



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 15, 2020

Sara Seltzer
Registration Specialist
Diversey, Inc.
P.O. Box 19747
Charlotte, NC 28219-0747

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Envy Foaming Disinfectant Cleaner
EPA Registration Number: 70627-35
Application Date: March 13, 2020
Decision Number: 561350

Dear Sara:

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 is large non-enveloped and 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 Poliovirus Type 1 (ATCC VR-192) 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 the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

ENVY™ FOAMING DISINFECTANT CLEANER

Foaming Disinfectant Cleaner

Ready-To-Use (RTU) - Just Spray and Wipe

Spray On • No Rinsing • No Abrasives • One-Step Formula; Foams Away Dirt; Disinfects (Kills) in 3 Minutes!; Will not (Won't) Scratch or Dull Surfaces; Cleans & Disinfects In One Step; Dissolves Soap Scum; Leaves (Toilet) Bowls Sparkling (Clean); Leaves (Bathroom) Surfaces (Sparkling) Clean (and Fresh); Cleans Without (Acids) (Abrasives) Fumes; For Effective Mold and Mildew Control; (Non-Abrasive) No Rinse Formula; The Fast & Easy Way to Clean and Disinfect (Surfaces); Contains No Abrasives (Non-Abrasive (Formula)); Meets OSHA Bloodborne Pathogen Standard for *HBV & *HIV

Fresh (Pleasant) (Apple) (Citrus) (Lemon) (Floral) (Outdoor Fresh) (Country Breeze) (Spring Orchard) Fragrance (Scent)

Bactericidal • *Virucidal • Mildewstatic • Fungicidal • Deodorizer (Odor Counteractant) (Odor Neutralizer)
• Ready-To-Use (RTU)

For (Hospital,) (Foodservice,) (Food Plant), (Commercial), Industrial & Institutional Use (Only)

ACTIVE INGREDIENTS:

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chloride0.106%

n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chloride0.106%

INERT (OTHER) INGREDIENTS:99.788%

TOTAL100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

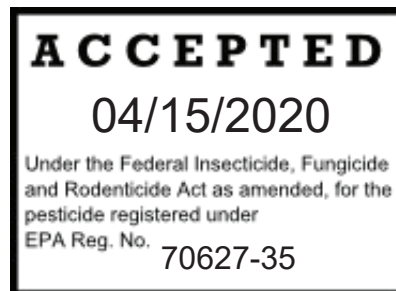
See directions and additional precautionary statements on back (side) (left) (right) (of) (panel) (label) (below).

(See reference sheet (enclosed in each case) for (a complete list of pathogenic organisms) (additional features, claims, direction for use) (claimed for this product).)

Net Contents:

(Product of XXXXXXXX)

Contains no CFCs or other known ozone depleting substances.
Federal Regulations Prohibit CFC Propellants in Aerosols.



(FEATURES, CLAIMS & USES:)

(General Uses:)

This product cleans and disinfects surfaces with a simple spray and wipe. No mixing, no buckets, no rinsing required (other than food contact surfaces). Foam dissolves dirt, grime, mold, mildew and other common soils and even stains found in hospitals, nursing homes, schools and colleges, (day care centers), (medical) offices, funeral homes, veterinary clinics, pet shops, (equine farms), animal life science laboratories, hotels, motels, public restrooms, food processing plants, and food service establishments (restaurants). Use it on all hard, non-porous environmental (restroom) surfaces.

Its non-abrasive formula is designed for use on (Use daily on) (the following) (hard, non-porous environmental surfaces:) vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces associated with walls, ceilings, tables, chairs, countertops, microwave ovens, kitchen areas, telephones, fixtures, glazed tile, toilets, urinals, sinks, shower rooms and locker rooms areas - any washable (food and non-food contact) surface where disinfection is required. A potable water rinse is required for all food contact surfaces. This product must not be used to clean the following surfaces: utensils, glassware, and dishes. It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Hospitals/Health Care Facilities:)

This product 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) hard, non-porous environmental surfaces. Foam quickly dissolves 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.

This product cleans, disinfects and deodorizes hard, non-porous environmental hospital (medical) surfaces in one step (with no rinsing required). Use daily on the following hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, laminated surfaces and baked enamel surfaces associated with walls, ceilings, tables, chairs, countertops, telephones, fixtures, glazed tile, toilets, urinals, sinks found in (health care facilities [hospitals],) patient rooms, operating rooms, ICU areas, shower rooms, and locker rooms. (It can also be used to pre-clean and disinfect hospital items such as wheelchairs, [hospital] [patient] bed rails and linings, washbasins, bedpans, medical equipment surfaces) - any washable (food and non-food contact) surface (where disinfection is required). A potable water rinse is required for all food contact surfaces. This product must not be used to clean the following surfaces: utensils, glassware, and dishes.

(Food Service:)

This product can be used to clean food contact surfaces as well as the restroom and general areas. It cleans by foaming away dirt, grime and food soils in food preparation and processing areas. Its non-abrasive formula will not harm (scratch) surfaces. It cleans, disinfects and eliminates odors leaving surfaces smelling clean and fresh. Use where odors are a problem. A potable water rinse is required for all food contact surfaces.

Its non-abrasive formula is designed for use on (Use daily on) the following hard, non-porous environmental surfaces: vinyl, painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, aluminum, stainless steel, brass, copper, laminated surfaces and baked enamel surfaces associated with walls, ceilings, tables, chairs, countertops, non-porous cutting boards, fixtures, glazed tile, toilets, (toilet bowls), urinals, sinks found in food establishments, (restaurants), (commercial kitchens) & restrooms. A potable water rinse is required for all food contact surfaces. This product must not be used to clean the following surfaces: utensils, glassware, and dishes.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(Animal Housing Facilities:)

This product cleans by foaming away dirt, grime, mold, mildew, blood, urine, fecal matter and other common soils found in animal housing facilities, livestock, swine or poultry facilities, grooming facilities, farms, 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 environmental 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 environmental surfaces:) plated or stainless steel, aluminum, chrome, glazed porcelain, glazed tile, laminated surfaces (associated with floors, walls, countertops, cages, kennels, animal equipment) found in (barns, pens and stalls) animal housing facilities.

(Public Restrooms:)

This product 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 environmental surfaces.

Powerful foam cleans, disinfects and deodorizes surfaces by killing odor-causing germs and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use on (restroom surfaces such as:) glazed ceramic (restroom) tile, 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 is (also) a (ready-to-use) non-acid (bowl and) bathroom cleaner which cleans, disinfects and deodorizes in one easy step. Simply apply it like you would a non-acid bowl cleaner. 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 environmental 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 germs and prevents (inhibits) (controls) the growth of mold and mildew. Its non-abrasive formula is designed for use (Use it daily) on (restroom surfaces such as:) glass, glazed ceramic (restroom) tile, glazed porcelain, chrome, stainless steel, and plastic surfaces associated with floors, walls, fixtures, toilets, urinals, sinks, shower rooms and locker rooms.

(CLAIMS:)

This product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew. See reference sheet enclosed (in each case) for a complete list of organisms.). Using the Germicidal Spray Test Method (under Good Laboratory Practices [GLPs]), 10% organic soil load and a 3 minute contact time (unless otherwise noted), this product kills the following on hard, non-porous environmental surfaces:

Bacteria (Bactericidal Activity) - kills on hard non-porous environmental surfaces:

<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Flavobacterium meningosepticum</i> , (ATCC 13253)	<i>Salmonella gallinarum</i> , (ATCC 9184)
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Haemophilus influenza</i> , (ATCC 10211)	<i>Salmonella schottmuelleri</i> , (ATCC 10719)
<i>Salmonella enterica</i> , (ATCC 10708)	<i>Hafnia alvei</i> , (ATCC 13337)	<i>Salmonella typhi</i> , (ATCC 6539)
(formerly known as <i>Salmonella choleraesuis</i>)	<i>Klebsiella oxytoca</i> , (ATCC 13182)	<i>Salmonella typhimurium</i> , (ATCC 13311)
<i>Acinetobacter calcoaceticus</i> , (ATCC 9957)	<i>Klebsiella pneumoniae</i> , (ATCC 13883)	<i>Serratia grimesii</i> , (ATCC 14460)
<i>Brevibacterium ammoniagenes</i> , (ATCC 6872)	<i>Legionella pneumophila</i> , (ATCC 33153)	<i>Serratia liquefaciens</i> , (ATCC 14460)
<i>Burkholderia cepacia</i> , (ATCC 25416)	<i>Listeria monocytogenes</i> , (ATCC 15313)	<i>Shigella dysenteriae</i> , (ATCC 29026)
(formerly known as <i>Pseudomonas cepacia</i>)	<i>Micrococcus luteus</i> , (ATCC 4698)	<i>Shigella flexneri</i> , (ATCC 25875)
<i>Campylobacter fetus</i> , (ATCC 27374)	<i>Micrococcus luteus</i> , (ATCC 14452)	<i>Shigella sonnei</i> , (ATCC 25931)
<i>Citrobacter freundii</i> , (ATCC 8090)	<i>Micrococcus sedentarius</i> , (ATCC 27573)	<i>Staphylococcus aureus</i> , (ATCC 25923)
<i>Chlamydia psittaci</i> , (VR-125)	<i>Morganella morganii</i> , (ATCC 25830)	<i>Staphylococcus aureus</i> (Toxic Shock), (ATCC 33586)
<i>Enterobacter aerogenes</i> , (ATCC 13048)	<i>Neisseria gonorrhoeae</i> , (ATCC 43069)	<i>Staphylococcus epidermidis</i> , (ATCC 14990)
<i>Enterobacter agglomerans</i> , (ATCC 27155)	<i>Pasteurella multocida</i> , (ATCC 43137)	<i>Staphylococcus haemolyticus</i> , (ATCC 29970)
<i>Enterobacter cloacae</i> , (ATCC 23355)	<i>Proteus mirabilis</i> , (ATCC 9240)	<i>Staphylococcus saprophyticus</i> , (ATCC 15305)
<i>Enterobacter gergoviae</i> , (ATCC 33028)	<i>Proteus vulgaris</i> , (ATCC 13315)	<i>Staphylococcus species</i> , (ATCC 12715)
<i>Enterobacter liquefaciens</i> , (ATCC 14460)	<i>Pseudomonas diminuta</i> , (ATCC 11568)	<i>Streptococcus agalactiae</i> , (ATCC 13813)
<i>Enterococcus faecalis</i> , (ATCC 19433)	<i>Pseudomonas fluorescens</i> , (ATCC 13525)	<i>Streptococcus mutans</i> , (ATCC 25175)
(formerly known as <i>Streptococcus faecalis</i>)	<i>Pseudomonas putida</i> , (ATCC 12633)	<i>Streptococcus pyogenes</i> , (ATCC 19615)
<i>Enterococcus hirae</i> , (ATCC 10541)	<i>Pseudomonas stutzeri</i> , (ATCC 17588)	<i>Vibrio cholera</i> , (ATCC 11623)
<i>Escherichia coli</i> , (ATCC 11229)	<i>Salmonella choleraesuis pullorum</i> , (ATCC 19945)	<i>Yersinia enterocolitica</i> , (ATCC 9610)
<i>Escherichia coli</i> O157:H7, (ATCC 43890)	<i>Salmonella enteritidis</i> , (ATCC 13076)	

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) – kills on hard non-porous environmental surfaces:

- | | | |
|---|---|--|
| <i>E. coli</i> , (ATCC 55244, 47041 & 29181)
(Resistant to Kanamycin, Tetracycline, Trimethoprim, Streptomycin) | <i>Klebsiella oxytoca</i> , (ATCC 15764) (Resistant to Ampicillin, Dihydrostreptomycin) | <i>Staphylococcus aureus</i> , (ATCC 14154)
(Resistant to Erythromycin, Penicillin, Streptomycin, Tetracycline) |
| <i>Enterococcus faecalis</i> , (ATCC 51299)
(Resistant to Vancomycin (VRE)) | <i>Micrococcus sedentarius</i> , (ATCC 27573)
(Resistant to Methicillin) | <i>Staphylococcus aureus</i> , (ATCC 33592)
(Resistant to Methicillin (MRSA), Gentamicin (GRSA)) |
| <i>Enterococcus faecium</i> , (ATCC 51559)
(Resistant to Vancomycin (VRE), Ampicillin, Ciprofloxacin, Gentamicin, Risampin, Teicoplanin) | <i>Staphylococcus aureus</i> , (CDC HIP-5836)
(Intermediate resistance to Vancomycin (VISA)) | <i>Streptococcus pneumoniae</i> , (ATCC 51915)
(Resistant to Penicillin (PRSP)) |

***Viruses (*Virucidal Activity) – kills on hard non-porous environmental surfaces:**

- | | | |
|-------------------------------------|--|---------------------------------------|
| *Adenovirus Type 2, (VR-846) | *Human Coronavirus, (VR-740) | *Respiratory syncytial virus, (VR-26) |
| *Cytomegalovirus, (VR-538) | *Influenza Type A ₂ (Hong Kong), (VR-544) | *Rhinovirus Type 39, (VR-340) |
| *Hepatitis A virus (HAV), (VR-1073) | *Parainfluenza Type 3, (VR-93) | *Rotavirus, (Strain WA) |
| *Herpes simplex Type 1, (VR-733) | *Poliovirus Type 1, (VR-192) | *Vaccinia virus, (VR-119) |
| *Herpes simplex Type 2, (VR-734) | | |

Kills *HBV, *HCV and *HIV-1 (AIDS virus) (HTLV-III_B) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

Fungi (Fungicidal Activity) – kills on hard non-porous environmental surfaces:

Geotrichum candidum, (ATCC 18301)

Kills *Trichophyton mentagrophytes*, (ATCC 9533) (athlete’s foot fungus) in 10 minutes when applied to shower and locker room floors, benches, and floor mats and other hard, non-porous environmental surfaces where *Trichophyton mentagrophytes*, (athlete’s foot fungus) may be found.

Mold/Mildew Control (Mildewstatic Activity) – controls and prevents (inhibits) the growth of mold and mildew (such as *Aspergillus niger* (ATCC 6275)) (and the odors caused by them) when applied to previously cleaned hard, non-porous environmental surfaces.

Malodor(s) Control (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, garbage cans and storage areas (and other places where bacterial growth can cause malodors).

(Emerging Pathogens 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

<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 Viruses	Poliovirus Type 1 (ATCC VR-192)
Large Non-Enveloped Viruses	Poliovirus Type 1 (ATCC VR-192)

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Acceptable claim language:

Envy Foaming Disinfectant Cleaner has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, Envy Foaming Disinfectant Cleaner can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 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]. Envy Foaming Disinfectant Cleaner kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.”

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A₂ (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *This product 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 has demonstrated effectiveness against Influenza Type A₂ (Hong Kong), (VR-544), 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.

DIRECTIONS FOR USE:

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

(Note to reviewer: This paragraph will be used only on labels that list semi-critical devices as defined by FDA.)
(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 blood stream 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

This product can be applied by cloth, sponge, paper towel or sprayed directly on surface. Change cloth, sponges or towels frequently to avoid redeposition of soil.

For General Cleaning and/or Deodorizing:

Hold can upright. Spray foam evenly over surface. Wipe with clean cloth, sponge or paper towel. For heavily soiled areas or stubborn spots, let (foam) solution stay on the surface longer before wiping.

For One-Step Cleaning/Disinfecting:

1. Spray foam evenly over surface. Be sure to wet all surfaces thoroughly.
2. Let this product remain on surface for three (3) minutes.
3. Wipe with clean cloth, sponge or paper towel.
4. A potable water rinse is required for all food contact surfaces.

Note: All food contact surfaces such as appliances and kitchen countertops must be rinsed with potable water. Do not use on glassware, utensils, and dishes.

Non-Acid Cleaning and Disinfecting Toilet Bowls and Urinals:

1. With swab applicator, remove water from bowl by forcing water over trap.
2. Press swab applicator against side of bowl to remove excess water.
3. Apply this product foam to swab applicator, cloth, mop, sponge or directly to surface.
4. Swab entire surface area especially under the rim. Be sure to wet all surfaces thoroughly.
5. Allow entire surface to remain wet for three (3) minutes.
6. Flush toilet or urinal and rinse swab applicator thoroughly.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Fungi:

1. Spray foam evenly over surface. Be sure to wet all surfaces thoroughly.
2. Let this product remain on surface for three (3) minutes. For Trichophyton mentagrophytes (athlete's foot fungus) let remain on surface for ten (10) minutes.
3. Wipe with clean cloth, sponge or paper towel.

To Prevent Mold and Mildew:

1. Thoroughly clean surface prior to treatment.
2. Spray foam evenly over surface. Be sure to wet all surfaces thoroughly.
3. Let this product remain on surface for three (3) minutes.
4. Allow to air dry.
5. Repeat application weekly or when growth reappears.

For Use in Food Processing Plants:

1. Before using this product, food products and packaging materials must be removed from the room or carefully protected.
2. Spray foam evenly over surface. Be sure to wet all surfaces thoroughly.
3. Let this product remain on surface for three (3) minutes.
4. Wipe with clean cloth, sponge or paper towel.
5. A potable water rinse is required for all food contact surfaces.

For Use For Treatment of Animal Housing Facilities:

1. Remove all animals and feed from areas being treated.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
3. Empty or cover all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap and rinse with water.
5. Spray foam evenly over floors, walls, cages and other washable hard, non-porous environmental surfaces until all surfaces are wet. To disinfect, all surfaces must remain wet for three (3) minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats and other closed spaces. Do not house animals or employ equipment until product has dried.
8. For disinfection of feed racks, troughs, automatic feeders, fountains and watering appliances spray foam evenly over surfaces, let stand three (3) minutes. Then thoroughly scrub all treated surfaces with soap or detergent and rinse with potable water before reuse.

***(This product) Kills HBV, HCV and HIV-1 in one minute on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids** in health care settings (Hospitals, Nursing Homes) and 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 Hepatitis B Virus, Hepatitis C Virus and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

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

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HBV, HCV and HIV-1. Allow 10 minutes for Trichophyton mentagrophytes and 3 minutes to kill all other organisms cited on the label.

Disposal of Infectious Material: Blood and other body fluids must be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store away from heat or flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

Do not puncture or incinerate. Nonrefillable container. Do not reuse or refill this container. If empty, this container may be recycled in aerosol recycling centers. At present there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label. If recycling is not available, wrap the container in newspaper and discard in trash. If partly filled, call your local solid waste agency for disposal instructions.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

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 temperatures above 130°F may cause bursting.

FIRST AID

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

1-XXX-XXX-XXXX

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

EPA Reg. No. 70627-35

EPA Est. No.

(MSDS Ref. No. xxxxxxxxxxxx)

(Lot code letters indicate manufacturing location)

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Pictogram for ENVY™ FOAMING DISINFECTANT CLEANER





ENVY™ FOAMING DISINFECTANT CLEANER REFERENCE SHEET

This product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew. See reference sheet enclosed (in each case) for a complete list of organisms.). Using the Germicidal Spray Test Method (under Good Laboratory Practices [GLPs]), 10% organic soil load and a 3 minute contact time (unless otherwise noted), this product kills the following on hard, non-porous environmental surfaces:

Bacteria (Bactericidal Activity) - kills on hard non-porous environmental surfaces:

<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Flavobacterium meningosepticum</i> , (ATCC 13253)	<i>Salmonella gallinarum</i> , (ATCC 9184)
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Haemophilus influenza</i> , (ATCC 10211)	<i>Salmonella schottmuelleri</i> , (ATCC 10719)
<i>Salmonella enterica</i> , (ATCC 10708)	<i>Hafnia alvei</i> , (ATCC 13337)	<i>Salmonella typhi</i> , (ATCC 6539)
(formerly known as <i>Salmonella choleraesuis</i>)	<i>Klebsiella oxytoca</i> , (ATCC 13182)	<i>Salmonella typhimurium</i> , (ATCC 13311)
<i>Acinetobacter calcoaceticus</i> , (ATCC 9957)	<i>Klebsiella pneumoniae</i> , (ATCC 13883)	<i>Serratia grimesii</i> , (ATCC 14460)
<i>Brevibacterium ammoniagenes</i> , (ATCC 6872)	<i>Legionella pneumophila</i> , (ATCC 33153)	<i>Serratia liquefaciens</i> , (ATCC 14460)
<i>Burkholderia cepacia</i> , (ATCC 25416)	<i>Listeria monocytogenes</i> , (ATCC 15313)	<i>Shigella dysenteriae</i> , (ATCC 29026)
(formerly known as <i>Pseudomonas cepacia</i>)	<i>Micrococcus luteus</i> , (ATCC 4698)	<i>Shigella flexneri</i> , (ATCC 25875)
<i>Campylobacter fetus</i> , (ATCC 27374)	<i>Micrococcus luteus</i> , (ATCC 14452)	<i>Shigella sonnei</i> , (ATCC 25931)
<i>Citrobacter freundii</i> , (ATCC 8090)	<i>Micrococcus sedentarius</i> , (ATCC 27573)	<i>Staphylococcus aureus</i> , (ATCC 25923)
<i>Chlamydia psittaci</i> , (VR-125)	<i>Morganella morganii</i> , (ATCC 25830)	<i>Staphylococcus aureus</i> (Toxic Shock), (ATCC 33586)
<i>Enterobacter aerogenes</i> , (ATCC 13048)	<i>Neisseria gonorrhoeae</i> , (ATCC 43069)	<i>Staphylococcus epidermidis</i> , (ATCC 14990)
<i>Enterobacter agglomerans</i> , (ATCC 27155)	<i>Pasteurella multocida</i> , (ATCC 43137)	<i>Staphylococcus haemolyticus</i> , (ATCC 29970)
<i>Enterobacter cloacae</i> , (ATCC 23355)	<i>Proteus mirabilis</i> , (ATCC 9240)	<i>Staphylococcus saprophyticus</i> , (ATCC 15305)
<i>Enterobacter gergoviae</i> , (ATCC 33028)	<i>Proteus vulgaris</i> , (ATCC 13315)	<i>Staphylococcus species</i> , (ATCC 12715)
<i>Enterobacter liquefaciens</i> , (ATCC 14460)	<i>Pseudomonas diminuta</i> , (ATCC 11568)	<i>Streptococcus agalactiae</i> , (ATCC 13813)
<i>Enterococcus faecalis</i> , (ATCC 19433)	<i>Pseudomonas fluorescens</i> , (ATCC 13525)	<i>Streptococcus mutans</i> , (ATCC 25175)
(formerly known as <i>Streptococcus faecalis</i>)	<i>Pseudomonas putida</i> , (ATCC 12633)	<i>Streptococcus pyogenes</i> , (ATCC 19615)
<i>Enterococcus hirae</i> , (ATCC 10541)	<i>Pseudomonas stutzeri</i> , (ATCC 17588)	<i>Vibrio cholera</i> , (ATCC 11623)
<i>Escherichia coli</i> , (ATCC 11229)	<i>Salmonella choleraesuis pullorum</i> , (ATCC 19945)	<i>Yersinia enterocolitica</i> , (ATCC 9610)
<i>Escherichia coli O157:H7</i> , (ATCC 43890)	<i>Salmonella enteritidis</i> , (ATCC 13076)	

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity) – kills on hard non-porous environmental surfaces:

<i>E. coli</i> , (ATCC 55244, 47041 & 29181) (Resistant to Kanamycin, Tetracycline, Trimethoprim, Streptomycin)	<i>Klebsiella oxytoca</i> , (ATCC 15764) (Resistant to Ampicillin, Dihydrostreptomycin)	<i>Staphylococcus aureus</i> , (ATCC 14154) (Resistant to Erythromycin, Penicillin, Streptomycin, Tetracycline)
<i>Enterococcus faecalis</i> , (ATCC 51299) (Resistant to Vancomycin (VRE))	<i>Micrococcus sedentarius</i> , (ATCC 27573) (Resistant to Methicillin)	<i>Staphylococcus aureus</i> , (ATCC 33592) (Resistant to Methicillin (MRSA), Gentamicin (GRSA))
<i>Enterococcus faecium</i> , (ATCC 51559) (Resistant to Vancomycin (VRE), Ampicillin, Ciprofloxacin, Gentamicin, Rifampin, Teicoplanin)	<i>Staphylococcus aureus</i> , (CDC HIP-5836) (Intermediate resistance to Vancomycin (VISA))	<i>Streptococcus pneumoniae</i> , (ATCC 51915) (Resistant to Penicillin (PRSP))

*Viruses (*Virucidal Activity) – kills on hard non-porous environmental surfaces:

*Adenovirus Type 2, (VR-846)	*Human Coronavirus, (VR-740)	*Respiratory syncytial virus, (VR-26)
*Cytomegalovirus, (VR-538)	*Influenza Type A ₂ (Hong Kong), (VR-544)	*Rhinovirus Type 39, (VR-340)
*Hepatitis A virus (HAV), (VR-1073)	*Parainfluenza Type 3, (VR-93)	*Rotavirus, (Strain WA)
*Herpes simplex Type 1, (VR-733)	*Poliovirus Type 1, (VR-192)	*Vaccinia virus, (VR-119)
*Herpes simplex Type 2, (VR-734)		

Kills *HBV, *HCV and *HIV-1 (AIDS virus) (HTLV-III_B) when used as directed on hard, non-porous inanimate surfaces with a 1 minute contact time.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Fungi (Fungicidal Activity) – kills on hard non-porous environmental surfaces:

Geotrichum candidum, (ATCC 18301)

Kills *Trichophyton mentagrophytes*, (ATCC 9533) (athlete's foot fungus) in 10 minutes when applied to shower and locker room floors, benches, and floor mats and other hard, non-porous environmental surfaces where *Trichophyton mentagrophytes*, (athlete's foot fungus) may be found.

Mold/Mildew Control (Mildewstatic Activity) – controls and prevents (inhibits) the growth of mold and mildew (such as *Aspergillus niger* (ATCC 6275)) (and the odors caused by them) when applied to previously cleaned hard, non-porous environmental surfaces.

Malodor(s) Control (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria in restroom areas on hard, nonporous surfaces, behind and under sinks and counters, garbage cans and storage areas (and other places where bacterial growth can cause malodors).

(Note to reviewer: We will choose one or more of these statements depending on available space on the product label.)

- *Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A₂ (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- *This product 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 has demonstrated effectiveness against Influenza Type A₂ (Hong Kong), (VR-544), 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.

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