

777-103

4-7-2008

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

April 7, 2008

Jennifer L. DeCarlo  
Registration & Regulatory Compliance Specialist  
**Reckitt Benckiser Inc.**  
399 Interpace Parkway, P.O. Box 225  
Parsippany, NJ 07054-0225

Subject: Product name: Duraguard  
EPA Reg. Number: 777-103  
Application Date: 20-Mar-2008  
Receipt Date: 24-Mar-2008

Dear Ms. DeCarlo:

The following master text label amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the following condition:

- On page 8, add the words "protective gloves and protective clothing" at the end of the statement "Wear protective eyewear [safety glasses / goggles]."

Submit three (3) copies of the final printed labeling bearing the revision as stated above. A stamped copy of the label is enclosed for your record. Please note that the Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label:

[http://www.epa.gov/oppfead1/eds/esr\\_guidance.htm#overallsub](http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub). If you have questions concerning electronic labeling, a list of contacts is available at the following site:  
<http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>

2/10

If you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at [heyward.adam@epamail.epa.gov](mailto:heyward.adam@epamail.epa.gov) during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management II  
Antimicrobials Division (7510P)

3/10

<< Front Panel >>

<b>ACTIVE INGREDIENT:</b>	
Hydrogen Chloride .....	9.50%
<b>OTHER INGREDIENTS:</b> .....	<u>90.50%</u>
<b>TOTAL:</b> .....	100.00%

KEEP OUT OF REACH OF CHILDREN

**DANGER:** CORROSIVE. See back (side) panel for additional precautionary statements. Harmful or fatal if swallowed.

<b>NET CONTENTS:</b>	16 FL. OZ. (1 PT.)	473 mL
	24 FL. OZ. (1 PT. 8 FL. OZ.)	709 mL
	32 FL. OZ. (1 QT.)	946 mL

- (2) 24 FL. OZ. (1 PT. 8 FL. OZ.) 709 mL TOTAL: 48 FL. OZ. (1 QT. 1 PT.) 1.42 L
- (3) 24 FL. OZ. (1 PT. 8 FL. OZ.) 709 mL TOTAL: 72 FL. OZ. (2 QTS. 8 FL. OZ.) 2.13 L
- (4) 32 FL. OZ. (1 QT.) 946 mL TOTAL: 1 GAL. (4 QT.) 3.79 L

<< Front or Back Panel >>

EPA Reg. No.: 777-103  
EPA Est. No.: 777-NJ-2 8155-OH-1  
777-OH-1 11525-IL-1  
55179-IN-1  
75371-IN-1  
68777-NY-1  
09019-OH-001  
09019-OH-002  
312-WI-1

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR - 7 2008

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

See bottom or side (for Lot / Date code)

777-103

<< Back Panel >>

**Questions? Comments? Call: (1-800-228-4722) (1-800-677-9218)**  
(or) Visit us at ([www.lysol.com](http://www.lysol.com)) ([www.reckittprofessional.com](http://www.reckittprofessional.com))  
Made in U.S.A. © RBI (year)  
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054 (-xxxx)  
Contains no phosphates (Phosphate free)  
This (bottle) (container) is made of x% post-consumer recycled plastic.

<< Back Panel – Optional text >>

Important facts (about this product)  
Encourage your state and local authorities to establish a program to recycle this (bottle) (container).  
Recycle Symbol

<< Back Panel – Optional text - PROFESSIONAL USE products only >>

Company Logo (Reckitt Benckiser Professional)  
An important part of a comprehensive infection control program  
Meets AOAC Use-dilution Efficacy test standards for hospital disinfectant toilet bowl cleaners  
Part of an infection control program  
This product contains no phosphates and is germicidal when used as directed but differs in composition from  
other Lysol® Brand products.

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To use the term "germ\*" the product must be efficacious against 2 of the 3 major classes of organisms.  
The product label must identify the specific bacteria\*, virus\*, fungus\* & mold\*.

4/10

<< FRONT or BACK PANEL CLAIMS - use as bullet point or in paragraph format >>

<< INTRODUCTORY 6-mos. CLAIMS >> (New) (Improved) (Formula)

<< MARKETING CLAIMS >>

(Bactericidal\*) (Germicidal\*\*) (Sanitizer\*\*\*) (Virucidal†) (Toilet Bowl Cleaner) (Toilet Bowl Disinfectant)

(Cleans) (Deodorizes) (Disinfects) (Sanitizes)

(Deep cleaning) (Thick) (Tough stain) (Formula)

Duraguard's thick formula coats above and below the waterline. This coating action provides longer contact time to help dissolve tough rust stains and mineral deposits on contact to make cleaning easier.

<< USAGE CLAIMS >>

For use in {insert site}

Great for everyday (cleaning) (deodorizing) (disinfecting) (and) (sanitizing)

Use in conjunction with other Lysol® products for a clean bathroom

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5/10

<< CLEANING CLAIMS >>

Create (Maintain) a (protective) barrier against stains (where germs may live) (for up to 150 flushes)  
Destroys tough (the toughest) stains  
For a bright (shiny) (white) (clean) toilet bowl  
Helps keep water flow optimal  
Its thick formula coats above and below the waterline  
Keeps stains (where germs may live) from sticking  
Keeps working to fight and (help) prevent stains from sticking (to the toilet bowl)  
Leaves bowl disinfected, clean and shiny  
Leaves your bowl (disinfected) clean and shiny  
Long-lasting (stain protection) formula  
Penetrates and dissolves tough stains  
Penetrates (Dissolves) (Removes) even the toughest {insert soils}  
Powerful cleaner  
Powerful cleaning (formula)  
Powerful cleaning formula dissolves tough stains and mineral deposits (under the rim) (and) (deep into the 'S' bend)  
(into the mouth trap)  
Powers out {insert soils}  
Provides (long-lasting) stain protection (between flushes)  
Removes {insert soils}  
Removes {insert soils} through (the 'S' bend) (the mouth trap) (and) (the pipes)  
Removes tough rust and mineral stains  
Specially designed to (remove) (penetrate) (destroy) (dissolve) the toughest {insert soils}  
Specially designed to (remove) (penetrate) (destroy) (dissolve) tough (stubborn) {insert soils}  
Thick clinging action

<< Use Sites / Surfaces / Soils >>

Sites: (Clinics) (Day Care Centers) (Dental Offices) (Doctor Offices) (Health Care Facilities) (Homes) (Households)  
(Hospitals) (Hotels / Motels) (Infirmaries) (Institutions) (Laboratories) (Nursing Homes) (Office Buildings)  
(Physician's Offices) (Restaurants) (Schools)

Surfaces: (Vitreous china) (Porcelain) (toilets) (bidets) (urinals)

Soils: (rust) (lime scale) (hard water) (mineral) (toilet rings) (build-up) (stains) (deposits)

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6/10

<< SANITIZING CLAIMS (Hard non-porous, non-food contact surface) >>

<< front / back panel claim >> Kills 99.9% of bacteria in seconds\*\*\*

<< back panel sanitization qualifier >> \*\*\*Kills 99.9% of (Enterobacter aerogenes) (Escherichia coli O157:H7) (Staphylococcus aureus) inside the toilet above the waterline in 30 seconds.

<< DISINFECTING CLAIMS >>

Cleans as it disinfects  
Disinfects above and below the waterline  
Disinfects below the waterline  
Disinfects in hard to reach areas (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)  
Disinfects in hard to reach places (like) (into the 'S' bend) (into the mouth trap)  
Disinfects the entire toilet bowl (interior)  
Disinfects where you can't see (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)  
Gives you (full) (complete) (total) disinfection inside the toilet  
Kills (99.9% of) germs above and below the waterline\*\*  
Kills (99.9% of) bacteria and viruses above and below the waterline\*\*  
Kills (99.9% of) germs in hard to reach areas (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)\*\*  
Kills (99.9% of) bacteria and viruses in hard to reach areas (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)\*\*  
Kills (99.9% of) germs where you can't see (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)\*\*  
Kills (99.9% of) bacteria and viruses where you can't see (like) (under the rim) (and) (into the 'S' bend) (into the mouth trap)\*\*  
Kills Germs\*\*  
Kills Rotavirus WA in 30 seconds.  
Total disinfection for inside your toilet (above and below the waterline)

<< back panel disinfection qualifier >>

- \* Kills: (Enterococcus faecalis) (Escherichia coli) (Klebsiella pneumoniae) (Pseudomonas aeruginosa) (Salmonella enterica) (Shigella dysenteriae) (Staphylococcus aureus)
- \*\* Kills: (Enterococcus faecalis) (Escherichia coli) (Klebsiella pneumoniae) (Pseudomonas aeruginosa) (Salmonella enterica) (Shigella dysenteriae) (Staphylococcus aureus) and (Hepatitis A Virus) (Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]) (Poliovirus Type 1) (Rotavirus WA)
- † Kills: (Hepatitis A Virus) (Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]) (Poliovirus Type 1) (Rotavirus WA)

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7/10

<< USE DIRECTIONS >>

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using product.

<< OPENING INSTRUCTIONS – back panel >>

**To Open Child Resistant Cap:** Hold bottle firmly with one hand on a flat surface. With other hand, while pushing down on top of cap, turn cap counterclockwise. **Avoid squeezing bottle when opening.** To reseal, twist cap clockwise until tightly closed.

**To Open Child Resistant Cap:** Hold bottle firmly with one hand on a flat surface. With other hand, squeeze sides of cap where indicated while turning counterclockwise. (Do not remove cap.) **Avoid squeezing bottle when opening.** To reseal, twist cap clockwise until tightly closed.

<< Non-removable cap >>

**To Open Child Resistant Cap:** Hold bottle firmly with one hand. **DO NOT SQUEEZE BOTTLE WHEN OPENING.** With other hand:  
1. Place fingers on marked ridges on opposite sides of cap.  
2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**  
3. To reseal, squeeze cap again and turn clockwise until tightly closed.

<< Removable cap >>

**To Remove Child Resistant Cap:** Hold bottle firmly with one hand. **DO NOT SQUEEZE BOTTLE WHEN OPENING.** With other hand:  
1. Place fingers on marked finger pads on opposite sides of cap.  
2. Squeeze cap firmly and turn counterclockwise to unscrew.  
3. Remove cap. 4. To reseal, replace cap and turn clockwise until tightly closed.

<< Optional Side panel pictograms - can only be used in conjunction with required back panel instructions >>

<< Non-removable >>



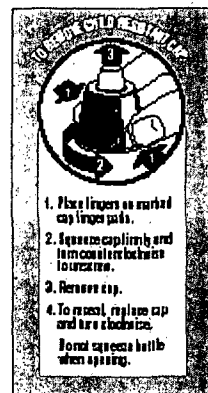
1. Place fingers on marked cap ridges.  
2. Squeeze cap firmly and turn counterclockwise until it stops. Do not remove cap.  
3. To reseal, squeeze cap again and turn clockwise.  
DO NOT squeeze bottle when opening.

<< Removable – 1 >>



1. Place fingers on marked cap finger pads.  
2. Squeeze cap firmly and turn counterclockwise to unscrew.  
3. Remove cap.  
4. To reseal, replace cap and turn clockwise.  
DO NOT squeeze bottle when opening.

<< Removable – 2 >>



1. Place fingers on marked cap finger pads.  
2. Squeeze cap firmly and turn counterclockwise to unscrew.  
3. Remove cap.  
4. To reseal, replace cap and turn clockwise.  
DO NOT squeeze bottle when opening.

<< Pictogram text >>

**To Open Child Resistant Cap:**  
1. Place fingers on marked cap ridges.  
2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**  
3. To reseal, squeeze cap again and turn clockwise.  
**DO NOT** squeeze bottle when opening.

**To Remove Child Resistant Cap:**  
1. Place fingers on marked cap finger pads.  
2. Squeeze cap firmly and turn counterclockwise to unscrew.  
3. Remove cap.  
4. To reseal, replace cap and turn clockwise.  
**DO NOT** squeeze bottle when opening.

**To Remove Child Resistant Cap:**  
1. Place fingers on marked cap finger pads.  
2. Squeeze cap firmly and turn counterclockwise to unscrew.  
3. Remove cap.  
4. To reseal, replace cap and turn clockwise.  
**DO NOT** squeeze bottle when opening.

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8/10

<< CLEANING / DISINFECTING / SANITIZING – hard non-porous surfaces & non-porous, non-food contact surfaces>>

**To Clean, Disinfect / Sanitize:**

1. Flush first and remove excess dirt and grime before cleaning and disinfecting.
2. Wet all surfaces of bowl interior, including sides of bowl and under the rim, with at least 4 oz. of liquid [squeeze bottle approximately 15 seconds]. (Replace cap securely.)
3. **Disinfect:** Let soak for at least 10 minutes. **Sanitize:** Let stand for 30 seconds. **Do not close toilet bowl lid.**
4. Brush entire bowl thoroughly with a bowl brush and flush.
5. Rinse brush in fresh water after use.

**To Remove Tough Stains:** Apply a generous amount of liquid directly onto the tough stains. For severe rust stains, if possible, remove water from bowl before applying liquid. Let soak for 15 minutes. **Do not close toilet bowl lid.** Brush entire bowl thoroughly with a bowl brush and flush. Rinse brush in fresh water after use. Repeat if necessary.

**For Long-Lasting Stain Prevention:** Surface must be pre-cleaned according to above directions. Apply 4 oz of product under the rim and on the side of the bowl, letting it run down into the water. **Do not brush. Do not close toilet bowl lid.** Leave for 10-15 minutes then flush.

<< IMPORTANT: The following is required for professional use products making claims against HIV-1: >>

**KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1] [AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS,** in health care settings 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:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks or eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**CONTACT TIME:** Allow surface / object to remain wet for 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

<< ADVISORY STATEMENT – MUST BE INCLUDED on all products>>

Duraguard has been specially formulated for use only in (vitreous china) (porcelain) toilet bowls (bidets) (and urinals). It should not be used or placed on toilet bowl lids, vanities, sinks, bathtubs, cabinets, countertops, rugs, etc. Clean up spills and drips immediately. **Do not use with chlorine bleach or any other chemical products.** Will not harm plumbing or septic systems. Fumes are corrosive to metal.

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9/10

<< MICROORGANISMS - must be identified by genus & species. Abbreviations may be included in (parens). >>

<< 10-min. Disinfection against Bacteria >>

Enterococcus (Streptococcus) faecalis	(ATCC # 838)	(leads to blood infections)
Escherichia coli	(ATCC # 11229)	(a leading cause of diarrhea, vomiting, food poisoning and bloody diarrhea)
Klebsiella pneumoniae	(ATCC # 4532)	(a leading cause of pneumonia and lung illnesses)
Pseudomonas aeruginosa	(ATCC # 15442)	(a leading cause of pneumonia and lung illnesses)
Salmonella enterica	(ATCC # 10708)	(a fecal / orally transmitted bacteria which may lead to food borne disease, food poisoning, diarrhea, dehydration, stomach cramps, fever and vomiting.)
Shigella dysenteriae	(ATCC # 11835)	(a leading cause of bloody diarrhea, breaks down intestinal lining.)
Staphylococcus aureus	(ATCC # 6538)	(a leading cause of skin infections, boils, food poisoning, blood infections)

<< 10-min. Disinfection against Viruses >>

Hepatitis A		
Human Immunodeficiency Virus Type 1 [HIV-1]		(cause of AIDS virus)
Poliovirus Type 1		
Rotavirus WA		(a leading cause of infectious diarrhea in children)

<< 30-sec. Disinfection against Virus >>

Rotavirus WA		(a leading cause of infectious diarrhea in children)
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<< 30-sec. Sanitization against Bacteria on hard, non-porous, non-food contact surfaces >>

Enterobacter aerogenes	(ATCC # 13048)
Escherichia coli O157:H7	(ATCC # 43888)
Staphylococcus aureus	(ATCC # 6538)

Symbol Designation – used on product labels:

Single asterisk (*)	bacteria*	used for identifying disinfection against specific bacteria.
Dagger (†)	viruses <sup>†</sup>	used for identifying disinfection against specific viruses.
Double Dagger (††)	soils <sup>††</sup>	used for identifying cleaning of specific soils
Double asterisk (**)	germs**	used for identifying disinfection against specific bacteria and virus or fungi.
Triple asterisk (***)	sanitizes***	used for all claims of sanitization

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10/10

<< PRECAUTIONARY / FIRST AID / STORAGE-DISPOSAL INSTRUCTIONS >>

**PRECAUTIONARY STATEMENTS:** Hazards to Humans and Domestic Animals

**DANGER: CORROSIVE.** Causes irreversible eye damage and skin burns. Harmful or fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear [safety glasses / goggles]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. Do not breathe vapor or fumes. Keep out of reach of children.  
**Contains Hydrochloric Acid.**

NOTE: First Aid statement will not appear in "box" format for 16 oz. individual containers do to label constraint

FIRST AID	
<b>If in Eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"><li>• Call a Poison Control Center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the Poison Control Center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li><li>• Call a Poison Control Center or doctor for further treatment advice.</li></ul>
CONTACT NUMBER	
Questions? Comments or In case of an emergency call toll free (1-800-228-4722) (1-800-677-9218). Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

<< Storage and Disposal language – Household containers >>

**STORAGE AND DISPOSAL:** Store in original container out of reach of small children. Keep securely closed in a cool, well-ventilated area. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

<< Storage and Disposal language – Professional containers >>

**STORAGE AND DISPOSAL:**

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

**STORAGE:** Store in cool, well-ventilated area, inaccessible to small children.

**DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly and discard in trash or offer for recycling, if available.

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