



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 26, 2020

Amanda Burwell
Registration Specialist
Stephan Company
22 W Frontage Rd.
Northfield, IL 60093

Subject: Label Amendment – Emerging Viral Pathogens Claim
Product Name: Detergent Disinfectant Pump Spray
EPA Registration Number: 1839-83
Application Date: June 17, 2020
Decision Number: 564031

Dear Ms. Burwell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are small non-enveloped, large non-enveloped, enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Human Rotavirus (ATCC VR-2018) or Rhinovirus Type 39 (ATCC VR-340) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

DETERGENT DISINFECTANT PUMP SPRAY

FRONT PANEL

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.105%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.105%
INERT INGREDIENTS	<u>99.790%</u>
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

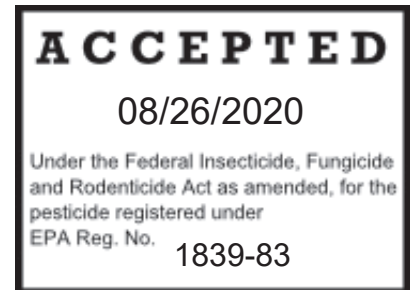
See (product container)((side)(back) panels)) for additional (precautionary statements)(directions for use)
(and)(first aid).

FRONT, BACK, OR SIDE PANEL

EPA REG. NO. 1839-83
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NET CONTENTS
U.S. Patent No. 5,444,094



MARKETING CLAIMS

- CLEANER
- DEODORIZER
- DISINFECTANT
- *VIRUCIDE
- *VIRUCIDAL
- BACTERICIDAL
- TUBERCULOCIDAL
- MILDEWSTAT (on hard inanimate surfaces)
- MILDEWSTATIC
- FUNGICIDE (against pathogenic fungi)
- FUNGICIDAL
- Contains no abrasives or bleach
- Contains no phosphates or phosphorous
- All Purpose Cleaner
- Cleans, Disinfects and Deodorizes in One Easy Step
- Orange Scent, Lemon Scent, Fresh Scent, Citrus Scent
- Ready-To-Use (RTU or R-T-U) (Disinfectant Spray)
- Eliminates Odors
- Cleans and Deodorizes in One Easy Step
- Cuts (Tough) Grease and Grime (without Scrubbing)
- Kills 99.9% of Germs
- Kills 99.9% of Bacteria
- Kills 99.9% of Household Bacteria
- Meets OSHA Bloodborne Pathogen Standard for HIV, HBV & HCV
- For Use in Animal Housing Facilities (Poultry (Swine) Housing Facilities) (Public Restrooms) (as a Non-Acid Bowl (& Bathroom) Disinfectant Cleaner)
- Kills Pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu)
- Kills the virus that causes the common cold^{††}
- This product has demonstrated effectiveness against rhinovirus a causative agent for colds^{††}
- †† Rhinovirus
- Use in veterinary facilities to kill canine parvovirus
- (Easily) Removes Soap Scum
- (2)(3)(X)-pack
- Refill(pack)(container)(bottle)(size)
- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product (Product Name) has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product (Product Name) has demonstrated effectiveness against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.
- (This product) (product name) contains no phosphates or phosphorous.
- EFFICACY TESTS HAVE DEMONSTRATED THAT (THIS PRODUCT or PRODUCT NAME) IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).
- (Clean)(and)(Disinfect) after spills!
- (Clean)(and)(Disinfect) hard, non-porous surfaces following a spill [(involving bodily fluids) OR (of bodily fluids)]
- (Helps) (employees)(staff) respond to clean up (and disinfection) of (blood) spills spill [(involving bodily fluids) OR (of bodily fluids)]
- An effective (cleaner and disinfectant)(standardized cleaning and disinfecting procedure) following a spill [(involving bodily fluids) OR (of bodily fluids)]
- (Helps) protect (employees)(staff) involved (with)(in) the clean up of (spills)(spills containing potentially infectious material) spill [(involving bodily fluids) OR (of bodily fluids)]
- (Can be used to)(Helps) (employers)(institutions) comply with OSHA's bloodborne pathogen standard

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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- Contains supplies needed (for)(to clean up)(x) spill(s)
- (Can be (used)(sold) with)(includes): (gloves)(latex gloves)(nitrile gloves)(vinyl gloves)(masks)(face masks)(trigger spray)(bottle)(nozzle)((insert product brand name))(scoops)(scoop/scraper)((insert color)disposal bags)(absorbent material)(fluid control solidifier)(shoe covers)(twist ties)(spatula)(paper towels)(disposable towels)(bonded wipes)(wipes)(aprons)(carrying case)(gowns)(goggles)(eye shield with ear loop mask)(bonnet)
<Note to reviewer> Label may identify X amount of each individual item listed above.
- Detergent Disinfectant Pump Spray (or this product or product name) is designed specifically as a general (non-acid) (ready-to-use) (non-abrasive) cleaner and disinfectant for use in homes, hospitals, nursing homes, patient rooms, operating rooms, ICU areas, shower rooms, locker rooms, public restrooms, schools, food processing plants, food service establishments (restaurants) (commercial kitchens), transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses, veterinary clinics, pet shops, animal life science laboratories and athlete/recreational facilities where housekeeping is of prime importance in controlling the hazard of cross contamination. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, chrome, brass, copper, laminated surfaces, baked enamel surfaces, bathrooms, shower stalls, bathtubs, and cabinets. **For plastic and painted surfaces, spot test on an inconspicuous area before use.** May be used in the kitchen on counters, sinks, appliances, and stovetops. A rinse with potable water is required for surfaces in direct contact with food. (In addition), (this product or product name) deodorizes those areas that generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, basements, restrooms and other areas which are prone to odors caused by microorganisms.
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- For best [cleaning][disinfection] results, always test a small inconspicuous area first.
- Cost Effective and Time Efficient when used with (the) (refillable spray bottle)(mechanical spray device) (cordless)(backpack) (sprayer) (low pressure sprayer)(trigger sprayer)(handheld mechanical sprayer) (applicator/sprayer name).
- This product is (designed)(formulated) for use with (refillable spray bottle)(mechanical spray device) (cordless)(backpack)(handheld)(sprayer)(low pressure sprayer)(trigger sprayer)(handheld mechanical sprayer)(applicator/sprayer name).
- (Refer to (applicator)(sprayer)(equipment)(user) manual for (additional)(specific) operation instruction before use.
- Refer to the *insert applicator/sprayer name* -and/or- user manual -or- safety data sheet (SDS) for (more information)(any additional PPE).
- See (online) (service) (instruction) manual (insert) for (more) (detailed) (usage) information. (The most restrictive (label language) (instructions) (language) (statements) will apply.)
- When used as directed, (this product or product name) (contains 2100 ppm of active germicide making it) (is) highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew.)
- (This product or product name) is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (and controlling mold and mildew on) (of) hard, non-porous inanimate surfaces. Quickly removes dirt, grime, mold, mildew, food residue, blood and other organic matter commonly found in hospitals (in health care facilities) (on medical surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.
- **Animal Housing Facilities (and Poultry and Swine Premises):** (This product or product name) removes dirt, grime, mold, mildew, blood, urine, fecal matter and other common soils found in animal housing facilities, grooming facilities, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.
- It cleans, disinfects and deodorizes hard, non-porous inanimate surfaces in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) hard, non-porous inanimate surfaces: plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces associated with floors, walls, countertops, cages, crates, kennels, and animal equipment found in animal housing facilities.
- **Public Restrooms:** (This product or product name) is a one-step disinfectant cleaner and deodorant (odor-counteractant) (odor-neutralizer) designed for general cleaning, (and) (disinfecting) (deodorizing) (and controlling mold and mildew) on hard, non-porous inanimate surfaces.
- It cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use on (restroom surfaces): glazed

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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ceramic (restroom surfaces), glazed porcelain, chrome, stainless steel and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

- **Non-Acid Bowl (& Bathroom) Disinfectant Cleaner.** (This product or product name) is (also) a (ready-to-use) non-acid (bowl and) bathroom cleaner that cleans, disinfects and deodorizes in one easy step. It cleans, disinfects and deodorizes toilet bowls, urinals, rims, sinks, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel, and all non-porous inanimate surfaces found in the bathroom (restroom) (in the presence of organic soil).
- It eliminates odors, leaving bathrooms (restrooms) smelling clean and fresh. Use where odors are a problem. It cleans, disinfects, and deodorizes surfaces by killing odor-causing microorganisms and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use (Use it daily) on (restroom surfaces): glass, glazed ceramic (restroom surfaces), glazed tile, glazed porcelain, chrome, stainless steel, and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms, and locker rooms.
- **Cooling Coils Disinfectant Cleaner.** (This product or product name) is a (ready-to-use) (non-abrasive) (one-step) disinfectant cleaner for (small air conditioner) (commercial air handling unit) (HVAC) cooling coils and (refrigeration equipment) (refrigerator) (freezer) evaporation coils. When using (this product or product name) to disinfect and clean (cooling coils) (evaporation coils), disconnect power to the unit before applying product. **Follow directions under the DISINFECTION, DEODORIZING AND CLEANING section.**

[NOTE TO REVIEWER: NOT FOR USE ON FINAL IN-COMMERCE PRODUCT LABEL]

Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below:

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses
- Small non-enveloped viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Human Rotavirus (ATCC VR-2018)
Large, non-enveloped virus	Rhinovirus Type 39 (ATCC VR-340)
Small non-enveloped virus	Rhinovirus Type 39 (ATCC VR-340)

Acceptable Claim Language:

[Product Name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on **hard, non-porous surfaces**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Human Rotavirus or Rhinovirus Type 39** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Human Rotavirus or Rhinovirus Type 39** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.”

MICRO-ORGANISMS

BACTERICIDAL ACTIVITY (BACTERIA): (Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a **3 minute** contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:)

Organism	ATCC Number	Contact Time
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	3 minutes
<i>Staphylococcus aureus</i>	(ATCC 6538)	3 minutes
<i>Salmonella (choleraesuis) enterica</i>	(ATCC 10708)	3 minutes
<i>Escherichia coli</i>	(ATCC 11229)	3 minutes
<i>Escherichia coli O157:H7</i>	(ATCC 43895)	3 minutes
<i>Streptococcus pyogenes</i> (Necrotizing Fasciitis-Group A) (V.A. Medical Center Isolate 04001)		3 minutes
<i>Listeria monocytogenes</i>	(ATCC 35152)	3 minutes
<i>Yersinia enterocolitica</i>	(ATCC 23715)	3 minutes
<i>Enterococcus faecium</i>	(ATCC 6569)	3 minutes
<i>Corynebacterium ammoniagenes</i>	(ATCC 6871)	3 minutes
<i>Salmonella (typhi) enterica</i>	(ATCC 6539)	3 minutes

ANTIBIOTIC-RESISTANT (STRAINS OF) (ANTIBIOTIC-RESISTANT BACTERICIDAL ACTIVITY):

(Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a **3 minute** contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:)

<i>Methicillin resistant Staphylococcus aureus</i> (MRSA)	(ATCC 33593)	3 minutes
<i>Vancomycin resistant Enterococcus faecalis</i> (VRE)	(ATCC 51575)	3 minutes
<i>Vancomycin intermediate resistant Staphylococcus aureus</i> (VISA)	(CDC Isolate 99287)	3 minutes
<i>Methicillin resistant Staphylococcus epidermidis</i> (MRSE)	(ATCC 51625)	3 minutes
<i>Community Associated Methicillin resistant Staphylococcus aureus</i> (CA-MRSA)	(NRS 123) Genotype USA400	3 minutes
<i>Community Associated Methicillin resistant Staphylococcus aureus</i> (CA-MRSA)	(NRS 384) Genotype USA300	3 minutes

VIRUCIDAL ACTIVITY (Viruses)	ATCC Number	Contact Time
<i>Virus Enveloped</i>		
HIV-1 (associated with AIDS)		1 minute
Avian Influenza A strain H3N2	(ATCC VR-2072)	2 minutes
Avian Influenza A strain H9N2		2 minutes
Hepatitis B Virus (HBV)		1(or)5minute(s)
Hepatitis C Virus (HCV)		1(or)5minute(s)
Duck Hepatitis B Virus (DHBV)		1(or)5minute(s)
Bovine Viral Diarrhea Virus (BVDV)		1(or)5minute(s)
Human Coronavirus	(ATCC VR-740)	2 minutes
SARS associated Coronavirus		2 minutes
Rabies Virus		30 seconds
Paramyxovirus (Mumps)	(ATCC VR-1438)	3 minutes
<i>Virus Large Non-Enveloped</i>		
Rotavirus	(ATCC VR-2018)	3 minutes
<i>Virus Small Non-Enveloped</i>		
Norovirus (Norwalk virus),		30 seconds
Feline Calicivirus	(ATCC VR-782)	30 seconds
Canine Parvovirus	(ATCC VR-2017)	10 minutes
Poliovirus Type 1	(ATCC VR-1000)	10 minutes
Rhinovirus type 39	(ATCC VR-340)	3 minutes
Hepatitis A Virus (HAV) (University of Ottawa)		10 minutes
Mildew / Fungi		
Trichophyton mentagrophytes (athlete's foot fungus)	(ATCC 9533)	10 minutes

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)

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 enter normally sterile areas of the body.

or

This product is not for use on critical or semi-critical medical device surfaces.

NOTE TO REVIEWER: Mandatory label language when product is supplied in large containers (1 gallon or greater) to be used with refillable pump spray bottles (less than 1 gallon).

Fill or refill the X ozs. (this product or product name) spray bottle with (this product or product name) refill. Pour product into spray bottle over sink or tub basin.

DISINFECTION, DEODORIZING AND CLEANING - Remove gross filth or heavy soil prior to application of the product. Hold container six to eight inches from surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and the surface to remain wet for **3 minutes** (for Bloodborne Pathogens: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **1 (or) (5) minute(s)**). No scrubbing is necessary. (Wipe (off)(dry)(with a clean (cloth)(mop)(paper towel)(or sponge)(or)(allow to air dry)).The product will not leave grit or soap scum.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL ACTIVITY – (This product or product name) is fungicidal against the pathogenic fungus, Trichophyton mentagrophytes (ATCC 9533) (Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot), when used with a 10 minute contact time on clean, non-porous, hard surfaces as found in bathrooms, shower stalls, locker rooms, or other areas commonly contacted by bare feet.

TUBERCULOCIDAL ACTIVITY – (This product or product name) exhibits disinfectant efficacy against Mycobacterium tuberculosis BCG (Mycobacterium bovis) at 20 degrees Centigrade (20°C) when the treated surface is allowed to remain wet for **5 minutes**.

***VIRUCIDAL ACTIVITY** – (This product or product name) kills on hard, non-porous inanimate surfaces when allowed to remain wet for a **10 minute** contact time against:

Canine Parvovirus (ATCC VR-2017)

Hepatitis A Virus (HAV) (University of Ottawa)

Poliovirus Type 1 (ATCC VR-1000)

(This product or product name), when used on environmental, inanimate hard surfaces exhibits virucidal activity against: **Human Coronavirus** (ATCC VR-740), **SARS associated Coronavirus** (ZeptoMetrix), **Avian Influenza A strain H3N2** (ATCC VR-2072) and **Avian Influenza A strain H9N2** (Charles River Laboratories) (Avian Influenza strains H3N2 and H9N2) for **2 minutes**; **Paramyxovirus** (Mumps) (ATCC VR-1438), **Rhinovirus type 39** (ATCC VR-340) and **Rotavirus** (University of Ottawa) for **3 minutes**; **HIV-1 (associated with AIDS)** (Advanced Biotechnologies, Inc.) for **1 minute**; **Hepatitis B Virus (HBV)** (Hepadnavirus Testing, Inc.), **Hepatitis C Virus (HCV)** and **Bovine Viral Diarrhea Virus (BVDV)** (NVSL) when the treated surface is allowed to remain wet for **1 (or) (5) minute(s)**; and **Norovirus (Norwalk virus)**, **Feline Calicivirus** (University of Ottawa) and **Rabies Virus** (CDC) for **30 seconds**.

(The following statements must be used for Bloodborne Pathogens: HIV-1, HBV and HCV:)

KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) 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), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier] .

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PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, and 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 to remain wet for HBV and HCV **1 (or) (5) minute(s)**, for HIV-1 **1 minute**. These contact times will not control other common types of viruses and bacteria.

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

SITE AND APPLICATION SPECIFIC DIRECTIONS FOR USE

One-step cleaning and disinfection of toilet bowls and urinals: Remove water from bowl by forcing water over trap with a swab mop applicator. Press swab mop against side of the bowl to remove excess water from applicator. Apply 1 to 2 ounces of (this product or product name) evenly, allowing sufficient time for product to cover entire surface of bowl for maximum cleaning. Swab bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for **3 minutes** (for Bloodborne Pathogens: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **1 (or) (5) minute(s)**) and flush.

To disinfect food processing premises: Before using (this product or product name) food products and packaging materials must be removed or carefully protected. For floors, walls and storage areas, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow (product or product name) to penetrate and remain wet for **3 minutes** (for Bloodborne Pathogens: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **1 (or) (5) minute(s)**). Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product.

To disinfect food service establishment food contact surfaces: Before using (this product or product name) food products and packaging materials must be removed or carefully protected. For countertops, appliances, tables, hold container six to eight inches from the surface to be treated and spray area until it is covered with the solution. Allow (product or product name) to penetrate and remain wet for **3 minutes** (for Bloodborne Pathogens: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **1 (or) (5) minute(s)**). Wipe off with a clean cloth, mop or sponge and thoroughly rinse all surfaces in the area with potable water. Heavily soiled areas must be pre-cleaned before using this product. Do not use on eating utensils, glassware and cookware.

Disinfection of animal quarters and kennels: Before using (this product or product name), remove all animals and feed from premises. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply (this product or product name) for disinfection of pre-cleaned animal quarters and kennels. Saturate the surfaces with (this product or product name) for a period of **3 minutes** (for Bovine Viral Diarrhea Virus (BVDV) **1 (or) (5) minute(s)**) (for Feline Calicivirus and Rabies virus **30 seconds**) (for Canine Parvovirus **10 minutes**). Ventilate building and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

The following language is required for products supplied with supplemental labeling: inserts, hang tags and reference sheets.

The following language is required to appear on inserts, hangtags and reference sheets:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Labeling must be in the possession of the user at the time of using the product. See container label for FIRST AID and PRECAUTIONARY STATEMENTS and complete DIRECTIONS for USE before applying. Use of this product is subject to the precautions and limitations imposed by the label affixed to the container for this product.

The following language is required to appear on the container label:

See (insert) (hangtag) (reference sheet) for (complete) (additional) information.

(For household/consumer label use pages 8 & 9)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

General Household Cleaning – Hold container six to eight inches from surface to be treated. Spray (soiled) area to be cleaned then dry with a clean (cloth), (mop), (paper towel) (or) (sponge) or (lint free cloth) (or) (allow to air dry). (No rinsing is necessary).

DISINFECTION, DEODORIZING AND CLEANING – Remove heavy soil prior to the application of this product. Hold container six to eight inches from surface to be treated. Spray area until (it is covered with solution) (wet). Allow the surface to remain wet for **3 minutes** (for Bloodborne Pathogens: allow surface to remain wet for HIV-1 **1 minute** and for HBV and HCV **1 (or) (5) minute(s)**). No scrubbing is necessary. (Wipe)(off)(dry)(with a clean (cloth)(mop)(paper towel)(or sponge)(or)(allow to air dry). (The product) (Product name) will not leave grit or soap scum.

When using on food contact surfaces: (counter tops), (stovetops), (highchairs), (kitchen appliances), thoroughly rinse all treated areas with potable water. This product is not to be used to clean eating utensils, glassware and dishes.

Bactericidal Activity – When used as directed, (this product or product name) (kills) (is an effective disinfectant against) the following organisms on hard, non-porous inanimate surfaces: *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Salmonella (choleraesuis) enterica* (ATCC 10708), *Escherichia coli* (ATCC 11229), *Escherichia coli O157:H7* (ATCC 43895), *Streptococcus pyogenes* (Necrotizing Fasciitis-Group A) (V.A. Medical Center Isolate 04001), *Listeria monocytogenes* (ATCC 35152), *Yersinia enterocolitica* (ATCC 23715), *Enterococcus faecium* (ATCC 6569), *Corynebacterium ammoniagenes* (ATCC 6871), *Salmonella (typhi) enterica* (ATCC 6539), *Methicillin resistant Staphylococcus aureus (MRSA)* (ATCC 33593), *Vancomycin resistant Enterococcus faecalis (VRE)* (ATCC 51575), *Vancomycin intermediate resistant Staphylococcus aureus (VISA)* (CDC Isolate 99287), *Methicillin resistant Staphylococcus epidermidis (MRSE)* (ATCC 51625), *Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA)* Genotypes USA400 (NRS 123) and USA300 (NRS 384).

FUNGICIDAL ACTIVITY – (This product or product name) (kills) (is fungicidal against) (the pathogenic fungus), Trichophyton mentagrophytes (Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot), when used with a 10 minute contact time on clean, non-porous, hard surfaces as found in (bathrooms), (showers), (tubs), (shower stalls), (locker rooms), (or other areas commonly contacted by bare feet).

MILDEWSTAT – To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

Tuberculocidal Activity - (This product or product name) is an effective disinfectant against Mycobacterium tuberculosis BCG (Mycobacterium bovis) at 20 degrees Centigrade (20C) when treated surface is allowed to remain wet for **5 minutes**.

Virucidal Activity – When used as directed, (this product or product name) (kills) (is an effective virucide against) the following organisms on hard, non-porous inanimate surfaces: **Canine Parvovirus** (ATCC VR-2017), **Hepatitis A Virus** (University of Ottawa) and **Poliovirus Type 1** (ATCC VR-1000) when the treated surface is allowed to remain wet for **10 minutes**; **Human Coronavirus** (ATCC VR-740), **SARS associated Coronavirus** (ZeptoMetrix), **Avian Influenza A strain H3N2** (ATCC VR-2072) and **Avian Influenza A strain H9N2** (Charles River laboratories) for **2 minutes**; **Paramyxovirus** (Mumps) (ATCC VR-1438), **Rhinovirus type 39** (ATCC VR-340) and **Rotavirus** (University of Ottawa) for **3 minutes**; **HIV-1 (associated with AIDS)** (Advanced Biotechnologies, Inc.) for **1 minute (60 second)**; **Hepatitis B Virus (HBV)** (Hepadnavirus Testing, Inc.), **Hepatitis C Virus (HCV)** and **Bovine Viral Diarrhea Virus (BVDV)** (NVSL) for **1 (or) (5) minute(s)**; and **Norovirus (Norwalk virus)**, **Feline Calicivirus** (University of Ottawa) and **Rabies Virus** (CDC) for **30 seconds**.

(The following statements must be used for Bloodborne Pathogens: HIV-1, HBV and HCV:)

KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) 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), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier] .

(page 8 of 13)

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, and 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 to remain wet for HBV and HCV **1 (or) (5) minute(s)**, for HIV-1 1 minute. These contact times will not control other common types of viruses and bacteria.

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

SITE AND APPLICATION SPECIFIC DIRECTIONS FOR USE

(Non-Acid) (Bathroom) Disinfectant Cleaner: (This product or product name) is (also) a (ready-to-use) (non-acid) (bowl and) bathroom cleaner that cleans, disinfects and deodorizes in one easy step. It cleans, disinfects and deodorizes sinks, sink rims, sink basins, faucets, tubs, glazed tiles, glazed ceramic, glazed porcelain, chrome, stainless steel, and all non-porous inanimate surfaces found in the bathroom (in the presence of organic soil).

It eliminates odors, leaving (bathrooms) (restrooms) smelling clean and fresh. It cleans, disinfects, and deodorizes surfaces by killing odor-causing microorganisms and (prevents) (inhibits) (controls) the growth of mold and mildew. (Its non-abrasive formula is designed for use) (Use it daily) on (bathroom surfaces): glass, glazed ceramic, glazed tile, glazed porcelain, chrome, stainless steel, and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms, and locker rooms.

Disinfection of animal quarters and kennels: For disinfection of pre-cleaned animal quarters and kennels, apply (this product or product name). Remove all animals and feed from premises. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate the surfaces with the disinfecting solution for a period of 3 minutes (for Bovine Viral Diarrhea Virus (BVDV) **1 (or) (5) minute(s)**) (for Feline Calicivirus and Rabies virus 30 seconds) (for Canine Parvovirus 10 minutes). Ventilate building and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse. Kills Pandemic 2009 H1N1 Influenza A virus

(Large Container Dispensing System)(Dispensing System Brand Name):

Cap Removal: With carton in upright position, hold spout firmly with one hand while removing cap with other hand. Position fingertips under edge of top flange of cap and pull up and back.

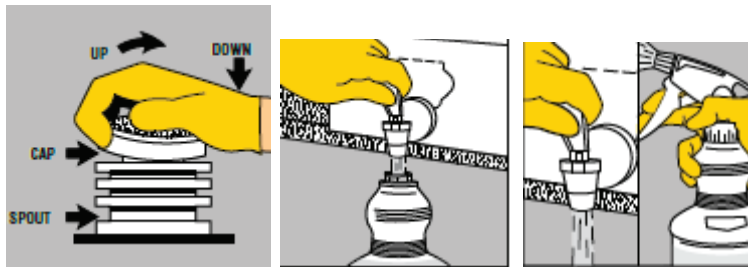
1. Punch out circle.
2. Lift flap and slide spout into circle.
3. Lower flap and place lock spout in place.
4. Attach spigot before tipping box or placing on shelf.

This end up to attach (brand name spigot or dispensing system attachment). Do not remove liner until empty.

Dispensing unit: easy to store, easy to pour container.

Stores on shelf for quick dispensing.

(Brand name spigot or dispensing system attachment)(available separately)



Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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(Optional Directions for Product Supplied in Refill Bottles):

Refill only with this product.

(Alternate for Non-Refillable Bottles with use in conjunction with applicator/sprayer name):

To Connect with insert applicator/sprayer name

[Remove]

Remove cap [and induction seal] [from bottle].

[Connect]

Connect adaptor cap [from *insert applicator/sprayer name*] [to bottle] and twist until tight[ened]. [Refer to user manual for specific operating instructions before use]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

KEEP OUT OF REACH OF CHILDREN. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

FIRST AID	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed:	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:	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) (one of the following statements may be used) You may contact xxx/xxx-xxxx for emergency medical treatment information. Questions? Comments or in case of an emergency call toll free: 1-800-xxx-xxxx.	

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

(Required for products supplied in containers 5 gallons or greater.)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

(For products only with household/residential use sites)

STORAGE AND DISPOSAL

Store in a dry place no lower in temperature than 50°F or higher than 120°F. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Container disposal for Refill Spray Bottle: Do not reuse empty spray bottle except with refill bottle, otherwise discard in trash. Do not reuse empty refill bottle. Wrap refill bottle and discard in trash. Offer for recycling, if available.

(For products with industrial, institutional and commercial use sites)

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying.

(Containers 5 gallons or less)

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Offer for recycling or reconditioning, if available. If not available, puncture and dispose in a sanitary landfill.

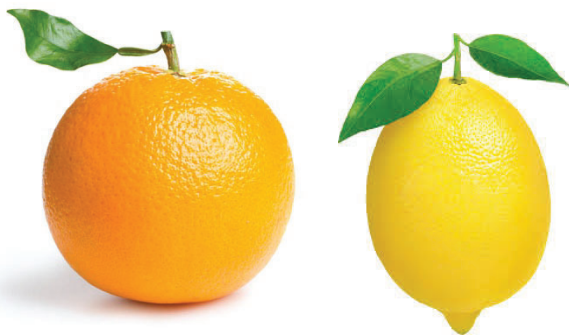
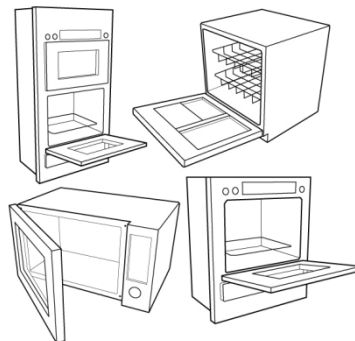
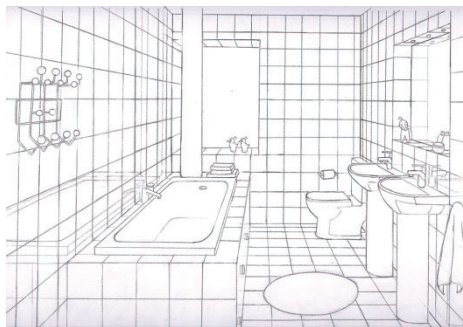
(Containers greater than 5 gallons)

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Repeat this procedure two more times. Offer for recycling or reconditioning, if available. If not available, puncture and dispose in a sanitary landfill.

Container disposal for Refill Spray Bottle: Do not reuse empty spray bottle except with refill bottle, otherwise discard in trash. Do not reuse empty refill bottle. Wrap refill bottle and discard in trash. Offer for recycling or reconditioning, if available.

GRAPHICS

The graphics below, or other pictograms representative of these graphics, may appear on the product label.



Note to Reviewer: These are representative icons for use sites/application methods that may appear on the label listed in the location/surfaces section of this label with the appropriate directions for use, PPE or package type.)

(spray dispensing container)
(sprayer system)
(sink with faucet)
(work station tub or sink)
(rubber gloves) (masks) (PPEs)
(table)
(chair)
(bed frame)
(wall)
(cabinet)
(doorknob)
(garbage can)
(non-wooden picnic table)
(outdoor furniture except cushions and wood frames).
(Telephone)
(non-food contact counter tops, equipment, shelves, racks and carts)
(shower stalls)
(shower doors and curtains)
(tubs)
(glazed tiles)
(toilets)
(urinals)
(glazed porcelain tile) and (restroom fixtures).

Bracketed information is denoted as: {insert as noted}, (optional text), [required qualifier].

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NOTE TO REVIEWER: *When product is supplied in large containers (1 gallon or greater) to be used with refillable pump spray bottles (less than 1 gallon), the refillable spray bottle can be labeled with the complete refill master container label or the following small package label.*

REFILL SPRAY BOTTLE LABEL TO BE USED WITH MASTER CONTAINER LABEL:

DETERGENT DISINFECTANT PUMP SPRAY

ACTIVE INGREDIENTS:

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.105%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.105%
INERT INGREDIENTS:	<u>99.790%</u>
TOTAL	100.000%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE REFILL (CONTAINER, DRUM, BOTTLE) FOR PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

FURTHER SALE OR DISTRIBUTION OF THIS PRODUCT IS STRICTLY PROHIBITED

DISPOSAL: Do not refill empty spray bottle with any product other than product from the labeled refill (container, drum, bottle).
When refill spray bottle is no longer in use, wrap it and discard in trash.

EPA Reg. No. 1839-83
EPA Est. No. 1839-IL-1

NET CONTENTS: (X) FLUID OZ.

STEPAN COMPANY
22 W. Frontage Rd.
Northfield, IL 60093