



000777-00066-092498

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Systems Integration Group, Inc.

PM 31

10/14

SEP 24 1998

Household Products Division
Reckitt & Colman Inc.
1655 Valley Road
Wayne, NJ 07474

ATTENTION: Bruce Paoella

SUBJECT: Lysol® Brand Disinfectant Direct Multi-Purpose Cleaner
EPA Registration Number 777-66
Your Amendment Dated: April 6, 1998

This is to acknowledge receipt of your amendment submitted in conjunction with Section 3 (c) 7 a of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to add sanitization claims. This amendment is acceptable subject to the following label comments. We inadvertently accepted these claims and the alternate language for such claims (page 12 of the label) in our letter to you dated September 8th, 1998. Make the following changes to the enclosed stamped accepted label prior to releasing this product for shipment.

The first comment below is reiterated from our letter of 9/8/98. The remaining comments are required based on the efficacy review of the submitted studies to support sanitization claims.

1) Under part 2 of the "General Bathroom Cleaning Directions"(page two), "while showering" should be removed and replaced with "when shower surfaces are damp. For best results, wipe immediately after showering."

2) Provide the complete name including genus and species for **all** public health organisms listed on your label. This includes the second paragraph on page three, the section beginning "Disinfect/Deodorize" near the bottom of page five, and items 4a) and 4b) on page 12. For example, change "E. Coli" to read "Escherichia coli", "Salmonella" to read "Salmonella cholerasuis", "Listeria" to read "Listeria monocytogenes", etc. The phrases "Staphylococcus", "Streptococcus germs", "Salmonella", "Pseudomonas", "Listeria", and "E. coli" are all unacceptable.

3) On page nine change the statement which reads "Effectively works on multiple/many household surfaces" to read as follows "Effectively works on multiple/many hard non-porous household surfaces". On page ten change ~~the statement~~ which reads "Kills germs and bacteria on

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DATE	9/23/98						

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

household surfaces" to read as follows "Kills germs and bacteria on hard non-porous household surfaces". Also on page ten change the statement which reads "Cleans and disinfects most washable surface with no rinsing" to read as follows "Cleans and disinfects most hard non-porous household surfaces with no rinsing".

4) On page twelve "Additions to the Front Label" revise your statements to include the phrase "on hard non-porous surfaces in 30 seconds" in items 1a) and 1c). Then add the phrase "on hard non-porous surfaces" to items 1b) and 1d) in the same section.

5) On page twelve "Additions to the Back Label" add the phrase "on hard non-porous surfaces" to items 1a), 1b), and 1f). Then revise your statement to include the phrase "on hard non-porous surfaces in 30 seconds" in item 1e) of the same section.

Since you submitted data to support the addition of sanitization claims, the Agency is requiring you to submit a Certification with Respect to Citation of Data form along with a complete Data Matrix for this product. Submit these forms to the Agency within 60 days of the date of this letter so that they may be included in this file.

A stamped copy of the label is enclosed for your records. Please submit five copies of the final printed label.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure

7510W:T.Lantz:9/22/98:777-66c

CONCURRENCES

SYMBOL	SURNAME	DATE						

FRONT LABEL

777-66

**LYSOL® Brand Disinfectant Direct
Multi-Purpose Cleaner**

Confidence in Cleaning
Cleans Without Bleaching
Leaves a Fresh Clean Scent
Citrus Fresh Scent
Floral Fresh Scent
Lemon Scent

No Mixing
No Scrubbing, Wiping or Rinsing (For Leave on Product Only)

Cleans and Disinfects
Cuts Tough Kitchen Grease and Grime!
Kills Germs
Kitchen Cleaner
Antibacterial
Kills Household Bacteria
Eliminates Bacteria From Kitchen Surfaces
Kills Bacteria commonly found in the kitchen
Economical Refill
Value Refill
Easy Pour Spout for Big Jobs
Gel

Active Ingredients:
Alkyl (67% C12, 25% C14, 7% C16, 1% C8-C10-C18)
dimethyl benzyl ammonium chlorides.....0.08%
Alkyl (50% C14, 40% C12, 10% C16) dimethyl
benzyl ammonium chlorides.....0.02%
Inert Ingredients* :.....99.90%
*Includes detergents and other grease cutting agents

KEEP OUT OF REACH OF CHILDREN
CAUTION: See back panel for additional precautionary statements.

Net 17 Fl. oz. (1 Pt. 1 oz.) 502 mL
22 Fl. oz. (1 Pt. 6 oz.) 650 mL.
24 Fl. oz. (1 Pt. 8 oz.) 709 mL
25 Fl. oz. (1 Pt. 9 oz.) 739 mL
26 Fl. oz. (1 Pt. 10 oz.) 768 mL.
32 Fl. oz. (1 Qt.) 946 mL
36 Fl. oz. (1 Qt. 4 oz.) 1064 mL.
40 Fl. oz. Refill Unit
Economy Size, One Gallon (128 fl. oz.) 3.79 Liters

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 24 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
777-66

BACK LABEL

LYSOL® Brand Disinfectant Direct Multi-Purpose Cleaner

LYSOL® DIRECT meets AOAC use-dilution efficacy test standards for hospital disinfectants.

LYSOL® DIRECT is a highly versatile and convenient disinfectant cleaner that you use straight from the bottle. LYSOL® DIRECT cleans and disinfects most nonporous kitchen surfaces and leaves your house with a fresh and clean scent. Use straight from the bottle in the kitchen, bathroom and other household areas.

Alternate for Spray Applicator:

LYSOL® DIRECT is a versatile and convenient disinfectant cleaner for most washable surfaces. Cleans and disinfects most washable surfaces with no rinsing. LYSOL® DIRECT cleans and shines. No rinsing! Fresh Scent! Great for use in the kitchen, bathroom and other household areas.

Alternate for Twist/Turn Applicator:

Easy to Control! No Splashing! Easy to Rinse!

Alternate for Leave on Spray Product:

Easy to use - Just mist and walk away

Effective - Cleans Soap Scum and Prevent (s) Mildew Stains

Disinfects - Kills germs for a deep down clean.

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Alternate Language for Leave on Spray Product:

With Daily use, Lysol Brand Disinfectant Direct Multi-Purpose Cleaner will keep your shower clean.

Safety First: Run the shower before entering to rinse shower/tub. Always stand on a non-slip surface when in shower or tub.

General Bathroom Cleaning Directions:

1. For best results, start with a clean shower. Immediately after showering, lightly mist (spray) all shower surfaces including curtain and (or) door. No need to rinse, wipe or scrub, if you see streaks, rinse off and apply less.

2. If you start with a partially soiled shower, it will take 2-4 weeks for Lysol Brand Direct Multi -Purpose Cleaner to loosen build-up and clean your shower. If deposits remain, simply wipe off with a soft cloth while showering.

To Disinfect: Start with a clean shower. Spray until wet and leave on at least 10 minutes or until dry

LYSOL® DIRECT cleans and disinfects most kitchen surfaces. It cuts through grease and grime and kills bacteria such as Salmonella, E. coli, Listeria, Staphylococcus and Pseudomonas in the kitchen. It also kills other bacteria which cause odors in the kitchen (kills odor-causing germs).

Alternate for Refill bottle:

TO REFILL BOTTLE OF LYSOL® DIRECT CLEANER:

- | | | |
|--|--|--|
| 1. Remove trigger sprayer or cap from empty bottle of LYSOL® DIRECT cleaner. | 2. Unscrew cap on Smart Pack Refill and pour contents into empty bottle. | 3. Replace trigger sprayer or cap and use LYSOL® Direct cleaner as you normally would. |
|--|--|--|

LYSOL® DIRECT cleaner can also be used straight from this Smart Pack Refill.

Easy To Pour	Smart Pack Refill
Resealable	Uses 75% less plastic

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BACK LABEL CONTINUED

Help reduce plastic waste in your community. Reuse your LYSOL® DIRECT bottle by refilling it with this convenient refill package. Smart Pack Refill uses 75% less plastic* than regular packaging so there's much less to throw away. BE SMART...Save Money and Reduce Trash.

*This package contains 75% less plastic by weight than the 22oz. trigger bottle of LYSOL® DIRECT.

This is not a concentrate. Do not add water.

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

BIG JOBS: For convenience, use the easy-pour, push-pull spout or remove cap to refill your Lysol® Direct spray bottle.

GENERAL HOUSEHOLD / KITCHEN CLEANING: Apply LYSOL® DIRECT cleaner straight from the bottle onto a damp sponge or squeeze directly onto surfaces, then wipe clean. On painted surfaces, test a small area. Not recommended for use on acrylic plastics.

Alternate for Spray Applicator:

TO OPERATE: Turn nozzle counter clockwise to "spray" or "stream". Adjust to desired pattern. If the last portion of LYSOL® DIRECT is difficult to dispense, turn the trigger 180° to face the opposite direction. This will ensure full use of contents.

GENERAL HOUSEHOLD / KITCHEN CLEANING: Spray soiled area, then wipe clean. No rinsing! LYSOL® DIRECT removes (it cuts through) grease, food stains, soap scum, fingerprints, tough soils, crayon/pencil marks, and dirt and grime in and around the house / kitchen. On painted surfaces, test a small area. Not recommended for use on acrylic plastics.

LYSOL® DIRECT cleans all washable kitchen surfaces such as stoves, countertops, sinks, appliances, cabinets, walls, floors, woodwork, tables, chairs and high chairs.

To Clean Refrigerator / Freezer Interiors and Microwave Interiors: Remove all food, ice trays, etc. Spray soiled area, then wipe clean.

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Under the Federal Insecticide,
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777-66

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BACK LABEL CONTINUED

Alternate for Twist/Turn Applicator:

TO OPERATE: Turn tip counter clockwise. Adjust to desired level of dispensing.
GENERAL HOUSEHOLD/KITCHEN CLEANING: Apply gel cleaner to surface using a damp sponge or cloth, then wipe clean.

FLOORS: Cleans all washable floors including no-wax floors, linoleum, vinyl and ceramic tile. For easy cleaning, squeeze straight from the bottle and wipe clean with a damp mop. For waxed floors or sealed ceramic tile floors, mix one cup of LYSOL® DIRECT cleaner per gallon of water and apply with a mop.

Alternate for Spray Applicator:

For spot cleaning, spray straight from bottle and wipe clean with damp sponge or mop. For waxed floors or sealed ceramic tile floors, or to clean larger areas of any floors, remove trigger sprayer and mix one cup of LYSOL® DIRECT per gallon of water and apply with a mop.

BATHROOM: To clean and deodorize the toilet bowl, squirt LYSOL® DIRECT cleaner liberally (½ cup) on sides and under rim of bowl; swab all surfaces thoroughly and flush. To clean tubs and tile, apply straight from the bottle onto damp sponge or squeeze directly onto surface, then wipe clean.

DISINFECT/DEODORIZE: For heavily soiled surfaces, first clean according to General (Kitchen) Cleaning Directions. To disinfect/deodorize hard, nonporous surfaces such as floors, walls, counters, sinks, tubs and tile, apply full strength. Let stand 10 minutes before wiping. Kills germs such as Influenza Virus Type A₂ (Japan), dangerous Staphylococcus and Streptococcus germs, Salmonella, Pseudomonas, Herpes Simplex virus Type 1 and Type 2, E. Coli, Listeria monocytogenes, Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus) and Athlete's Foot Fungus. Kills odor-causing household germs and mold and mildew in damp and musty places. Repeat application as necessary.

Alternate for Spray Applicator:

Spray until thoroughly wet. Let stand for 10 minutes before wiping.

Alternate for Twist/Turn Applicator

Apply gel cleaner generously on surface and spread evenly. Let stand for 10 minutes before wiping.

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SEP 24 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for use as a disinfectant,
registered under FIFRA Section 24(b)

777-66

DISINFECT /DEODORIZE: For hard, nonporous surfaces such as counters, sinks, appliances, refrigerator / freezer interiors, microwave interiors, high chairs, stove tops and hoods, tables, garbage pails, faucets, and walls, hold container 6" to 8" from surface and spray until thoroughly wet. Let stand 10 minutes before wiping. Rinse after use on surfaces that come in contact with food. For heavily soiled surfaces, first clean according to GENERAL KITCHEN CLEANING directions.

To disinfect nonporous cutting boards, spray until thoroughly wet, let stand 10 minutes, then rinse thoroughly.

KILLS HIV-1 ON PRECLEANED 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 LYSOL® DIRECT.

CONTACT TIME: Allow surface 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.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

CAUTION: MAY CAUSE EYE IRRITATION. AVOID CONTACT WITH EYES.

STATEMENT OF PRACTICAL TREATMENT: If splashed in eyes, immediately remove contact lenses and rinse eyes with plenty of water for at least 15 minutes.

Alternate for Spray Applicator:

STATEMENT OF PRACTICAL TREATMENT: If sprayed or splashed in eyes, immediately remove contact lenses and rinse eyes with plenty of water for at least 15 minutes.

STORAGE/DISPOSAL: Store in areas inaccessible to small children. Refill container only with LYSOL® DIRECT. If not refilling, rinse empty container thoroughly and discard in trash or recycle.

ACCEPTED with COMMENTS in EPA Letter Dated: SEP 24 1998 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this pesticide, Reg. No. 777-66

BACK LABEL CONTINUED

Alternate for Smart Pack Refill bottle:

STORAGE/DISPOSAL: Store in areas inaccessible to small children. Do not reuse SMART PACK refill. Discard in trash.

Alternate for HDPE refill bottle:

STORAGE/DISPOSAL: Store in areas inaccessible to small children. Do not reuse refill. Discard in trash or recycle.

Important facts about LYSOL® DIRECT:

Contains no phosphates.

Contains biodegradable cleaning agents.

This bottle is made of 25% post-consumer recycled plastic.

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

Questions? Comments? Call 1-800-228-4722

EPA Reg. No. 777-66

EPA Est. No. 777-NJ2, OH-1, IL-1; 11525-IL-01 (see bottom or side)

Household Products Division
Reckitt & Colman Inc.
Montvale, NJ 07645

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with COMMENTS
in EPA Letter Dated:

SEP 24 1998

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

777-66

100A14

Lysol® Brand Disinfectant Direct Multi-Purpose Cleaner
EPA Reg. No. 777-66

ADDITIONS TO LABEL

Streak-Free Shine

Cleans kitchen surfaces to a streak-free shine

New Streak-Free Formula

New Improved Cleaning Formula

New Improved Streak-Free Formula

New Improved Formula! Streak-Free Shine

Improved Cleaning Power

New Streak-Free Formula with Improved Cleaning Power!

New Streak-Free Formula with Advanced Cleaning Power!

New Streak-Free formula with Improved Shine!

New Formula! Combines Streak-Free shine with improved cleaning power

New Formula! Gives you a Streak-Free shine while it cleans

LYSOL Antibacterial Kitchen Cleaner gives you unsurpassed streak-free cleaning on all kitchen surfaces from appliances to greasy stovetops.

Streak-Free Shine

Cleans kitchen surfaces to a Streak-Free shine

New Streak-Free Formula

New Improved Cleaning Formula

New Improved Streak-Free Formula

New Improved Formula! Streak-Free Shine

Improved Cleaning Power

New Streak-Free Formula with Improved Cleaning Power!

New Streak-Free Formula with Advanced Cleaning Power!

New Streak-Free formula with Improved Shine!

New Formula! Combines Streak-Free shine with improved cleaning power

New Formula! Gives you a Streak-Free shine while it cleans

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LYSOL Antibacterial Kitchen Cleaner thoroughly cleans surfaces throughout your kitchen to a streak-free shine.

LYSOL Antibacterial kitchen Cleaner gives you unsurpassed streak-free cleaning on all kitchen surfaces from appliances to greasy stovetops.

LYSOL Antibacterial Kitchen Cleaner cleans appliances, chrome stovetops, stainless steel, countertops and fiberglass without leaving a dull residue behind. No streaks!

Use LYSOL Antibacterial Kitchen Cleaner throughout your home to clean dirt, grease, and grime to a streak-free shine on appliances, counter tops, fiberglass and ceramic tile.

110214

**Additions to Lysol Brand Disinfectant Direct Multi-Purpose Cleaner
EPA Registration 777-66**

One product to thoroughly clean surfaces throughout the kitchen! Eliminates grease without streaking.

- One product to thoroughly clean surfaces throughout the kitchen!
- Cuts through grease and grime
- Cleans to a streak-free shine
- Contains Powerful Grease Cutters
- Only LYSOL Antibacterial Kitchen Cleaner combines

Glass & Surface Cleaner with Antibacterial Formula

Antibacterial Glass & Surface Cleaner

With Antibacterial Formula

Glass & Surface Cleaner

From the Makers of Lysol

(New) Fresh (Country) (Lemon)(Citrus)(Spring Time) Scent

Easy-to-use Refill

Streak-Free Cleaning

Eliminates mold and mildew

Effectively works on multiple/many household surfaces

Multiple cleaning tasks

No Residue

The easy way to feel confident

Cleaning with confidence

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777-66

**Additions to Lysol Brand Disinfectant Direct Multi-Purpose Cleaner
EPA Registration 777-66**

Get the most out of your cleaning with antibacterial cleaning

Use to clean, shine and disinfect on high-touch areas, food germ, hand prints, or pet smudges
and simply replace cap with trigger sprayer from the empty bottle

Gives you a streak-free shine while it eliminates harmful bacteria

Wipes away everyday grease and grime

) Use only one cleaning product to get a streak-free shine plus antibacterial protection

Gives you streak-free cleaning results while it eliminates harmful bacteria

Lysol Direct gives you streak-free cleaning

Gives you a streak-free shine while it cleans

Kills germs and bacteria on household surfaces

Streak-Free shine on glass

Cleans and disinfects most washable surfaces with no rinsing

) Great for use in most household areas

For a beautiful streak-free shine, just spray and wipe clean with a paper towel

Not recommended for use on acrylic plastics or finished wood surfaces

Disinfects/Deodorizes: For nonporous surfaces throughout your home such as walls,
glass/windows, mirrors, tile, porcelain, stoves, Computer & TV screens.

For use in your living room, bedroom, dinning room, family room/den, laundry room. childrean
play room/nursery

Perfect for use on glass, windows, mirrors, appliances, chrome, stainless steel, aluminum,
ceramic tile, porcelain surfaces, fiberglass, patio doors, and washable wall paper.

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

777-66

**Additions to Lysol Brand Disinfectant Direct Multi-Purpose Cleaner
EPA Registration 777-66**

Plus, it's unique antibacterial formula kills the germs and bacteria to give you the confidence that your home is as clean as it can be.

Removes, grease, food stains, soap scum, fingerprints, tough soils, crayon/pencil marks, and dirt and grime in and around the house.

Picture (Glass Table) (Window)	Picture (Counter & Sink)	Picture (Nursery)	Picture (Auto)
Windows, glass tables, mirrors, and other shiny surfaces	Counters, sinks, walls, appliances, microwaves, Stove tops	Changing tables highchairs and other household surfaces	Windshields, chrome mirrors

Lysol Direct gives you streak-free cleaning while killing household germs.

Lysol Direct Glass & Surface Cleaner is specifically formulated to provide streak-free cleaning results while it eliminates harmful bacteria.

Lysol Direct glass and surface cleaner to combines streak-free cleaning with the added reassurance of antibacterial protection.

Lysol Direct is uniquely formulated to give effective streak-free shine while it cleans away dirt and grime.

Lysol Direct cleans glass, appliances, chrome, stovetops, stainless steel, countertops, and fiberglass without leaving a dull residue.

Use Lysol Direct throughout your home to clean dirt, grease, and grime to a streak-free shine on glass, appliances, countertops, fiberglass and ceramic tile.

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SEP 24 1998

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

777-66

140/14

Alternate Language for Sanitization Claims 777-66

Additions To Front Label

- 1a) Kills 99.9% of Bacteria (Germs) in seconds.*
- 1b) Eliminates 99.9% of Bacteria (Germs) in 30 seconds.*
- 1c) Kills Bacteria (Germs) in seconds.*
- 1d) Kills Bacteria (Germs)

Additions to Back Label

- 1a) Kills 99.9% of Bacteria (Germs) in 30 seconds.*
- 1b) Eliminates 99.9% of the Bacteria (Germs) in 30 seconds.*
- 1c) Kills 99.9% of bacteria (germs) on hard nonporous surfaces in 30 seconds.*
- 1d) Eliminates 99.9% of germs (bacteria) on hard nonporous surfaces in 30 seconds.*
- 1e) Kills Bacteria (Germs) in seconds.*
- 1f) Kills Bacteria (Germs)

2a) Sanitize/Deodorize: For hard nonporous surfaces such as counters, sinks, refrigerators, microwaves, appliances, stove tops, faucets, cabinets, kitchen tables, glass tabletops, stainless steel, chrome, fiberglass, high chairs and garbage pails (cans), spray until thoroughly wet. Let stand for 30 seconds before wiping. For heavily soiled surfaces, first clean according to GENERAL KITCHEN CLEANING directions.

2b) For hard nonporous surfaces such as counters, sinks, refrigerators, microwaves, appliances, stove tops, faucets, cabinets, kitchen table, glass tabletops, stainless steel, chrome, fiberglass, high chairs, and garbage pails (cans), spray until thoroughly wet.

To sanitize/deodorize: Let stand for 30 seconds before wiping
 To disinfect/deodorize: Let stand for 10 minutes before wiping
 For heavily soiled areas, a precleaning is required.

3) Fast Acting Sanitizer

4a) *Kills 99.9% of Salmonella choleraesuis (salmonella), E. coli, Staphylococcus aureus (staphylococcus), Streptococcus pyogenes (streptococcus) and Klebsiella pneumoniae (K. pneumoniae) on hard non-porous surfaces in 30 seconds.

4b) *Eliminates 99.9% of Salmonella choleraesuis (salmonella), E. coli, Staphylococcus aureus (staphylococcus), Streptococcus pyogenes (streptococcus) and Klebsiella pneumoniae (K. pneumoniae) on hard non-porous surfaces in 30 seconds.

ACCEPTED
 with COMMENTS
 SEP 24 1998

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

777-66