



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

87656-4

Date of Issuance:

3/4/2020

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Bio-Spear Sanitizing Spray

Name and Address of Registrant (include ZIP Code):

Stephanie Evans
Contego America
C/O Spring Regulatory Sciences
6620 Cypresswood Drive, Suite 250
Spring, TX 77379

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.


On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:


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

Date:

3/4/2020

2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. 3(trihyoxysilyl)propyldimethloctadecyl ammonium chloride GDCI-107401-1635
 - b. DDAC GDCI-069149-30869; GDCI- 069149-0681

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 87656-4.”
5. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

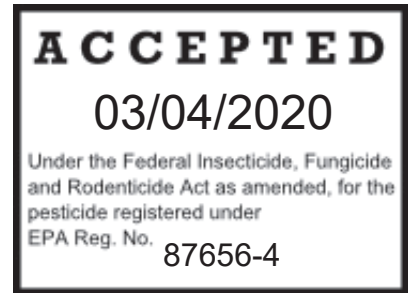
- Basic CSF dated 09/25/2019

If you have any questions, please contact Emilia Oiguenblik by phone at 703 347 0199, or via email at Oiguenblik.emilia@epa.gov or Eric Miederhoff by phone at 703 347 8028, or via email at Miederhoff.eric@epa.gov.

Enclosure: Stamped label

Bio-Spear Sanitizing Spray

[Kitchen and Bath Spray]
[Kitchen and Bath Spray for Hard, Non-Porous Surfaces]
[Kills 99.99% of bacteria]
[Sanitizes]
[Kills 99.99% of odor causing bacteria]
[Kills, Cleans and Deodorizes]
[Bleach Free]
[{'bac te ri o stat ic'} Noun 'To inhibit the further growth of bacteria']
[Clean.]
[Sanitize.]
[We've Got You Covered]
[Made in the USA]



[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed on the production label.]

[Bracketed information is optional text.]
[All footnotes are on the last page, unless they are part of EPA's mandated text.]
[The word "and" may be substituted with "&".]
[All directions may be written in numbered form or in paragraph form.]

[Optional text may be placed anywhere on the label/container.]

[[•] BACTERICIDAL] [[•] [BACTERIOSTATIC]

[For Commercial Use]
[For Household Use]
[For Professional and Household Use]

ACTIVE INGREDIENTS:

3(trihyoxysilyl)propyldimethloctadecyl) ammonium chloride	0.54%
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.....	0.90%
INERT INGREDIENTS:.....	98.56%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

[See other panel for additional precautionary statements.]

EPA Reg. No. 87656-X
EPA Est. No. 87656-XX-X

Reorder No.

Net Contents: # ___ fl. oz.

[Packed For:]	ICPG LLC DBA Contego America
[Distributed By:]	3680 Yale Street
[Sold By:]	Houston, TX 77018

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING

Causes substantial but temporary eye injury. Harmful if inhaled. Avoid contact with eyes or clothing. Avoid breathing mist. Wear appropriate protective eyewear such as goggles, face shield, or safety glasses. 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 use. [See [side] [back] [other] panel for additional precautionary statements.]

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 further advice.

For Chemical Emergency ONLY (spill, leak, fire, exposure or accident), call CHEMTREC at 1 -800-424-9300.

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 further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center at 1-800-858-7378 (NPIC web site: npic.orst.edu/). For emergencies, call the poison control center 1-800-222-1222.

Bio-Spear [Sanitizing Spray] [is] intended for use on hard, non-porous surfaces and are for non-food contact surface sanitization only.

[Bio-Spear] [Spray] [is] intended for use on hard, non-porous surfaces] in [kitchens (non-food contact)] [and] [bathrooms] [and] [salon settings,] [and] [non-food contact surfaces in food preparation areas,] [and] [correctional facilities,] [and] [schools,] [and] [health club facilities,] [and] [tanning salons,] [and] [daycare centers,] [and] [police and fire vehicles,] [laundry rooms,] [and] [pet areas]

Bio-Spear is effective against the following microorganisms on hard, non-porous surfaces when used as directed:

[Staphylococcus aureus (ATCC 6538)]

[Klebsiella aerogenes (ATCC 13048)]

DIRECTIONS FOR USE

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

Bio-Spear Spray is intended for use on hard, non-porous, non-food contact surfaces.

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels is required. The last equipment/instruments/hard, non-porous surface listed will be preceded with the word "and".]

Bio-Spear will clean and Sanitize hard, non-porous surfaces, when used as directed, such items as [bassinets and cribs,] [infant/child care equipment surfaces,] [diaper changing stations,] [diaper pails,] [oxygen hoods,] [laboratory equipment and surfaces,] [physical therapy (PT) equipment surfaces,] [spine back boards,] [ambulance equipment surfaces,] [slit lamps,] [eye glasses (do not use on contact lenses),] [workstations,] [stools,] [nail/hair care implements,] [tanning beds,] [hair dryers,] [hair clippers,] [shears,] [razors,] [hair cutting implements,] [clipper blades,] [salon surfaces,] [scissors,] [combs,] [brushes,] [manicure implements,] [washable nail files,] [floors,] [walls,] [handrails,] [door knobs,] [bed railings,] [tables,] [chairs,] [faucets,] [bathroom fixtures,] [exterior toilet surfaces,] [garbage cans,] [computers,] [keyboards,] [carts,] [baskets,] [grocery carts,] [shopping carts,] [weight-lifting surfaces,] [drained whirlpool tank surfaces,] [cabinets,] [lights,] [telephones,] which are made of plastic (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene), and use sites listed on this label consisting of non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, Formica® and glass.

This product is not for use on medical devices and equipment.

Non-Food Contact Surfaces:

[High chairs,] [stoves,] [vanity tops,] [tiles,] ;
Exterior surfaces of [refrigerators,] [microwaves,] [food processors,]

Cleaning and Sanitizing Instructions:

Bio-Spear is a one-step process. Completely preclean surface of all visible debris. Apply to surface using a trigger pump sprayer or pressure sprayer. Spray entire surface from 4-6 inches distance until completely covered. Thoroughly wet surface with **Bio-Spear**. If spotting occurs, wipe with moist cloth or sponge. Repeated use of the product may be required to ensure that the surface remains visibly wet for 5 minutes. Allow to dry thoroughly before use/no rinsing necessary.

STORAGE AND DISPOSAL

Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use.

Nonrefillable container. Do not reuse or refill this container. Securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available.

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets, [], are optional or instructional. Italicized words in brackets are not included on production labels. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviating are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.

[The following graphics are optional for canister containers only. They will be affixed to the label/canister so that it does not interfere with any label text. Due to size constraints, they will not appear on individually wrapped packets.]

