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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 21 2003

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

Sani-T-10

Subject:

EPA Registration No. 5741-13 Amendment Date: September 17, 2003 EPA Receipt Date: September 22, 2003

Dear Mr. Cook,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Response to Agency letter dated August 18, 2003

Conditions

Revise the label as follows:

- 1. Page 2: Revise the claim under "disinfectant/sanitizer/algicide" by aligning the use sites with the applicable claim. The claim must state "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 algicidal activity which makes it ideal for treating pools."
- 2. Page 2: Under Disinfection and Deodorization, revise the last statement to read "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."

3.	Under	"sanitizer"	, state	"to sanitize	hard.	nonporous	fooc	i contact	surfaces	"

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

The proposed "Food Contact Sanitizing" directions limit the use of this product to sanitizing "glasses and utensils" whereas this product may be used to sanitize an array of hard, nonporous food contact surfaces. On page 2, the label states this product may be used to sanitize food contact surfaces, food preparation equipment, and utensils. You must revise the directions to by stating:

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. 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.

- 5. Under Swimming Pool directions, add the statement "swimmers may reenter the swimming pool after 6 hours."
- 6. Storage and Disposal Revisions

4.

a) Containers one gallon or less do not require the "Do not contaminate....water" statement or subheadings (Pesticide Storage and Container Disposal). The statements must reflect the following:

Store in original container in a locked storage area inaccessible to children. Do not reuse container. Discard in trash.

b) Containers greater than 1 gallon require separate storage instructions with an appropriate subheading. The statement and subheading under the statements for one gallon or less should be placed in this section.

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General Comments

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

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Tracy Lat

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure:

Stamped Label

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Sani-T-10 EPA Reg. No. 5741-13 Spartan Chemical Company, Inc. Revised 9/17/2003

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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. 5741-0H-1

ACTIVE INGREDIENTS:

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	5.0%
n-alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	
INERT INGREDIENTS:	90.0%
Totak	100.0%

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

NET CONTENTS: 2 Liters / 67.6 Fl. Oz. NET CONTENTS: 1 U.S. gallon / 3.79 Liters NET CONTENTS: 5 U.S. gallons / 18.95 Liters

> ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fingicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 5741-13



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Back Side Label Copy Sani-T-10_{TM} DISINFECTANT/ SANITIZER/ALGICIDE

Sani-T-10 is a truly versatile product. It makes an excellent disinfectant or sanitizer for use in hospitals, schools, bars, restaurants and institutions, and its algicidal activity makes it ideal for treating pools. Sani-T-10 may be used to disinfect and sanitize floors, walls, sinks, food contact surfaces, food preparation equipment & utensils and other similar hard, nonporous surfaces made of stainless steel, chrome & other metals, glazed porcelain, glazed ceramic tile and plastic.

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. Treated surfaces may be rinsed with potable water, wiped off or allowed to air dry.

When used as directed for disinfection, Sani-T-10 is effective against the following pathogenic bacteria: Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis; and the 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 precleaned surface with a mop, cloth, spray device or as a dip. Treated surfaces must remain wet for ten minutes. 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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As a Sanitizer:

To sanitize food contact surfaces

- 1. Scrape and pre-wash utensils and glasses whenever possible.
- 2. Wash with a compatible Spartan detergent. Articles must be thoroughly clean before sanitization.
- 3. Rinse with clean potable water.
- 4. Sanitize in a solution of 1/4 oz. Sani-T-10 to 1 gallon of water (200 ppm). Immerse all utensils for at least two minutes or for time specified by governing sanitary code.
- 5. Place sanitized utensils on a rack or drain board to air dry.

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.

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 maintenance dose more frequently.

If make-up water is added at the rate of more than 10% per 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.

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

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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.

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.

(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 sever systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Sani-T-10

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(NOTE TO EPA: The following text will be used on one gallon and smaller containers)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **Pesticide Storage:** Store in original container in a locked storage area inaccessible to children.

Container Disposal: Do not reuse empty container. Wrap container and discard in the trash.

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

STORAGE AND DISPOSAL:

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

Pesticide Disposal: Pesticide wastes are acutely 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: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities by burning. If burned, stay out of smoke.

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, OH 43537 1-800-537-8990/ <u>www.spartanchemical.com</u> / 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)

(C) SCC 9/03

