

777-83

12-10-2009

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



Office of Pesticide Programs

DEC 10 2009

Liane Jenkins
Senior Regulatory & Registration Compliance Specialist
Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

FILE COPY

Subject: Lysol Brand Disinfectant Bleach Plus
EPA Registration No. 777-83
Application Date: September 11, 2009
Receipt Dated: September 14, 2009

Dear Ms. Jenkins:

The following amendments, submitted in connection with registration under the Federal Insecticide, are acceptable with the following conditions:

Conditions:

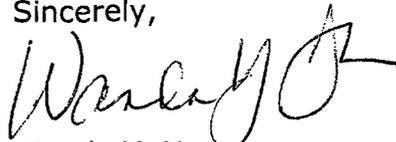
1. The term "All Purpose" is not acceptable and has been removed from the label. The Agency will accept "Multi-Purpose" in place of All Purpose.
2. The heightened efficacy claim "Powerful" in your marketing section is unacceptable and has been removed from the label.
3. On, page 3 of your label in the section involving "non-living allergen removal" information. This section has been removed per the instruction on page 7 of the label.
4. Mold Allergens and Spores are public health claims which have been removed.
5. Correct the typographical error for "where" in the Advisory Statements.
6. There are 2 separate contact times for Disinfection of Viruses on Page 7 of the label you must clarify under what circumstances each is applicable. The contact time differences are 5 minutes and 30 seconds for the exact same organisms.
7. The marketing text declares to claims for killing viruses and bacteria. The first virus and bacteria kill claim is 99.9% and second is 100%. Please provide documentation to support the 100% claim.

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me at (703) 308-6345.

Sincerely,



Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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<< Front Panel >>

ACTIVE INGREDIENT:

Sodium Hypochlorite..... 2.0%

OTHER INGREDIENTS:..... 98.0%

TOTAL:..... 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING: Eye and skin irritant. See back (side) panel for additional precautionary statements and first aid.
Use only in well ventilated areas.

NET CONTENTS:

16 FL. OZ.	(1 PT.)	473 mL
17 FL. OZ.	(1 PT. 1 FL. OZ.)	502 mL
22 FL. OZ.	(1 PT. 6 FL. OZ.)	650 mL
24 FL. OZ.	(1 PT. 8 FL. OZ.)	709 mL
26 FL. OZ.	(1 PT. 10 FL. OZ.)	768 mL
28 FL. OZ.	(1 PT. 12 FL. OZ.)	828 mL
30 FL. OZ.	(1 PT. 14 FL. OZ.)	887 mL
32 FL. OZ.	(1 QT.)	946 mL
36 FL. OZ.	(1 QT. 4 FL. OZ.)	1.06 L
38 FL. OZ.	(1 QT. 6 FL. OZ.)	1.12 L
40 FL. OZ.	(1 QT. 8 FL. OZ.)	1.18 L
64 FL. OZ.	(2 QT.)	1.89 L
128 FL. OZ.	(1 GAL.)	3.79 L

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(2) 24 FL. OZ. (1 PT. 8 FL. OZ.) 709 mL TOTAL: 48 FL. OZ. (1 QT. 1 PT.) 1.43 L

<< Front or Back Panel >>

EPA Reg. No.:	777-83			
EPA Est. No.:	777-NJ-2	55179-IN-1	312-WI-1	312-WI-3
	11525-IL-1	71354-NC-1	09019-OH-1	
	8791-MO-1	68777-NY-1	09019-OH-2	
	046813-CN-6	75371-IN-1	8155-OH-1	

See bottom or side (for Lot/Date code)

<< Back Panel >>

Questions? (symbol of telephone)

(Call:) (1-800-228-4722) (1-800-677-9218)

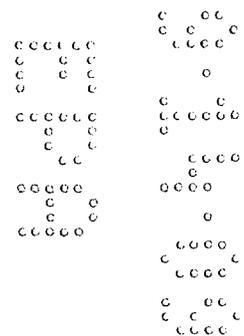
For ingredient (and other) information, (www.lysol.com) (www.reckittprofessional.com)

Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054 (-xxxx)

Made in {insert country} © RBI {insert year}

Contains no phosphates

This (bottle) (container) is made of x% post-consumer recycled plastic.



<< Back Panel-Optional text >>

Monday – Friday, 8:45 a.m. – 4:30 p.m. (Eastern time)

Company Logo (Reckitt Benckiser) (rb) (Reckitt Benckiser Professional)

Recycle Symbol

Important facts (about this product)

Encourage your local authorities to establish a program to recycle this (bottle) (container).

Important: For directions for use and first aid instructions in Spanish, please call {insert phone number}

If the last portion of product is difficult to dispense, turn the trigger 180° (degrees) to face opposite direction; this will help ensure full use of contents.

Learn more about (the importance of good hygiene habits) (and) (the appropriate use of disinfectants) (in good hygiene) (and the many ways that Lysol® is promoting good hygiene habits) (for your family and community) go to www.spreadinghealth.com

Note:

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The term "x" is a place holder for a number between 1 and 99.

<< Front or Back Panel – Cleaning & Deodorizing claims – use as bullet point or in paragraph format >>

(Cleans) (Cuts through) (Eliminates) (Powers out) (Powers through) (Removes) (tough) (stubborn) (Bathroom) (Kitchen) (dirt) (grease) (grime) (soap scum) (soils) (stains) (and) (everyday messes) (with the power of bleach)

Cleans as it disinfects

Cleans greasy dirt better than ordinary bleach alone

Complete Clean

Cuts tough grease

Cuts through dirt, grease and stains

Cuts through kitchen grease and stains

Cuts through tough food stains and greasy soils on {insert use sites}

(Even) removes x% of allergens^{††}

(Even) removes x% of mold allergens^{††}

(Even) removes x% of mold spores^{††}

(Great) Whitening action

Leaves a sparkling shine

Powers out greasy dirt, mildew stains and tough food stains.

Powers through (soap scum) (and) (grease) (better than ever)

Powers through (tough) (grease) (and) (soap scum) (better than ever)

(Reduces) (removes) (controls) (more than) (up to) (x% of) (the most) (common)

(household) (allergens) (around your home) (around your kitchen) (around your bathroom) (on your floors)^{††}

(Reduces) (removes) {insert allergens}

Removes 90% of allergens^{††}

Removes {insert soils} from {insert use sites}

Removes greasy dirt better than bleach alone

Removes mildew stains and soap scum

Removes soap scum

Removes (the toughest) (tough) stains

Removes tough {insert soils}

Removes tough: soap scum, bathtub rings, mildew (stains), hard water (stains)

Removes tough spots and stains

Removes tough stains and soap scum

Whitening power

Whitening stain remover

Whitens and removes mold (stains) and mildew stains

Whitens and removes stains and greasy dirt

Whitens as it cleans

Whitens cutting surfaces and grout in floors and walls

Whitens grout in bathtubs, showers, floors and walls

Whitens to a (sparkling) shine

<< Back panel – non-living allergen removal claim qualifier >>

^{††} This product removes the following allergens: (cat allergens) (cockroach allergens) (cockroach debris)

(cockroach matter) (cockroach particles) (dog allergens) (dust mite debris) (dust mite particles)

(dust mite allergens) (hair) (mold allergens) (mold spores) (pet allergens) (pet dander) (pet hair) (pollen allergens).

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<< Front or Back Panel – Sanitizing – Hard, non-porous surface claims – use as bullet point or in paragraph format >>

Fast acting sanitizer

Kills bacteria on hard, non-porous surfaces in seconds***

Kills (Eliminates) 99.9% of bacteria in 30 seconds***

Kills (Eliminates) 99.9% of bacteria on hard, non-porous surfaces in 30 seconds***

Sanitizes in 30 seconds: (Campylobacter jejuni) (Enterobacter aerogenes) (Escherichia coli O157:H7)
(Listeria monocytogenes) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus)
(and) (Vibrio cholerae)

<< Back Panel - Sanitization Qualifier >>

*** Kills (Eliminates) 99.9% of (Campylobacter jejuni), (Enterobacter aerogenes), (Escherichia coli), (Listeria monocytogenes), (Pseudomonas aeruginosa), (Salmonella (choleraesuis) enterica), (Staphylococcus aureus), (and) (Vibrio cholerae) on hard, non-porous surfaces in 30 seconds.

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<< Front or Back Panel – Disinfecting claims – use as bullet point or in paragraph format >>

Controls the growth of mold and mildew
Destroys mold and mildew
Disinfects, deodorizes and (kills) (eliminates) odor-causing germs**
Disinfects with Bleach
Disinfects with the power of bleach
Easily removes tough (mold) (and) mildew) from grout
Effective against: (insert organisms)
Effective against: (the) common cold, infectious diarrhea, athlete's foot fungus, mold & mildew**
Even mold isn't too tough for Lysol®
Got Mold? (Kill) (Destroy) (Eliminate) (Wipe Out) (Remove it) with Lysol®
Helps prevent the growth of mold and mildew
Kills 99.9% of germs**
Kills 99.9% of viruses and bacteria**
Kills 99.9% of viruses†
Kills 100% of bacteria and viruses**
(Kills) (Destroy) (Eliminate) (Wipes Out) (Removes) visible mold
(Kills) (Destroys) (Eliminates) (tough) (mold) (and) (mildew) without scrubbing
(Kills) (Destroys) (mold) (and) (mildew)
(Kills) (Eliminates) 99.9% of germs in 30 seconds**
(Kills) (Eliminates) 99.9% of germs on hard, non-porous surfaces in 30 seconds**
(Kills) (Eliminates) germs**
(Kills) (Eliminates) (Removes) mold and mildew
Kills germs on hard, non-porous surfaces in seconds**
Kills (household) germs**
Kills in 30 seconds: (Rhinovirus Type 39) (Rotavirus WA) (Human Immunodeficiency Virus Type 1 [AIDS Virus])
(Aspergillus niger) (and) (Trichophyton mentagrophytes).
Kills in 3 minutes: Campylobacter jejuni
Kills in 5 minutes: (Enterococcus faecalis) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus)
(Herpes Simplex Virus Type 1 & 2) (and) (Respiratory Syncytial Virus [RSV])
Kills more than 99.9% of bacteria and viruses**
Kills odor-causing bacteria*
(Kills) (Removes) (mold) (mildew)
Kills viruses†
Penetrates to (kill) (eliminate) and destroy tough mold, mildew and bacteria at its source
Prevents mold and mildew
Prevents the growth of mold and mildew
Removes general soils, food stains, mold, mildew and soap scum.

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<< Back Panel - Disinfection claim qualifier >>

*Kills (Campylobacter jejuni), (Enterococcus faecalis), (Pseudomonas aeruginosa), (Salmonella enterica), (and) (Staphylococcus aureus) (on hard non-porous surfaces) (in 5 minutes).

** Kills (Campylobacter jejuni), (Enterococcus faecalis), (Pseudomonas aeruginosa), (Salmonella enterica), (Staphylococcus aureus), (Herpes Simplex Virus Type 1 & 2), (Human Immunodeficiency Virus Type 1 [AIDS virus]), (Rhinovirus Type 39), (Rotavirus WA), (Respiratory Syncytial Virus), (Aspergillus niger) (and) (Trichophyton mentagrophytes) (on hard non-porous surfaces) (in 5 minutes).

** Kills 99.9% of (Campylobacter jejuni), (Enterobacter aerogenes), (Escherichia coli), (Listeria monocytogenes), (Pseudomonas aeruginosa), (Salmonella enterica), (Staphylococcus aureus), (Vibrio cholerae) and (Human Immunodeficiency Virus Type 1 [AIDS virus]), (Rhinovirus Type 39), (Rotavirus WA), (Aspergillus niger), (Trichophyton mentagrophytes) (on hard non-porous surfaces) (in 30 seconds).

† Kills (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1 [AIDS Virus]) (Rhinovirus Type 39) (Rotavirus WA) (and) (Respiratory Syncytial Virus) (on hard, non-porous surfaces) (in 5 minutes).

† Kills (99.9% of) (Human Immunodeficiency Virus Type 1 [AIDS Virus]) (Rhinovirus Type 39) (and) (Rotavirus WA) (on hard, non-porous surfaces) (in 30 seconds).

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<< Back Panel - Use directions – IMPORTANT: Advisory statements must be included where appropriate >>

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Apply Carefully - Contains Bleach

Avoid contact with clothes, fabric, wood, rubber, carpet, painted / paper surfaces, non-porous vinyl surfaces, and finished floors. Rinse immediately after use on metal to avoid pitting or discoloration. Prolonged contact with metal, old porcelain, plastic laminate and marble may cause discoloration.

To Operate: Turn nozzle counter clockwise to preferred usage.

To Operate: Turn nozzle to ("ON") (desired) position.

(To Operate): **To Open:** Lift tab up, push back and press tab down to lock into open position.
To Close: Release tab from locked position, push tab down and snap closed.

To Refill (Bottle): Remove trigger sprayer. Pour in product from refill container and replace trigger.

To Refill (Bottle): Remove trigger unit from empty bottle and attach to new bottle.

To Clean (/ Deodorize) (/ Remove Allergens):** (Spray) (Apply to) surface until thoroughly wet. Wipe with a clean cloth or sponge and then rinse.

To Clean (Lime Scale) (Soap Scum) (and) (Greasy Soil): Allow product to sit 15-20 seconds to penetrate soil before wiping clean. Repeat if necessary.

To Sanitize / Disinfect: Pre-clean surface. (Spray) (Apply to) surface until thoroughly wet. **To Sanitize:** Leave for 30 seconds before wiping. **To Disinfect:** Leave for 5 minutes before wiping. Rinse all food contact surfaces with water after use. If the vapors bother you, leave the room while the product is working.

Kills Mold & Mildew: Apply to pre-cleaned surface. Let surface remain wet for 5 minutes and then allow to air dry. Repeat application at weekly intervals or when mold and mildew growth appears.

To Clean No-wax Floors: Mix 1 cup [8 oz.] of product per 1 gallon of water; mop until clean. Rinse for the best shine.

<< Advisory Statements – must be included were appropriate >>

Do not use on eating/cooking utensils, glasses/dishes or cookware.
Rinse bathtub / shower surfaces with water after using product.

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<< This page is for information purposes only. >>

<< Tested on hard non-porous surfaces >>

5-min. Disinfection against Bacteria:	(ATCC # 838) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538)	Enterococcus faecalis Pseudomonas aeruginosa Salmonella enterica Staphylococcus aureus
3-min. Disinfection against Bacteria:	(ATCC # 29428)	Campylobacter jejuni
5-min. Disinfection against Viruses:	(ATCC # VR-733 & 734) (ATCC # VR-340) (ATCC # VR-2018) (ATCC # VR-26)	Herpes Simplex Virus Type 1 & 2 Human Immunodeficiency Virus Type 1 [AIDS virus] Rhinovirus Type 39 (common cold) Rotavirus WA (infectious diarrhea) Respiratory Syncytial Virus [RSV]
30-sec. Disinfection against Viruses:	(ATCC # VR-340) (ATCC # VR-2018)	Human Immunodeficiency Virus Type 1 [AIDS virus] Rhinovirus Type 39 (common cold) Rotavirus WA (infectious diarrhea)
5-min & 30-sec. Disinfection against Fungi:	(ATCC # 6275 & 16404) (ATCC # 9533)	Aspergillus niger (mold & mildew) Trichophyton mentagrophytes (Athlete's Foot Fungus)

<< Tested on hard, non-porous, non-food contact surfaces >>

30-sec. Sanitization against Bacteria:	(ATCC # 29428) (ATCC # 13048) (ATCC # 43888) (ATCC # 19111) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538) (ATCC # 11623)	Campylobacter jejuni Enterobacter aerogenes Escherichia coli O157:H7 Listeria monocytogenes Pseudomonas aeruginosa Salmonella (choleraesuis) enterica Staphylococcus aureus Vibrio cholerae
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Symbol Designation – used on product labels:

Single asterisk (*)	bacteria*	used for identifying disinfection against specific bacteria.
Dagger (†)	viruses†	used for identifying disinfection against specific viruses.
Double asterisk (**)	germs**	used for identifying disinfection against specific bacteria and virus or fungi.
Triple asterisk (***)	sanitizes***	used for all claims of sanitization
Double Dagger (††)	allergens††	used for identifying the removal of specific allergens

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<< Soil / Surface / Use Sites - May be listed on product label in plural form >>

Soils: (Graphic - depicting soil)

Food stains General soils	Greasy soils Mildew stains	Mold stains Soap scum	Tough soils
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Non-living Allergens:

Cat dander allergens	Dog dander allergens	Mold allergens
Cockroach matter (allergens)	Dust mite matter (allergens)	Pet dander (allergens)
Cockroach debris (allergens)	Dust mite debris (allergens)	Pet dander
Cockroach matter (allergens)	Dust mite matter (allergens)	Pet hair (Hair)
Cockroach particles (allergens))	Dust mite particles	Pollen particle (allergens)

Hard Non-porous Surfaces: (Graphic - depicting surface)

Appliance exterior	Food Carts	Refrigerator / Freezer exterior
Cabinet (non-wood)	Garbage (Can)(Pail)(Container)	Shower (Shower Stall)
Counter (Countertop)	Glazed Ceramic Tile	Sink
Faucet	Glazed Porcelain Surface	Stove (Stovetop)
Fiberglass Fixtures	Grout	Toilet exterior
Fixtures (Chrome)	Highchair (non-wood)	Tub (Bathtub)
Fixtures (Stainless Steel)	Kitchen Table	Tiled Wall
Floors (No-wax)	Microwave exterior	Vinyl Shower Curtain
Floors (Sealed Ceramic Tile)	Non-medical (Chrome)	Water Fountain
Floors (Vinyl)	Non-medical (Stainless Steel)	

Household Use Sites: (Graphic - depicting site)

Bathroom	Family Room	Laundry Room	Storage area/room
Bedroom	Garage	Living Room	
Den/Study	Home/House	Nursery	
Dining Room	^ Kitchen	Play Room	

^ This product is not approved for use on food-contact surfaces.

Professional Use Sites:

^ Cafeteria	Health Care Facility	Nursing Home	Restroom
Day Care Center	Hospital	Office Building	School
Dental Office	Hotel / Motel	Physicians Office	^ Food Service Areas
Doctor's Office	Infirmiry	Restaurant	

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<< The following is required for PROFESSIONAL USE products making claims against: >>

<< Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus] >>

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 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 30 seconds.

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

<< The following Terminal Sterilant Statement is required for PROFESSIONAL USE products making claims against: >>

<< Qualified metal surfaces >>

This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.

<< Unqualified metal surfaces >>

This product is not to be used as a terminal sterilant / high level disinfectant on any surface that ⁽¹⁾ is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body; or ⁽²⁾ contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

WARNING: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Vapors may irritate. Use only in well-ventilated areas. Avoid prolonged breathing of vapors. Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. Harmful if swallowed. For sensitive skin or prolonged use, wear rubber gloves.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• 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.• Call a Poison Control Center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a Poison Control Center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the Poison Control Center or doctor.• Do not give anything by mouth to an unconscious person
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for further treatment advice.
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.	

<< Physical and Chemical Hazard language >>

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not mix with other (household) chemicals such as products containing ammonia, toilet bowl cleaners or acid cleaners as hazardous gases may be released.

<< Storage and Disposal language – Household containers >>

<< Trigger bottle >>

STORAGE AND DISPOSAL:

Store in a cool, well-ventilated area, inaccessible to small children. Keep securely closed. Refillable container. Do not reuse or refill except as described in the directions for use. Refill trigger bottle only with this product. If not refilling, discard in trash or offer for recycle, if available.

<< Pourable container >>

STORAGE AND DISPOSAL:

Store in a cool, well-ventilated area, inaccessible to small children. Keep securely closed. Non-refillable container. Do not reuse or refill this container. Then discard in trash or offer for recycle, if available.

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The term "this product" used throughout this document may be replaced with the marketed product brand name.
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*.
The term "x" is a place holder for a number between 1 and 99.

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<< Storage and Disposal language – Institutional & Industrial Containers >>

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in original container in areas inaccessible to children. Keep securely closed.

PESTICIDE DISPOSAL: To avoid waste, use all materials in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Discard in trash or offer for recycling, if available.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 10 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 777-83

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The term "this product" used throughout this document may be replaced with the marketed product brand name.
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The term "x" is a place holder for a number between 1 and 99.