



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 4, 2020

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

Subject: Label Amendment – To update label language  
Product Name: Tumult  
EPA Registration Number: 5741-28  
Application Date: October 30, 2020  
Decision Number: 567599

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](mailto:Oiguenblik.emilia@epa.gov) or Eric Miederhoff by phone at 703 347 8028, or via email at [Miederhoff.eric@epa.gov](mailto:Miederhoff.eric@epa.gov)



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

Enclosure: Stamped label

Front Panel Copy:

**Tumult**

[RTU Bleach Disinfectant]

[Multipurpose] [Broad spectrum] [Hospital] [Healthcare]

[Cleaner Disinfectant with Bleach] [Cleans, Disinfects, Deodorizes, Virucidal\*]

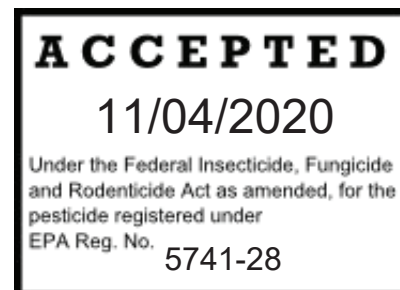
[Bactericidal]

[RTU Handi Spray]

[Kills spores of Clostridium difficile on hard, non-porous surfaces.]

[Alternate brand name:]

Diffense



**ACTIVE INGREDIENTS:**

Sodium hypochlorite.....0.74%

**INERT INGREDIENTS:** .....99.26%

Total .....100.00%

[Available Chlorine 0.70%]

[7000 PPM [Parts Per Million] Available Chlorine]

EPA Reg. No. 5741-28

EPA Est. No. 5741-OH-1

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See side [back] panel[s] for additional precautionary statements [and first aid]

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 43537  
1-800-537-8990 /www.spartanchemical.com

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*(Note to EPA:* Bracketed information is denoted as: (optional text), [ optional text ]. The term “this product” used throughout this document may be replaced with the marketed product brand name. The term “x” is a place holder for numerical digits. Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

*(Note to EPA: the following statements are optional)*

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

(This product) (product name) is a (broad spectrum) (multipurpose)(hospital) (healthcare) cleaner disinfectant for use on hard, non-porous which can be used (including) (such as): (Insert **Use Site** selection)(and other) (Insert **Use Site** selection).

(This product) (product name) may be used to clean and disinfect (hard nonporous surfaces) (such as) (Insert **Objects** selection) (,) (and) (Insert **Objects** selection).

(This product) (product name) can be used on hard, non-porous surfaces made of (Insert **Materials** selection]

- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2<sup>2</sup> virus
- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2<sup>2</sup> virus, the cause of COVID-19
- (Kills) (Eliminates) 99.9% - SARS-Related Coronavirus 2<sup>2</sup> [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 2<sup>2</sup> [SARS-CoV-2] [USA-WA1/2020] (in One step)
- Kills (99.9% of) SARS-CoV-2<sup>2</sup>, which causes COVID-19
- (Kills) (Effective against) the virus that causes COVID-19<sup>1,2</sup>
- (This Product)(Product Name) kills SARS-CoV-2<sup>2</sup> the virus that causes COVID-19
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> virus
- (This Product) (Product Name) kills (99.9% of) COVID-19<sup>1,2</sup> virus
- (This Product) (Product Name) kills (99.9% of) COVID-19 Coronavirus<sup>1,2</sup>
- (This Product) (Product Name) kills (99.9% of) COVID-19<sup>1,2</sup> Coronavirus in (just) (X seconds)
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> in (just) (X seconds)
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> the virus that causes COVID-19 in (just) (X seconds)
- (This Product) (Product Name) has demonstrated effectiveness against (COVID-19 Coronavirus<sup>1,2</sup>) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus<sup>1,2</sup>) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) in just one step(!)<sup>3</sup> on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus<sup>1,2</sup>) (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) in one easy step(!)<sup>3</sup> on hard, nonporous surfaces.

**Note:** This product may discolor or otherwise damage colored fabric, clothing, metal trim, electronic devices/components or other surfaces which could be harmed by sodium hypochlorite. Check manufacturer's cleaning and disinfection recommendations before use on equipment surfaces.

<sup>1</sup>SARS-Related Coronavirus 2

<sup>2</sup>On hard, non-porous surfaces

<sup>3</sup>When used according to the disinfection directions.

**Efficacy Table:**

| <b>BACTERICIDAL ACTIVITY (BACTERIA):</b> (Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a 30 second contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:) |                                |                     |
|--|--------------------------------|---------------------|
| <b>Organism</b>  | <b>ATCC Number</b>             | <b>Contact Time</b> |
| Escherichia coli, extended beta-lactamase resistant (ESBL)   | ATCC BAA-196                   | 30 seconds          |
| Acinetobacter baumannii  | ATCC 19606                     | 30 seconds          |
| Staphylococcus aureus  | ATCC 6538                      | 60 seconds          |
| Pseudomonas aeruginosa   | ATCC 6538                      | 60 seconds          |
| Staphylococcus aureus, methicillin resistant (MSRA)  | ATCC 33592                     | 60 seconds          |
| <b>Bacteria Sporicidal Activity</b>  | <b>ATCC Number</b>             | <b>Contact Time</b> |
| Clostridium difficile, spore form  | ATCC 43598                     | 8 minutes           |
| *See Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores  |                                |                     |
| <b>*Virucidal Activity</b>   | <b>ATCC Number</b>             | <b>Contact Time</b> |
| Hepatitis A Virus  | Strain HM-175                  | 30 seconds          |
| Hepatitis B Virus  | Hepadnavirus Testing, Inc      | 30 seconds          |
| Hepatitis C Virus (Bovine Viral Diarrhea Virus (BVDV))   | Oregon C24v-genotype 1 Strain  | 30 seconds          |
| Poliovirus Type 1  | ATCC VR-1562, Strain Chat      | 30 seconds          |
| Norovirus (Norwalk virus)  |                                | 30 seconds          |
| Feline Calicivirus   | ATCC VR-782                    | 30 seconds          |
| Rotavirus  | Strain WA                      | 30 seconds          |
| Influenza A [(H1N1)] Virus   | ATCC VR-1469, Strain A/PR/8/34 | 30 seconds          |
| HIV Type 1 (HIV-1)   | Strain HTLV-III                | 30 seconds          |
| Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).  |                                |                     |
| Kills Pandemic 2009 H1N1 influenza A virus.  |                                |                     |
| SARS-CoV-2   | COVID-19 virus                 | 30 seconds          |

**List of Use Sites, hard, non-porous surfaces:**

Covers Medical/ General / Veterinary / Food Processing / Hospitality and Lodging / Education)

Hospitals

Nursing homes

Healthcare (settings)(facilities)

Doctor's offices

Patient care (rooms)(areas)

Long term healthcare facilities

Acute healthcare facilities Hospice facilities

Surgery rooms

Operating rooms

Office(s)((building)(s))

Schools

Hotels

Athletic facilities

Recreational facilities

(Lodging)(Hospitality) establishments

Any public place with restroom facilities

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Veterinarian offices  
Veterinary clinics  
Kennels  
Catteries  
Animal ((hospital(s)) (facilities)  
Animal care facilities  
Pet care areas  
Kitchens  
Restaurants  
Cafes  
Cafeterias  
Food processing facilities  
Food preparation areas  
Bars  
Cruise ships  
Jails  
Prisons  
Correction(al) Facilities

(List of **Objects:** Within Medical/ General / Veterinary / Food Processing / Hospitality and Lodging /  
Education / Correctional Facilities Use Sites)

Bed railings  
Bed frame  
TV remote  
Bedside table  
Telephone  
Chair arm  
Exam(ination) (table(s)(room)  
Blood pressure cuff  
IV Pole  
High touch surfaces  
Critical touch points  
Bedpans  
Floors  
Walls  
Countertops  
Tables  
Table tops  
Door knobs  
Light switch  
Waste receptacles  
Trash can  
Showers  
Shower stalls  
Shower handles  
Shower head  
Faucets

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Urinals (above waterline)  
Toilets (above waterline)  
Toilet fixtures  
Toilet paper dispenser  
Restroom dispenser  
Sink fixture  
Restroom fixtures  
Cages  
Crates  
Veterinary surfaces  
Food cases  
Food trays  
Food preparation surfaces  
Food prep surfaces  
Dish racks  
High touch points  
Reusable restraints  
Exercise equipment  
Shared work equipment

(List of **Materials:** Product may be used on objects made from these materials)

Hard plastics  
Stainless steel  
Laminated counter tops  
Laminated table tops  
Glazed ceramic tile  
Sealed fiberglass  
Glass Nonporous flooring material  
Glazed porcelain

(General Claims)

See expiration date on bottle  
Bactericidal  
Disinfectant  
Virucidal\*

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.

**EMERGING VIRAL PATHOGENS:**

*Product Name* – or - 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.

*Product Name* – or - this product meets the criteria to makes claims against certain emerging viral pathogens from the following viral category:

- Small, non-enveloped virus
- Large, non-enveloped virus
- Enveloped virus

| <b>For an emerging viral pathogen that is a/an:</b> | <b>...follow the direction for use for the following organisms on the label:</b> |
|---|--|
| Enveloped virus                                     | Feline Calicivirus<br>Rotavirus  |
| Large, non-enveloped virus                          | Feline Calicivirus<br>Rotavirus  |
| Small, non-enveloped virus                          | Feline Calicivirus<br>Rotavirus  |

Tumult [product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard non-porous surfaces. Therefore this product [product name] can be used against **[name of emerging virus]** when used in accordance with the directions for use against Norovirus (Norwalk virus) and Feline Calicivirus 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.

**To Clean & Deodorize**

Spray area with this product [product name] [product] until surface is completely wet. Wipe off with a clean damp cloth or sponge.

**Quick One Minute Disinfection Action**

For one-minute disinfectant activity in the presence of 5% organic soil:

1. Spray area with this product [product name] [product] until surface is completely wet.
2. Allow surface to remain visibly wet for one minute
3. Wipe off with a clean damp cloth or sponge.

Preliminary cleaning is required for visibly soiled areas.

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(**Note to EPA:** These statements to be used when food contact surfaces are included on the label)

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinsed with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes, or cookware.

**Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores:**

**Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

**Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/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, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

**Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

**Disinfection Procedure:** Spray area with [product name] [this product] [product] until surface is completely wet. Allow surface to remain visibly wet for 8 minutes. Wipe off with a clean damp cloth or sponge.

**KILLS HIV-1, HBV, AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS**

in health care settings or other 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 Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

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

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable impervious gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

**CONTACT TIME:** Allow surface to remain wet for 30 seconds. For all other organisms, see directions for contact times.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

**To Clean and Disinfect in Veterinary Applications:**

Use to clean and disinfect hard nonporous surfaces such as floors, walls, counter tops, cages, crates, utensils, kennels, stables, catteries, feeding and watering equipment, etc. Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from walls, floors and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with [this product] [product] [product name] and let stand for [one] [1] minute. Rinse all surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or use equipment until treated surfaces have been allowed to dry. Thoroughly scrub all treated feeding and watering appliances with soap or detergent and rinse with potable water before reuse.

**PRECAUTIONARY STATEMENTS**

**Hazards to humans and domestic animals**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**FIRST AID**

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

**24 HOUR MEDICAL EMERGENCY NUMBER: 888-314-6171**

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

**PHYSICAL OR CHEMICAL HAZARDS**

Mixing or using this product with gross filth such as feces or urine, ammonia, acids, or other chemicals may release hazardous gases irritating to the eyes, lungs and mucous membranes.

**(Note to EPA:** The following text will be used on five gallon pails and larger containers only.)

**ENVIRONMENTAL HAZARDS**

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 agency 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.

(Note to EPA: The following text will be used on five gallon pails or less.)

**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 ¼ 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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**Container Disposal:** Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ¼ 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.

**[QUESTIONS OR COMMENTS? Call (800) 537-8990]**

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Maumee, Ohio 43537 1-800-537-8990 /www.spartanchemical.com