



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

December 23, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Jacqueline Kemper
Florida Biotech, LLC
Regulatory Agency
100 S. Ashely Dr.; Suite 600
Tampa, FL 33602

Subject: Notification per PRN 98-10 – Change Primary Brand Name, Add Alternate Brand Name, and other minor label changes
Product Name: STIZE
EPA Registration Number: 100629-2
Received Date: December 15, 2021
Action Case Number/Decision Number: 00337409

Dear Jacqueline Kemper:

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.

The primary brand name “STIZE” has been added to the product record. The primary brand name “Durisan RTU+” has been marked as inactive.

The alternate brand name “Stize RTU +” has been added to the product record.

If you have any questions, you may contact Joe Daniels via email at daniels.joseph@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'E. Miederhoff', written over a faint circular stamp or watermark.

for

Eric Miederhoff, Product Manager 31
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Note to Reviewer: [Items in brackets [AAA] are optional and may/may not be included on the final label]
{Items in braces {AAA} are for information purposes and will not appear on the final label}

STIZE

{Alternate brand names:} [Stize RTU+]

ACTIVE INGREDIENT:

1-Decanaminium, N-decyl-N,N-dimethyl-, chloride ... 1.5%
OTHER INGREDIENTS 98.5%
TOTAL 100.0%

NOTIFICATION

100629-2

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:

12/23/2021

KEEP OUT OF REACH OF CHILDREN WARNING

See [left] [right] [side] [back] [panel] [insert] for additional Precautionary Statements

Manufactured [by] [for] [or for]:

Florida Biotech, LLC
100 S Ashley Dr., Ste 600
Tampa, FL 33602
Phone Number: 941-879-3565

EPA Reg. No. 100629-1

EPA Est. No. 100966-FL-001

Net Contents: (insert net contents here)

[Made in the USA] [Product of the USA]

[Patent Pending] [Patent [#] [No.] [US Patent [#] No.]]: (insert patent number here)

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: WARNING: Causes skin irritation and moderate eye irritation. Harmful if inhaled. Avoid breathing spray mist. Do not get on skin or clothes. Avoid contact with eyes. Wear protective gloves (rubber or chemical resistant) and long sleeve shirt, long pants, and shoes when using. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID	
In case of emergency, 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 when going for treatment.	
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice
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 INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth is possible.
[You may contact the poison control center at 1-800-222-1222 for emergency medical treatment information]	

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DIRECTIONS FOR USE

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

PRE-CLEANING: Remove visible soil; then apply product, scrub, and rinse.

TO DISINFECT [AND DEODORIZE] hard, non-porous surfaces: Prior to disinfection, follow precleaning instructions listed above. Apply solution with a cloth, sponge, mop, brush, or coarse spray to visibly wet the surface. Allow treated surface to remain visibly wet for 10 minutes. Let air dry [or wipe with a clean dry cloth or sponge]. For non-porous food contact surface applications, rinse with potable water following application.

{The following statement is required for hospital/medical disinfectants only:}

This product is not to be used as a terminal 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

MARKETING CLAIMS

{Note to Reviewer: These use sites/surfaces have been grouped for space purposes only. They can be used individually or grouped together in any order. If multiple use sites/surfaces are chosen, an "and" "&" "or" may be used to link use sites/surfaces. }

[This product] [Stize] is for use on hard, non-porous surfaces [in] [including] [such as] (insert location/use site/surface) For non-porous food contact surface applications, rinse with potable water following application.]

[This product] [Stize] [when used as directed] [can be used] to [disinfect] [sanitize] [deodorize] hard, non-porous surfaces [such as] [including]: (insert location/use site/surface) For non-porous food contact surface applications, rinse with potable water following application.]

For use [in] [at] [on] (insert location/use site/surface)

Use Sites¹:

[[Travel] [and] [Transportation Industry]] [Agriculture] [Residential] [Commercial] [Hospitality] [Lodging] [Industrial] [Office and workspaces] [Life sciences] [Emergency Services] [Automotive Industry] [Retail] [Recreation Sports and Fitness] [High Traffic Public settings] [Institutional Facilities and equipment] [Industrial Research Facilities] [Theaters] [Rodeos] [Public Gathering Setting]

Locations¹:

[Hospitals] [Healthcare Settings] [Medical Clinics] [Ambulances] [Ambulatory Surgical Centers (ASC)] [CAT Labs] [Cardiac Care Unit (CCU)] [Dental Offices] [Dialysis Clinics] [Doctor Offices] [Emergency Rooms [E.R.]] [Surgical Centers] [Surgical Care Unit (SICU)] [Eye Surgical Centers] [Skilled Nursing Facility] [Pediatric Offices] [Long Term Care Centers] [Hospices] [[Intensive Care Unit] [or] [ICU]] [Rehabilitation] [Transport Vehicles] [Home Healthcare] [Laboratory] [Laundry Rooms] [Emergency Vehicles] [Donation Centers] [Patient Care Areas] [Recovery Rooms] [Nursing Homes] [Operating Rooms (OR)] [Healthcare Facilities] [Newborn Nursery] [X-ray Rooms] [Homes] [Apartments] [Households] [Bathroom] [Restrooms] [Vehicles] [Cars] [Trucks] [Public transportation] [Boats] [Ships] [Cruise lines] [Airline terminals] [Buses] [Bus stations] [trains] [Hotels] [Motels] [Veterinary Clinics] [Day care centers] [Schools] [Churches] [Libraries] [Playgrounds] [Recreational facilities] [Campgrounds] [Bedrooms] [Offices] [Classrooms] [Colleges] [Universities] [Gyms] [Gymnasiums] [Sports complexes] [Factories] [Breakrooms] [Warehouses]

Surfaces¹:

[counters] [countertops] [floors] [walls] [bed railings] [filing cabinets] [cabinets] [gym equipment] [blood pressure meters] [carts] [dental chairs] [dental trays] [dental counter tops] [exam tables] [operating room tables] [gurneys] [IV poles] [IV pumps] [laboratory equipment]

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[operating room lights] [operating room tables] [physical therapy equipment] [patient lift equipment] [vinyl curtains]
[bed frames] [delivery equipment] [spine back boards] [ambulance equipment] [cardiac equipment] [chairs]
[stethoscopes] [stretchers] [telephones] [patient monitors] [patient monitoring equipment] [schools] [classrooms]
[desks] [work stations] [sinks] [tubs] [chairs] [Showers] [windows] [doorknobs] [handles] [garbage cans] [bathroom
fixtures] [gym equipment]

Use on hard nonporous surfaces of [bathrooms] [or] [public restrooms]: [Outside surfaces of toilets] [bathroom sinks],
[bathroom fixtures], [[bathroom] floors], [handrails] [toilet seats and handles]. Use on hard nonporous surfaces [made
of] [such as] [plastic] [vinyl] [Formica] [glazed tile] [sealed stone] [stainless steel] [glass]

General Claims: {Choose from the following claims as appropriate, location optional. "This product" "**Stize**" "It" "and"
"&" "or" "is" "is a(n)" can be used to form and group claims together in any order:}

- Fragrance free
- An effective way to deodorize and disinfect hard, nonporous, [environmental] surfaces
- [including:] [*insert surfaces from above list*]
- [Can help] [Use to] [reduce] [to reduce] cross contamination between treated surfaces [in] [hospitals][schools]
[institutions] [and] [industry]
- Compatible for use on hard non-porous surfaces commonly found in healthcare settings
- [including:] [*insert use sites from above list*]
- Hospital Disinfectant
- **Medical [grade] disinfectant**
- Non-staining
- Nonabrasive formula [that] will not [harm] [scratch] most Hard, Non-Porous Surfaces [*insert use sites from
above list*]
- Will not leave soap scum [or grit]
- Can be used on non-food contact surfaces [of] [in] [kitchens] [and] [restaurants]
- Easy to use
- Ready to use
- Made in the USA

Disinfection/Deodorizing Claims: {Choose from the following claims as appropriate, location optional. "This product"
"**Stize**" "It" "and" "&" "or" "is" "is a(n)" can be used to form and group claims together in any order:}

- [Removes] [eliminates] [destroys] odors [caused by bacteria]
- [Removes] [eliminates] [destroys] odor causing bacteria
- [Leaves] [leaving] surfaces smelling clean and fresh
- [Disinfects] [Deodorizes] [Kills Bacteria] [eliminates 99.9% bacteria] [kills odors] [eliminates odors][removes
odors] without [discoloring] [or] [lightening] [surfaces]
- Odor neutralizer
- Antibacterial
- Kills bacteria**
- [*location optional:*] ***Staphylococcus aureus, Pseudomonas aeruginosa*
- Antiviral*
- Kills viruses*
- [*location optional:*] *Feline calicivirus
- Kills [Staphylococcus aureus] [and] [Pseudomonas aeruginosa]
 - Bactericidal
 - Viricidal
 - Deodorizes [Deodorizer] [Deodorizing]

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- **[Medical [grade]]** Disinfectant [Disinfects] [Disinfecting]
- Disinfects *(insert use sites from above list)*
- Disinfects hard nonporous [(insert use site/location)] surfaces
- [Reduces [odor causing] bacteria [and viruses*]]
- Has demonstrated effectiveness against [Staphylococcus aureus] [Pseudomonas aeruginosa][and] [Feline calicivirus]
- Is an effective [bactericide] [and] [virucide*]

List of Approved Organisms:

{ATCC numbers are not required to be listed on the production label}

Staphylococcus aureus [ATCC 6538] Pseudomonas aeruginosa [ATCC 15442] Feline calicivirus [Human Norovirus] [ATCC VR-782] Rhinovirus Type 39 [Picornaviridae] [ATCC VR-340]

EMERGING VIRAL PATHOGEN CLAIMS

{Note to Reviewer: These statements for claims against enveloped viruses, large non-enveloped viruses, and small non-enveloped viruses shall not appear on marketed (final print) product labels.}

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:

- Enveloped virus
- Large, nonenveloped virus
- Small, nonenveloped virus

For an emerging viral pathogen that is a/an...	Follow the directions for the use for the following organisms on the label:
Enveloped virus	Rhinovirus Type 39 Feline calicivirus
Large, non-enveloped virus	Rhinovirus Type 39 Feline calicivirus
Small, non-enveloped virus	Rhinovirus Type 39 Feline calicivirus

The following statements may be used only in off-label communications as described in EPA’s Emerging Viral Pathogens guidance, and only under the conditions outlined in the guidance:

1. **Stize** has demonstrated effectiveness against viruses similar to **[Name of Emerging Virus]** on hard, non-porous surfaces. Therefore, **Stize** can be used against **[Name of Emerging Virus]** when used in accordance with the directions for use against **Rhinovirus Type 39 and/or Feline calicivirus** on hard, non- porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.
2. **[Name of Illness or Outbreak]** is caused by **[Name of Emerging Virus]**. **Stize** kills similar viruses and therefore can be used against **[Name of Emerging Virus]** when used in accordance with the directions for use against **Rhinovirus Type 39 and/or Feline calicivirus** on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

STORAGE AND DISPOSAL

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

{Note to Reviewer: One or more of the following paragraphs for Container Handling will be selected, depending on packaging use and type.}

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{For residential/household use}

Storage: Store in original container and in areas inaccessible to children. **Container handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash.

{For commercial, industrial, or institutional uses}

Storage: Store in original container in areas inaccessible to children. **Pesticide Disposal:** To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, wastes must be disposed of on site or at an approved waste disposal facility.

Container Handling: *{Choose one or more:}*

{Nonrefillable container, less than or equal to 5 gallons:}

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and recap. Shake vigorously and dispose of rinsate. Offer container for recycling if available or place in trash.

{Nonrefillable container, greater than 5 gallons:}

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Offer container for recycling if available or place in trash.

{Refillable container, less than or equal to 5 gallons:}

Refillable container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple rinse as follows: Fill container $\frac{1}{4}$ full with water and recap. Shake vigorously and dispose of rinsate. Offer container for recycling if available or place in trash.

{Refillable container, greater than 5 gallons:}

Refillable container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple rinse as follows: Fill container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Offer container for recycling if available or place in trash.

1. For non-porous, non-food contact surfaces.

OPTIONAL WARRANTY STATEMENT [DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Florida Biotech, LLC makes no warranties, express or implied, or merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label.]

[For more information concerning this product, please consult the SDS, available from the manufacturer]

OPTIONAL GRAPHICS

