



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 10, 2022

Abigail T.D. Wacek
Senior Regulatory Consultant
The Gilla Company, LLC
Electronic Transmittal: Abigail.wacek@tsgconsulting.com

Subject: Label Amendment – Adding a new source of active and updating label
Product Name: PELS 422
EPA Registration Number: 91176-2
Received Date: 5/11/2022
Action Case Number: 00370266

Dear Abigail T.D. Wacek:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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

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with FIFRA section 6. If you have any questions, please contact Aidan Fife by phone at 202-566-0822, or via email at fife.aidan@epa.gov.

Sincerely

A handwritten signature in cursive script, appearing to read "Marcel Howard".

Marcel Howard
Product Manager, Team 34
Regulatory Management Branch II
Antimicrobials Division (7510)

Enclosure

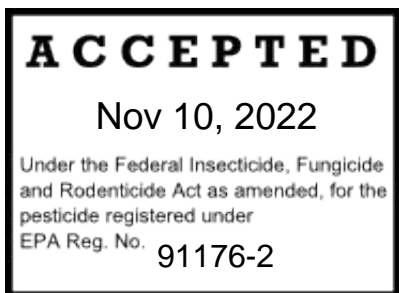
Notes to the Reviewer: [Brackets] throughout label indicate optional or instructional language. ATCC numbers may not appear on final printed labeling.

PELS 422

[Alternate Brand Name: Gilla]

One-step liquid cleaner, deodorizer, sanitizer, and disinfectant for use on hard, non-porous, non-food contact surfaces.

For Hospital, Commercial, Institutional, and Residential Use



Active Ingredient:

1,2-Hexanediol.....4.25%

Other Ingredients.....95.75%

Total.....100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No: 91176-2

EPA Est. No.: XXXXX-XX-XXX

Net Contents:

Manufactured By:

The Gilla Company, LLC DBA Protein Express Laboratories
312 Walnut Street, Suite 1400
Cincinnati, OH 45202

DIRECTIONS FOR USE

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

Use [this product] to clean, deodorize, sanitize, and disinfect hard, non-porous surfaces in one step. Approved Use Sites are listed [below] [above] [under label]. For heavily soiled surfaces, pre-clean by spraying soiled area and wiping clean. Apply solution to visibly clean, hard, non-porous surfaces by spraying 6-8 inches from the surface. Reapply as necessary to ensure that surface remains wet for required contact time. Allow to air dry.

DISINFECTANT

*Organisms	[ATCC]	Contact Time
<i>Pseudomonas aeruginosa</i>	[15442]	10 minutes
<i>Salmonella enterica</i>	[10708]	10 minutes
<i>Staphylococcus aureus</i>	[6538]	10 minutes
Influenza A H1N1 [virus]	[VR-1520]	10 minutes
Human Coronavirus [strain 229E]	[VR-740]	10 minutes

SANITIZER

Organisms	[ATCC]	Contact Time
<i>Enterobacter aerogenes</i>	[13048]	5 minutes
<i>Staphylococcus aureus</i>	[6538]	5 minutes
<i>Staphylococcus aureus MRSA</i>	[33592]	5 minutes
<i>Streptococcus pyogenes</i>	[19615]	5 minutes
<i>Escherichia coli O157:H7 (E. coli)</i>	[35150]	5 minutes

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Use Sites (hard, non-porous, nonfood contact surfaces only)

- Airplanes
- Airports
- Ambulances
- Athletic facilities
- Barber shops
- Bars – nonfood contact surfaces only
- Bathroom fixtures
- Bathtubs
- Boats
- Buses
- Business and office buildings
- Cabinets
- Camp grounds
- Campers
- Cars
- Chairs
- Clinics
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Colleges
- Conductive flooring
- Convenience stores
- Correctional facilities
- Day care centers
- Dental offices
- Desks
- Doorknobs
- Dressing rooms
- Emergency (Police) (EMS) (Fire) (Rescue) vehicles
- Exercise facilities
- Factories
- Floors
- Garbage cans
- Health Care Facilities
- Hospitals
- Hotels
- Institutional facilities
- Institutional kitchen floors/walls
- Institutions
- Kitchens floors/walls
- Locker rooms
- Medical Offices
- Medical Related facilities
- Mobile homes
- Motels
- Nurseries
- Nursing homes
- Pet shops
- Playground equipment surfaces only
- Prisons
- Public facilities
- Public rest rooms
- Refrigerated storage and display equipment (room temperature)
- Restaurants (floors/walls)
- Salons [Beauty] [Tanning]
- Schools
- Ships
- Shower and bath areas
- Shower stalls [Fiberglass]
- Showers
- Sick Rooms
- Sinks [bathroom] [Fiberglass]
- Tanning beds
- Taxis
- Telephones
- Tiles, glazed
- Toilet bowl exterior surfaces
- Toilet bowls – exterior surfaces
- Toilets – exterior surfaces
- Trailers
- Trains
- Transportation terminals
- Tubs [Fiberglass]
- Ultrasonic baths
- Universities
- Urinals – exterior surfaces
- Walls
- Whirlpool bathtubs

Non-critical, hard, non-porous medical device surfaces:**

- Medical and Hospital Lamps
- Medical and Hospital Scales
- Medical and Hospital Examining tables
- Bed frames
- Bed rails
- Medical and Hospital Beds
- Crutches
- Defibrillators
- Gurneys
- Non-critical hospital and medical equipment
- Rescue tools
- Resuscitators
- Stands
- Stethoscopes
- Stretchers
- Walkers
- Wheel chairs

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** 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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection

Optional Label Claims:

- An everyday sanitizer [Note to the reviewer: Arrow to point from the claim to the qualifying statement] and disinfectant [Note to the reviewer: Arrow to point from the claim to the qualifying statement]



Enterobacter aerogenes,
Staphylococcus aureus,
Staphylococcus aureus MRSA,
Streptococcus pyogenes, Escherichia coli O157:H7 (E. coli).



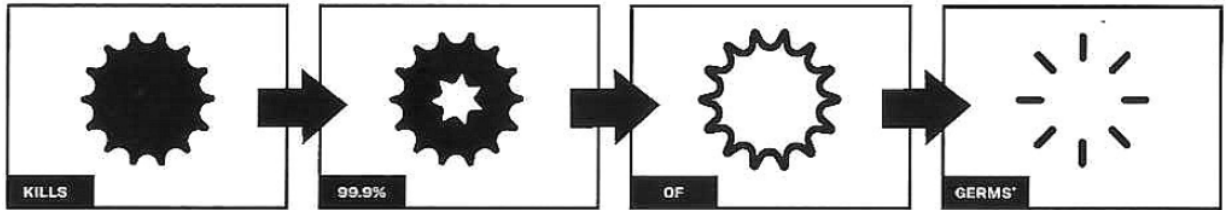
Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus,
Influenza A H1N1 [virus], Human
Coronavirus [strain 229E].

- An everyday sanitizer and disinfectant.
- Antibacterial
- Cleans
- Deodorizes
- Disinfectant
- Disinfects
- Disinfects: airplanes, athletic facilities, bathroom fixtures, bathtubs, cabinets, cars, chairs, desks, doorknobs, floors, garbage cans, locker rooms, showers, toilets – exterior surfaces, telephones, tanning beds,
- Eliminates Odors
- Gilla and The Germ Killa are trademarks of The Gilla Company, LLC
- Kills 99.9% of germs*
- Kills Germs*
- Made using Zsolt's Formula, a proprietary, patented formula. [See U.S. Patent Nos. 10,194,657 and 10,813,353.] [Patents: See www.thegillacompany.com/patents]
- Patents: See www.thegillacompany.com/patents
- Peel back here
- Sanitizer
- Sanitizes
- See www.thegillacompany.com for additional information
- The Germ* Killa
- UPC Code Placeholder
- U.S. Patents Nos. 10,194,657 and 10,813,35

*Kills *Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus, Influenza A H1N1, Human Coronavirus [strain 229E]*

Notes to the Reviewer: [Brackets] throughout label indicate optional or instructional language. ATCC numbers may not appear on final printed labeling.

- Optional graphic:



STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal

STORAGE: Store away from children. Reclose cap tightly after use. Store this product upright in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

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

OR

To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill container.

Clean container promptly after emptying. Offer for recycling if available or reconditioning if appropriate or place in trash.