

875-106

11/24/2009

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



Office of Pesticide Programs

Kresti A. Lyddon,  
Johnson Diversity,  
P.O Box 902  
Sturtevant, WI 53177-0902

NOV 24 2009

Subject: Product Name: Render II  
EPA Registration No.: 875-106  
Notification Date: August 27, 2009  
EPA Receipt Date: August 28, 2009  
Submission #: 856844

Dear Mr. Isaac,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

**Label amendment to revise the label for Render II:**

- Correct the HIV box to meet current state requirements, to revise the Environmental Hazard statement, remove the Terminal Rinse Sterilant Statement, as well as bed frames from label.

**General Comments**

Based on a review of the submitted materials, your label amendment is found to be acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble, PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 **Amendment**  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number <b>875-106</b>	2. EPA Product Manager <b>Velma Noble</b>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) <b>Render II</b>	PM# <b>31</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>JohnsonDiversey, Inc. 8310 16<sup>th</sup> Street, MS 707 Sturtevant, WI 53177-1964</b>		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional Page(s) if necessary. (For section I and Section II)

Label Amendment: Updated HIV box to meet state requirements; modified Environmental Hazards Statement in accordance with the ADBAC/DDAC RED, removed terminal rinse sterilant statement and removed bed frames.

Contact Information: Kresti.Lyddon@johnsondiversey.com or via fax: 262-631-2731 or  
 Secondary Contact lisa.amadio@johnsondiversey.com

**Section - III**

**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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\* **Certification must be submitted**

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container <b>32 oz, 1 gallon</b>	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____

**Section - IV**

**1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)**

Name <b>Kresti A. Lyddon</b>	Title <b>Senior Registration Specialist</b>	Telephone No. (Include Area Code) <b>262-631-4030</b>
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**Certification**  
 I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title <b>Senior Registration Specialist</b>	6. Date Application Received (Stamped)
4. Typed Name <b>Kresti A. Lyddon</b>	5. Date <b>August 27, 2009</b>	

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JohnsonDiversey, Inc.  
8310 16th Street  
P.O. Box 902  
Sturtevant, WI 53177-0902

Tel: 262 631 4001

JohnsonDiversey  
Clean is just the beginning



August 27, 2009

Office of Pesticide Programs (Amend – No Fee)  
U. S. Environmental Protection Agency  
Attn: Ms. Velma Noble  
Antimicrobial Division (7510P)  
One Potomac Yard,  
2777 S. Crystal Drive  
Arlington, VA 22202

Dear Velma:

Subject: Label Amendment – Render® II  
EPA Reg. No. 875-106

JohnsonDiversey, Inc. is submitting a label amendment to revise the label for the above-referenced product. We wish to correct the HIV box to meet current state requirements, to revise the Environmental Hazards statement to meet the requirements of the ADBAC/DDAC RED and to remove the Terminal Rinse Sterilant Statement, as well as bed frames from the label. This product is not sold or used in setting that would require the Terminal Rinse Sterilant Statement.

The following documents are included in support of this amendment:

- An Application Form (EPA Form 8570-1).
- Five (5) copies of the draft labeling for Render® II
- Electronic copy of the label with certification

If you have any questions or need additional information for this label amendment, please contact me at 262-631-4830 or [Kresti.Lyddon@johnsondiversev.com](mailto:Kresti.Lyddon@johnsondiversev.com).

Best regards,

A handwritten signature in black ink, appearing to read "Kresti A. Lyddon", written in a cursive style. The signature is positioned above the printed name and title.

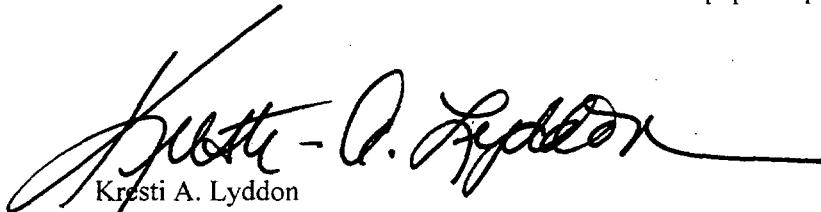
Kresti A. Lyddon  
Senior Registration Specialist

Enclosures

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August 27, 2009

This document is to certify that the electronic copy of the label supplied with this application for amendment is identical to the text and format of the paper copies supplied herein.

A handwritten signature in black ink, appearing to read "Krestin A. Lyddon". The signature is fluid and cursive, with a long horizontal line extending to the right.

Krestin A. Lyddon  
Senior Registration Specialist

Render® II  
EPA Reg. No. - 875-106

Marked Copy 5/9

JohnsonDiversey



**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%

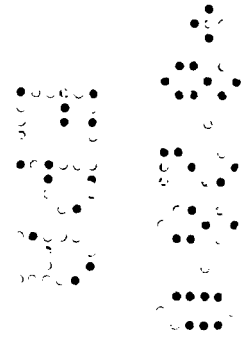
**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

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)



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

**DIRECTIONS FOR USE:**

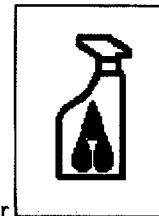
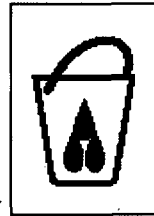
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.


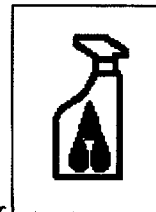
**To Prepare (Disinfectant) Use Solution:**

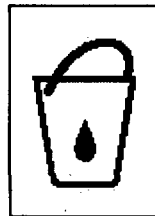
Add the product at 2 oz. per gallon water. Prepare fresh solution daily or more frequently if soil is apparent.



*(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).)

**\*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:** 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)

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.



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

**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.**

**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.

**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.

(Lot code letters indicate manufacturing location)

(MSDS Ref. No. XXXXXXXXXXXX)

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