

5736-102

12-10-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Kresti Lyddon
JohnsonDiversey
8310 16th Street
Sturtevant, WI 53177-0902

DEC 10 2009

Subject: Super-Bol
EPA Registration No.: 5736-102
Notification Date: November 12, 2009
EPA Receipt Date: November 13, 2009

Dear Ms. Lyddon,

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

Proposed Notification

- Add Pandemic 2009 H1N1 Influenza A Virus claim
- Add asterisks beside term, viruses
- Minor Label Revisions

General Comments

Based on a review of the submitted materials, your notification to add Pandemic 2009 H1N1 Influenza A Virus claims and asterisks next to term, virus, to the label is acceptable and apart of the records on file.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble
Velma Noble

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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060 Approval Expires 5-31-98



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 5736-102	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SUPER-BOL	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) JohnsonDiversey, Inc. 8310 16th Street, MS 707 Sturtevant, WI 53177-1964 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. 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 _____	

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 to 1. Add Influenza H1N1 claim 2. Clarification to malodors statement per California DPR 3. Add asterisks to viruses.

Fee statement: FQPA. No fee required.

Contact Information: Kresti.Lyddon@johnsondiversev.com or via fax: 262-631-2731
Secondary Contact: Lisa.Amadio@johnsondiversev.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt	No. per Container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Unit Package wgt.	No. Per Container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" 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 Kresti A. Lyddon	Title Registration Specialist	Telephone No. (Include Area Code) 262-651-4289
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Senior Registration Specialist	
4. Typed Name Kresti A. Lyddon	5. Date November 13, 2009	

JohnsonDiversey, Inc.
8310 16th Street
P.O. Box 902
Sturtevant, WI 53177-0902
Tel: 262 631 4001

JohnsonDiversey
Clean is just the beginning



November 13, 2009

Document Processing Desk (AMEND)
Attn: Velma Noble
Office of Pesticide Programs (7510P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

COURIER

Dear Velma:

Subject: Label Amendment for SUPER-BOL
EPA Reg. No. – 5736-102

JohnsonDiversey, Inc. is submitting a label amendment to add Influenza H1N1 efficacy claims to the above-referenced product. Additionally, we wish to add the clarifying statement “on hard, nonporous surfaces” to the Malodors claim on pages 3 and 6, and to add asterisks before all viruses and use of the term virus, per California DPR. We have also made minor corrections throughout the label as highlighted on one copy of the label. The following documents are included in support of this amendment:

- An Application Form (EPA Form 8570-1)
- Five (5) copies of the proposed label (one copy with changes marked)
- Electronic copy of the label with certification

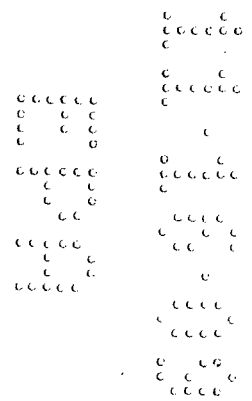
If you have any questions or need additional information for this label amendment, please contact me at 262-631-4830 or Kresti.Lyddon@johnsondiversey.com.

Best regards,



Kresti A. Lyddon
Senior Registration Specialist

Enclosures



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

JohnsonDiversey



SUPER-BOL

Non-Acid Bowl & Bathroom Disinfectant Cleaner

Ready-To-Use (RTU)

Bactericidal • *Virucidal • Mildewstatic • Deodorizes (Odor Counteractant) (Odor Neutralizer)
• Pseudomonacidal • Staphylocidal • Salmonellacidal

For (Hospital) (Foodservice) (Food Plant) (Commercial) Industrial & Institutional Use (Only)

Specifically formulated for (sale to,) (use,) (and) (storage) by service persons (food service operators).

Cleans, Disinfects and Deodorizes In One Step; Will not (Won't) Scratch or Dull Surfaces; Leaves (Toilet) Bowls Sparkling (Clean); Leaves (Bathroom) Surfaces (Sparkling) Clean (and Fresh); Cleans Without (Harmful) (Acids) (Abrasives) Fumes; Contains No Abrasives (Non-Abrasive (Formula)); Fresh (Pleasant)(Mint)(Citrus)(Pine) Fragrance, (Mint)(Citrus)(Pine) Scent; Neutralizes Odors (At Their Source); For Effective Daily Maintenance of Restroom Surfaces. (Tested in 10% serum!) (Neutral pH formula!) Meets OSHA Bloodborne Pathogen Standard for HBV & HIV

ACTIVE INGREDIENTS:

n-Alkyl (60%C₁₄; 30%C₁₆; 5%C₁₂; 5%C₁₈) dimethyl benzyl ammonium chloride 0.106%
n-Alkyl (68%C₁₂; 32%C₁₄) dimethyl ethylbenzyl ammonium chloride 0.106%

INERT INGREDIENTS: 99.788%

TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See directions and 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 eliminated by this product.)

Net Contents:

(Product of XXXXXXXXXX)

November 13, 2009
Page 1 of 5
EPA Reg. No. 5736-102

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

(Features, Claims and Uses)

(Features:) This product is formulated to be an essential part of your daily restroom maintenance program because it combines effective pH neutral cleaning, germ-killing efficacy and consistent odor neutralizing - all in one product. Its convenient ready-to-use formulation requires no pre-mixing (diluting). It is recommended for use in schools, universities, hospitals, nursing homes, industrial and manufacturing facilities, office buildings, food processing plants, restaurants, government facilities, retail outlets, supermarkets and any commercial facilities with public restrooms.

It cleans, disinfects and deodorizes toilet bowls, urinals and other bathroom fixtures in one easy step. It stops odors right at their source by killing odor-causing bacteria. Use it (daily) on all hard non-porous inanimate surfaces such as toilet bowls, urinals, bowls, rims, sinks, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel - especially where odors are a problem. This product can be applied directly on the surface using the (convenient) flip top bottle, by hand pump trigger sprayer, or with a cloth, sponge or bowl mop. It contains no abrasives. (This product can be used in Federally Inspected Meat and Poultry Facilities.)

To Refill Product from Large Containers into Smaller Containers:

This product may be used to fill and refill clean, properly labeled application containers for use elsewhere within your facility.

1. Make sure the small ready-to-use container has been cleaned, dried and properly labeled. Also make sure other items (such as trigger spray tubes and heads, and funnels) are properly cleaned and dried.
2. To refill, simply pour (or pump product) from the larger container directly into the smaller being careful not to spill any product.
3. Keep both containers sealed when not in use.

(CLAIMS:)

This product is an effective germicide and disinfectant, (containing 2120 ppm of active quaternary germicides, making it) effective against a wide spectrum of microorganisms. Using EPA-approved test methods for germicides (under Good Laboratory Practices [GLPs]), in 10% serum and a 10 minute contact time, unless otherwise noted, This product kills the following (on hard non-porous inanimate surfaces):

Bacteria (Bactericidal Activity) - (kills on hard non-porous inanimate surfaces:)

<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Escherichia coli</i> 0157:H7, (ATCC 43890)	<i>Salmonella choleraesuis</i> , (ATCC 10719)
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Klebsiella pneumoniae</i> , (ATCC 13883)	(formerly known as <i>Salmonella schottmuelleri</i>)
<i>Salmonella enterica</i> , (ATCC 10708) (formerly known as <i>Salmonella choleraesuis</i>)	<i>Listeria monocytogenes</i> , (ATCC 15313)	<i>Salmonella typhi</i> , (ATCC 6539)
<i>Campylobacter fetus</i> , (ATCC 27374)	<i>Micrococcus sedentarius</i> , (ATCC 27573)	<i>Shigella sonnei</i> , (ATCC 25931)
<i>Enterobacter aerogenes</i> , (ATCC 13048)	<i>Proteus mirabilis</i> , (ATCC 9240)	<i>Shigella dysenteriae</i> , (ATCC 13313)
<i>Escherichia coli</i> , (ATCC 11229)		<i>Staphylococcus species</i> , (ATCC 12715)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) – (kills on hard non-porous inanimate surfaces:)

<i>Enterococcus faecalis</i> , (ATCC 51299) (resistant to Vancomycin [VRE])	<i>Staphylococcus aureus</i> , (ATCC 33591) (resistant to Methicillin [MRSA])
<i>Escherichia coli</i> , (ATCC 47041) (Tetracycline resistant)	<i>Streptococcus pneumoniae</i> , (ATCC 51915) (resistant to Penicillin [PRSP])

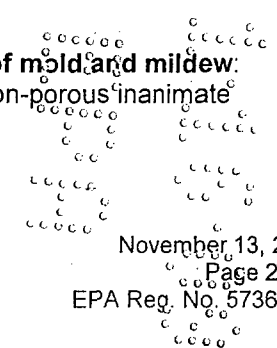
***Viruses (*Virucidal Activity) – (kills on hard non-porous inanimate surfaces:)**

* <i>Herpes simplex Type 1</i> , (VR-733)	* <i>Herpes simplex Type 2</i> , (VR-734)	* <i>Influenza Type A₂</i> (Hong Kong), (VR-544)
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Kills *Hepatitis B (HBV) virus, *Hepatitis C (HCV) virus and *HIV-1 (AIDS virus) (HTLV-III_B) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Mold/Mildew (Mildewstatic Activity) - controls and prevents (inhibits) the growth of mold and mildew:

Aspergillus niger (ATCC 16404) (and the odors caused by them when applied to hard non-porous inanimate surfaces.



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

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria in restroom areas on hard, nonporous surfaces, behind and under sinks and counters, garbage cans and storage areas (and other places where bacterial growth can cause malodors).

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A₂ (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- *This product has demonstrated effectiveness against Influenza Type A₂ (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- *Kills Pandemic 2009 H1N1 Influenza A virus.

DIRECTIONS FOR USE:

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

For use as a One-Step Non-Acid Bowl Cleaner/Disinfectant for Toilet Bowls:

1. Remove gross filth and heavy soil deposits.
2. With swab applicator, remove water from bowl by forcing water over trap.
3. Press swab applicator against side of bowl to remove excess water.
4. Apply 1 oz. of this product to swab applicator, cloth, mop, sponge or directly to surface.
5. Swab entire surface area especially under the rim.
6. Allow entire surface to remain wet for ten (10) minutes.
7. Flush toilet and rinse swab applicator thoroughly.

For use as a Non-Acid Cleaner/Disinfectant for Urinals:

1. Remove gross filth and heavy soil deposits.
2. Apply product directly to urinal surfaces including water outlets areas for general cleaning.
3. Then pour an additional 1 oz. of product on applicator.
4. Clean entire unit, especially under the rim at water outlets with applicator.
5. Remove screen trap to deodorize drain and apply 1 oz. directly on edge and into drain.
6. Wait 10 minutes, flush and rinse applicator.

One-Step Disinfecting Glazed Ceramic Tile, Glazed Porcelain, Shower Walls, Floors and Other Hard Non-Porous Inanimate Bathroom Surfaces:

1. To disinfect hard non-porous inanimate surfaces, use full strength.
2. Apply product with a cloth, sponge, sprayer or mop. Treated surfaces must remain wet for 10 minutes.
3. Rinse thoroughly. Pre-cleaning is required for heavily soiled surfaces.

For General Deodorizing and Cleaning: Dilute product 1:10 (12 oz./gal of water) for general deodorizing and cleaning of hard non-porous inanimate bathroom surfaces. Apply use solution to surfaces. Wipe surfaces or let air dry.

To Control Mold and Mildew: Apply at full strength to hard non-porous inanimate surfaces. Allow to air dry. Repeat application weekly or when growth reappears.

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

***(EFFECTIVE AGAINST HBV, HCV and HIV-1 (AIDS VIRUS):** This product was evaluated and found to be an effective virucide in the presence of 10% serum against the viruses HBV, HCV and HIV-1 (AIDS Virus) on hard non-porous surfaces.) **KILLS HBV, HCV and HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings where 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 Hepatitis B virus, Hepatitis C virus and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS). **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV, HCV and HIV-1 (AIDS VIRUS) ON 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 disinfectant.

Contact Time: For HBV, HCV and HIV-1 allow surface to remain wet for 1 minute. Allow 10 minutes for the other organisms listed on this label.

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

(Note to reviewer: This product is exempt from the requirements of PR Notice 2007-4: "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment".)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a cool; dry area inaccessible to children.

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

(Plastic Containers A – for containers larger than 1 gallon:) 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.

(Plastic Containers B - for containers 1 gallon or smaller:) Wrap container and put in trash. Do not reuse empty container except to refill with this product.

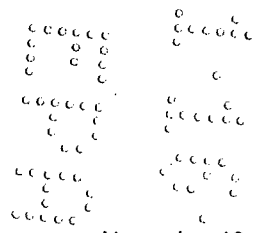
KEEP FROM FREEZING.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates.

(For containers 5 gallons and larger)

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 is done to show optional text.)

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

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

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.

**IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.
1-XXX-XXX-XXXX**

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

ADVERTENCIA:

Si no puede leer en ingles, pregunte a su supervisor por el modo de empleo apropiado antes trabajar con este producto.

EPA Reg. No. 5736-102

EPA Est. No.

(Lot code letters indicate establishment number.)

(MSDS Ref. No.xxxxxxxxxx)

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



SUPER-BOL REFERENCE SHEET

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Bacteria (Bactericidal Activity) - (kills on hard non-porous inanimate surfaces:)

- | | | |
|---|---|---|
| <i>Pseudomonas aeruginosa</i> , (ATCC 15442) | <i>Escherichia coli</i> , (ATCC 11229) | <i>Salmonella choleraesuis</i> , (ATCC 10719) |
| <i>Staphylococcus aureus</i> , (ATCC 6538) | <i>Escherichia coli</i> 0157:H7, (ATCC 43890) | (formerly known as <i>Salmonella schottmuelleri</i>) |
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| (formerly known as <i>Salmonella choleraesuis</i>) | <i>Listeria monocytogenes</i> , (ATCC 15313) | <i>Shigella sonnei</i> , (ATCC 25931) |
| <i>Campylobacter fetus</i> , (ATCC 27374) | <i>Micrococcus sedentarius</i> , (ATCC 27573) | <i>Shigella dysenteriae</i> , (ATCC 13313) |
| <i>Enterobacter aerogenes</i> , (ATCC 13048) | <i>Proteus mirabilis</i> , (ATCC 9240) | <i>Staphylococcus species</i> , (ATCC 12715) |

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) – (kills on hard non-porous inanimate surfaces:)

- | | |
|--|--|
| <i>Enterococcus faecalis</i> , (ATCC 51299)
(resistant to Vancomycin [VRE]) | <i>Staphylococcus aureus</i> , (ATCC 33591)
(resistant to Methicillin [MRSA]) |
| <i>Escherichia coli</i> , (ATCC 47041)
(Tetracycline resistant) | <i>Streptococcus pneumoniae</i> , (ATCC 51915)
(resistant to Penicillin [PRSP]) |

*Viruses (*Virucidal Activity) – (kills on hard non-porous inanimate surfaces:)

- | | | |
|---|---|---|
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