

875-106

04-06-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Kresti A. Lyddon  
Senior Registration Specialist  
JohnsonDiversey, Inc.  
8310 16<sup>th</sup> Street, MS 707  
Sturtevant, WI 53177-1964.

APR - 6 2010

SUBJECT:           Render II  
                      EPA Registration Number: 875-106  
                      Application Date: January 7, 2010  
                      Receipt Date: January 8, 2010

Dear Ms. Lyddon:

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

1) Your label indicates that a reference sheet will accompany this product. Any written materials which accompany this product must be in agreement with the stamped accepted label for this product. The reference sheet may not include additional organisms, claims or features which have not been previously approved by the Agency. This reference sheet was not submitted to the Agency for review. Submit this reference sheet to the Agency for review within 30 days of the date of this letter. Include this sheet along with the label in any subsequent actions for this product.

2) Revise your labeling to be in agreement with PR Notice 2000-5 by using mandatory language on page 2 as follows: "This product is for use as a sanitizer..." deleting the word "recommended."

3) Correct the name of the organism *Salmonella choleraesuis* to read *Salmonella enterica*.

CONCURRENCES							
SYMBOL	7510P						
SURNAME	J. Lyddon						
DATE	4/5/10						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4) Place the section beginning: "Modes of Application..." and ending "...must remain wet for 10 minutes." in the directions for use section of the label.

5) Delete the entire section "Nonrefillable ready to use formulas" on page five. This product is a dilutable concentrate. It should not be packaged or marketed as a ready to use product.

6) Since this product is effective against public health organisms, your label must not include language indicating that the container rinsate may be reused as this rinsate would not be efficacious. Delete the following statements from the Small nonrefillable containers, both sections of the Large nonrefillable containers and the Refillable container section:

**Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal.**

**Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal.**

**Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal.**

**"...empty the remaining contents from this container into application equipment or mix tank."**

**"Pour or pump rinsate into application equipment or rinsate collection system."**

Replace each statement with the following: *"Dispose of rinsate as pesticide waste."*

7) Add the following statement regarding the handling of the container to the Small nonrefillable containers and both sections of the Large nonrefillable containers:

*"Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."*

8) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: *"... Wash thoroughly with soap... before eating, drinking, using tobacco or using the toilet. Remove contaminated..."*

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SURNAME							
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**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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



for

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

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR -6 2010

# JohnsonDiversey



Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 875-106

## RENDER® II Detergent/Disinfectant

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

For Institutional Use (Only)

<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 chloride .....	2.25%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chloride .....	2.25%
<b>INERT (OTHER) INGREDIENTS:</b> .....	95.50%
<b>TOTAL:</b> .....	100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

### 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.  
XXX-XXX-XXXX**

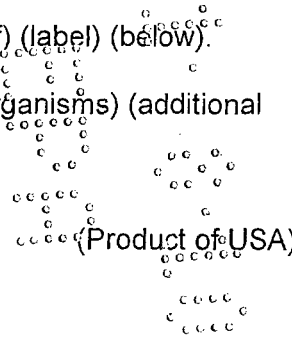
Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

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

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:



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

**(MARKETING CLAIMS:)**

**(FEATURES, CLAIMS & USES:)**

This product 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. This product deodorizes areas which are generally hard to keep fresh smelling, including garbage storage areas, empty garbage bins and cans.

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

This product 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:)**

This product, 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 against the following organisms on hard, non-porous inanimate surfaces (See reference sheet for a complete list of organisms):

**Bacteria:**

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

**\*Viruses:**

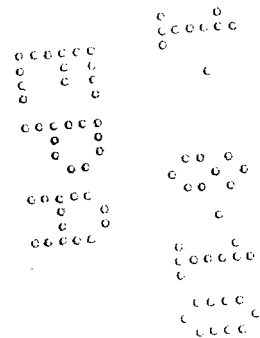
- HIV-1 (AIDS virus)
- Adenovirus type 2 (causative agent of upper respiratory infections)
- Herpes Simplex Type 1 (causative agent of fever blisters)
- Influenza A<sub>2</sub>/Asian Virus (representative of the common flu virus)
- Vaccinia virus (representative of the pox virus group)

**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:)**

This product 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.



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

**DIRECTIONS FOR USE:**

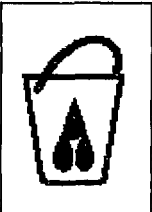

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

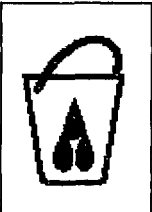

**To Prepare (Disinfectant) Use Solution:**

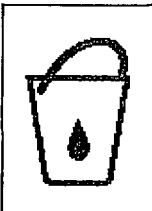

Add the product at 2 oz. per gallon water. Prepare fresh solution daily or more frequently if soil is apparent.

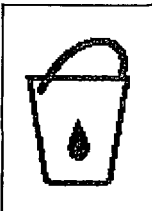

*(Note to EPA: The directions that appear for specific container sizes will be substituted for the sentence above only on that container size.)*

**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).)

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

**\*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 and 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 must 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:** (Note to Reviewer: we will choose one of the following statements, depending on product container type:)

**NONREFILLABLE SEALED CONTAINERS:** *Note to reviewer: Several of our packaging options are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

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

**NONREFILLABLE NON-RIGID CONTAINERS:** *Note to reviewer: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers. These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

**NONREFILLABLE READY-TO-USE FORMULATIONS:** *Note to reviewer: The following text will be used on nonrefillable RTU container labels:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

**SMALL NONREFILLABLE CONTAINERS:** *Note to reviewer: The following text will be used on rigid, nonrefillable containers small enough to shake (5 gallons or smaller):*

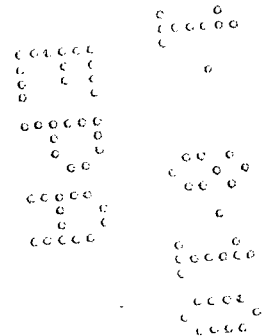
Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available.

**LARGE NONREFILLABLE CONTAINERS:** *Note to reviewer: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):*

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for reconditioning, if appropriate.

OR

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.





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

**REFILLABLE CONTAINERS:** *Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name pesticide) only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

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

This product is toxic to fish and aquatic invertebrates. 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.

**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.

EPA Reg. No. 875-106

EPA Est. No.

(Lot code letters indicate manufacturing location)

(MSDS Ref. No. XXXXXXXXXXXX)

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