



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 3, 2015

Jaime N. Venable  
Regulatory Affairs Specialist  
Spartan Chemical Company, Inc.  
1110 Spartan Drive  
Maumee, OH 43537

Subject: PRIA Label and CSF Amendment – *Adding new claim Clostridium difficile to the label and adding additional suppliers to basic CSF*  
Product Name: Tumult  
EPA Registration Number: 5741-28  
Application Date: 01/07/2015  
Decision Number: 499130

Dear Mr. Venable:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 01/07/2015

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 with FIFRA section 6. If you have any questions, please contact Ben Chambliss by phone at (703) 308-8174, or via email at [chambliss.ben@epa.gov](mailto:chambliss.ben@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "D. Fuller", with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

**Diffense**

EPA Reg. No. 5741-28

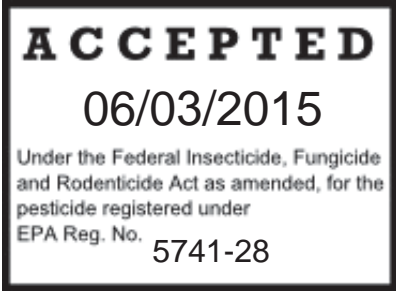
Spartan Chemical Company, Inc.

5/19/2015

Front Panel Copy:

**Diffense**

- [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.]



**ACTIVE INGREDIENT:**

Sodium hypochlorite..... 0.74%

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

Total ..... 100.00%

[Available Chlorine 0.70%]

[7000 PPM [Parts Per Million] Available Chlorine]

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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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## Diffense

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### Back Panel Copy:

This product [product name] is a [broad spectrum] [multipurpose][hospital] [healthcare] cleaner disinfectant which can be used in many areas [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 surfaces made of (Insert **Materials** selection)

**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.

This product [product name] has been proven to be effective against the following pathogenic microorganisms on hard nonporous surfaces:

#### **Bactericidal Activity -30 Second contact time with 5% blood serum:**

-*Escherichia coli*, extended beta-lactamase resistant [(ESBL)] [(ATCC BAA-196)]

-*Acinetobacter baumannii* [(ATCC 19606)]

#### **Bactericidal Activity -60 Second contact time with 5% blood serum:**

-*Staphylococcus aureus* [(ATCC 6538)]

-*Pseudomonas aeruginosa* [(ATCC 15442)]

-*Staphylococcus aureus*, methicillin resistant [(MSRA)] [(ATCC 33592)]

#### **Bacteria Sporicidal Activity- 8 Minute contact time:**

-*Clostridium difficile*, spore form [(ATCC 43598)]

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

#### **\*Virucidal Activity- 30 second contact time with 5% blood serum:**

-Hepatitis A Virus [(Strain HM-175)]

-Hepatitis B Virus [(Hepadnavirus Testing, Inc.)]

-Hepatitis C Virus [(Bovine Viral Diarrhea Virus (BVDV) Oregon C24v-genotype 1 Strain)]

-Poliovirus Type 1 [(ATCC VR-1562, Strain Chat)]

-Norovirus [(Norwalk virus)]

-Feline Calicivirus [(ATCC VR-782)]

-Rotavirus [(Strain WA)]

-Influenza A [(H1N1)] Virus [ (ATCC VR-1469, Strain A/PR/8/34)]

-HIV Type 1 [(HIV-1)] [ (Strain HTLV-III)]

-Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus.

**(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)**

(List of **Use Sites:**

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

Hospitals

Nursing homes

Healthcare settings

Healthcare facilities

Doctor's offices

Patient care rooms

Patient care areas

Rest homes

Long term healthcare facilities

Acute healthcare facilities

Hospice facilities

Surgery rooms

Operating rooms

Office buildings

Offices

Schools

Hotels

Athletic facilities

Recreational facilities

Lodging establishments

Hospitality establishments

Any public place with restroom facilities

Veterinarian offices

Veterinary clinics

Kennels

Catteries

Animal hospitals

Animal hospital facilities

Animal care facilities

Pet care areas

Kitchens

Restaurants

Cafes

Cafeterias

Food processing facilities

Food preparation areas

Bars

Cruise ships

**(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)**

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Jails

Prisons

Correctional Facilities

Correction 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 tables

Examination table

Examination room

Blood pressure cuff

IV Poll

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

Urinals (above waterline)

Toilets (above waterline)

Toilet fixtures

Toilet paper dispenser

Restroom dispenser

Sink fixture

Restroom fixtures

**(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)**

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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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)**

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### 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 the product to wet surface for one minute.
3. Wipe off with a clean damp cloth or sponge.

Preliminary cleaning is required for heavily soiled areas.

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

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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.

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### 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 the product to wet surface for 8 minutes. Wipe off with a clean damp cloth or sponge.

**(Note to EPA:** *[Bracketed] words & statements are optional unless specified in 40 CFR 156.10)*



**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.

#### 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.

*(Note to EPA: [Bracketed] words & statements are optional unless specified in 40 CFR 156.10)*

**(Note to EPA:** *The following text will be used on containers of greater than 5 gallons.*)

#### **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  $\frac{1}{4}$  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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