

7176-25

12-10-2009

18

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: Bath Mate Acid-Free Disinfectant Washroom Cleaner
EPA Registration No.: 7176-25
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

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
Product Manager (31)

CONCURRENCES
Regulatory Management Branch I
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

 <p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 7176-25	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bath Mate Acid Free Disinfectant Washroom Cleaner	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) The Butcher Company 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"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional Page(s) if necessary. (For section I and Section II)

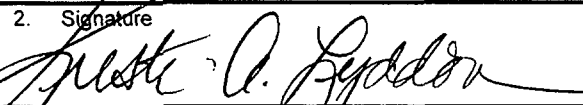
Label Amendment to add H1N1 Claims, and address formatting and other minor corrections.

Fee explanation: FQPA - No Fee Required; 3 Months.
 Primary Contact Information: Kresti.Lyddon@johnsondiversey.com or via fax: 262-631-2731
 Secondary contact: Lisa Amadio, 262-631-4241 or 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) _____
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 quart	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 Senior Registration Specialist	Telephone No. (Include Area Code) 262-631-4289	
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 12, 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 12, 2009

COURIER

Document Processing Desk (AMEND)
Attn: Velma Noble, Antimicrobial Division
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Velma:


Subject: Label Amendment for Bath Mate Acid-Free Disinfectant Washroom Cleaner
EPA Reg. No. – 7176-25

JohnsonDiversey, Inc. is submitting a label amendment to add Influenza H1N1 efficacy claims to the above-referenced product. Additionally, we wish to add asterisks before all viruses and use of the term virus, per California DPR, and we have made minor corrections throughout the label as highlighted on one copy of the label. The following documents are included in support of this amendment:

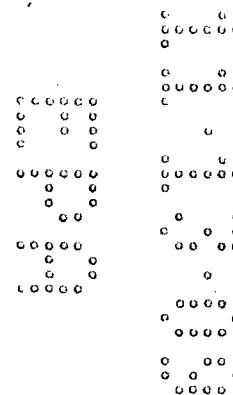
- An Application Form (EPA Form 8570-1)
- Five (5) copies of the proposed label (one with changes highlighted)
- Electronic copy of the label with certification

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

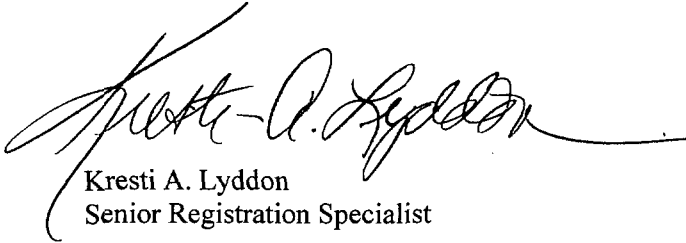


3/8

212

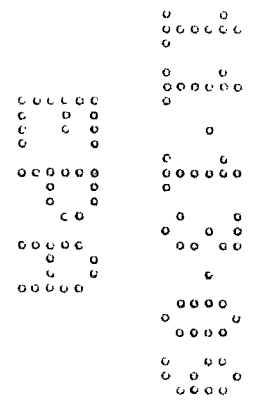
November 12, 2009

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.



Krestin A. Lyddon
Senior Registration Specialist

Bath Mate Acid-Free Disinfectant Washroom Cleaner
EPA Reg. No. - 7176-25



8/5

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



Bath Mate Acid-Free Disinfectant Washroom Cleaner

Cleans • Disinfects • Deodorizes • Ready-To-Use • Mildewstatic

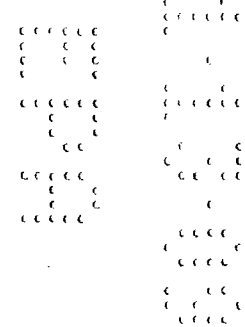
Active Ingredients:	
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	0.06%
Didecyl dimethyl ammonium chloride	0.02%
Other (Inert) Ingredients:	99.92%
Total:	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

Net Contents:

(Product of XXXXXXXX)



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

(Marketing Text/Claims)

Cleans, disinfects and deodorizes toilet bowls, urinals, tubs, showers and other hard, non-porous washroom (restroom) surfaces. Use on glazed porcelain, glazed ceramic, sealed grout, stainless steel, Formica, Plexiglas, fiberglass sinks, bathtubs or shower stalls and chrome.

An effective one-step cleaner disinfectant in the presence of organic soil load. For daily washroom (restroom) cleaning in hospitals, motels, hotels, nursing homes, business and industrial buildings, restaurants and food plants. Non-acid formula with a fresh floral fragrance.

Kills *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, (formerly known as *Salmonella choleraesuis*), *Staphylococcus aureus* (Methicillin resistant (MRSA)), Influenza A/Hong Kong, Herpes Simplex Type 1 and Type 2, *Trichophyton mentagrophytes* (athlete's foot fungus) and *Chlamydiae trachomatis* on hard, non-porous environmental surfaces in the presence of organic soil (5% blood serum).

*Kills HIV-1 (Human Immunodeficiency Virus Type 1) which causes AIDS (Acquired Immunodeficiency Syndrome) and *Hepatitis B Virus (HBV). This product is virucidal against HIV-1 after 1 minute (contact time) and HBV after 5 minutes in the presence of organic soils (5% blood serum).

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

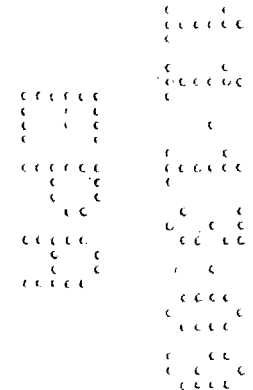
- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A₂ (Hong Kong), (VR-544), and is expected to inactivate all Influenza A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

Cleaning, Disinfecting and Deodorizing Toilet Bowls and Urinals:

1. Flush toilet or urinal. Lower the water level in the bowl by forcing water over trap with a bowl swab.
 2. Remove excess water from bowl swab.
 3. Apply 2 oz. of disinfectant solution to the bowl swab.
 4. Swab all surfaces. Start under the rim and work down.
 5. Leave treatment on surfaces for at least 10 minutes.
 6. Flush toilet or urinal. Rinse bowl swab.
- Preliminary cleaning is required for heavily soiled surfaces.



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

Cleaning, Disinfecting and Deodorizing Sinks, Tubs and Other Hard Non-Porous Surfaces:

1. Apply product with a cloth, sponge, mop or spray applicator to wet all surfaces thoroughly.
2. For heavier soils, agitate with a hand pad or brush if necessary.
3. Let treated surfaces remain wet for 10 minutes and rinse thoroughly.

Pre-clean heavily soiled surfaces before disinfecting.

To Control Mold and Mildew:

Apply product to pre-cleaned hard, non-porous environmental surfaces. Allow to air dry. Repeat application weekly or when growth reappears.

***KILLS HIV-1 AND HBV ON PRE-CLEANED INANIMATE SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings and 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) and Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV 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 body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1 and 5 minutes to kill HBV. For other organisms 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 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 Containers and Containment".)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store only in tightly closed, original container in a secure area inaccessible to children.

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:

(For containers 1 gallon for less:)

Do not reuse empty container. Rinse thoroughly, securely wrap in several layers of newspaper and discard empty container in trash.

(For containers greater than 1 gallon:)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, 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.

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

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates.

(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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing spray mist. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

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

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

**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.

EPA Reg. No. 7176-25

EPA Est. No.

(Lot code letters indicate manufacturing location)

(MSDS Ref. No. xxxxxxxxxxx)

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