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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



Employers Office of Pesticide Programs

August 28, 2007

Mary Joy Stuart The Procter & Gamble Company Ivorydale Technical Center 5299 Spring Grove Avenue Cincinnati, OH 45217

Subject:

CSP-3002-3

EPA Registration No. 3573-77 Submission Dated: April 26, 2007 Receipt Date: April 27, 2007

Dear Ms. Stuart:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, for an additional organism (Avian Influenza A virus (H3N2)) to revise the label, is accepted with comments.

- 1. The proposed label claims that the product, CSP-3002-3 Master Label, is an effective disinfectant on hard, non-porous surfaces against the Avian Influenza A virus (H3N2) in the presence of a 5% organic bioload for a contact time of 5 minutes at the Ready To Use (RTU) product. Data provided by the applicant support only the (RTU) product. The proposed label references "For products that require dilution only: when diluted 1:4 in the presence of 171 ppm hard water\10 gpg water hardness [and 5% fetal bovine serum [according to the AOAC Use-Dilution test]. The registrant must clarify which organisms are supported by this statement. Claims of effectiveness for the dilutable product have not been demonstrated and are unacceptable for Avian Influenza A virus (H3N2).
- 2. This product is for use on hard non-porous surfaces. This use site is not optional for the disinfectant claim. Therefore, you must remove the parenthesis from hard non-porous surfaces everywhere it appears on the label.
- 3. The deodorization claim must be accompanied by complete directions for use and adequate dosage recommendations requirements per DIS/TSS-15.

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- 4. A potable water rinse is required when disinfectants are used on food contact surfaces.
- 5. The claim "prevents the spread of" should consistently include the organism. Briefly, the statement should read "Prevents the spread of Salmonella enterica on treated surfaces" OR "Prevents the spread of Salmonella enterica on surfaces treated for 5 minutes.
- 6. The correct designation for "Norwalk" virus is "Norovirus." Feline Calicivirus was the tested surrogate to support claims for Norovirus. Therefore, the claim should be written as Norovirus (Feline Calicivirus as surrogate).
- 7. The efficacy of the product has been confirmed by the submitted data. However, claims for effectiveness on airplanes requires acceptance of compatibility data by Federal Aviation Administration (FAA) The Agency requests a copy of airline compatibility data for its records.
- 8. As stated in the Agency's letter dated April 12, 2007, the use of the following abbreviation is not acceptable: ---Staph
- 9. Remove or provide additional information for the statement "Minimizes training time."

General Comments

A stamped copy of the labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,

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



FRONT Panel

KEEP OUT OF REACH OF CHILDREN
CAUTION: EYE AND SKIN IRRITANT. See back\side panel for other precautions.

Net Weight Statement

Optional:

Ready-to-Use

Refill

For Automatic Dilution

Concentrate

5X Concentrate

Disinfectant

Hospital Use\Grade\Level Disinfectant

Bactericide\Bactericidal\Bacteriostat

Virucide\Virucidal

Germicide\Germicidal\Germistat

Sanitizer

Deodorizer

Institutional

Commercial

Disinfects

Disinfecting

ACCEPTED
with COMMENTS
== EPA Letter Dated:

AUG 2 8 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 3573-77

BACK\SIDE Panel

DIRECTIONS FOR [HOUSEHOLD] [INSTITUTIONAL] [COMMERCIAL] USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **Gallon size:** Refill [into] properly labeled spray bottle[s]. \Refill [only] properly labeled [Product name] [Cleaner with Bleach] spray bottle[s]. \Refill only [Product name] Cleaner with Bleach spray bottle[s].

Use the following usage instructions for concentrate

CONCENTRATED PRODUCT – DILUTE BEFORE USING [(1 gallon makes 5 gallons of diluted\disinfecting\sanitizing product and 10 gallons of cleaning\deodorizing product)]

Closed chemical container: ATTACHING THIS PRODUCT TO THE [P&G] [AUTOMATIC] DILUTION CENTER: Remove the [white] shipping cap.

Closed chemical container: DO NOT REMOVE [WHITE] PLUG FROM BOTTLE THROAT! Screw on [white] dispensing cap from dilution center tube. Push down while twisting.

PREPARING \MANUAL PREPARATION OF CLEANING \[DEODORIZING] SOLUTION: Mix 1 part [of this] product\concentrate per 9 parts water into a [Product Name] [Cleaner with Bleach] spray bottle [using the dilution center].\Mix this product\concentrate with water using the [P&G] [AUTOMATIC] dilution center.

PREPARING \MANUAL PREPARATION OF DISINFECTING \[SANITIZING\] SOLUTION: Mix 1 part [of this] product\concentrate per 4 parts water into a [Product Name] [Cleaner with Bleach] spray bottle [using the dilution center].\Mix this product\concentrate with water using the [P&G] [AUTOMATIC] dilution center.

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES\OBJECTS PREVIOUSLY SOILED WITH BLOOD\BODY FLUIDS, in health care 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES\OBJECTS SOILED WITH BLOOD\BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Thoroughly wet surfaces with disinfecting solution for 5 minutes, then rinse or wipe clean.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

GENERAL CLEANING [DIRECTIONS]: Apply to hard, non-porous surfaces. Spray\Pour\spray directly onto surface [or] [damp sponge] [cloth] [paper towel] [towel]. Rinse or wipe clean. For tough stains or soil, let soak\stand [1 minute\60 seconds].\For tougher soils, allow to soak. [FLOORS: Add 250 ml\1 cup [concentrate\product] per 3.78 L\1 gallon warm water. Mop and rinse.]

TO DEODORIZE: Apply to hard, non-porous surfaces. Spray\Pour\spray directly onto surface [or] [damp sponge] [cloth] [paper towel] [towel]. Rinse or wipe clean. [For light\daily [duty] deodorizing, dilute 1 part concentrate\product to 9 parts water.]

POULTRY FARM DISINFECTION [DIRECTIONS]: Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils). Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

DAIRY FARM DISINFECTION [DIRECTIONS]: Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the recommended disinfecting solutions for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(Note to reviewer: For labels that list medical environments, hospitals, nursing homes, medical and dental offices and clinics, operation rooms, isolation wards, patient chairs, examination chairs and wheelchairs, the following statement must be used:)

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.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

CAUTION: Harmful if absorbed through skin. Causes moderate eye irritation. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing vapor or spray mist. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. For sensitive skin or prolonged use, wear gloves. Remove contaminated clothing and wash clothing before use.

FIRST AID: If on skin or clothing, take off contaminated clothing. Rinse skin immediately with plenty of water for 15 -20 minutes. 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 the eye. If breathing is affected, get to fresh air immediately.

Contact a poison control center or doctor for treatment advice. Have the product container or label with you when calling the poison control center or doctor, or going for treatment.

PHYSICAL AND CHEMICAL HAZARDS: Contains Bleach. Do not mix with other products, especially toilet bowl cleaners or products that contain ammonia as hazardous vapors\fumes may result. Avoid contact with clothes, fabric, carpet, wood, rubber, painted or paper surfaces, as they will discolor. Rinse immediately after use on metal, old glazed porcelain, or worn countertops to avoid discoloration or pitting.

STORAGE/DISPOSAL: Store in cool place. Gallon Size: Discard empty bottle in trash. Spray container only: Do not reuse bottle except with [Product Name] [Cleaner with Bleach] [product] refill. If not refilling, discard in trash.

Biodegradable cleaning agents **Contains No Phosphate**

UPC Code Kosher Symbol

[1-800-332-7787] or [X-XXX-XXX-XXXX] [pgbrands.com] [pgproline.com] Questions? MSDS?

PROCTER & GAMBLE Cincinnati, OH 45202 MADE IN USA EPA Reg. No. 3573-77 **EPA Est. No XXXXXXXX**

SANITIZING

TO [CLEAN AND] SANITIZE (hard, non-porous surfaces):

Clean surfaces prior to sanitizing heavily soiled areas.\For heavily soiled areas, clean before sanitizing\following sanitizing directions. Thoroughly wet hard, non-porous surfaces [with [sanitizing] solution] for 1 minute\60 seconds, then rinse or wipe clean.\Spray product on surface and let stand 1 minute\60 seconds [before wiping]. TOILETS BOWLS [AND URINALS]: Empty water from the toilet bowl [or urinal]. [Hold 6-8" from surface.] Spray [covering] exposed surfaces. Brush thoroughly over surfaces and under the rim to completely wet surfaces, let stand for 1 minute\60 seconds, then flush. *Spray and refill containers only:* [For sanitizing and light\daily [duty] [soil] cleaning, dilute 1 part concentrate\product to 4 parts water.]

- Kills\Eliminates\Destroys\Removes [and prevents the spread of 99%\99.9% Staphylococcus aureus\S. aureus\Staph and (For products that require dilution only:) when diluted 1: 4 in the presence of 171 ppm hard water\10 gpg water hardness [and 5% fetal bovine serum] [according to the AOAC Use-Dilution test.]
- Kills\Eliminates\Destroys\Removes [and prevents the spread of] 99%\99.9% of bacteria\germs (For products that require dilution only:) when diluted 1: 4 in the presence of 171 ppm hard water\10 gpg water hardness [and 5% fetal bovine serum] [according to the AOAC Use-Dilution test.]
- Cleans and kills\eliminates\destroys\removes [99%\99.9%] of bacteria\germs [in 60 seconds\ 1 minute] (For products that require dilution only:) when diluted 1: 4 in the presence of 171 ppm hard water\10 gpg water hardness [and 5% fetal bovine serum] [according to the AOAC Use-Dilution test.]

- Sanitizer
- Antibacterial Cleaner
- Cleaner\Sanitizer
- Sanitizing Cleaner
- Cleans and sanitizes
- Fast acting sanitizer
- Sanitizes non-food contact surfaces.
- Leaves surfaces [clean and] sanitized.
- Sanitizes in 60 seconds.



5 MINUTE DISINFECTION

TO [CLEAN AND] DISINFECT (hard, non-porous surfaces):

Clean surfaces prior to disinfecting heavily soiled areas.\For heavily soiled areas, clean before disinfecting\following disinfecting directions. Thoroughly wet hard, non-porous surfaces [with [disinfecting] solution] for 5 minutes, then rinse or wipe clean.\Spray product on surface and let stand 5 minutes [before wiping]. TOILETS BOWLS [AND URINALS]: Empty water from the toilet bowl [or urinal]. [Hold 6-8" from surface.] Spray [covering] exposed surfaces. Brush thoroughly over surfaces and under the rim to completely wet surfaces, let stand for 5 minutes, then flush. [For disinfecting and light\daily [duty] [soil] cleaning, dilute 1 part concentrate\product to 4 parts water.]

This product is a hospital use\level disinfectant that kills\eliminates\ destroys\ removes a broad\wide range\ spectrum of germs [and viruses]: [Kills\eliminates\destroys\ removes and prevents the spread of] [Cleans and kills\eliminates\ destroys\ removes] list of and\or options:

- Salmonella enterica
- Staphylococcus aureus
- Pseudomonas aeruginosa
- Hepatitis A
- Human Immunodeficiency Virus type I \HIV-1
- Avian Influenza A [virus] \ Avian Influenza A (H3N2) [virus] (For products that require dilution only:) when diluted 1:4 in the presence of 171 ppm hard water\10 gpg water hardness [and 5% fetal bovine serum] [according to the AOAC Use-Dilution test.]

- Cleans and disinfects
- Disinfects as it cleans
- Fast acting disinfectant
- One step cleaner and disinfectant
- Disinfects
- Disinfects and deodorizes
- Restroom\Bathroom and kitchen disinfectant
- Cleans and disinfects [outside of] appliances
- Combines cleaning, disinfecting and stain removal in one\1 product
- Disinfecting bleach cleaner
- Disinfectant
- Hospital Use\Level Disinfectant
- Bactericide\Bactericidal\ Bacteriostat
- Virucide\Virucidal
- Germicide\Germicidal\ Germistat

10 MINUTE DISINFECTION

TO [CLEAN AND] DISINFECT (hard, non-porous surfaces):

Clean surfaces prior to disinfecting heavily soiled areas.\For heavily soiled areas, clean before disinfecting\following disinfecting directions. Thoroughly wet hard, non-porous surfaces [with [disinfecting] solution] for 10 minutes, then rinse or wipe clean.\Spray product on surface and let stand 10 minutes [before wiping]. TOILETS BOWLS [AND URINALS]: Empty water from the toilet bowl [or urinal]. [Hold 6-8" from surface.] Spray [covering] exposed surfaces. Brush thoroughly over surfaces and under the rim to completely wet surfaces, let stand for 10 minutes, then flush. [For disinfecting and light\daily [duty] [soil] cleaning, dilute 1 part concentrate\product to 4 parts water.]

This product is a hospital use\level disinfectant that kills\eliminates\destroys\removes a broad\wide range\spectrum of germs [and viruses]: [Kills\eliminates\destroys\ removes and prevents the spread of] [Cleans and kills\eliminates\ destroys\ removes] list of and\or options:

- Feline calicivirus
- Norwalk virus
- Listeria monocytogenes

(For products that require dilution only:) when diluted 1.4 [and 5% fetal bovine serum] [according to the AOAC Use-Dilution test.]

- Cleans and disinfects
- Disinfects as it cleans
- Fast acting disinfectant
- One step cleaner and disinfectant
- Disinfects
- Disinfects and deodorizes
- Restroom\Bathroom and kitchen disinfectant
- Cleans and disinfects [outside of] appliances
- Combines cleaning, disinfecting and stain removal in one\1 product
- · Disinfecting bleach cleaner
- Disinfectant
- Hospital Use\Level
 Disinfectant
- Bactericide\Bactericidal\ Bacteriostat
- Virucide\Virucidal
- Germicide\Germicidal\ Germistat

Note: Bold, italicized text is for reader clarity only. Bracketed [] text denotes optional text. Backslash \ denotes alternate text.

GENERAL CLAIMS

- Institutional [Size]
- Institutional use
- Professional Line [size]
- Commercial
- Contains biodegradable ingredients\cleaning agents
- Not harmful to\will not harm septic systems
- Suitable for septic systems [and] [wastewater systems] [and] [treatment plants]
- Contains sodium hypochlorite plus a cleaner
- All-purpose\Multi-purpose\Multi-use\Multisurface\toilet bowl cleaner [with bleach]
- Developed\Formulated\Designed for [foodservice] [and] [hospital] [and] [restroom] use
- This product\Product name complies with consumer volatile organic compound (VOC)\VOC laws

- A clean you can trust
- Fresh\pleasant scent

Closed chemical container only:

- Tamper proof bottle
- Bottle\Sealed bottle\Container\Closed chemical system designed for employee safety
- Bottle\Sealed bottle\Container\Closed chemical system designed to prevent spills and accidental concentrate\product exposure.

Concentrate:

- Concentrate
- 5X Concentrate
- 10X Concentrate

Spray container only:

• For Household Use

CLEANING, DEODORIZING & STAIN REMOVAL

- Cuts through tough food stains and greasy soils on sinks, counters, stove tops, food carts, appliances\appliance exteriors, and floors.
- Removes\Cleans\Eliminates soils, mildew stains, mold stains, soap scum and hard water stains from sinks, toilets, bathtubs, showers, shower stalls, and floors.
- Dissolves\Cleans\Cuts through tough [greasy soils] [and] [soap scum] [and] [hard water stains].
- Removes\Cleans\\Eliminates\Bleaches tough
 [stains] [food stains] [and] [mildew stains] [and]
 [soap scum] [and] [hard water stains] [and]
 [greasy soils].
- Cleans [and] [shines] [and] disinfects [and] [deodorizes] [washable] [kitchen] [and] [restroom\ bathroom] [surfaces] [and] [fixtures].
- Safely cleans kitchen and restroom surfaces, such as counters, sinks, tubs, toilets, showers, floors, etc.
- Helps clean tough soils & bleaches stains without scrubbing
- Kitchen cuts through tough grease and bleaches troublesome food stains.
- Restrooms great all-around restroom cleaner makes employee tasks simple, cutting through soap scum and hard water stains
- Powerful restroom & all-purpose\multi-surface cleaner
- Supercharges your cleaning with the power of bleach
- Designed to help improve cleaning productivity
- Saves time little to no scrubbing needed!

- Deodorizer
 - Deodorizes
- Freshens
- Freshens\Deodorizes as you clean.
- Removes\Eliminates stains on contact.
- · Cleans dirt and stains.
- Cleans and removes\eliminates tough dirt and stains.
- Whitens [and removes stains and greasy dirt.]
- Brightens
- Non-abrasive [formula]
- Non-abrasive [formula] won't scratch surfaces.
- Rinses away easily.
- Cleans with the power of bleach
- Contains a powerful cleaner plus bleach
- Eliminates\Removes odors caused by bacteria\germs.
- Disinfects and deodorizes by killing germs [and controlling odors].
- Cuts grime
- A clean you can trust.
- As simple as 1-2-3
- Attacks and bleaches mold and mildew stains with little or no scrubbing.
- Makes employee tasks\job\life simple\easy
- Powers away tough stains [and] [soap scum] [and] [hard water stains] [and] [greasy soils] and disinfects in one step.
- Eliminates the need for multiple cleaners
- Bleaches and eliminates mold & mildew stains without scrubbing.
- Minimizes training time
- Fewer products broad range of applications



WHERE TO USE

This product may be used in (list of and\or options)

- foodservice establishments
- restaurants
- bars
- cafeterias
- [institutional] kitchens
- · fast food operations
- food storage areas
- medical environments
- hospitals
- nursing homes
- medical and dental offices and clinics
- operation rooms
- isolation wards
- medical research centers
- ambulance
- schools
- colleges
- dormitories
- classrooms
- athletic facilities
- gymnasiums
- locker rooms
- day care centers
- nurseries
- retail establishments
- wholesale establishments
- supermarkets
- convenience stores
- dressing rooms
- laundries
- laundromats
- crime scenes
- funeral homes
- office buildings
- hotels
- motels
- factories

- laboratories
- recreational facilities
- campgrounds
- playgrounds
- health clubs
- household areas
- kitchens
- bathrooms\restrooms
- basements
- household garages
- automotive garages
- boats
- ships
- campers
- RVs
- trailers
- mobile homes
- cars
- buses
- trains
- taxis
- airplanes
- transportation terminals
- food processing plants
- diary farms
- poultry farms
- turkey farms
- · egg processing plants
- veterinary clinics
- animal life science laboratories
- kennels
- breeding and grooming establishments
- pet\animai quarters
- zoos
- pet shops
- churches
- manufacturing facilities
- military installations
- blood banks



	•		TASK	AREAS
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Task areas:

- Restroom surfaces
- Kitchen surfaces
- Glazed Porcelain
- Plexiglass
- Stainless Steel
- Floors [no wax] [and\or] [washable]
- Glazed Ceramic Tile
- Linoleum
- Resilient flooring
- [Synthetic] [Cultured] marble
- [Outside] of appliances [such as]
 [refrigerators] [microwaves] [freezers]
- Salad bar sneeze guard[s]
- Food serving area[s]
- Outdoor furniture excluding cushions and other porous surfaces
- Wading pool[s]
- Telephone[s]
- Pet dishes
- Pet soiled surface[s]
- Patient chair[s]
- Examination table[s]

- Toilets
- Urinals
- Countertops
- Sinks
- Showers\Tubs
- Appliances
- Laminated surface[s]
- Sealed Granite
- Enamel
- Diaper pails
- Diaper changing tables
- [High] chairs
- Table top[s]
- Dish rack[s]
- Dish pail[s]
- Bed frame[s]
- Door knob[s]
- [Baby] [Children's] Toys
- Lamp[s]
- Desk[s]
- Wheelchair[s]

Picture Icons

Bathroom Surfaces	Kitchen Surfaces	Kitchen Appliances	Floor Surfaces