

56392-7

1-26-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

January 26, 2007

Rhonda Jones
 Agent for Caltech
 c/o Scientific & Regulatory Consultants, Inc.
 PO Box 1014
 Columbia City, IN 46725

Subject: Dispatch Hospital Cleaner Disinfectant
 EPA Registration No. 56392-7
 Application Date: December 13, 2006
 Receipt Date: December 13, 2006

Dear Ms. Jones:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the comments listed below:

Proposed Amendment

- Addition of "Avian Influenza A" claims
- Minor labeling changes and corrections

General Comments

1. Featured statements/phrases emphasized/enlarged lettering, special graphics, or any product name that employs the terms "Avian Influenza A" or "Bird Flu", are unacceptable. Featured statements/phrases, emphasized/enlarged lettering or special graphics that are employed for the primary purpose of especially promoting or drawing attention to product efficacy against Avian Influenza A, are also unacceptable. For example, a featured, incomplete phrase such as "Kills Avian Influenza A" will not be permitted, but the phrase "Kills Avian Influenza A on pre-cleaned environmental surfaces" is acceptable.

2. You must include the following text directly beneath the First Aid Statement:
 "Have the product container or label with you when calling a poison control center or doctor, or going for treatment."

		CONCURRENCES					
SYMBOL	7510P	7510P					
IRNAME	E. Berg	E. Mitchell					
DATE	1/26/07	2/1/07					

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3. A stamped copy of the labeling accepted with comment is enclosed. Submit one (1) copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Y. Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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DISPATCH® HOSPITAL CLEANER DISINFECTANT
WITH BLEACH (5500 ppm)

- Cleans & disinfects in one step
- Stabilized bleach & detergent solution
- Ready-to-use
- Meets OSHA Bloodborne Pathogen Standards
- For Hospital, Veterinary, & Food Contact Hard, Non-Porous Surfaces
- For Instrument Pre-cleaning & Disinfection of Non-critical Instruments

Kills bacteria, viruses[†], & fungi on hard, non-porous surfaces in One Minute:

Kills bacteria, viruses[†] & fungi in 1 Minute: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica* (formerly *choleraesuis*), Methicillin resistant *Staphylococcus aureus* (MRSA), *Streptococcus pyogenes*, Vancomycin resistant *Enterococcus faecalis* (VRE), *Clostridium difficile* (vegetative), *Trichophyton mentagrophytes* (Athlete's Foot Fungus), HIV-1 (AIDS Virus)[†], Poliovirus Type 1 (Mahoney)[†], Herpes Simplex Virus (HSV-2)[†], Rotavirus, Hepatitis A Virus (HAV)[†], Hepatitis B Virus (HBV)[†], Hepatitis C Virus (HCV)[†], Norovirus[†], Avian Influenza Virus[†]

Active Ingredient: Sodium Hypochlorite.....0.55%
Other Ingredients:.....99.45%
TOTAL.....100.0%

ACCEPTED
with COMMENTS
EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN
CAUTION

JAN 26 2007

Read Complete Directions and Precautions on Package

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

NET CONTENTS

56392-7

EPA Reg. No. 56392-7

EPA Est. No. 74592-OH-1

50757-WI-1

62801-MI-1

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DISPATCH® HOSPITAL CLEANER DISINFECTANT WITH BLEACH

Multipurpose, broad spectrum cleaner disinfectant for use on hard, non porous surfaces. May be used for instrument pre-cleaning and disinfection of non-critical instruments * **Surfaces:** May be used on stainless steel, glazed ceramic tile, hard plastics, nonporous vinyl, painted surfaces, plexiglas, laminated plastic countertops, fiberglass (sealed) surfaces, glazed porcelain, and glass * **Applications: Medical** – hard, non porous hospital surfaces such as autoclaves, blood glucose monitors, external surfaces of medical equipment, IV poles, exam tables, bed railings, external surfaces of dialysis machines, gurneys, mammography equipment, plastic mattress covers, phlebotomy trays, reception counters, external surfaces of respiratory equipment, stretchers, external surfaces of ultrasound transducers and probes, wash basins, and wheelchairs * **Dental** – chairs, counters, operatory hard surfaces, and light lens covers * **Veterinary** – animal equipment, cages, fountains, vet clinic surfaces * **Other** –changing tables, doorknobs, hand railings, highchairs, playpens * **Food service** –both food and non food contact surfaces. * **Use Sites: Medical** – ambulance, central service, critical care, dialysis clinics, emergency rooms, exam rooms, home health care, hospitals, intensive care, laboratories, neonatal nursery, nurses' stations, nursing homes, operating room, orthopedic clinics, outpatient clinics, patient rooms, physical therapy rooms, physician offices, radiology, recovery room, respiratory therapy, and surgery * **Dental** – dental clinics, labs * **Veterinary** – animal housing, veterinary clinics/hospitals * **Other** – blood banks, correctional facilities, day care, funeral homes, health clubs, recreational centers, restrooms, schools.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

To Clean, Disinfect, and Deodorize in One Step: Spray 6"- 8" from surface until surface is completely wet. To disinfect, let stand for one minute. Wipe with a clean, damp cloth or paper towel. Allow to air dry. For food contact surfaces, rinse with potable water. For all other surfaces no rinsing is required. Gross soil must be removed prior to disinfecting.

To Clean and Disinfect in a Veterinary Application: Use to clean and disinfect hard, non-porous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Pre-clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with DISPATCH and allow to remain wet for one minute. Rinse all surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treated surfaces have been thoroughly rinsed with water and allowed to dry. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before re-use.

To Preclean Instruments Prior to Terminal Sterilization/high level disinfection:

As a pre-cleaning spray – Place instruments into a suitable container. Spray DISPATCH® onto instruments to thoroughly wet all surfaces. Allow to stand for up to 10 minutes. Rinse instruments.

As a pre-cleaning immersion solution – Fill appropriate size container with a sufficient amount of DISPATCH® to completely submerge instruments. Place instruments into the container of DISPATCH®, cover, and allow to soak for up to 10 minutes. Remove and rinse, and follow with an appropriate cleaning and disinfecting process. Change solution daily.

As a manual instrument cleaner – Thoroughly pre-rinse dirty instruments under running water to remove visible, gross debris. Immerse pre-rinsed instruments into an appropriate size container filled with DISPATCH®. Scrub instruments using a stiff bristle brush until visibly clean. Submerge instruments while scrubbing. Rinse instruments thoroughly. Change solution daily. Follow with an appropriate disinfection process.

Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

To disinfect non-critical, pre-cleaned instruments – Instruments must be thoroughly pre-cleaned to remove excess organic debris, rinsed, and rough dried. (Clean and rinse lumens of hollow instruments before filling with DISPATCH® or before immersion.) Immersion method - using a soaking tray, immerse instruments into DISPATCH® and allow to remain submerged for one minute at room temperature (68-77°F). Remove and wipe with a clean, damp cloth or paper towel and allow to air dry. Change solution for each use. Spray method–Spray all surfaces of instruments with DISPATCH until thoroughly wet. Allow one minute contact time. Wipe with a clean, damp cloth or paper towel and allow to air dry.

Use DISPATCH on stainless steel instruments only.

†KILLS HIV, HAV, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood /body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus), HAV, HBV and HVC on Surfaces/Objects Soiled with Blood/Body Fluids. •**Personal Protection:** When handling items soiled with blood/body fluids, personal protective equipment such as disposable gloves, gowns, masks, or eye coverings should be used. •**Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before disinfecting. •**Contact Time:** Leave surfaces wet for 1 minute. •**Disposal of Infectious Materials:** Blood, body fluids, and cleaning materials should be autoclaved and disposed according to federal, state, and local regulations for infectious waste disposal.

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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STORAGE AND DISPOSAL

Store this product in a cool, dry area, away from direct sunlight and heat. Refill empty DISPATCH spray container only from DISPATCH refill bottle. Do not fill other spray containers. When discarding container, place in trash collection or take to recycling center.

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.

PHYSICAL AND CHEMICAL HAZARDS: Do not use this product with ammonia or acids such as vinegar, rust removers, or toilet bowl cleaners. This product not intended for use on fabrics.

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REORDER NO:

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See Expiration Date on Bottle

Midland, MI 48642

1-800-234-7700

NFPA

HEALTH 0 FLAMMABILITY 0 REACTIVITY 1 SPECIFIC OX

0=None 1=Slight 2=Moderate 3=High 4=Extreme OX=Oxidizer