complete list of pathogenic organisms) (additional features, claims, direction for use) (claimed for this product).)

Net Contents:

(Product of USA)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 14 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
and 40 CFR Part 152, the
registrant shall list EPA Reg. No. 875-106

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(MARKETING CLAIMS:)

(FEATURES, CLAIMS & USES:)

Render II is a phosphate-free concentrated detergent/ disinfectant which provides effective cleaning, deodorizing, disinfection, and sanitation. It has been designed specifically for hospitals, nursing homes, operating rooms, patient care facilities, restrooms, schools, food processing plants, food service establishments, and other institutions where housekeeping is of prime importance for controlling cross contamination. Render II deodorizes areas which are generally hard to keep fresh smelling, including garbage storage areas, empty garbage bins and cans.

Render II is formulated to disinfect the following hard, non-porous, inanimate surfaces: walls, floors, sinks, countertops, toilet bowls, tables, chairs, telephones and bed frames.

Render II is recommended for use as a sanitizer in restaurants, dairies, food processing plants and bars. For use on: chopping blocks, countertops, tables, glasses, dishes and utensils.

(CLAIMS:)

Render II when diluted at 2 oz. per gallon of water in the presence of 5% blood serum and 10 minute contact time is an effective disinfectant (See reference sheet for a complete list of organisms.) against the following organisms on hard, non-porous inanimate surfaces:

Bacteria:

<i>Pseudomonas aeruginosa</i> (PRD-10)	<i>Enterobacter aerogenes</i>	<i>Shigella dysenteriae</i>
<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>	<i>Salmonella salivarius</i>
<i>Salmonella choleraesuis</i>	<i>Klebsiella pneumoniae</i>	<i>Streptococcus faecalis</i>
<i>Brevibacterium ammoniages</i>		

***Viruses:**

HIV-1 (AIDS virus)
Adeno virus type 2 (causative agent of upper respiratory infections)
Herpes Simplex Type 1 (causative agent of fever blisters)
Influenza A ₂ /Asian Virus (representative of the common flu virus)
Vaccinia virus (representative of the pox virus group)

Fungi: *Trichophyton mentagrophytes*

Mold/Mildew (Mildewstatic Activity) – controls and prevents (inhibits) the growth of mold and mildew: *Aspergillus niger* (and the odors caused by them) when applied to hard, non-porous inanimate surfaces.

(Modes of Application:)

Render II can be applied by mop, sponge, cloth, paper towel or (hand pump) coarse trigger sprayer. For disinfection, all surfaces must remain wet for 10 minutes.

DIRECTIONS FOR USE:

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

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 disinfection.



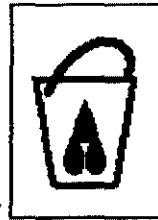
Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

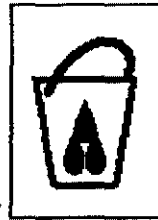

To Prepare (Disinfectant) Use Solution:

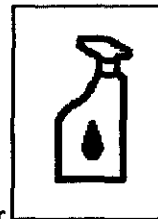
Add the product at 2 oz. per gallon water. Prepare fresh solution daily or more frequently if soil is apparent.

(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on that container size.)

RTD™ SYSTEMS (1.5 or 5 L containers) - Using the RTD unit, dispense product into a (trigger sprayer), (auto scrubber,) (or) bucket.



For Cleaning (and Disinfection) set the control knob to the ( or ) setting which provides 2 oz. per gallon dilution (1:64).



For Sanitization set the control knob to the ( or ) setting which provides 2 ½ oz. per 3 gallon dilution (1:224).

To Disinfect: Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous inanimate surfaces. To disinfect, all surfaces must remain wet for 10 minutes. Allow to air dry.

For Use as a (General) Cleaner (and/or Deodorizer):

Apply Use Solution to surfaces. Wipe surfaces (and let air dry).

To Control Mold and Mildew: Apply Use Solution to hard, non-porous environmental surfaces. Allow to air dry. Repeat application weekly or when growth reappears.

To Disinfect Toilet Bowls: Pre-clean heavily soiled areas. Flush toilet, add 2 oz. Render II directly to bowl water. Swab bowl completely using toilet brush or mop, making sure to get under the rim. Let stand for 10 minutes. Flush.

For Use as a Fungicide: Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous environmental surfaces in areas such as locker rooms, dressing rooms, shower and bath areas. Allow surface to remain wet for ten (10) minutes. (Wipe surfaces (and let air dry).)

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***Kills HIV 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: Disposable latex or vinyl gloves, gowns, face masks or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

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

Wisconsin Sanitizer Instructions)

Sanitizing Food Contact Surfaces:

1. Pre-flush, scrape or pre-soak articles to be washed.
2. Wash areas or items to be sanitized with clean water and a recommended detergent.
3. Rinse with potable water.
4. Sanitize in a solution prepared by diluting 2 oz. Render II per 3-1/2 gallon water to 200 ppm quaternary level. Immerse or wet all surfaces for at least 60 seconds (1 minute) or as required by local sanitation regulations. When solution depreciates or becomes soiled, discard. Test sanitizer solution periodically with a Quaternary Test Kit to ensure 200 ppm active quaternary.
5. Drain and allow equipment or utensils to air dry.

Note: NO POTABLE WATER RINSING of equipment is required. Prepare a fresh solution daily or more frequently if soil is apparent.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not reuse empty container. Store in a dry place at 50° F to 120° F.

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 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 incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS (for containers of 5 gallons 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.

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

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear chemical splash-proof goggles or face shield, rubber gloves and protective clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

1-800-851-7145

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

PELIGRO

Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.

EPA Reg. No. 875-106
EPA Est. No.

DiverseyLever, Inc., Cincinnati, OH 45241

00-21-01

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