

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

October 14, 2020

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Jeremy Malone Consultant for, ICPG Contego America c/o Spring Regulatory Sciences, 6620 Cypresswood Dr, Suite 250 Spring, TX 77379

Subject: Notification per PRN 98-10 – To Update the

Label Product Name: Bio-Spear Sanitizing Wipes

EPA Registration Number: 87656-3 Application Date: October 1, 2020

Decision Number: 566669

Dear Mr. Malone:

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.

Page 2 of 2 EPA Reg. No. 87656-3 Decision No. 566669

If you have any questions, you may contact Karen M. Leavy at (703)-308-6237 or via email at Leavy.Karen@epa.gov.

Sincerely,

Eric Miederhoff Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Laven M. Leary for,

Bio-Spear Sanitizing Wipes

NOTIFICATION

87656-3

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:

10/14/2020

[Extra large] Sanitizing Towelettes

[Kitchen and Bath Wipes]

[Kitchen and Bath Wipes 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.]

[Protect.]

[We've Got You Covered]

[Made in the USA]

[No rinse needed]

[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 Professional 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†:	
TOTAL	

† Does not include the weight of the dry [towelette] [[or] wipe].

KEEP OUT OF REACH OF CHILDREN

WARNING

[See other panel for additional precautionary statements.]

EPA Reg. No. 87656-3 EPA Est. No. 87656-XX-X

Reorder No.

Net Contents: # Ibs. (ozs.)

Pre-Saturated Towelette # x # in.

[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. Do not get in eyes or on clothing. 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. [See 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.

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

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

[Bio-Spear Sanitizing Towelettes are non-woven disposable towelettes pre-saturated with Bio-Spear.]

[Bio-Spear] [are] [non-woven] [disposable] [surface] [Sanitizing] [towelettes] [wipes] [that] [are] 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)]

[Enterobacter 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 [wipes] [towelettes] are 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. DO NOT USE AS A BABY WIPE. [Not For Use On Skin]

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,]

[Use A or B as applicable depending on the container type.]

[A - canister]

Dispenser Directions:

To start feed, remove cover and discard seal. From center of towelette roll, pull up a towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and tear off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When not in use, keep center cap closed to prevent solution loss.

[B - packet]

Packet Directions:

Open packet, remove towelette and unfold.

[Directions for use for A and B]

Cleaning Instructions:

Use one Bio-Spear Towelette to completely wipe surface clean with this product. Let air dry.

For use as a sanitizer:

Bio-Spear is a one-step Sanitizing product. For heavily soiled items, clean surface of all visible debris prior to sanitizing. Use Bio-Spear Sanitizing Wipes to sanitize surface. Wipe surface; use enough wipes for treated surface to remain visibly wet for 5 minutes. Let surface air dry. Do not reuse dried out wipes.

<u>Contact Time:</u> Thoroughly wet surface with a new **Bio-Spear** towelette. Repeated use of the product may be required to ensure that the surface remains visibly wet for 5 minutes.

[Use A or B as applicable depending on the container type.]

[A - canister]

STORAGE AND DISPOSAL

Towelette - Do not reuse towelette. Dispose of used towelette in trash.

Dispenser - Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. [Wrap container and discard in trash.]

[B - packet]

STORAGE AND DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. **Towelette** - Do not reuse towelette. Dispose of used towelette and empty packet in trash.

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.]













{Note to reviewer: The following is considered optional marketing language. Each item below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}













Glass



Painted Surfaces



Electronics



Do not use as a baby wipe



Do not flush