UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

JAN 2 7 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Ronald T. Cook Spartan Chemical Company, Inc. 1110 Spartan Drive Maumee, Ohio 43537

Subject:

Sani-T-10

EPA Registration Number: 5741-13 Application Date: October 21, 2009 Receipt Date: October 29, 2009

Dear Mr. Cook:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide (FIFRA), as amended, is acceptable with conditions listed below.

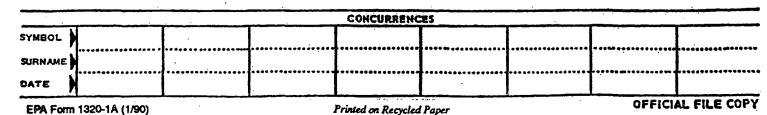
Proposed Amendment:

Label revisions per PR Notice 2007-4 and other minor formatting revisions.

Conditions

Revise the label as follows:

- 1.) Revise the claim "For Institutional and Industrial Only" on page 1 to read "For Institutional and Industrial Use."
- 2.) The nomenclature for Vaccinia, Influenza A2, and Herpes simplex Type 2 is incomplete on page 2. You need to indicate that the microorganisms are viruses by stating "Vaccinia Virus, Influenza A2 Virus, and Herpes Simplex Virus Type 2."
- 3.) The "Swimming Pool" directions on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the terms, "recommended," and "should." Replace the term, "should" with "must."
- 4.) Revise the 6th statement under the "Precautionary Statements" on page 4 to read "Wash thoroughly with soap and water after handling and before eating, drinking, smoking tobacco, chewing gum, or using the toilet."



- 5.) Revise the first statement under Environmental Hazards section on page 4 to be in agreement with the ADBAC RED by adding the phrase, "... and aquatic invertebrates."
- 6.) The Agency has concerns regarding the Container Rule rinsate statement for public health products. We are concerned that the efficacy will be compromised if the rinsate is poured into the application equipment and used to disinfect hard surfaces. Therefore, revise the "Container Disposal" instructions to read as follows:

(5 gallons or less)

Nonrefillable Container. Do not refill or reuse 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.

(5 gallons or more)

Nonrefillable Container. Do not refill or reuse 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 the 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.

General Comments:

A stamped label acceptable with conditions is enclosed for your records. . Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacquelline@epa.gov or Velma Noble by telephone at (703) 308-6233 or by email at noble.velma@epa.gov.

1. 1.

Velma Noble

Product Manager (Team 31)
Regulatory Management Branch I

Antimicrobials Division (7510P)

CONCURRENCES								
SYMBOL				,				
SURNAME	***************************************						,	
DATE								
EPA Form 1320-1A (1/90)			Printed on Recycled Paper				OFFICIAL FILE COPY	

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Front Label Copy:

Sani-T-10

DISINFECTANT/SANITIZER/ ALGICIDE

SANITIZES IN WATER UP TO 750 PPM HARDNESS

Bactericidal/Fungicidal/Virucidal*/Algicidal/Deodorizer

EPA Reg. No. 5741-13 EPA Est. No. 5741-OH-1 ACCEPTED with CCMMENTS in HPA Letter Dated:

JAN 2 7 2010

Inder the Federal Executeide, Americide, and Recardings Act acceptation, for the Destinite, registered under HPA Res. No.

5748-13

ACTIVE INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN **DANGER**

See back panel for additional precautionary and first aid statements.

FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY

Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, Ohio 43537

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Back Label Copy:

Sani-T-10

DISINFECTANT/ SANITIZER/ALGICIDE

Sani-T-10 is a versatile product. It makes an excellent disinfectant for use in hospitals, schools, bars, restaurants, and industrial and commercial areas on floors, walls, sinks, and other hard nonporous surfaces made of stainless steel, chrome, other metals, glazed porcelain, glazed ceramic tile, and plastic. It is also an excellent food contact sanitizer for use in bars, restaurants, hospital/school cafeterias on food processing equipment, food preparation surfaces, utensils and similar hard nonporous surfaces made of plastic, stainless steel, chrome, and other metals. This product provides algaecide activity which makes it ideal for treating pools.

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.

General Cleaning: Surfaces to be disinfected or sanitized must be thoroughly cleaned and rinsed with water before application of this product.

Disinfection and Deodorization:

To disinfect and deodorize hard nonporous environmental surfaces, use Sani-T-10 at 3/4 oz. per gallon of water. Apply with a mop, cloth, spray device or as a dip. Treated surfaces must remain wet for ten minutes. Wipe dry with cloth, mop, sponge, or allow to air dry. Rinse food contact surfaces such as counters, tables, food processing equipment with potable water. Do not use on utensils, glasses, or dishes. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled.

When used as directed for disinfection, Sani-T-10 is effective against the following pathogenic bacteria: Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica, and the cocce following pathogenic viruses*: Vaccinia, Influenza A₂ (England), Herpes simplex Type II and Adenovirus Type 5.

As a Fungicide: For fungicidal activity on shower room floors, locker room benches, showers and bath areas, etc., apply Sani-T-10 at 2 oz. per gallon of water to a pre-cleaned surface with a mop, cloth, spray device or as a dip. Treated surfaces must remain wet for ten filtilities. Treated surfaces may be rinsed with potable water, wiped off or allowed to air dry. When used as directed as a fungicide, Sani-T-10 has been proven effective against the pathogenic fungi Trichophyton mentagrophytes.

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To Sanitize Hand, Nonporous Food Contact Surfaces:

Use Sani-T-10 for sanitizing hard nonporous surfaces of food processing equipment, food, utensils, dishes, silverware, glasses, sink tops, appliances, counters, tables refrigerated storage and display equipment, and other hard nonporous surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, prescrape, or presoak. Then thoroughly wash with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply use solution of 1/4 oz. per gallon of water (200 ppm). Thoroughly saturate immobile surfaces with cloth, sponge, or brush. Immerse mobile objects such as glassware, dishes, silverware, cookware, or similar size food processing equipment. Surfaces must remain wet for at least 1 minute or time specified by governing sanitary code, (2 minutes for Wisconsin State Division of Health). Allow immobile surfaces to adequately drain and air dry. Place mobile objects and equipment on a rack or drain board to air dry.

Prepare a fresh solution daily or more often if solution becomes visibly diluted, clouded, or soiled. For mechanical application, use solution may not be reused for sanitizing applications.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 21 CFR 178.1010 (a)).

Sani-T-10 was approved under the regulations of the Wisconsin State Division of Health.

For Use as an Algicide in Swimming Pools

Add this product directly to the pool water by pouring the required dose around the entire outside perimeter of the pool. Allow the filter to run for at least six hours after application to assure complete dispersion of the product. Swimmers may reenter the swimming pool after 6 hours.

Initial Dose: 1 gallon Sani-T-10 to 50,000 gallons of water.

Maintenance Dose: 1 quart Sani-T-10 to 50,000 gallons of water.

Initial dose is used when filling pool at beginning of swimming season. If pool has visible algae growth, treat with initial dose. Vacuum pool after 24 hours to remove algae debris. If visible algae are still present, or re-appear, repeat this treatment procedure as necessary. When pool is free of visible algae, use the recommended maintenance dose. Maintenance dose should be added at 3-5 day intervals. If high temperatures prevail or pool has unusually heavy use, add when week of pool capacity, add 1 quart of Sani-T-10 for each 10,000 gallons of fresh make-up water added per week. When swimming season is over, add 1 gallon of Sani-T-10 to 50,000 gallons of water in treating water left in pool. This dose helps provide a measure of control of algae growth during the winter months. This treatment will also help the servicing of the pool before it is returned to use the following season.

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When Sani-T-10 is used as directed, it will kill and prevent development of Chlorella pyrenoidosa (green), Phormidium inundatum (black algae), Phormidium retzii (Square D algae), Lyngba versicolor (blue-green) and other swimming pool algae.

Sani-T-10 is compatible with most commonly used swimming pool chemicals but should not be mixed with soap or other cleaners or pre-mixed with other water-treating chemicals.

Sani-T-10 works best when added by itself directly to pool water.

Sani-T-10 at use dilution is non-corrosive to inanimate surfaces.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get into eyes, on skin or on clothing. Wear protective eye wear (goggles/face shield/safety glasses) protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

(Note to EPA: The following text will be used on five-gallon and larger containers)

Environmental Hazards: This product is toxic to fish. 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.

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 eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for 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 going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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(Note to EPA: The following text will be used on containers of 2 liters 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 five gallon pails or less, but greater than 2 liters.)

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 this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ½ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(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 this container. Offer for recycling if available. Triple rinse container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at lest one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, OH 43537 1-800-537-8990/ www.spartanchemical.com / Medical Emergency: 888-314-6171

(Note to EPA: The following is an optional phrase)

Fax On Demand Material Safety Data Sheet: 888-383-4666, No. (XXXX)