

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 21 2004

Ms. Lisa M. Amadio
JohnsonDiversey, Inc.
8310 16th Street, MS 486
Sturtevant, WI 53177-0902

Subject: NADBC-101
EPA Registration No. 70627-3
Application Date: 4/6/04
Receipt Date: 4/7/04

Dear Ms. Amadio:

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

Label amendment to add additional organism for Hepatitis C virus

EFFICACY

1. The submitted data supports this product, NADBC-101, as an effective disinfectant against the Hepatitis C virus when used in the presence of a 10% organic soil load for a contact time of 1 minute at full strength. This claim is supported by the submitted data.
2. You may want to make the following change to the proposed label:

On page 3, Change the first sentence in the text box to read: "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."

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.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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DATE								

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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended 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)

Enclosure: Stamped Label

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JohnsonDiversey



NADBC-101

Non-Acid Bowl & Bathroom Disinfectant Cleaner

Ready-To-Use (RTU)

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) Fragrance (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%C ₁₄ ; 30%C ₁₆ ; 5%C ₁₂ ; 5%C ₁₈) dimethyl benzyl ammonium chloride.....	0.106%
n-Alkyl (68%C ₁₂ ; 32%C ₁₄) dimethyl ethylbenzyl ammonium chloride.....	0.106%
INERT INGREDIENTS:	<u>99.788%</u>
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)

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

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

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

See reference sheet (enclosed in each case) for a complete list of pathogenic organisms eliminated by NADBC-101 (this product).

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

Net Contents:

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

70627-3

(Features, Claims and Uses)

(Features:) NADBC-101 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. NADBC-101 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:

NADBC-101 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:)

NADBC-101 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, NADBC-101 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) (formerly known as <i>Salmonella schottmuelleri</i>)
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Klebsiella pneumoniae</i> , (ATCC 13883)	<i>Salmonella typhi</i> , (ATCC 6539)
<i>Salmonella choleraesuis</i> , (ATCC 10708)	<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)
<i>Escherichia coli</i> , (ATCC 11229)		

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 or brackets is done to show optional text.)

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

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 NADBC-101 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.

***(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 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, 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 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 should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

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

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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 more than 1 gallon sizes:) 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 1 gallon or less sizes:) Wrap container and put in trash. Do not reuse empty container except to refill with NADBC-101.

KEEP FROM FREEZING.

ENVIRONMENTAL HAZARDS *(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.

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.

1-800-851-7145

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. 70627-3

EPA Est. No.

(MSDS Ref. No.xxxxxxxxxx)

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NADBC-101 REFERENCE SHEET

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