UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

67619-12 1/14/2006

Page 178

JAN 1 4 2006

Ms. J. Evelyn Lawson Clorox Professional Products Company c/o PS &RC; P.O. Box 493 Pleasanton, CA 94566-0803

Subject:

(

CPPC Tsunami

EPA Registration Number 67619-12

Application Date: 10/13/05 Receipt Date: 10/17/05

Dear Ms. Lawson:

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

 To add additional organisms (Clostridium difficile, Streptococcus pneumoniae, and Avian Influenza A virus) to your label.

Conditions

- 1. On front panel, center the signal word "CAUTION" underneath "Keep Out Of Reach Of Children".
- 2. In the "Ingredient" Statement delete the "s" on Active Ingredients.
- On page 4, change "bathroom wipe" to read: "For use on bathroom surfaces" and "nursery wipe" to read: "For use on nursery surfaces".
- 4. You must place a "net weight" or "net content" on your label.
- 5. The label needs to be revised to comply with DIS/TSS-18 (Label Requirements for Farm Premise Disinfectants) and DIS/TSS-19 (Label Requirements for Poultry House Disinfectants).

General Comments

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

CONCURRENCES									
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DATE	-31-45	2/13/06			-	***********			
EPA Form 1320-1A (1/90)				Printed on Recycled Paper			OFFICIAL FILE COI		

Should you have any questions or comments concerning this letter, please contact Delores Williams at (703) 308-6372.

Sincerely,

Emily Mitchell Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosures - DIS/TSS-18 and 19 Efficacy Review

3 8-8

Nota: Bold, Italicized text and (Italicized text within parentheses) is information for the reader and is not part of the label. [Bracketed] information and phrase sequence are optional unless specified in 40 CFR 156.10. Variables such as CAPITALIZATION, plurals or singular, bold and Italics are optional unless specified in 40 CFR. The term "wipe(s)", is interchangeable with towel(s), towelette(s) and cloth(s) throughout except for the product brand name which can only be changed by notification or amendment. Listed uses and use sites can be used partially or in their entirety. <u>Underlined text is new.</u> Strike-through (New) means removed.

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CPPC

Sunam

ACCEPTED with COMMENTS EPA Letter Dated:

JAN 1 4 2003

Under the Federal Insecticide. Fungicide, and Rodenticide Act as amended, for the pesticide,

[*Does not include weight of dry wipe.]

KEEP OUT OF REACH OF CHILDREN CAUTION: Liquid causes moderate eye irritation.

See back label for additional precautionary statements

___ Premoistened Wipes

Mtd. for & ©2004 Clorox Professional Products Company, Oakland, CA 94612 Commercial Solutions is a registered trademark of Clorox Professional Products Company, Clorox is a registered trademark of The Clorox Company, Made in the USA EPA Reg. No. 57619-12 EPA Est. No. 5813-CA-03, CA-04, GA-01, 2686-WI-08, 8251-WI-01, WI-02, WI-03, WI-04, WI-05. Actual EPA Est. No. near batch code Visit us at www.cloroxprofessional.com

For use with basic formula and alternates A02, A04, A06,

A08 and A10: Contains no phosphorus.

A0618-4.1

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Liquid causes moderate eye irritation. Do not get in eyes or on clothing. Avoid contact with clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. [[For sensitive skin or prolonged use,] wear gloves.]

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. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For further information, call 1-888-797-7225. -or- Questions? Call 1-888-797-7225.

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not use this product with other chemicals such as ammonia, tollet bowl cleaners, rust removers, or acid, as this releases hazardous gases. [Avoid contact with clothes, fabric, wood, rubber, painted and paper surfaces. Do not use on aluminum, silver or chipped enamel. APPLY CAREFULLY - This product contains bleach. I

STORAGE: Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration.

DISPOSAL: Dispose of wipe in trash after use. Do not flush. Do not reuse empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

DIRECTIONS FOR USE

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

Not for cleaning or sanitizing skin. Do not use as a diaper wipe or for personal cleansing. For surfaces that may come in contact with food, a potable water rinse is required.

DISPENSER DIRECTIONS: Remove lid and discard seal. Insert corner of center sheet through flap opening on lid. DO NOT push finger through opening. Replace lid and pull wipe at an angle. The next sheet pops up automatically. When finished, close lid flap to retain moisture.

DISINFECTION

TO [CLEAN AND] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: Wipe [hard, nonporous] surface to be disinfected. Use enough wipes for treated surface to remain visibly wet for the contact time listed below -or- on label, [Rinse.] Let air dry, Gross filth should be removed prior to disinfecting, (If streaking is observed, wipe with a clean, damp [cloth or] paper towel after appropriate contact time has expired.]

Pathogen: Bacteria *Viruses #Bloodborne Pathogens TB Contact Time: 30 seconds 1 minute 1 minute 2 m	B Parvoviruses Mold/Mildew/Fungi minutes 5 minutes 5 minutes
-----------------------------------------------------------------------------------------------------	-----------------------------------------------------------------

-and/or-

ORGANISMS:

Bacteria:

¹Enterococcus faecalis, vancomycin resistant (VRE)

[ATCC 51575]*
Escherichia coli (E. coli) [ATCC 11229]

'Klebsiella pneumoniae [ATCC 4352]'

Legionella pneumophilia (ATCC 33153)

Listeria monocytogenes [ATCC 19117]

Pseudomonas aeruginosa [ATCC 15442]

Salmonella choleraesuis [ATCC 10708]

'Shigella dysenteriae [ATCC 11835]*

'Staphylococcus aureus [ATCC 6538]*

1 Staphylococcus aureus, methicillin resistant (MRSA) [ATCC 33592]*

1Streptococcus pneumoniae [ATCC 6305]*

Streptococcus pyogenes [ATCC 12344]

Clostridium difficile (Vegetative Form⁵) [ATCC 9689]**

5 Killing the vegetative cells can help reduce the bioburden of Clostridium difficile on environmental surfaces

Viruses Non-enveloped:

*Adenovirus type 2 [ATCC VR-846]

[(Strain Adenoid 6)]**

(common cause of respiratory infections)]

*Human Hepatitis A [(Strain HM-175)]**
*Poliovirus type 1 [ATCC VR-1000]

[(Strain Brunhilde)]**

Rhinovirus type 37 [ATCC VR-1147] [(Strain 151-1)]

[([leading] causative agent of the common cold)]

*Rotavirus [(Strain WA)]

[(causative agent of viral diarrhea)]

Viruses Enveloped:

*Avian Influenza A [ATCC VR-2072]**

*Herpes simplex virus type 2 [ATCC VR-734] [(Strain G)]**

(causative agent of genital herpes)

#HIV type 1 [(Strain HTLV-IIIB)]* # Human Coronavirus [ATCC VR-740]

(Strain 229E))**

[([additional] causative agent of the

common cold)] * # Human Hepatitis B [(as duck HBV)] **

*Influenza A [ATCC VR-544] [(Strain Hong Kong)]**

[(representative of the common flu virus)]

*Respiratory syncytial virus [ATCC VR-26]

[(Strain Long)]*

I(cause of respiratory infections in infants)]

Bloodborne Pathogens:

HIV type 1 [(Strain HTLV-IIIB)]*

*#Human Hepatitis B [(as duck HBV)]**

Mycobacterium:

Mycobacterium bovis BCG (Tuberculosis -or- TB)
[OT 105401]***

Parvoviruses Non-enveloped:

Canine parvovirus [ATCC VR-2017]

[(Strain Cornell)]

Feline panleukopenia virus [ATCC VR-648]

[(Strain Philips-Roxane)]*

[(feline parvovirus)]

Mold, Mildew, Fungi:

Aspergillus niger (ATCC 16404)**** Trichophyton mentagrophytes [ATCC 9533]****

*30 second contact time

**1 minute contact time

***2 minute contact time

****5 minute contact time

5 28

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- (Claims:
٠	(30 second) broad spectrum no-rinse disinfectant for non-food contact su
•	A Clorox breakthrough in [medical/dental/veterinary/health care] bleach disinfection
•	A disinfectant cloth for use on (insert use site(s) from table 1-5)
•	[A] one-step cleaner/disinfectant
•	Aids in reducing -or- in the reduction of cross-contamination between trea surfaces
•	Assures proper dilution strength, product effectiveness and standardizes technique

- · Bactericide -or- Bactericidal
- · Bathroom disinfectant wipes
- . Broad spectrum disinfectant [with Clorox Bleach]
- [Cleans and] disinfects _____ (insert use site(s) from table 1-5)
- [Cleans and] disinfects [hard, nonporous surfaces]
- . Cleans, deodorizes and disinfects
- . Deodorizes by killing the germs that cause odors
- . Disinfecting formula
- · Disinfects [and deodorizes]
- . Disinfects and deodorizes by killing germs and their odors
- Disinfects hard, nonporous surfaces [throughout the _____ (insert use site(s) from table 1-5)]
- Easy and convenient disinfecting (throughout the _____ (insert use site(s) from table 1-5)]
- · Easy, one-step cleaning and disinfecting
- Effective against -or- Kills _____ (insert any organism(s) from table above) [in the presence of organic soit [(5% blood serum)]]
- Effective against -or- Kills a wide range of bacteria including Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa [in the presence of organic soil [(5% blood serum))]
- [Effectively] disinfects [hard, nonporous] [environmental] surfaces
- Eliminates odors at their source (caused by germs -or- bacteria -and/or-mildew)
- Eliminates -or- Reduces odors [caused by germs -or- bacteria -and/or- mildew]
- · Exhibits effective virucidal activity

- irfaces Fungicide -or- Fungicidal
 - · Germicidal disposable wipes
 - Germicide -or- Germicidal
 - · Just wipe to clean and disinfect
 - · Kills bacteria, viruses, mold, mildew
 - Kills many common bacteria and viruses
 - Kills odor-causing bacteria -or- germs
 - . Kills -or- Destroys mold and mildew
 - · Kills -or- Effective against bacteria
 - Kills -or- Effective against germs
 - . Kills -or- Effective against viruses
 - Meets [the disinfection requirements of] OSHA['s] Bloodborne Pathogen Guidelines -or- Standards
 - · Mildeweide -or- Mildeweidal
 - Multi-purpose disinfectant
 - . One-step cleaner and disinfectant
 - . One-step cleaning and disinfecting [saves time]
 - One-step disinfectant cleaner designed for general cleaning and disinfecting hard, nonporous environmental surfaces in health care facilities -or- (insert use site(s) from table 1)
 - · Prevents -or- controls mold and mildew growth
 - Pseudomonocidal
 - · [Ready-to-use] hospital [grade] disinfectant
 - · Reduces the risk of infection and cross-contamination
 - · Staphylocidal
 - . The answer to your disinfecting needs
 - . The easy, convenient way to clean and disinfect with Clorox Bleach
 - [The] quick -and/or- easy -and/or- convenient way to disinfect
 - [This product] controls the spread of germs on most hard, nonporous surfaces
 - This product meets AOAC efficacy testing requirements -or- standards for hospital disinfection
 - Tuberculocide -or- Tuberculocidal
 - Use where control of the hazards of cross-contamination between treated surfaces is of prime importance
 - · Virucide -or- Virucidal

Use Siles: See Tables 1-5.

The following is only for products with medical devices listed on the label:

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.

Special Instructions for Use Against HIV-1

This product kills HIV-1 on precleaned environmental surfaces/objects previously soiled 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 (HIV-1) (associated with AIDS).

Special instructions for using this product to clean and decontaminate against HIV-1 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 Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Allow surfaces to remain wet for 30 seconds, [rinse and] let air dry. For all other organisms, see directions for contact times.

Disposal of Infectious Materials: Use disposable impervious gloves, gowns, masks and eye coverings. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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CLEANING AND STAIN REMOVAL

To clean -and/or- remove stains: Wipe surface with a wipe; [rinse and] let air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel.]

Claims:

- Cleans
- Removes
 - es _____ (insert stain(s)/soil(s) from table below)
- Removes stains

· Coffee [stains]

Stains/Soils:

• Blood • Body oils

• Dead skin

- Dirt
- Fecal matter
- FingerprintsFood residue[s] -or- soil[s]
- Fruit (stains)

- Grease
- Grime
- Laboratory stains
- Mildew stains
- Mold stains

- (Other) common soils -and/or- stains
- [Other] organic matter
- Tea (stains)
- Urine

ALLERGEN DESTRUCTION

To [clean and] destroy specified allergens: Wipe surface. Use enough wipes for treated surfaces to remain visibly wet for 1 minute. [Rinse.] Let air dry. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel after contact time has expired.]

Allergens:

- . Cockroach matter -or- particles
- . Dust mite matter -or- particles
- . Pet dander -or- dog and cat dander

Claime

- . Breaks Down Many Allergens[!]
- . Destroys Many Allergens[!]
- Destroys -or- deactivates dust mite matter -or- particles, cockroach matter -orparticles, and pet dander allergens [found in dust]
- [Penetrates and] breaks down dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens (found in dust)
- Reduces dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens [found in dust]
- · Reduces Many Allergens(!)
- This product kills germs and destroys many allergens while cleaning hard, nonporous surfaces.

GENERAL CLAIMS

- · A solution impregnated in a wiping cloth
- · Bathroom wipes
- . [Clorox] essential for the purest clean
- Convenient
- Disposable
- . Does not contain mercury
- Does not contain nonylphenol ethoxylates (NPEs) -and/or- alkylphenol ethoxylates (APEs)
- Does not contain VOCs
- . Easy and convenient to use
- Easy to handle
- · Eliminates airborne particles associated with sprays
- Eliminates (daily) mixing and measuring
- [For] general use
- . Fresh lingering bleach scent
- · Leaves a fresh bleach scent
- Mercury free
- Moist wipes
- . No measuring
- No mixing

- . Nonyiphenol ethoxylate (NPE) -and/or- alkylphenol ethoxylate (APE) free
- Nursery wipes
- Pre-measured
- · Pre-moistened (towelettes)
- · Ready to use
- . Shelf-stable formula
- · Soft hand feel
- Specifically -or- Specially designed for the Medical/Dental/Veterinary/Health Care industry
- [Strong,] [Durable,] cloth-like wipes
- [Strong,] [Durable,] non-woven disposable cloth
- [Strong,] [Durable,] non-woven wipe does not leave lint on surfaces [following use]
- Suitable for hospital use
- . [Contains] the power of Clorox Bleach
- [The] smell of clean
- VOC free
- VOC's below laboratory detection limits

SURFACE SAFETY CLAIMS

- Safe for use on _____ (insert surface material(s) from table 5)
- Safe on hard, nonporous inanimate environmental surfaces
- Will not harm (titanlum-coated) [medical grade] stainless steel

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TABLE ONE Medical:

USE SITES

Ambulances -or- [Emergency Medical] Transport Vehicles

Anesthesia Rooms -or- Areas

[Assisted Living -or- Full Care] Nursing Homes

CAT Lab(oratories)

Central Service Areas

Central Supply Rooms -or- Areas

Critical Care Units -or- CCUs

Dialysis Clinics

Emergency Rooms -or- ERs

Health Care Settings -or- Facilities

Home Health Care [Settings]

Hospitals

[Hospital] Kitchens

Intensive Care Units -or- ICUs

Laboratories

[Medical] Clinics

Medical Facilities

Medical -or- Physician's -or- Doctor's Offices

Newborn -or- Neonatal Nurseries

Nursing -or- Nurses' Stations

Orthopedics

Outpatient Clinics

Patient Restrooms

Patient Rooms

[Pediatric] Examination Rooms -or- Areas

Pharmacies

Physical Therapy Rooms -or- Areas

Radiology -or- X-Ray Rooms -or- Areas

Recovery Rooms

Respiratory Therapy Rooms -or- Areas

Surgery Rooms -or- Operating Rooms -or-ORs

SURFACES

bed pans

[exam -or- examination] tables

external surfaces of [medical] equipment -or- [medical]

equipment surfaces

external [surfaces of] ultrasound transducers

gurneys

hard, nonporous [environmental] hospital -or- medical surfaces

[hospital -or- patient] bed railings -or- linings -or- frames

IV poles

patient chairs

plastic mattress covers

reception counters -or- desks -or- areas

stretchers

wash basins

wheelchairs

TABLE TWO Dental:

USE SITES

Dental Operatories

Dental -or- Dentist's Offices

SURFACES

dental countertops

dental operatory surfaces

dentist -or- dental chairs

hard, nonporous [environmental] dental surfaces

light lens covers

reception counters -or- desks -or- areas

TABLE THREE Veterinary:

USE SITES

Animal Housing Facilities

Animal Life Science Laboratories

[Animal -or- Pet] Grooming Facilities

Equine Farms

Farms

Kennels

Livestock -and/or- Swine -and/or- Poultry Facilities

Pet Areas

Pet Shops -or- Stores

Small Animal Facilities

Veterinary Clinics -or- Facilities Veterinary Offices

Veterinary -or- Animal Hospitals

SURFACES

animal equipment automatic feeders

cages

external surfaces of [veterinary] equipment

feed racks

fountains

hard, nonporous [environmental] veterinary surfaces

pens

reception counters -or- desks -or- areas

stalls

troughs

veterinary care surfaces

watering appliances



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TABLE FOUR Food Service:

USE SITES

Bars Cafeterias

Commercial -or- Institutional Kitchens

Fast Food Chains -or- Restaurants Food Preparation and Processing Areas

Food [Service -or- Processing] Establishments

Food Serving Areas

Other Food Service Establishments

School Kitchens

Restaurants

SURFACES

any washable (food and non-food contact) surface where disinfection is required

appliances dish racks drain boards food cases food trays freezers hoods

outdoor furniture (excluding wood frames and upholstery)

ovens

refrigerators

microwaves

salad bar sneeze guards stoves -or- stovetops

A potable water rinse is required for food contact surfaces.

Do not use on glassware, utensils, or dishes.

TABLE FIVE Miscellaneous/General:

USE SITES

Airplanes

Blood Banks

Bowling Alleys

Butcher Shops

Churches

Colleges

Correctional Facilities

Day Care Centers

Dormitories

Factories

Funeral Homes

Grocery Stores

Gymnasiums -or- Gyms

Health Club Facilities

Hotels

Industrial Facilities

Laundromats

Laundry Rooms

Locker Rooms

Manufacturing Plants -or- Facilities

Military Installations

Motels

Produce Areas

Public Areas Recreational Centers -or- Facilities

Restrooms -or- Restroom Areas

School Buses Schools

Shelters

Shower Rooms

Storage Rooms -or- Areas

Supermarkets

Trains Universities **SURFACES**

[bathroom] fixtures

[bath|tubs

behind and under counters

behind and under sinks booster chairs

cabinets

ceilings

cell[ular] -or- wireless -or- mobile -or- digital phones

chairs

[computer] keyboards

[computer] monitors

counters -or- countertops

cribs desks

[diaper -or- infant] changing tables

diaper pails

dictating equipment [surfaces]

doorknobs

exterior -or- external toilet surfaces

exterior -or- external urinal surfaces

faucets

floors

garbage -or- trash cans

[grocery store -or- supermarket] carts

hampers hand railings headsets highchairs lamps

linoleum

other telecommunications equipment [surfaces] playpens

shelves showers -or- shower stalls

sinks

stall doors

tables telephones (tiled) walls toilet rims toilet seats

towel dispensers toys

vanity tops -or- vanities

SURFACE MATERIALS

[baked] enamel

chrome

[common] hard, nonporous [household -or

environmental] surfaces

Formica

glass

glazed ceramic [tile]

glazed porcelain

laminated surfaces

Marlite

plastic (laminate) porcelain enamel

stainless steel

synthetic marble

vinyl [tile]

similar hard, nonporous surfaces

except for those excluded by the label

Not Recommended For Use On

-or- Avoid contact with:

aluminum brass

chipped enamel

clear plastic clothes

copper fabric

> natural marble painted surfaces

paper surfaces rubber

sealed granite

silver unfinished wood

wood

80618-4.1