

11/10/2004

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

NOV 10 2004

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Janice L. Dhonau
The Procter & Gamble Company
11530 Reed Hartman Highway
Cincinnati, OH. 45241-2422

SUBJECT: August 13, 2004 Application for Amendment
CSP-3002-3
EPA Registration 3573-77

Dear Ms. Dhonau:

The labelling amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable with the following conditions:

Add the words "Master Label" in brackets and delete all references to Alternate Brand Name.

Change Front Label to Front Panel. Change Back/Side Label to Back/Side Panel.

Change the EPA Registration Number from 3573-XX to 3573-77.

Under precautionary statements add the following sentence to the end of the first paragraph: Remove contaminated clothing and wash clothing before reuse.

Under First Aid insert the word "immediately" between skin and with.

In addition to the label revisions, you submitted a formulation change. Your revised basic Confidential Statement of Formula (CSF) submitted on OMB Form 2070-0060 dated August 11, 2004 is not acceptable and can not replace the most recently approved CSF in our files. The lower certified limit is far beyond the guidelines of 40 CFR § 158.175 and the Sodium and Calcium Hypochlorite Registration Guidance. You must submit a revised CSF. You must determine the percentage of available chlorine and list it under the ingredient statement on your front panel and submit that information as a notification.

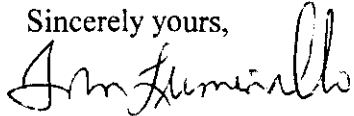
The storage stability study you submitted, MRID 463435-02, is not acceptable and must be repeated and performed under the Good Laboratory Practices statement. However, the Agency will not require the 4 month shelf life statement at this time.

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The Agency has considered the designation of your product as an Toxicity IV for Acute Inhalation and agrees. Copies of our reviews are enclosed.

A copy of your conditionally accepted label is enclosed. Submit a copy of the revised finished label. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,


Emily H. Mitchell
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobial Division (7510-C)

Enclosures

{ Master Labels

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CSP-3002-3 or ~~Alternate Brand Name~~
EPA Registration Number 3573-XX

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FRONT Label

Panel

Active Ingredients: Sodium Hypochlorite.....1.45%
Inert Ingredients:98.55%
Total: 100.00%

~~Available Chlorine~~

KEEP OUT OF REACH OF CHILDREN

CAUTION: EYE AND SKIN IRRITANT. See back/side panel for other precautions.

Net Weight Statement

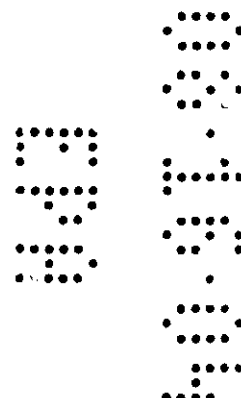
Optional:

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
in EPA Letter Dated:

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BACK/SIDE Label 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].

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, vinyl, painted or paper surfaces, as they will discolor. Rinse immediately after use on metal, old porcelain, or worn countertops to avoid discoloration or pitting.

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. [(For non-disinfecting light\daily [duty] [soil] cleaning, dilute up to 1 part concentrate\product to 9 parts water).] **[FLOORS:** Add 1 cup [concentrate\product] per 1 gallon warm water. Mop and rinse.

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 including the rim to completely wet surfaces], let stand for 5 minutes, then flush.] [For light\daily [duty] [soil] cleaning & disinfecting, dilute 1 part concentrate\product to 4 parts water]

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 including the rim to completely wet surfaces], let stand for 1 minute\60 seconds, then flush.] **Spray and refill containers only:** [For light\daily [duty] [soil] cleaning & sanitizing, dilute 1 part concentrate\product to 4 parts water.]

Use the following usage instructions for concentrate

CONCENTRATED PRODUCT – DILUTE BEFORE USING [(1 gallon makes 5\10 gallons of diluted\disinfecting 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 [DISINFECTING] SOLUTION: Mix 1 part [of this] product\concentrate per 4\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.

ACCEPTED
WITH COMMENTS
m. n. [illegible]

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[illegible]
[illegible]
[illegible]
[illegible]

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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.

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.

FIRST AID: If on skin or clothing, take off contaminated clothing. Rinse skin 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.

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
TM

®
©

[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-XX.
EPA Est. No XXXXXXXX

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Remove contaminated clothing
immediately
and wash
clothing
before
reuse.

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DISINFECTION	
<p>This product is a hospital use\grade\level disinfectant that kills\eliminates\destroys\removes a broad\wide range\spectrum of germs [and viruses]:</p> <p><i>list of and/or options:</i></p> <ul style="list-style-type: none"> • Salmonella choleraesuis\Salmonella • Staphylococcus aureus\S. aureus\Staph • Pseudomonas aeruginosa\Pseudomonas • Hepatitis A\HEP A • Human Immunodeficiency Virus type I <p>\HIV-1\AIDS Virus</p> <p><i>(For products that require dilution only:)</i> 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.]</p> <p>Kills\eliminates\destroys\removes and prevents the spread of <i>list of and/or options:</i></p> <ul style="list-style-type: none"> • Salmonella choleraesuis\Salmonella • Staphylococcus aureus\S. aureus\Staph • Pseudomonas aeruginosa\Pseudomonas • Hepatitis A\HEP A • Human Immunodeficiency Virus type I <p>\HIV-1\AIDS Virus</p> <p><i>(For products that require dilution:)</i> 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.]</p> <p>Cleans and kills\eliminates\destroys\removes <i>list of and/or options:</i></p> <ul style="list-style-type: none"> • Salmonella choleraesuis\Salmonella • Staphylococcus aureus\S. aureus\Staph • Pseudomonas aeruginosa\Pseudomonas • Hepatitis A\HEP A • Human Immunodeficiency Virus type I <p>\HIV-1\AIDS Virus</p> <p><i>(For products that require dilution:)</i> 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.]</p>	<ul style="list-style-type: none"> • 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 [inside and outside] of appliances. • Combines cleaning, disinfecting and stain removal in one\1 product. • Disinfecting bleach cleaner • Disinfectant • Hospital Use\Grade\Level Disinfectant • Bactericide\Bactericidal\Bacteriostat • Virucide\Virucidal\ • Germicide\Germicidal\Germistat

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SANITIZING	
<ul style="list-style-type: none"> 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.] 	<ul style="list-style-type: none"> 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.

GENERAL CLAIMS	
<ul style="list-style-type: none"> 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\Multi-surface\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 	<ul style="list-style-type: none"> A clean you can trust Fresh\pleasant scent Closed chemical container only: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Concentrate 5X Concentrate 10X Concentrate Spray container only: <ul style="list-style-type: none"> For Household Use

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Accepted for registration under
FIFRA Act, 1972, as amended
by the Administrator, EPA
Registration Division, EPA
Washington, D.C. 20460
EPA Reg. No. 3573-77

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

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CLEANING, DEODORIZING & STAIN REMOVAL

- | | |
|---|--|
| <ul style="list-style-type: none"> • Cuts through tough food stains and greasy soils on sinks, counters, cutting boards, 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! | <ul style="list-style-type: none"> • 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 |
|---|--|

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WHERE TO USE	
<p>This product may be used in (<i>list of and/or options</i>)</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 • dairy farms • poultry farms • turkey farms • egg processing plants • veterinary clinics • animal life science laboratories • kennels • breeding and grooming establishments • pet/animal quarters • zoos • pet shops • churches • manufacturing facilities • military installations • blood banks

APPROVED
FOR DISTRIBUTION
BY EPA REGION 10

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Task Areas	
<p>Task areas:</p> <ul style="list-style-type: none"> • Restroom surfaces • Kitchen surfaces • Porcelain • Fiberglass • Ceramic • Stainless Steel • Floors [no wax] [and/or] [washable] • [Glazed] [Ceramic] Tile • Vinyl Tile • Linoleum • Resilient flooring • [Synthetic] [Cultured] marble • [Inside] [or] [Outside] of appliances [such as] [refrigerators] [microwaves] [freezers] • Salad bar sneeze guard[s] • Food serving area[s] • Outdoor furniture • Wading pool[s] • Plastic mattress cover[s] • Telephone[s] • Pet dishes • Pet soiled surface[s] • Patient chair[s] • Examination table[s] 	<ul style="list-style-type: none"> • Toilets • Urinals • Countertops • Sinks • Showers/Tubs • Cutting boards • Appliances • Laminated surface[s] • Plastic laminate • Sealed Granite • Enamel • Plastic • 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
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ACCEPTED
WITH COMPLAINTS
in EPA Letter Date:

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