



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 27, 2021

Matthew Rhodes
Celeste Industries Corporation
8221 Teal Drive #405
Easton, MD 21601

Subject: PRIA Label Amendment – Adding Human Coronavirus and SARS CoV-2 Organisms, lower dwell times and 1-step for all listed claims and additional 2-step instructions for SARS-CoV-2 at 1-minute dwell
Product Name: Sani-Cide EX3 (10X) RTU
EPA Registration Number: 42048-4
Application Date: 03/16/21
Case Number: 00297246

Dear Mr. Rhodes:

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.

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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 Stacey Grigsby by phone at 703-305-6440, or via email at grigsby.stacey@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

f/Lorena Rivas
Acting Team Leader Team 34
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Enclosure: Approved label

SANI-CIDE EX3 (10X) RTU

{Alternate Brand Names: Sani-Cide EX3,

Spray Nine (optional additional Brand names - Disinfecting Automotive Cleaner, Disinfecting Multi-Purpose Cleaner, Multi-Purpose Disinfecting Cleaner, Multi-Purpose Disinfectant, Multi-Surface Cleaner, Automotive Cleaner & Disinfectant, Automotive Disinfecting Cleaner, Automotive Disinfectant & Cleaner, Automotive Cleaner & Disinfectant, Automotive Disinfecting Cleaner)

Ready-to-Use Broad Spectrum Disinfectant and Cleaner

Ready-to-Use Broad Spectrum Disinfectant and Cleaner

For Use on Airplane Hard, Non-Porous Surfaces

For Use on Rail Car Hard, Non-Porous Surfaces

For Use on Hard, Non-Porous Surfaces in Manufacturing, Warehousing and Maintenance Facilities

For Use on Hard, Non-Porous Surfaces in Hospitals And Emergency Vehicles

For Use on Nonfood Contact, Hard, Non-Porous Surfaces in Agricultural Premises and Equipment

For Use on Nonfood Contact, Hard, Non-Porous Surfaces in Food Handling/Storage

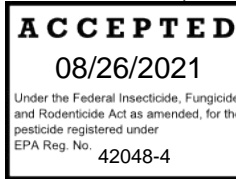
Establishments, Premises and Equipment

For Use on Hard, Non-Porous Surfaces in Commercial, Institutional and Industrial Premises and Equipment

For Use on Nonfood Contact, Hard, Non-Porous Surfaces in Residential and Public Access Premises

For Use on Hard, Non-Porous Surfaces in Medical Premises and Equipment

For Use on Hard, Non-Porous Surfaces in Education Buildings, Schools, Universities and Vocational Schools



{Note to Reviewer: this fragrance descriptor may be used for product formulated without fragrances:}
FRAGRANCE FREE

Active Ingredient

L-Lactic Acid..... 0.40%

Inert Ingredients 99.60%

Total 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See (inside) (back) (side) (panel) for Additional Precautionary Statements (and First Aid)]

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. Call a poison control center or doctor for treatment advice.

Hot Line Number

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

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EPA Est. No. 42048-MD-001

Net Contents:

{Note to Reviewer: The batch code number may appear on the label or on the individual container}

Master label 08/24/2021

Bracketed Language (“[]”) denotes optional text

Batch Code:

Manufactured by: Celeste Industries Corp., [+1.410.822.5775.] 8221 Teal Drive, Suite 405, Easton, MD 21601

Precautionary Statements

Hazards to Humans and Domestic Animals

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Environmental Hazards

[If container size is 5 gallons or greater the following statement will be used:]

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Sani-Cide EX3 can be used to disinfect nonfood contact, hard non-porous surfaces in the home, schools, universities, vocational schools and education buildings as well as institutional, industrial, warehousing, medical and maintenance facilities, hospitals, emergency vehicles, doctors' offices, medical premises and agricultural premises and equipment. Sani-Cide EX3 may also be used to disinfect nonfood contact, hard non-porous surfaces in food handling or storage establishments, residential/public access areas, airplanes, rail cars, boats and other private or commercial transportation vehicles.

To Refill: Remove trigger sprayer and pour in product from refill container. Replace trigger sprayer.

Sani-Cide EX3 (Alternate Brand Name) is proven effective against the following bacteria† and viruses*

Bacteria†	Contact Time	Pre-Cleaning required
<i>Staphylococcus aureus</i>	3 minutes	No
<i>Salmonella enterica</i>	3 minutes	No
<i>Pseudomonas aeruginosa</i>	3 minutes	No
Methicillin-Resistant <i>Staphylococcus aureus</i>	3 minutes	No
Viruses*		
Influenza A & B	3 minutes	No
Feline Calicivirus (surrogate for Norovirus)	3 minutes	No
Human Coronavirus	3 minutes	No
SARS-Related Coronavirus 2	3 minutes	No
SARS-Related Coronavirus 2	1 minute	Yes

Directions for Use

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

1-Step Cleaning and Disinfection Application Instructions for all listed organisms:

Preclean visibly dirty surfaces prior to disinfection.

To clean and disinfect, spray Sani-Cide EX3 (10X) RTU directly on the hard, non-porous surface. Spray 6-8 inches from surface. Allow surface to remain visibly wet for 3 minutes. After 3 minutes, wipe (dry if desired) with a cloth and let dry.

In the presence of a 5% organic soil load, Sani-Cide EX3 (10X) RTU is an effective disinfectant against †*Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC 33592), *Human Norovirus (Feline Calicivirus (ATCC VR-782, Strain F9, surrogate for human norovirus), Influenza A virus (ATCC VR-544, Strain A/Hong Kong/8/68), Influenza B virus (ATCC VR-823, Strain B/Hong Kong/5/72), Human Coronavirus (ATCC VR-740, Strain 229E) and SARS-Related Coronavirus 2 (BEI Resources NR-52281, Strain Isolate USA-WA1/2020).

2-Step Cleaning and Disinfection Application Instructions for SARS-CoV-2

Prior to disinfection, pre-clean hard non-porous surfaces by spraying Sani-Cide EX3 (10X) RTU directly on to the surface. Spray 6-8 inches from surface then wipe with a cloth and let dry.

To disinfect, spray Sani-Cide EX3 (10X) RTU directly on to the hard, non-porous surface. Spray 6-8 inches from surface. Treated surfaces must remain visibly wet for 1 minute. After 1 minute, wipe (dry if desired) with a cloth and let dry.

FOR FOOD-PROCESSING ESTABLISHMENTS AND EQUIPMENT: Food products and packaging materials must be removed or carefully protected prior to using this product. After use, thoroughly rinse surfaces with potable water before reuse.

MEDICAL USE STATEMENT: 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.

AGRICULTURAL USE STATEMENT: Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate the surfaces with the disinfecting solution for [contact time]. Ventilate building and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be scrubbed with soap or detergent and rinsed with potable water before reuse."

STORAGE AND DISPOSAL

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

Product Storage: Store in a cool, dry, well-ventilated area inaccessible to children. If leak or spill occurs – ventilate area of leak or spill. Remove all sources of ignition. Dilute with water and mop-up or absorb with an inert material (e.g., vermiculite, dry sand, earth) and place in a chemical waste container.

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

Container Disposal: Refillable container. Do not reuse or refill except as described. Refill this bottle only with this product. If not refilling, offer for recycling, if available. If recycling is not available, place empty container in trash or dispose of in a sanitary landfill.

[Optional Non-Pesticidal Marketing Language]

- Sani-Cide EX3 (10X) RTU will NOT discolor hard, non-porous surfaces in airplane cabins.
- Sani-Cide EX3 (10X) RTU has been tested according to (complies with) Aerospace Material Specification (AMS) 1550B, 1452C and Boeing D6-7127 test specifications.
- Auto Cleaning
 - Surface types: Glass, mirrors, plastic, metal, rubber
 - Surfaces: touchscreen, mirrors, non-leather steering wheel, door handles, non-leather gear shift, dashboard, parking brake, control knobs, rearview mirror, seatbelt buckle, windshield, windshield wiper switch, turn signal switch
- Home Cleaning
 - Surfaces: counter tops, appliance exteriors, handles, door knobs, cell phones, remotes, sealed cabinets, showers, bath tubs, sink, toilet exteriors, faucets, bathroom, hard non-porous surfaces in kitchens & living rooms, garbage cans, stove top, television screen, microwave exterior, outdoor furniture, tools, computer screen, computer mouse, keyboards, floors, refrigerator exteriors & freezer exteriors and handles, touchscreen, mirrors
- Leaves surfaces clean
- Streak free clean
- Streak free
- Leaves surfaces cleans and streak free!
- Will not damage touchscreens or electrical components
- Leaves surfaces streak-free
- Leaves behind no residue or build-up
- Won't discolor surfaces
- Cleans mold and mildew stains
- Removes mold and mildew stains
- Non-toxic
- non-corrosive
- Cleans countertops, appliance exteriors, bathroom tile
- No harsh solvents or bleach
- Bleach free
- No Bleach
- Contains no bleach
- Product should be tested on inconspicuous area for color fastness and compatibility
- Non-flammable
- Non-abrasive
- Contains no quaternary ammonia compounds
- Ready to use
- Easily cleans tough soils
- Cuts grease and grime

[Optional Pesticidal Marketing Language]

- Sani-Cide EX3 (10X) RTU is a broad spectrum disinfectant and All-purpose Cleaner which leaves surfaces with a Streak-Free appearance and leaves a fresh pleasant scent.
- Use Sani-Cide (10X) RTU on hard, non-porous surfaces in airplane cabins where bacteria or strong unpleasant odors are likely to be present.
- **Auto**
 - Disinfects hard non-porous surfaces:
 - ⊖ Surface types: Glass, mirrors, plastic, metal, rubber
 - Surfaces: touchscreen, mirrors, door handles, dashboard, parking brake, control knobs, rearview mirror, seatbelt buckle, windshield, windshield wiper switch, turn signal switch, non-leather steering wheel, non-leather gear shift
- **Home**
 - Disinfects hard non-porous surfaces:
 - Surface types: glass, mirrors, plastic, metal, rubber, glazed ceramic, glazed porcelain, sealed fiber glass, stainless steel, linoleum, acrylic, enamel,
 - Surfaces: counter tops, appliance exteriors, handles, door knobs, cell phones, remotes, sealed cabinets, showers, bath tubs, sink, toilet exteriors, faucets, bathroom, kitchen, living room, garbage cans, stove top (at room temperature), television screen, microwave exterior, outdoor furniture, tools, computer screen, computer mouse, keyboards, floors, refrigerator exteriors & freezer exteriors and handles, touchscreen, mirrors
- **Antibacterial (hard non-porous surfaces)**
- Eliminates odor causing bacteria†
- Disinfects hard non-porous kitchen surfaces
- Disinfects hard non-porous automotive surfaces
- Disinfects and Cleans hard non-porous surfaces
- Kills Viruses* and Bacteria†
- **Can be used to Disinfect Non-Food Contact, Hard, Non-porous surfaces in:**
 - **Agricultural Premises**
 - **Agricultural Equipment**
 - **Food Handling/Storage Establishments**
 - **Food Handling/Storage Premises**
 - **Food Handling/Storage Equipment**
 - **Commercial Premises and Equipment**
 - **Institutional Premises and Equipment**
 - **Industrial Premises and Equipment**
 - **Residential Premises**
 - **Public Access Premises**
 - **Medical Premises and Equipment**
 - **Education Buildings**
 - **Schools**
 - **Universities**
 - **Vocational Schools**
 - **Doctor's Offices**
 - **Retail Stores**
 - **Personal and Commercial Transportation Vehicles (cars, trucks, buses, taxis)**
 - **Office Spaces**

- Use Sani-Cide (10X) RTU {*Alternate Brand Name*} on hard, non-porous surfaces in pet habitats where viruses*, bacteria† or strong unpleasant odors are likely to be present in homes, pet stores, grooming facilities and veterinary clinics.
- Use Sani-Cide (10X) RTU {*Alternate Brand Name*} on hard, non-porous surfaces such as pet crates, pet carriers, vehicle surfaces, floors, examination tables and litter boxes.
- Product should be tested on an inconspicuous area for color fastness and compatibility
- Non-flammable
- Non-abrasive
- Contains no quaternary ammonia compounds
- Virucide*/Disinfectant
- Ready to use
- Contains no bleach
- Kills SARS-CoV-2 in as little as 1 minute on pre-cleaned, hard nonporous surfaces when used as directed

[*optional marketing language*]

(Brand name) effectively removes dirt and soils from automotive hard, non-porous surfaces. It disinfects high touch areas by killing viruses* and bacteria† on hard, non-porous surfaces. The streak-free formulation guarantees there will be no residue or build up, making this product the “all-in-one” choice for keeping every vehicle fresh and clean.

(Brand name) is the all-in-one cleaning solution that is tough on dirt but gentle on hard, non-porous surfaces. It disinfects high touch areas by killing viruses* and bacteria† on hard, non-porous surfaces. The streak-free formulation guarantees there will be no residue or build up, keeping every vehicle fresh and clean inside and out.

Back Label – Sani-Cide EX3 (10X) RTU {*Alternate Brand Name*}

Sani-Cide EX3 (10X) RTU {*Alternate Brand Name*} is the all-in-one cleaning solution that is tough on dirt but gentle on hard, non-porous surfaces. It disinfects high touch areas by killing viruses* and bacteria† on hard, non-porous surfaces. The streak-free formulation guarantees there will be no residue or build up, keeping every vehicle fresh and clean inside and out.

Disinfects: Glass, mirrors, plastic, metal, rubber, touchscreens, and other hard, non-porous surfaces

Application Instructions:

Directions for Use:

1-Step Cleaning and Disinfection Application Instructions for all listed organisms:

Preclean visibly dirty surfaces prior to disinfection.

To clean and disinfect, spray Sani-Cide EX3 (10X) RTU directly on the hard, non-porous surface. Spray 6-8 inches from surface. Allow surface to remain visibly wet for 3 minutes. After 3 minutes, wipe (dry if desired) with a cloth and let dry.

In the presence of a 5% organic soil load, Sani-Cide EX3 (10X) RTU is an effective disinfectant against †*Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC 33592), *Human Norovirus (Feline Calicivirus (ATCC VR-782, Strain F9, surrogate for human norovirus), Influenza A virus (ATCC VR-544, Strain A/Hong Kong/8/68), Influenza B virus (ATCC VR-823, Strain B/Hong Kong/5/72), Human Coronavirus (ATCC VR-740, Strain 229E) and SARS-Related Coronavirus 2 (BEI Resources NR-52281, Strain Isolate USA-WA1/2020).

2-Step Cleaning and Disinfection Application Instructions for SARS-CoV-2

Prior to disinfection, pre-clean hard non-porous surfaces by spraying Sani-Cide EX3 (10X) RTU directly on to the surface. Spray 6-8 inches from surface then wipe with a cloth and let dry.

To disinfect, spray Sani-Cide EX3 (10X) RTU directly on to the hard, non-porous surface. Spray 6-8 inches from surface. Treated surfaces must remain visibly wet for 1 minute. After 1 minute, wipe (dry if desired) with a cloth and let dry.

Back Label – Sani-Cide EX3 (10X) RTU {Alternate Brand Name}

Sani-Cide EX3 (10X) RTU {Alternate Brand Name} effectively removes dirt and soils from automotive hard, non-porous surfaces. It disinfects high touch areas by killing viruses* and bacteria† on hard, non-porous surfaces. The streak-free formulation guarantees there will be no residue or build up, making this product the “all-in-one” choice for keeping every vehicle fresh and clean.

Disinfects: Glass, mirrors, plastic, metal, rubber, and touchscreens

Application Instructions:

Directions for Use:

1-Step Cleaning and Disinfection Application Instructions for all listed organisms:

Preclean visibly dirty surfaces prior to disinfection.

To clean and disinfect, spray Sani-Cide EX3 (10X) RTU directly on the hard, non-porous surface. Spray 6-8 inches from surface. Allow surface to remain visibly wet for 3 minutes. After 3 minutes, wipe (dry if desired) with a cloth and let dry.

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Emerging Viral Pathogen 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 pathogen claims from the following viral category[ies]:

- 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 Virus	Feline calicivirus, Strain F-9, ATCC VR-782 (Surrogate for Norovirus)
Large, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782 (Surrogate for Norovirus)

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[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, 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/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.