



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 15, 2019

Jeremy Malone
Consultant for
Contego America
203 Dogwood Trail
Magnolia, TX 77354

Subject: Label Amendment – Addition of graphic and new marketing claims
Product Name: Bio-Spear Sanitizing Wipes
EPA Registration Number: 87656-3
Application Date: May 22, 2019
Decision Number: 551377

Dear Mr. Malone:

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.

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

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with FIFRA section 6. If you have any questions, please contact Tara Flint via email at flint.tara@epa.gov.

Sincerely,

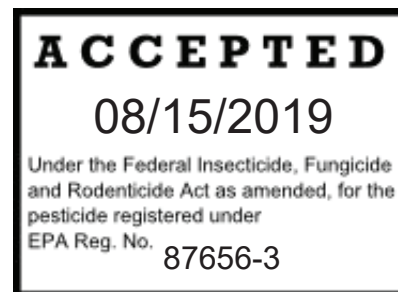


Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Bio-Spear Sanitizing Wipes

[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]
[*bae·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]



[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)propylidimethioctadecyl) ammonium chloride	0.54%
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.....	0.90%
INERT INGREDIENTS†:.....	98.56%
TOTAL.....	100.00%

† 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-X
EPA Est. No. 87656-XX-X

Reorder No.

Net Contents: # ___ lbs. (___ 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 preclean surface of all visible debris.

For use as a sanitizer:

Bio-Spear is a two-step Sanitizing product. One wipe is required to pre-clean then a second wipe is required to Sanitize.

Contact Time: 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 1 minute.

[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.]

