



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 15 2007

Ms. Mary C. Pisculli
Regulatory & Registration Compliance Specialist
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace parkway
Parsippany, NJ 07054-0225

Subject: **Lysol Brand Foaming Disinfectant Basin, Tub & Tile Cleaner II**
EPA Registration Number 777-71
Application Dated August 31, 2007
Received Date September 4, 2007

Dear Ms. Pisculli:

The following label revisions submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

Proposed Amendment:

- Label amendment - remove fungicidal claims

Label:

1. Delete the 19th claim on page 2, "Help protect your (family house)(workplace) from germs with Lysol Brand Disinfectant Products " because the Agency believes this phrase is misleading. It implies that the product offers health protection against germs. This type of claim is beyond the Agency's jurisdiction and the scope of this product's registration as a disinfectant that kills viruses and bacteria on hard, nonporous surfaces.
2. Delete the 3rd claim "Antibacterial cleaning power (on hard, non-porous surfaces for (bathrooms) (restrooms)" and 31st claims "The most powerful (bathroom) (restroom) cleaner you can buy" on page 3 and the 22nd claim " Kills germs that ordinary cleaners don't" on page 4 because they imply heighten efficacy.

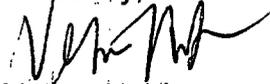
3. Revise the 5th claim "Effective against: (insert organisms) (in 10 minutes)" on page 4 by denoting where distributor should go/refer to for list of organisms that are mitigated in 10 minutes by placing the double asterisks in the {insert organism**}.
4. Revise the 6th claim "Effective against: (the) common cold, infectious diarrhes, salmonella" on page 4 by citing the organism that causes the disease; Rhinovirus Type 39 cause of common cold, E. coli O157:H7 cause of infectious diarrhea.
5. Revise the 21st statement on page 4, "Kills germs and controls the (spread)(growth) of mold and mildew," by adding the phrase "on hard, nonporous surfaces."
6. Revise the 25th claim "Prevents the spread of Harmful (household) germs" on page 4 by deleting the term, "harmful" and adding the phrase, "on hard nonporus surfaces."

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure

<< Front Panel >>

ACTIVE INGREDIENT:

Octyl decyl dimethyl ammonium chloride	0.050%
Dioctyl dimethyl ammonium chloride	0.025%
Didecyl dimethyl ammonium chloride	0.025%
OTHER INGREDIENTS:	99.900%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back (side) panel for additional precautionary statements.

NET WT.: 24 OZ. (1 LB. 8 OZ.) 680 g

<< Front or Back Panel >>

- EPA Reg. No.: 777-71
- EPA Est. No.: 777-NJ-2
- 11525-IL-1; RI-1
- 55179-IN-1
- 68777-NY-1
- 75371-IN-1
- 312-WI-1
- 09019-OH-001
- 09019-OH-002

See bottom or side (for Lot/Date code)
 Federal regulations prohibit CFC propellants in aerosols
 Graphic symbol (Contains no CFCs or other ozone depleting substances)

<< Back Panel >>

Questions? Comments? Call: (1-800-228-4722) (1-800-677-9218)
 (or) Visit us at (www.lysol.com) (www.reckittprofessional.com)
 Made in U.S.A. © RBI (year)
 Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)
 Important facts (about this product)
 Contains no phosphates
 This can is made from an average of 25% recycled steel [10% post-consumer].
 Encourage your local authorities to establish a program to recycle this (bottle) (container).

<< Back Panel – Optional text for Professional Use products only >>

Monday – Friday, 8:45 am – 4:30 pm [Eastern time]
 Company Logo (Reckitt Benckiser Professional)

**ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 NOV 15 2007**

*Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 777-71*

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4 8 11

<< Introductory 6-mos. Claims >> (Advanced) (Antibacterial Action) (Best) (Complete) (Improved) (New)
(Unbeatable) (Unique) (Formula)

<< Front or Back Panel - Marketing / Product Performance claims – use as bullet point or in paragraph format >>

(Country) (Fresh) (Green Apple) (Original) (Pacific Fresh) (Summer) (Summer Fresh) (Breeze)
(Scent) (Unfragranced) (Unscented) (Clean) (Pleasant) (Fragrance) (New & Improved Fragrance)
(New & Improved Scent)

(3-in-1) (4-in-1) (Foaming Action) (Foaming & Deodorizing Action) (Multi-Action) (Multi-Surface) (Triple Action)
(Versatile) (with Power Foam Action) (Quick & Easy) (Ready to use)
(Cleaning) (Cleans) (Deodorizes) (Disinfectant) (Disinfects) (Sanitizer) (Sanitizes) (Shines)

(Economy) (Great) (Mega) (Super) (Value) (Size)

Clings to vertical surfaces

Contains no (abrasives) (bleach) (or harsh acids) (so it won't scratch surfaces)

Easy to use

For a cleaner, fresher household

For any surface where germs are a concern

Good (for everyday cleaning) (and) (for your toughest bathroom stains) (your toughest restroom stains).

Good for most indoor and outdoor cleaning tasks

Great for (bathrooms) (restrooms) (insert use site)

Great for everyday use (in) (bathrooms) (restrooms)

(Great) For use on (insert surfaces) (hard non-porous surfaces located in: (insert use sites))

(Great) For use on (the following) (modern) washable surfaces (insert surfaces)

Great on (insert use surface / soil)

Leaves no sticky residue

Leaves your (bathroom) (restroom) (house) (home) smelling clean and fresh

Makes your (cleaning) job easier (in the) (bathroom) (restroom) (household) (all over the house).

No scrubbing (or streaking) (or filming)

Non-abrasive formula (will not scratch surfaces)

Powers through your toughest cleaning jobs

Protect your (family's home) (work place) from germs with (Professional) Lysol® Brand Disinfectant products

Starts to work before you do

(This product is) germicidal when used as directed for disinfecting.

Works on a wide range of (bathroom) (restroom) surfaces

People respect the Lysol® brand name for providing surface disinfection (and gain the added benefit of a clean, sanitary environment)

Use (this product) to clean, shine and disinfect hard, non-porous washable (bathroom) (restroom) surfaces and fixtures (around the home) (in) (insert use sites)

<< Front or Back Panel – PROFESSIONAL USE ONLY - Disinfecting & Deodorizing claims >>

(This product) meets AOAC Germicidal Spray efficacy standards for hospital aerosol disinfectants

For use on (medical) (lamps) (stands) (patient) (bed frames) (bedside tables) (wheelchairs) (and other similar equipment)

Formulated for medical institution's (infection control program) needs

Use this product to (both) clean and disinfect non-critical hard, non-porous environmental surfaces in all health care facilities (including dental and physician offices).

Tuberculocidal: Kills Mycobacterium bovis [BCG] after 40 minutes at 20°C (68°F) on inanimate surfaces.

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The product label must identify the specific bacteria, virus, fungus & mold.

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

- A clean that cares
- An efficient way to clean
- Antibacterial cleaning power (on hard, non-porous surfaces) for (bathrooms) (restrooms)
- Brilliant (streak-free) (bright) (glistening) shine
- Cleans and disinfects (all over the house) (bathrooms) (restrooms)
- Cleans and prevents mold and mildew
- Cleans as it disinfects
- Cleans everyday (bathroom) (restroom) messes
- Cleans everyday dirt and grime
- Cleans the toughest (soap scum) (and) (grime) (mold and mildew stains)
- Cleans to a brilliant shine
- Cleans tough messes fast
- Cleans tough (soap scum) (mold and mildew) (and grime)
- Cleans without bleaching
- Convenient: Just spray foam onto hard, non-porous surface. Even sprays upside down.
- Convenient: Just spray on to clean and wipe off. (No scrubbing or rinsing.) (Even sprays upside down.)
- Cuts (Cleans) (greasy dirt) (soap scum) (and) (bathroom soils) (restroom soils)
- Cuts cleaning time
- Cuts through tough (soap scum) (and) (mold and mildew)
- Deep down clean
- Destroys (Eradicates) (tough) (soap scum) (and grime)
- Foams and clings onto tough soap scum
- No scrubbing or rinse required
- Penetrates deep beneath the surface
- Powers (Cuts) through tough soap scum (and) (mold and mildew)
- Removes and cleans (insert soils)
- Removes and cleans: soap scum, bathtub rings, mildew (stains), hard water (stains)
- Removes tough dirt (and grime)
- Removes (tough) mold and mildew stains (at the root)
- Removes (tough) soap scum
- The most powerful (bathroom) (restroom) cleaner you can buy
- (The) One-step cleaner
- The ultimate clean
- Tough on (hard water stains) (lime scale) (soap scum) (mold and mildew)
- Use daily to help maintain a clean, fresh and shiny surface

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

- Fast Acting Sanitizer
- Kills (Eliminates) 99.9% of bacteria***
- Kills (Eliminates) 99.9% of bacteria in 30 seconds***
- Kills (Eliminates) 99.9% of bacteria on hard, non-porous surfaces in seconds***
- Kills (Eliminates) 99.9% of bacteria on hard, non-porous surfaces in 30 seconds.***
- Kills (Eliminates) 99.9% of bacteria and viruses on hard, non-porous surfaces in seconds***
- Leaves (household) (bathroom) (restroom) surfaces sanitary
- One step cleaning and sanitizing
- Sanitizes (household) (bathroom) (restroom) surfaces in 30 seconds***

<< Back Panel – Sanitizing claim qualifier >>

- < Bacteria > *** (Kills) (Eliminates) 99.9% of (Enterobacter aerogenes) (Enterococcus faecalis [VRE]) (Escherichia coli O157:H7) (Staphylococcus aureus) (Staphylococcus aureus [MRSA]) (on hard, non-porous surfaces) (in 30 seconds).
- < Bacteria & viruses > *** Kills 99.9% of (Enterobacter aerogenes) (Enterococcus faecalis [VRE]) (Escherichia coli O157:H7) (Staphylococcus aureus) (Staphylococcus aureus [MRSA]) (Rhinovirus Type 39) and (Rotavirus WA) (in 30 seconds):

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

(Antibacterial) (Antibacterial Action) (Bactericidal*) (Bactericide*) (Deodorizer) (Deodorizes) (Disinfectant) (Disinfects) (Fungistat) (Fungistic) (Germicidal**) (Hospital Disinfectant) (Mildewstatic) (Tuberculocidal*) (Virucidal¹)

An effective disinfectant cleaner (on non-food contact surfaces) and deodorizer (for use in the) (bathroom) (restroom)

An effective disinfectant cleaner (on non-food contact surfaces) and deodorizer for use on {insert use sites}

Controls mold and mildew growth (from its root)

Disinfects as it cleans

Effective against: {insert organisms} (in 10 minutes)

Effective against: (the) common cold, infectious diarrhea, salmonella**

Effective: Cleans, shine and disinfects

Effective: Cleans, shines, deodorizes and disinfects washable (bathroom) (restroom) surfaces and fixtures (around the home) (in schools) (and other public places).

Eliminates (Removes) odors

Eliminates (Removes) odors caused by (bacteria) (germs) (mildew)

For disinfecting against {insert organisms} on hard, non-porous surfaces.

For killing {insert organisms} on hard, non-porous surfaces

For use as a (disinfectant) (or) (sanitizer) in: {insert use sites}

Kills 99.9% of bacteria and viruses**

Kills (Disinfects) common (household) bacteria and (viruses) without bleaching**

Kills (Disinfects) common (household) germs without bleaching**

Kills (Eliminates) bacteria and viruses**

Kills (Eliminates) germs**

Kills germs**

Kills germs and controls the (spread) (growth) of mold and mildew**

Kills germs that ordinary cleaners don't**

Kills germs while it cleans**

Kills odor-causing bacteria (in the) (bathroom) (restroom)*

Prevents the spread of harmful (household) germs**

Removes odors from the following surfaces: {insert surfaces}

(The one step cleaner) (The two-job cleaner) that kills (common household) bacteria while it cleans (tough) everyday (bathroom) (restroom) (household) messes*

(The one step cleaner) (The two-job cleaner) that kills (common household) bacteria and viruses while it cleans (tough) everyday (bathroom) (restroom) (household) messes**

<< Back Panel – Disinfection claim qualifier >>

* Kills (99.9% of) (Enterococcus faecalis) (Escherichia coli 0157:H7) (Mycobacterium bovis [BCG]) (Pseudomonas aeruginosa) (Salmonella enterica) (and) (Staphylococcus aureus).

** Kills (99.9% of) (Enterococcus faecalis) (Escherichia coli 0157:H7) (Mycobacterium bovis [BCG]) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) and (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]) (Influenza A2 [Japan 305/57]) (Poliovirus Type 1) (Respiratory Syncytial Virus [RSV]) (Rhinovirus Type 39) (and) (Rotavirus WA) (on hard non-porous surfaces) (in 10 minutes).

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

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

Shake well before using.

(For) General (Bathroom) Cleaning: Point button to mark on rim. Hold can 6-8 inches from surface to be cleaned and spray the entire surface. Press button and cover area lightly with (white) foam. After a few seconds, wipe off with a clean cloth or sponge. For (heavily) (visibly) soiled surfaces allow foam to remain longer on surface before wiping.

General Disinfection: Hold can 6-8 inches from surface and thoroughly saturate surface with foam. Let stand for 10 minutes. Remove excess liquid with a cloth or sponge. For (heavily) (visibly) soiled surfaces, clean first according to Cleaning directions.

Tuberculocidal: To kill Mycobacterium bovis BCG: Spray on pre-cleaned surface until thoroughly covered with foam. Leave on for 40 minutes. Wipe with a damp cloth or sponge.

To Sanitize / Deodorize: For hard, non-porous (bathroom) (restroom) surfaces, spray surface until thoroughly wet. Let stand for 30 seconds before wiping. For (heavily) (visibly) soiled surfaces, clean first according to Cleaning directions.

To Sanitize / Deodorize / Disinfect: For hard, non-porous (bathroom) (restroom) surfaces, spray surface until thoroughly wet. **To Sanitize:** Let stand for 30 seconds before wiping. **To Disinfect:** Let stand for 10 minutes before wiping. For (heavily) (visibly) soiled areas, a pre-cleaning is required.

For Mold & Mildew Control on Hard, Non-porous Surfaces: Spray on surface until thoroughly covered with foam. Let stand for 3 minutes. Wipe with a damp cloth or sponge. Reapply as necessary.

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

Does not harm most (bathroom) (restroom) surfaces.
For other surfaces, spot test in an inconspicuous area.
Rinse all surfaces that come in contact with food with potable water before reuse.
Do not use on utensils, glasses and dishes

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<< IMPORTANT: All organisms must be identified by genus & species. >>

<< Disinfection - Hard non-porous surfaces >>

<< Bacteria >>	(ATCC # 828) (ATCC # 43888) (ATCC # 35743) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538)	Enterococcus faecalis Escherichia coli 0157:H7 Mycobacterium bovis [BCG] Pseudomonas aeruginosa Salmonella (choleraesuis) enterica Staphylococcus aureus
<< Virus >>	(ATCC # VR-733 & 734) (ATCC # VR-100) (ATCC # VR-192) (ATCC # VR-26) (ATCC # VR-340) (ATCC # VR-2018)	Herpes Simplex Virus Type 1 & 2 Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus] Influenza A ₂ [Japan 305/57] (flu virus) Poliovirus Type 1 Respiratory Syncytial Virus [RSV] Rhinovirus Type 39 (common cold) Rotavirus WA (infectious diarrhea)

<< Fungistatic - Hard non-porous surfaces >>

<< Fungi >>	(ATCC # 6275)	Aspergillus niger (mold & mildew)
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<< Sanitization - Non-Food Contact Surfaces >>

<< Bacteria >>	(ATCC # 13048) (ATCC # 51299) (ATCC # 43888) (ATCC # 6538) (ATCC # 33592)	Enterobacter aerogenes Enterococcus faecalis [VRE] Escherichia coli 0157:H7 Staphylococcus aureus Staphylococcus aureus [MRSA]
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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

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

Soils / Odors: (Graphic -- depicting soil)

- | | | | |
|---------------|------------------|---------------|----------------|
| Bathtub Rings | Grime | Mold stain | Smudges |
| Dirt | Hard Water Stain | Mud | Soap Scum |
| Fingerprint | Lime scale | Outdoor Grime | Stains / Soils |
| Grease | Mildew stain | Pet Stain | Tough Soil |

Surface Types: (~ Non-Medical or Fixture)

- | | | | |
|---------------------|------------------|--------------|-------------------|
| Chrome ~ | Glass | Hard Plastic | Synthetic Marble |
| Crystal | Glazed Ceramic | Linoleum | Stainless Steel ~ |
| Enamel | Glazed Porcelain | Metal | Vinyl |
| Fiberglass fixtures | | | |

Hard Non-porous Surfaces: (Graphic -- depicting use site)

- | | | |
|-----------------------------|-----------------------------------|-----------------------------------|
| Appliance exterior | Floor (linoleum) | Plastic laundry (basket) (Hamper) |
| Bathtub (Tub) | Floor (no-wax) | Shelves (drawers) |
| Bed frame | Floor (vinyl) | Shower (door) (vinyl curtain) |
| Cabinet | Garbage (can) (pail) (container) | Shower (stall) (area) |
| Chair | Glazed ceramic tile | Sink (basin) |
| Changing table | Glazed porcelain tile | Stove (stovetop) |
| Counter (Countertop) | Highchair (non-food contact area) | Table (tabletop) |
| Crib | Light fixture | Telephone |
| Diaper pail | Metal blinds | Toilet bowl exterior / Urinal |
| Door knob (handle) | Microwave exterior | Vanity top |
| Exhaust fan (hood) | Non-medical (chrome) | Washable wall |
| Fixture (chrome) | Non-medical (stainless steel) | Window (windowsill) |
| Fixture (stainless steel) | Painted woodwork | other hard, non-porous surfaces |
| Floor (glazed ceramic tile) | | |

Household Use Sites: (Graphic -- depicting use site)

- | | | | |
|----------|-------------|----------------|-----------------------|
| Basement | Den / Study | Home / House | Living Room |
| Bathroom | Family room | Household area | Playroom |
| Bedroom | Garage | Kitchen | other household areas |

Professional Use Sites: (Graphic -- depicting use site)

- | | | | |
|-----------------|----------------------|-------------------|---------------------|
| Cafeteria | Health Care Facility | Nursing Home | Restroom |
| Day Care Center | Hospital | Office Building | School |
| Dental Office | Hotel / Motel | Physicians Office | other public places |
| Doctors Office | Infirmery | Restaurant | |

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<< IMPORTANT: 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 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.

<< Terminal Sterilant Statement – qualified metal surfaces >>

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

<< Terminal Sterilant Statement – unqualified metal surfaces >>

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument 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 moderate eye irritation. Avoid contact with eyes, skin or clothing.
Wash thoroughly with soap and water after handling.

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.
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 / Chemical Hazards >>

PHYSICAL AND CHEMICAL HAZARDS: Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 120°F or in sun or discarding can in fire or incinerator may cause bursting.

<< Storage and Disposal language – Household containers >>

STORAGE AND DISPOSAL: Store in original container in areas inaccessible to small children. Do not reuse empty container. Replace cap and discard in trash. Do not incinerate or puncture.

<< Storage and Disposal language – Professional containers >>

STORAGE AND DISPOSAL

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

STORAGE: Store in original container in areas inaccessible to small children.

DISPOSAL: Do not reuse empty container. Replace cap and discard in trash. Do not incinerate or puncture.

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