

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 7, 2021

Laura E. Radevski Technical & Regulatory Compliance Manager Chaise Product Co. P.O. Box 70 Maywood, Il 60153

> Subject: PRIA Label Amendment – To add Rhinovirus claims Product Name: SprayPak Foaming Cleaner Disinfectant & Deodorizer EPA Registration Number: 498-62 Application Date: September 24, 2020 Decision Number: 566584

Dear Ms. Radevski:

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" (<u>www.cdc.gov/outbreaks</u>),
- 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 (<u>www.cdc.gov/hai/outbreaks</u>)

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 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.

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1. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 39 (ATCC VR-340), Strain 209 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) 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.

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, please contact John Hebert via email at hebert.john@epa.gov.

Sincerely,

Alu Milus

John Hebert, Chief Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure; Stamped label

S:/lara/epa/labels/498-62/RhinovirusType39/Label with changes per EPA's Memorandum 12-18-20 and e-mails12-28-2020/LER 01-06-2021

FRONT PANEL

ACCEPTED 01/07/2021 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 498-62

# **SPRAYPAK**

# FOAMING CLEANER DISINFECTANT AND DEODORIZER

#### **KILLS RHINOVIRUS TYPE 39\***

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD AND BODY FLUIDS.

Kills Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Trichophyton interdigitale, Influenza A H2N2, strain A/Japan/305/57; ATCC VR-100, Influenza B (Hong Kong); ATCC VR-823, Herpes Simplex Type 1 and Herpes Simplex Type 2 and Respiratory Syncytial virus on hard, nonporous inanimate surfaces.

Also effective against Escherichia coli, Campylobacter jejuni and Salmonella schottmuelleri.

# ANTIBACTERIAL KILLS GERMS ELIMINATES ODORS REMOVES MOLD AND MILDEW STAINS AND ODORS

#### **ACTIVE INGREDIENT:**

n-Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> )		
dimethylbenzyl ammonium chloride		0.384%
<b>*OTHER INGREDIENTS:</b>		99.616%
	Total	100.000%

\*Other ingredients include detergent, chelating agents, cleaners, builders and propellant.

EPA Reg. No. 498-62-XXXX

EPA Est. No. 498-IL-1

#### •]

#### #1 ENEMY OF DIRT CLEANS AND POLISHES WITHOUT SCRUBBING

#### NET WT X lb XX oz (XXX g)

# KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional precautionary statements.

# FORMULATED FOR HOSPITAL • SCHOOL • HOTEL • MOTEL • OFFICE • RESTAURANT • LOCKER AND REST ROOM • FACTORY • INSTITUTION • NAIL SALON • HOME

## FOAMING CLEANER

#### DISINFECTANT & DEODORIZER CLEANS - DISINFECTS - DEODORIZES POLISHES AS IT CLEANS

Cleans and deodorizes all hard, nonporous washable household surfaces such as bathtubs, sinks, toilet seats and exterior bowl surfaces, shower stalls, plastic and ceramic tile, chrome, stainless steel, baked enamel, plastic countertops, painted walls and woodwork, vinyl and leather. No scrubbing. No rinsing. Non-abrasive.

This product is a germicidal that kills Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Escherichia coli, Campylobacter jejuni and Salmonella schottmuelleri.

#### \*Kills Rhinovirus Type 39 – the leading cause of the common cold.

Kills viruses and fungi on hard, nonporous inanimate surfaces. **Viruses:** Rhinovirus Type 39, Influenza A H2N2, strain A/Japan/305/57; ATCC VR-100, Influenza B (Hong Kong); ATCC VR-823, Herpes Simplex Type 1 and Herpes Simplex Type 2 and Respiratory Syncytial virus. **Fungi:** Trichophyton interdigitale (athlete's foot).

Removes mold and mildew stains and odors.

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

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.

Kills HIV-1 (AIDS VIRUS) on precleaned environmental surfaces/objects previously soiled with blood and body fluids in health care settings 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 HIV.

# SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS.

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks and eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

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

**CONTACT TIME:** Leave surface visible wet for 10 minutes.

After surface is cleaned, hold can upright and spray 6 to 8 inches from surface to be treated until surface becomes wet.

Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of 10 minutes prior to wiping.

# **DIRECTIONS FOR USE**

# **DIRECTIONS TO CLEAN & DISINFECT**

#### SHAKE WELL BEFORE USING:

1. Hold can 8 to 10 inches from surface; spray a light coating of foam over area to be cleaned.

2. Allow foam to remain visible wet for 10 minutes.

3. Wipe surface clean with a damp cloth or sponge. On stubborn spots, allow foam to stand longer.

**DIRECTIONS TO REMOVE MOLD & MILDEW STAINS AND ODORS:** Hold dispenser upright and spray 6 to 8 inches from surface until surface is covered with foam. Allow foam to remain visible wet on the surface for 10 minutes before wiping off. Repeat application when new growth appears.

### **OTHER SUGGESTED USES**

Effective for cleaning and deodorizing refrigerators, freezers and garbage cans. Excellent for cleaning and disinfecting bedpans, wastebaskets and diaper pails in hospitals, nurseries, rest homes and sickrooms.

# **STORAGE & DISPOSAL**

**STORAGE:** Store in a cool, dry area away from heat or open flame.

**DISPOSAL:** Do not reuse empty container. This container may be recycled in one of the limited number of aerosol recycling centers in the country. Before recycling, empty the can by using the product according to the label. DO NOT PUNCTURE! If recycling is not available, wrap the container and discard in the trash.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

#### CAUTION

Do not spray in eyes. In case of contact, flush thoroughly with water. If irritation persists, get medical attention. Avoid spraying on food.

#### FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, 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.

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

#### PHYSICAL OR 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.

Use only as directed. Intentional misuse by deliberately concentrating and inhaling aerosol products can be harmful or fatal.

# THE USER OF THIS PRODUCT ASSUMES ALL RISKS OF USE, STORAGE AND HANDLING NOT IN ACCORDANCE WITH ITS DIRECTIONS AND CAUTIONS.

#### (MEDICAL INFORMATION -- MANDATORY ON CHASE PRODUCTS, OPTIONAL ON OTHER LABELS. MEDICAL SUPPORT ORGANIZATION MAY DIFFER. SAMPLE: Questions about this product? Call (708) 865-1000. MEDICAL EMERCENCY INFORMATION ONLY:

ChemTel, Inc. (800) 255-3924)

[OPTIONAL QR GRAPHIC FOR SDS]

[OPTIONAL RECYCLE SYMBOL]

[OPTIONAL MADE IN USA GRAPHIC]

[OPTIONAL UPC SYMBOL]

Chase Products Co. Putting the best at your fingertips.® P.O. Box 70 – Maywood, IL 60153 www.chaseproducts.com

# APPENDIX A

#### [EMERGING PATHOGEN CLAIM LANGUAGE

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 category:

Enveloped Viruses For an emerging viral pathogen that is an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus Type 39, (ATCC VR-340), Strain 209

SprayPak Foaming Cleaner Disinfectant & Deodorizer has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, SprayPak Foaming Cleaner Disinfectant & Deodorizer can be used against [name of emerging virus] when used in accordance with the directions for use against Rhinovirus Type 39 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

#### Or

[Name of illness/outbreak] is caused by [name of emerging virus].

SprayPak Foaming Cleaner Disinfectant & Deodorizer kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with directions for use against Rhinovirus Type 39 on hard, non-porous surfaces. Refer to [CDC or OIE] website at [pathogen-specific website address] for additional information.

(NOTE: Per the Emerging Viral Pathogen (EVP) guidance and terms of registration, these claims should only be communicated **off-label** in the event of an outbreak, for the duration permitted.)

#### 8-XXXX

#### BOTTOM OF LABEL

S:/lara/epa/labels/498-62/RhinovirusType39claim/with chnagesperEPA'sMemorandum12-18-20 & e-mail on 12-28-20/ler/01-06-2021.