

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 18, 2023

Glen Rosini Agent Zoono USA Holdings

Electronic Transmittal: grosini@Steptoe.com

Subject: Label Amendment – Changes to the label consistent with EVP guidance

Product Name: ZOONO Z-91 MICROBE SHIELD

EPA Registration Number: 100098-1

Received Date: 8/24/2022

Action Case Number: 00387707

Dear Glen Rosini:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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, FIFRA section 12(a)(1)(B). 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

Page 2 of 2 EPA Reg. No. 100098-1 Action Case Number 00387707

with FIFRA section 6. If you have any questions, please contact Carlos Corona via email at Corona.Carlos@epa.gov.

Sincerely,

Tara Flint Silva, Acting Product Manager 31

Regulatory Management Branch I

Antimicrobials Division

You M Ht Sh

Office of Pesticide Programs

Enclosure: Label

Zoono® Z-91 MICROBE SHIELD DISINFFCTANT and CLEANER

DOMESTIC, HOSPITAL AND COMMERCIAL USE

VIRUCIDE*
BACTERICIDE

KILLS BACTERIA and VIRUSES*

ACCEPTED

07/18/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

100098-1

ACTIVE INGREDIENTS:

3-(trimethoxysilyl)propyl dimethyl octadecyl ammonium chloride	0.50%
Alkyl (67% C12, 25% C14, 7% C16, 1% C18) dimethyl benzyl ammonium chloride	0.50%
Hydrogen peroxide	0.50%
INERT INGREDIENTS	<u>98.50</u> %
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

READ THE LABEL BEFORE USING

[Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.]

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.

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 mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.

June 8, 2023

If swallowed: Call a 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 by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the poison control center 1-800-222-1222. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu.

PRECAUTIONARY STATEMENTS:

Hazardous to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in skin, eyes or clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing (coveralls), and chemical-resistant gloves. Harmful if swallowed, absorbed through the skin or inhaled. Avoid breathing spray mist. 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.

Manufactured by:	
Zoono Holdings USA	
www.zoonousa.com	
Distributed by:	
Zoono Holdings USA	
NET L/mL	
FPA Registration No. 100098-1	FPA Establishment No. 66428-SC-001

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 viral pathogens from the following viral category[ies]:

- Enveloped virus

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Human Adenovirus Type 5, ATCC VR-
	5, strain Adenoid 75

[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, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

DIRECTIONS FOR USE

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

INSTITUTIONAL APPLICATIONS

(Office, Schools, Senior Citizens Residential Care Facilities, Industrial and Commercial settings)

Zoono® Z-91 MICROBE SHIELD is an easy to use, multipurpose disinfectant that kills viruses* and bacteria. It eliminates odor-causing mold and bacteria, controls mold and is effective on a range of hard non-porous, non-food contact surfaces such as floors, walls, countertops,

etc. Zoono® Z-91 MICROBE SHIELD disinfectant is effective inside offices, schools, industrial facilities and commercial areas on finished surfaces.

Use Zoono® Z-91 MICROBE SHIELD disinfectant on hard, non-porous, non-food contact surfaces in commercial and industrial buildings and facilities, in vehicles, on areas such as counter-tops, tables, furniture, cabinets, appliances, kitchen and bathroom fixtures, hardware, and other hard non-porous, non-food contact surfaces such as floors, tabletops, benchtops, drain troughs, drip pans, desks, locker room benches, and hard, non-porous bath mats (e.g., rubber or plastic). This product is for use in office buildings, institutions such as schools, public buildings, child-care facilities, day-care centers, nursing homes, churches, and correctional facilities, warehouses, manufacturing facilities, hotels and motels, retail business, and athletic and recreational facilities.

This product is a ready-to-use liquid, it is to be used at full strength and should not be diluted before use. Pre-clean soiled surfaces with a suitable surface preparation cleaner prior to application of Zoono® Z-91 MICROBE SHIELD.

- 1. Pre-clean all visibly soiled surfaces.
- 2. Spray Zoono® Z-91 MICROBE SHIELD disinfectant onto hard, non-porous inanimate surfaces to wet all surfaces thoroughly. Spray 6-8 inches from surface.
- 3. Ensure surface remains visibly wet for a minimum contact time of 10 minutes.
- 4. Allow to air dry

Microorganism	ATCC Number
Pseudomonas aeruginosa	15442
Salmonella enterica	10708
Staphylococcus aureus	6538
*Human adenovirus type 5, Strain Adenoid 75	VR-5

HEALTHCARE FACILITIES

Zoono® Z-91 MICROBE SHIELD disinfectant is for use on hard non-porous, non-food contact surfaces in hospitals, nursing homes, medical and dental offices and clinics, operating rooms, isolation wards, and medical research facilities. This product is a ready-to-use liquid, and it is to be used at full strength and is not to be diluted before use.

Zoono® Z-91 MICROBE SHIELD disinfectant is proven effective against bacteria and viruses* when used according to the directions on this label. Pre-clean soiled surfaces with a suitable surface preparation cleaner prior to application of Zoono® Z-91 MICROBE SHIELD.

NOTICE TO HEALTHCARE FACILITY USER

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 blood stream 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.

DIRECTIONS FOR USE FOR GENERAL DISINFECTION:

For hard non-porous, non-food contact work surfaces, floors and walls in patient care areas, non-porous bed frames, mattresses, etc. Pre-clean visibly soiled surfaces. Spray 6 - 8 inches from surface until visibly wet. Allow surface to remain visibly wet for 10 minutes. Allow to air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION OF SURFACES and/or OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

The special cleaning instructions listed below must be followed prior to disinfection:

- a. Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.
- b. Cleaning Procedure: Fecal matter and body fluids must be thoroughly cleaned from surfaces and objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces. Restrooms should be cleaned last. Do not reuse soiled cloths.
- c. Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/ bodily wastes are to be disposed of immediately in accordance with provincial regulations for infectious materials disposal.
- d. Disinfection: Apply Zoono® Z-91 MICROBE SHIELD disinfectant to visibly cleaned, hard non-porous, non-food contact surfaces with a coarse spray device. Spray 6-8 inches from surface. Allow to remain visibly wet for 10 minutes and allow to air dry. Do not breathe spray mist. All treated equipment that will contact food or drinking water should be rinsed with potable water before reuse.

Microorganism	ATCC Number
Pseudomonas aeruginosa	15442
Salmonella enterica	10708

Staphylococcus aureus	6538
*Human adenovirus type 5, Strain Adenoid 75	VR-5

RESIDENTIAL APPLICATIONS

Zoono® Z-91 MICROBE SHIELD disinfectant is an easy to use, multipurpose disinfectant that kills viruses* and bacteria. It eliminates odor-causing mold and bacteria on any hard non-porous, non-food contact surface and effectively cleans a wide range of hard non-porous, non-food contact surfaces, such as floors, walls, countertops, tables, and other furniture. This product is a ready-to-use liquid, and it is to be used at full strength and is not to be diluted before use. If the Zoono® Z-91 MICROBE SHIELD disinfectant becomes soiled (i.e., is not visibly clear) or diluted, replace and use fresh Zoono® Z-91 MICROBE SHIELD disinfectant.

Zoono® Z-91 MICROBE SHIELD disinfectant is also effective inside homes, cars, boats, recreational vehicles and on sealed drywall, plaster, finished wood, plastic, stone, sealed concrete or tile.

Pre-clean soiled surfaces with a suitable surface preparation cleaner prior to application of Zoono® Z-91 MICROBE SHIELD.

- 1. Pre-clean all visibly soiled surfaces.
- 2. Spray Zoono® Z-91 MICROBE SHIELD disinfectant onto hard, non-porous inanimate surfaces to wet all surfaces thoroughly. Spray 6-8 inches from surface.
- 3. Ensure surface remains visibly wet for a minimum contact time of 10 minutes.
- 4. Allow to air dry

Microorganism	ATCC Number
Pseudomonas aeruginosa	15442
Salmonella enterica	10708
Staphylococcus aureus	6538
*Human adenovirus type 5, Strain Adenoid 75	VR-5

ANIMAL HOUSING FACILITIES AND VETERINARY FACILITIES

Zoono® Z-91 MICROBE SHIELD disinfectant is recommended for use on hard non-porous, non-food contact surfaces such as floors, walls, troughs, racks, appliances, and processing equipment in animal housing facilities, kennels, animal hospitals, animal laboratories, zoos, animal housing areas of pet stores and pet spas, pet animal quarters, and livestock quarters.

For visibly soiled surfaces, a pre-cleaning step is required.

Remove all animals and feed from premises, vehicles, and enclosures.

Remove all visible soil such as litter, manure, urine and fecal matter from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed

by animals.

Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water.

DIRECTIONS FOR USE: Apply Zoono® Z-91 MICROBE SHIELD disinfectant with a topical spray trigger or coarse/trigger spray. Spray 6-8 inches from surface. Ensure surface remains visibly wet for a minimum contact time of 10 minutes. Allow to air dry.

For cleaning, immerse in Zoono® Z-91 MICROBE SHIELD disinfectant, all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Allow to air dry.

Microorganism	ATCC Number
Pseudomonas aeruginosa	15442
Salmonella enterica	10708
Staphylococcus aureus	6538
*Human adenovirus type 5, Strain Adenoid 75	VR-5

GENERAL CLEANING DIRECTIONS

Cleaning Solution: Use Zoono® Z-91 MICROBE SHIELD for cleaning of all hard non-porous, non-food contact surfaces – such as kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors, and large routine applications.

Apply Zoono® Z-91 MICROBE SHIELD to hard non-porous, non-food contact surfaces. Apply using a cloth, mop, sponge, or sprayer. Wipe or allow to air dry.

{Residential Containers}

STORAGE AND DISPOSAL

Nonrefillable container. Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse or refill this container. Place [container] in trash or offer for recycling if available.

PESTICIDE DISPOSAL: To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of at an approved waste disposal facility.

{Institutional Containers}

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in areas inaccessible to children. Keep securely closed.

PESTICIDE DISPOSAL: To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycling, if available.