

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 17, 2020

Abigail T.D. Wacek Consultant The Gilla Company, LLC DBA Protein Express Laboratories 600 Vine St, Suite 2800 Cincinnati, Ohio 45202

Subject: PRIA Label Amendment – Add the Emerging Viral Pathogens Claim

Product Name: PELS 422

EPA Registration Number: 91176-2 Application Date: 03/20/2020 Decision Number: 561220

Dear Ms. Wacek:

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.

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

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,

Kathryn Montague, Senior Regulatory Advisor

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped Label

## ACCEPTED

04/17/2020

[Brackets throughout label indicate optional or instructional language]

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 91176-2

### **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	<u>95.75%</u>
Total	100.00%

#### KEEP OUT OF REACH OF CHILDREN

EPA Reg. No: 91176-2 EPA Est. No.: XXXXX-XXX Net Contents:

Manufactured By:

The Gilla Company, LLC DBA Protein Express Laboratories 600 Vine Street, Suite 2800

Cincinnati, Ohio 45202

#### **DIRECTIONS FOR USE**

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

## TO CLEAN, DEODORIZE, SANITIZE, AND DISINFECT HARD, NON-POROUS SURFACES

Use this product to clean, deodorize, sanitize, and disinfect [surfaces listed in Use Sites below] in one step. 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]	<b>Contact Time</b>
Pseudomonas aeruginosa	[15442]	10 minutes
Salmonella enterica	[10708]	10 minutes
Staphylococcus aureus	[6538]	10 minutes
Influenza A H1N1	[VR-1520]	10 minutes
Human Coronavirus [strain 229E]	[VR-740]	10 minutes

#### **SANITIZER**

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

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

- Airplanes
- Airports
- Ambulances
- Animal laboratories
- Athletic facilities
- Barber shops
- Bars nonfood contact surfaces only
- Bathroom fixtures
- Bathtubs
- Boats
- Buses
- Business and office buildings
- Cabinets
- Cages
- Camp grounds
- Campers
- Cars
- Chairs
- Chicken farms nonfood contact surfaces only
- Clinics
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Colleges
- Conductive flooring
- Convenience stores
- Correctional facilities
- Dairy farms nonfood contact surfaces only
- Day care centers
- Dental offices
- Desks
- Doorknobs
- Dressing rooms

- Emergency (Police) (EMS) (Fire) (Rescue) vehicles
- Exercise facilities
- Factories
- Farms
- Floors
- Garbage cans
- Health Care Facilities
- Hog farms nonfood contact surfaces only
- Hospitals
- Hotels
- Institutional facilities
- Institutional kitchen floors/walls
- Institutions
- Kennel runs
- Kennels
- Kitchens floors/walls
- Locker rooms
- Medical Offices
- Medical Related facilities
- Mobile homes
- Motels
- Nurseries
- Nursing homes
- Pet animal quarters
- Pet shops
- Playground equipment
- Poultry farms nonfood contact 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]
- Turkey farms nonfood contact surfaces only
- Ultrasonic baths
- Universities
- Urinals exterior surfaces
- USDA inspected food processing facilities – nonfood contact surfaces only
- Walls
- Whirlpool bathtubs
- Zoos

#### 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
- \* 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:**

- Antibacterial
- Cleans
- Deodorizes
- Disinfectant

- Eliminates Odors
- Kills Germs\*
- Sanitizer
- The Germ\* Killa
- \*Kills *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*, Influenza A H1N1, Human Coronavirus [strain 229E]

#### 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.