



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 10, 2023

Mitch Whitney
Vice-President
QuestSpecialty Corporation
Electronic Transmittal: mitchw@questspecialty.com

Subject: Notification per PRN 98-10 – Minor edits to the label including a clarification statement and a note to reviewer
Product Name: GERM AWAY FOAMING GERMICIDAL CLEANER
EPA Registration Number: 44446-23
Received Date: 10/10/2022
Action Case Number: 00399852

Dear Mitch Whitney:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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) 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. 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.

If you have any questions, please contact Carlos Corona by email at Corona.Carlos@epa.gov.

Sincerely,

Carlos Corona

for
Tara Flint Silva, PM for Team 31
Regulatory Management Branch 1
Antimicrobials Division
Office of Pesticide Programs

NOTIFICATION

44446-23

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/10/2023

GERM AWAY

Foaming

Germicidal Cleaner

[Germicidal

Foaming Cleaner]

[DISINFECTANT - CLEANER - DEODORIZER]

[Evaporator Coil Cleaner & Disinfectant]

Cleans as it Disinfects

**Glazed Porcelain, Formica, Glazed Tile, Vinyl, Stainless Steel, Finished Woodwork and
Other Hard, Non-Porous Surfaces**

Virucidal Against HIV-1 (AIDS Virus)*,

Herpes Simplex Virus Type 1 & 2, Canine Parvovirus, Influenza A H1N1

[Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)]

[Kills Pandemic 2009 H1N1 influenza A virus]

Disinfects Against Legionella pneumophila

[Kills MRSA on Treated Surfaces]

[Kills Flu Virus]

[Kills Canine Parvovirus on hard surfaces or objects.]

ACTIVE INGREDIENTS:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)

dimethyl benzyl ammonium chloride 0.10%

n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl

ammonium chloride..... 0.10%

OTHER INGREDIENTS:..... 99.80%

TOTAL..... 100.00%

EPA Reg. No. 44446-23

EPA Est. No. 44446-TX-1

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See Additional Precautionary Statements on Back Panel

NET WT. 18 OZ. (510 g)

QuestSpecialty Corporation

P.O. Box 624 • Brenham, TX 77834



SPRAYS RIGHTSIDE UP/UPSIDE DOWN

This product [(product name)] has been designed specifically for Homes, Nursing Homes, Hospitals, Institutions, Offices, Schools, Motels and Hotels. When used as directed, this product [(product name)] is formulated to disinfect inanimate hard non-porous surfaces (such as walls, sink tops, tables, chairs, telephones, bathrooms, shower stalls, bathtubs, hampers, cabinets and bed springs, [HVAC catchpans and air conditioning evaporator coils]). In addition, this product [(product name)] deodorizes those areas which generally are hard to keep fresh smelling (such as garbage storage areas, empty garbage bins and cans, restrooms, shower stalls and other areas which are prone to odors caused by microorganisms). When used as directed, this product [(product name)] demonstrates effective disinfection against *Staphylococcus aureus*, *Methicillin Resistant Staphylococcus aureus* (MRSA), *Salmonella enterica*, *Pseudomonas aeruginosa*, *Canine Parvovirus*, *Herpes simplex type 1*, *Herpes simplex type 2*, *Legionella pneumophila*, and *Influenza A H1N1*, [thus meeting requirements for hospital use]. Efficacy tests have demonstrated that the product [(product name)] is an effective one-step cleaner disinfectant in the presence of organic soil (5% blood serum). This product [(product name)] is fungicidal against Pathogenic fungi (*T. interdigitale*), when used as directed on hard surfaces found in the bathroom, shower stall, and locker room, or other clean, hard, non-porous surfaces commonly contacted by bare feet. This product [(product name)] is a versatile disinfectant and virucide for veterinarian and animal care applications when used as directed below. This product [(product name)] can be used in Veterinary clinics, animal life science laboratories, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, tack shops and other animal care facilities.

MOLD AND MILDEWSTAT: This product [(product name)] controls mold, mildew and the odors they cause on hard, non-porous, inanimate surfaces when used as directed.

STORAGE AND DISPOSAL

Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

DIRECTIONS FOR USE

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

DISINFECTION, DEODORIZATION AND CLEANING:

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

This product [(product name)] 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 [(product name)] may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{or}

This product is not for use on medical device surfaces.

Surfaces which come into contact with food must be rinsed with potable water after disinfection.

Do not use this product [(product name)] to disinfect appliances, refrigerator interiors, microwave oven interiors.

Do not use this product [(product name)] to disinfect or clean dishes, glassware or eating utensils.

To disinfect [clean, deodorize] hard non-porous surfaces (such as glazed bathroom tiles, walls, fixtures, shower stalls, sinks, bathtubs, hampers, tables, chairs, HVAC catchpans and air conditioning evaporator coils), proceed as indicated below: (1) Shake can before using. (2) Hold six to eight inches from surface to be treated. (3) Spray area until it is covered with a white foam. Allow foam to penetrate and remain wet for 10 minutes. No scrubbing necessary. (4) Wipe off with a clean cloth, mop or sponge. This product [(product name)] will not leave grit or soap scum. For heavily soiled areas, remove gross soil before treatment.

For animal quarters and kennels, veterinary clinics, animal life science laboratories, pet shops, kennels, breeding and grooming establishments, tack shops: Remove all animals, poultry, and their feed/food from premises. Remove all litter, droppings and manure from all surfaces to be treated. Apply [this product] [(product name)] Germ Away as directed above. [This product] [(product name)] Germ Away will disinfect and clean the following surfaces: Equipment, utensils, instruments, cages, kennels, stables, stalls and catteries. After disinfection, ventilate buildings, coops and other closed spaces. Do not house poultry, or other animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water (racks, troughs, automatic feeders, fountains, waterers and other similar equipment) must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard, non-porous surfaces (such as floors, walls, table tops) spray surfaces to be treated, making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

***KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of hard non-porous 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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND
DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS)
OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings 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 disinfectant.

Contact Time: Effective against HIV-1 (AIDS virus) on hard non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) providing 1800 ppm of active quaternary water for a contact time of 10 minutes at room temperature (20-25°C). Use a ten (10) minute contact time for disinfection against all other bacteria and fungi claimed (listed on labeling).

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS**

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator.

FIRST AID

If swallowed:

- Call 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 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 on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:

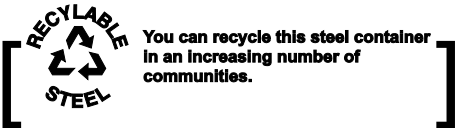
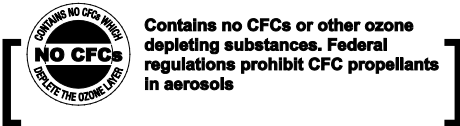
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

[INGREDIENTS (CAS#): Water (7732-18-5), 2-Butoxy Ethanol (111-76-2), Propane/n-Butane (68476-86-8), Isopropyl Alcohol (67-63-0), EDTA (60-00-4).]

[HMIS Ratings: Health – 1, Flammability – 0, Reactivity – 1, Personal – A.]

For MSDS or additional product information: www.questspecialty.com



[For Commercial/Institutional Use Only.]

Made in USA

[ITEM 2170000001-20AR

2-4-2020]

| | |
|------------------------------------|---------------------------------|
| [Herpes Simplex 1 | VR-733 |
| Herpes Simplex 2 | VR-734 |
| Canine Parvovirus | ATCC 2017 |
| Human Immunodeficiency Virus – HIV | HTLV-III RF |
| Salmonella enterica | ATCC 10708 |
| Pseudomonas aeruginosa | ATCC 15442 |
| Staphylococcus aureus | ATCC 6538 |
| Staphylococcus aureus – MRSA | ATCC 33592 |
| Legionella pneumophila | ATCC 33153 |
| Trichophyton interdigitale | ATCC 9533 |
| Influenza A H1N1 | ATCC VR-1469, Strain A/PR/8/34] |

NOTE: Language in brackets [] is alternate marketing language.

Language in braces {} are for information purposes only and will not appear on final label

Emerging Viral Pathogen Claims

This product qualifies for emerging 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 category:

- 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 | Canine Parvovirus, ATCC 2017 |

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to ***[name of emerging virus]*** on hard, ***[porous and/or non-porous surfaces]***. Therefore, ***[product name]*** can be used against ***[name of emerging virus]*** when used in accordance with the directions for use against ***[name of supporting virus(es)]*** on ***[hard, porous/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 ***[name of supporting virus(es)]*** on ***[hard, porous/nonporous surfaces]***. Refer to the ***[CDC or OIE]*** website at ***[website address]*** for additional information.