

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 3, 2020

Meghan Shoun Regulatory Affairs Specialist Spartan Chemical Company, Inc. 1110 Spartan Drive Maumee, OH 43537

Subject: PRIA Label Amendment – To add SARS-CoV-2 virus to the label

Product Name: Clean by 4D EPA Registration Number: 5741-30 OPP Decision Number: 565634 Application Date: August 20, 2020

Dear Ms. Shoun:

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) 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.

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 with FIFRA section 6.

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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

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

Enclosure; Stamped label

Spartan Chemical Company, Inc.

11/3/2020

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Clean by 4DTM Daily Cleaner Disinfectant

ACTIVE INGREDIENTS:
Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%)
dimethyl benzyl ammonium chlorides2.40%
Octyl decyl dimethyl ammonium chloride1.80%
Dioctyl dimethyl ammonium chloride 0.90%
Didecyl dimethyl ammonium chloride0.90%
INERT INGREDIENTS:94.00%
TOTAL:100.00%

ACCEPTED

11/03/2020

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

5741-30

E.P.A. Reg. No. 5741-30 E.P.A. Est. No. 5741-OH-1

Keep Out of Reach of Children **DANGER PELIGRO**

See side panel for additional precautionary statements.

FIRST AID		
If in eyes:	-Hold eye open and rinse slowly and gently with water for 15-20 minutesRemove contact lenses, if present, after the first 5 minutes, then continue rinsing eyeCall a poison control center or doctor for treatment advice.	
If on skin:	-Take off contaminated clothingRinse skin immediately with plenty of water for 15-20 minutesCall 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 further treatment advice.	
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 do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.	
Have the proceed treatment.	24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171 duct container or label with you when calling a poison control center or doctor or going for	
	NOTE TO PHYSICIAN	
	Probable mucosal damage may contraindicate the use of gastric lavage.	

FOR INSTITUTIONAL AND INDUSTRIAL USE SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 43537 **NET CONTENTS:**

Note to EPA: * - Virucide, ** - Anti-resistant bacteria, *** - Sanitizer. [optional text], (optional text), The term "this product" used throughout this document may be replaced with the marketed product brand name. Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

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(Note to EPA: the following statements are optional)

Clean on the Go® 26

For use only with Spartan Clean on the Go dispenser.

(Note to EPA: the following marketing claims are optional)

- Clean by 4DTM is a healthcare disinfectant that delivers effective performance
- Use (Clean by 4DTM) daily as part of a simple and effective cleaning and disinfection program for your entire facility.
- Sanitizer at 2 oz. per gallon⁴***
- 90 Second Sanitizing Activity!⁴ ***
- Sanitizes in 90 Seconds⁴ ***
- Bactericide/Virucide*
- Effective against Antibiotic-Resistant Bacteria**
- Kills 99.9% of bacteria*** in 90 Seconds.
- Kills Pseudomonas aeruginosa [ATCC 15442], Staphylococcus aureus [ATCC 6538], Salmonella enterica [ATCC 10708], Escherichia coli [ATCC 11229], Klebsiella pneumoniae (NDM-1)[CDC 1000527]
- (*)Kills Hepatitis C Virus (HCV) [Bovine Viral Diarrhea virus], Hepatitis B Virus (HBV) [Duck Hepatitis B Virus], HIV-1 (AIDS Virus) [Human Immunodeficiency Virus type 1], Influenza A Virus [2009 H1N1] and SARS-CoV-2 [USA-WA1/2020] on hard, nonporous inanimate surfaces.
- (**) Kills Staphylococcus aureus-MRSA [ATCC 33592], Enterococcus faecium-VRE [ATCC 51559] and Acinetobacter baumannii [ATCC 19606]
- (***)Staphylococcus aureus [ATCC 6538] and Klebsiella pneumoniae [ESBL][ATCC 700603]
- Quickly breaks down urine to eliminate odors and remove stains
- Eliminates (urine) stains and odors
- PROFECTTM
- Works great (to remove stains and odors from)(on) restroom tile and grout
- One product for all of your cleaning needs
- Removes stains and odors from grout lines
- Provides a restorative clean
- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2² virus
- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2² virus, the cause of COVID-19
- (Kills) (Eliminates) 99.9% SARS-Related Coronavirus 2² (SARS-CoV-2) [USA-WA1/2020] (causative agent of COVID-19) (the virus that causes COVID-19)
- Disinfects surfaces by killing (99.9%) SARS-Related Coronavirus 2² (SARS-CoV-2) [USA-WA1/2020] (in One step)
- Kills (99.9% of) SARS-CoV-2², which causes COVID-19
- (Kills) (Effective against) the virus that causes COVID-19^{1,2}
- (This Product) (Product Name) kills SARS-CoV-2² the virus that causes COVID-19
- (This Product) (Product Name) kills SARS-CoV-2²
- (This Product) (Product Name) kills COVID-19^{1,2} virus
- (This Product) (Product Name) kills COVID-19 Coronavirus^{1,2}
- (This Product) (Product Name) kills COVID-19 Coronavirus^{1,2} in (just) (10 minutes)
- (This Product) (Product Name) kills SARS-CoV-2² in (just) (10 minutes)
- (This Product) (Product Name) kills SARS-CoV-2² the virus that causes COVID-19 in (just) (10 minutes)

Note to EPA: * - Virucide, ** - Anti-resistant bacteria, *** - Sanitizer. [optional text], (optional text), The term "this product" used throughout this document may be replaced with the marketed product brand name. Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

- (This Product) (Product Name) has demonstrated effectiveness against (COVID-19 Coronavirus^{1,2}) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus^{1,2}) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) in just one step(!)³ on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus^{1,2}) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) in one easy step(!)³ on hard, nonporous surfaces.

Clean by 4DTM is for use in healthcare facilities as a hard surface disinfectant that delivers effective performance. With a fantastic fresh scent, Clean by 4DTM leaves the room clean and disinfected! [product name][this product] economically disinfects and deodorizes.

This product [or product name] is designed to disinfect, sanitize, clean and deodorize [insert surfaces] [and]. This product [or product name] is for use on hard, non-porous surfaces[throughout] [the] [in] [and] [Insert use sites]

This product [or product name] is used to clean, disinfect, sanitize, and deodorize [Insert Surfaces] on hard, non-porous surfaces [throughout] [the] [in] [and] [Insert use sites]

[Surfaces:]

Countertops, floors, walls, glazed ceramic tile, glazed porcelain, shower walls, exposed surfaces of toilet bowls and urinals, chrome, vanity tops, tub and sink surfaces and fixtures, bathtubs, showers, sinks, fiberglass, synthetic marble, stainless steel, glass, vinyl, other hard nonporous bathroom surfaces, other hard, non-porous environmental surfaces.

[Use Sites:]

Schools, public buildings, restaurants, bars, cafeterias, office buildings, transportation terminals, lodging/hospitality establishments, hotels, motels, churches, factories, manufacturing sites/facilities, food processing plants, apartment buildings, athletic/recreation facilities, public restrooms, bathroom, bathrooms, restrooms.

Directions for Use:

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

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

¹SARS-Related Coronavirus 2

²On hard, non-porous surfaces

³When used according to the disinfection directions

⁴ when used according to the sanitization directions

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Cleaning and Deodorizing Hard Non-Porous, Non-Food Contact Surfaces:

Use (Product)(Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth or coarse spray device. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist.

For grout and tougher stains:

Use (Product)(Product Name) at 2 fl. oz. per gallon of water. Apply directly onto stain until completely covered. Wait 5 minutes, then rinse with water or wipe dry. Do not breathe spray or mist.

One-Step Disinfecting Hard, Non-Porous Surfaces:

Preliminary cleaning is required for visibly soiled areas.

This product is not for use on food contact surfaces. For one-step cleaning, deodorizing, and disinfecting in the presence of 5% organic soil use (Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth or coarse spray device. Treated surface must remain visibly wet for 10 minutes. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed for disinfection, this product is effective against Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica, Escherichia coli, Klebsiella pneumoniae (NDM-1), Methicillin Resistant Staphylococcus aureus-MRSA, Vancomycin Resistant Enterococcus faecalis-VRE, and Acinetobacter baumannii.

*Virucidal Activity on Hard Non-Porous Surfaces:

Use (Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth or coarse spray device. Treated surfaces must remain visibly wet for 10 minutes. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed, this product is effective against Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Influenza A Virus and SARS-CoV-2.

*KILLS HCV, HBV AND HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HCV, HBV AND HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Exposure to blood or body fluids must be avoided by use of barrier protection such as latex or other impervious gloves. Face shields and impervious gowns must also be

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worn if splashing of blood or body fluids may occur.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (Product Name).

CONTACT TIME: Leave surfaces wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Contaminated cleaning materials, blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

To Control Mildew:

At 2 ounces per gallon dilution 200 ppm hard water and 5% organic blood serum, this product will control mildew (Aspergillus niger (ATCC 6275)) on pre-cleaned, hard non-porous surfaces. Apply solution with a cloth, mop, sponge, or hand pump trigger sprayer, making sure to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

Non-Food Contact Sanitizing Hard Non-Porous Surfaces:

Use (Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth or coarse spray device. Treated surface must remain visibly wet for 90 seconds. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed for sanitization this product is effective against Staphylococcus aureus [ATCC 6538] and Klebsiella pneumoniae [ATCC 4352].

Prepare fresh solution daily or more often if solution becomes visibly dirty, diluted, or soiled.

One-Step Cleaning and Disinfecting Toilet Bowls and Urinals

- 1. Remove water from the bowl by forcing it over the trap with a swab mop.
- 2. Liberally apply (Product Name) at 2 fl. oz. per gallon of water to the exposed surfaces. Swab the exposed surfaces including under the rim.
- 3. Allow to remain wet on surfaces for 10 minutes.
- 4. Flush toilet or urinal and rinse swab mop thoroughly.

Note: This product contains hydrogen peroxide. Do not use this product on brass. Do not use with metal drum pumps, check valves or equipment.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing Wear protective eye wear (goggles/face shield), rubber gloves and protective clothing (coveralls over long-sleeved shirt and long pants; socks and chemical resistant footwear; chemical resistant gloves.), and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved powdered air purifying respirator with HE filters. Do not breathe spray or mist. Wash thoroughly with soap and water after handling and before eating, drinking, smoking tobacco, chewing gum, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

(NOTE TO EPA - The following text will be used on five gallon pails and larger containers only)

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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(NOTE TO EPA -

The following text will be used on containers of 1 gallon or less which are unable to be rinsed.)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Replace cap and

discard in trash.

(NOTE TO EPA -

The following text will be used on containers of 5 gallons or less which are can be rinsed.)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container 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 procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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(NOTE TO EPA – The following text will be used on containers of 5 gallons or greater)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ½ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537 Questions? 800-537-8990/ www.spartanchemical.com

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Secondary Container Label for Diluted Product

[Clean by 4D] [Product Name] [Daily Cleaner Disinfectant]

User Prepared Ready-To-Use Solution

E.P.A. Reg. No. 5741-30

ACTIVE INGREDIENTS IN CONCENTRATED PRODUCT:

Alkyl (C₁₄-50%, C₁₂-40%, C₁₆-10%)

dimethyl benzyl ammonium chlorides......2.40%

Octyl decyl dimethyl ammonium chloride......1.80%

Dioctyl dimethyl ammonium chloride...... 0.90%

Didecyl dimethyl ammonium chloride......0.90%

The product in this container is diluted as directed on the pesticide product label.

Follow the directions for use on the pesticide label when applying this product. The product in this container with pesticide is not for sale and is for storage and use.

(Optional phrases)

Read material safety data sheet before using.

See first aid statement on pesticide product label.

KEEP OUT OF REACH OF CHILDREN

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing Wear protective eye wear (goggles/face shield), rubber gloves and protective clothing (coveralls over long-sleeved shirt and long pants; socks and chemical resistant footwear; chemical resistant gloves.), and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved powdered air purifying respirator with HE filters. Do not breathe spray or mist. Wash thoroughly with soap and water after handling and before eating, drinking, smoking tobacco, chewing gum, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID		
If in eyes:	-Hold eye open and rinse slowly and gently with water for 15-20 minutesRemove contact lenses, if present, after the first 5 minutes, then continue rinsing eyeCall a poison control center or doctor for treatment advice.	
If on skin:	-Take off contaminated clothingRinse skin immediately with plenty of water for 15-20 minutesCall 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 further treatment advice. 	
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 do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.	
24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171 Have the product container or label with you when calling a poison control center or doctor or g		

MEDICAL EMERGENCY: 888-314-6171

treatment.

SPARTAN CHEMICAL COMPANY, INC.

1110 Spartan Drive, Maumee, Ohio 43537

1-800-537-8990/ www.spartanchemical.com

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NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.