

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

EPA Reg.	Date of Issuance
Number:	

5741-28

MAR 1 2 2014

Term of Issuance:

Unconditional

Name of Pesticide Product:

TUMULT

NOTICE OF PESTICIDE:

x Registration

__ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Spartan Chemical Company, Inc.

1110 Spartan Drive

Maumee, OH 43537

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision Number: D-483533) is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
 - 2. Make the labeling changes listed below before you release the product for shipment:

Revise the EPA Registration Number to read, "EPA Reg. No. 5741-28.

Signature of Approving Official:

Demson Fuller

Product Manager Team 32

Regulatory Management Branch II Antimicrobials Division (7510P) MAR 1 2 2014

Date:

A stamped label with comments is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment.

Submit a one-year Storage Stability and Corrosion Characteristics studies (OPPTS 830.6317 and OPPTS 830.6320), when they are completed.

On page 6 of the current label we note the addition of a company web site. Should you wish to retain a reference to the company's website(s) on your label, then please be aware that such a reference transforms the websites into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p)(2). The web sites are then subject to review by the Agency. If the web site contents are false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the web site may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company web sites, if the Agency finds or if it is brought to our attention that a web site contains false or misleading statements or claims substantially differing from claims approved through the registration process, the web site may be referred to the EPA's Office of Enforcement and Compliance Assurance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8062 or by email at fuller.demson@epa.gov.

Sincerely.

Demson Fuller

Product Manager 32

Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

Tumult EPA Reg. No. 5741-EI Spartan Chemical Company, Inc.

3/11/2014

Front Panel Copy:

Tumult

[RTU Bleach Disinfectant]
[Multipurpose] [Broad spectrum] [Hospital] [Healthcare]
[Cleaner Disinfectant with Bleach]
[Cleans, Disinfects, Deodorizes, Virucidal*]
[Bactericidal]
[RTU Handi Spray]

ACTIVE INGREDIENT:

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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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:

<u>Bactericidal Activity</u> -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 [(MRSA)] [(ATCC 33592)]
- *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.

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(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

Jails

Prisons

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

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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-outside surfaces

Toilets-outside surfaces

Toilet fixtures

Toilet paper dispenser

Restroom dispenser

Sink fixture

Restroom fixtures

Cages

Crates

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

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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.

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3/11/2014

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.

Escherichia coli, Acinetobacter baumannii and many viruses *are killed in 30 seconds! Preliminary cleaning is required for heavily soiled areas.

(Note to EPA: These statements to 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.

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.

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

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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.

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(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: 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 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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