

page 139



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

September 2, 2005

Julie M. Froelicher Regulatory Affairs The Proctor & Gamble Company 5299 Spring Grove Avenue Cincinnati, OH 45217

Subject:

Comet Disinfecting Bathroom Cleaner

EPA Registration Number 3573-54 Application Date: August 10, 2005 Receipt Date: August 11, 2005

Dear Ms. Froelicher:

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

Proposed Amendment

Minor label revisions

General Comment

Submit three (3) copies of your final printed labeling for the file.

Should you have any questions concerning this letter, please contact me at (703) 308-6422 or Lisa McKelvin at (703) 308-7496.

Sincerely,

Adam Heyward

Product Manager 34

Regulatory Management Branch II
Antimicrobials Division (7510C)

August 10, 2005 Page 1 of 8 239

FRONT LABEL

COMET DISINFECTING BATHROOM CLEANER \ alternate brand name \ product name

*Cleaning Agents, Quality Control Agents, Perfume and Water.

KEEP OUT OF REACH OF CHILDREN

CAUTION: MAY BE HARMFUL IF SWALLOWED. See back \ side panel for other precautions.

Net Weight Statement

[Optional]:

For containers that display disinfecting usage instructions or claims:

Ready-to-Use

Refill

Disinfectant

Hospital Use \ Hospital Grade \ Hospital Level \ Medical Environment Disinfectant

For containers intended for dilution (no disinfecting instructions):

For Automatic Dilution

Concentrate

5X Concentrate

41 (P&G identification number)

For any container:

Bactericide\Bactericidal

Sanitizer

Institutional

Commercial

P&G ProLine \ Procter & Gamble Professional [or logo]

For Institutional Use \ For Industrial and Institutional Use

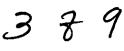
ACCEPTED
with COMMENTS
EPA Letter Dated:

SEP - 2 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 3573-5H

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

August 10, 2005 Page 2 of 8



BACK\SIDE LABEL

COMET DISINFECTING BATHROOM CLEANER \ alternate brand name \ product name

Note to reviewer: The Directions for Use on the final product label will display one of the two sets of general cleaning directions listed below. The Direction for Use with either display the bullet points of general cleaning directions (up to and including the "For best results \ On tougher soils..." paragraph) OR the alternate general cleaning directions beginning with the "GENERAL CLEANING [DIRECTIONS]...." paragraph up to and including the "Rinse all [kitchen] surfaces...." paragraph. The final product label will then display the "TO [CLEAN AND] DISINFECT (hard, non-porous surfaces)..." directions on the ready-to-use containers, or the "TO [CLEAN AND] SANITIZE (hard, non-porous surfaces)..." directions on any container to complete the Directions for Use.

DIRECTIONS FOR [HOUSEHOLD] [INSTITUTIONAL] [COMMERCIAL] USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- Lift flap and lock into arrow on top of sprayer. Picture of sprayer top. [or for gallon size refill container only: Refill [into] properly labeled spray bottle[s]. \Refill [only] [properly labeled] [product name] spray bottle[s]. Picture of refill process.]
- Spray soiled surface until thoroughly covered [Picture of spraying action]
- Wipe with a damp cloth [or sponge]... for a shiny clean surface [or Spray soiled surfaces until thoroughly covered and wipe with a damp cloth [or sponge] [Picture of wiping action on bathroom surface]

For best results \ On tougher soils, allow product to remain on surface longer [or allow to soak]. [For daily cleaning, dilute 1 part product to [plus] 3 \ 4 parts water [([1] 8 oz [cup] per 32 oz spray bottle \ 6.4 oz per 32 oz spray bottle)]. Spray and wipe. On tougher soils, use product full strength.]

OR, in place of the above usage instructions, use the following general cleaning directions up to and including the "Rinse all [kitchen]..." paragraph:

DIRECTIONS FOR [HOUSEHOLD] [INSTITUTIONAL] [COMMERCIAL] USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL CLEANING [DIRECTIONS]: Apply to hard, non-porous surfaces. Spray \ Pour directly onto surface [or damp sponge] [or cloth] [or paper towel] [or towel]. Rinse or wipe clean. For [On] tough stains [or soil], let soak \ stand. \ For tougher soils, allow to soak. [(For non-disinfecting light \ daily [duty] [soil] cleaning, dilute up to 1 part concentrate \ product to 9 \ 19 parts water).]

Rinse all [kitchen] surfaces that come in contact with food [such as countertops] with potable water before reuse. [Do not use on utensils, glasses or dishes.]

For ready-to-use containers only:

TO [CLEAN AND] DISINFECT (hard, non-porous surfaces): Clean surfaces prior to disinfecting heavily soiled areas. \ For highly \ 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 for 10 minutes [before wiping]. [TOILET 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 10 minutes, then flush.]

For any container:

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 5 minutes, then rinse or wipe clean. \ Spray product on surface and let stand 5 minutes [before wiping]. [TOILET 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 & sanitizing, dilute \ mix 1 part concentrate \ product to \ with 4 parts water.]

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

August 10, 2005 Page 3 of 8 4 3 9

Additional Directions for Use for closed chemical containers:

CONCENTRATED PRODUCT - DILUTE BEFORE USING [(1 gallon makes 5 gallons of diluted \ sanitizing product)]

ATTACHING THIS PRODUCT TO THE [P&G] [AUTOMATIC] DILUTION CENTER: Remove the [white] shipping cap. [Picture of automatic dilution center process]

DO NOT REMOVE [LIGHT] [GREEN] PLUG FROM BOTTLE THROAT! Screw on [light] [green] dispensing cap from dilution center [product tube]. Push down while twisting.

[PREPARING [SANITIZING] SOLUTION: Dilute \ Mix 1 part [of this] product \ concentrate with [4 parts] water using the [P&G] [AUTOMATIC] dilution center.]

Note to Reviewer: The order of the Directions for Use might differ on the product label from what is listed above, but the content of the information will be the same.

Note to Reviewer: The first aid information provided below is compliant with PR 2001-1 and was submitted to the Agency for review on June 25, 2003.

PRECAUTIONARY STATEMENT: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes eye irritation. Avoid contact with eyes. May be harmful if swallowed. Do not mix with bleach or mildew stain removers as irritating fumes may result.

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 SWALLOWED, drink 1-2 glasses of water and call a doctor or poison control center (product contains an alcohol ethoxylate). Do not induce vomiting unless told to do so by a poison control center or doctor.

Have the product container or label with you when calling or going for treatment.

Note to Reviewer: The boxed format as listed above will be used if label space permits; otherwise, an alternative format will be used to emphasize the text, such as bullet points, increased white space, increased font size or different colors.

STORAGE/DISPOSAL: Store in a cool place. Gallon refill size container and closed chemical container only: [Rinse and] Discard empty bottle in trash. Spray container only: Do not reuse bottle except with [product name] refill. If not refilling, [rinse and] discard in trash.

Recycling logo Bottle made from 35% post-consumer recycled plastic.

[Contains] biodegradable cleaning agents. [Contains] no phosphorus \ phosphate. Will not harm septic tanks.

UPC code Kosher Symbol

тм (8)

©

Phone symbol Questions? [Comments?] [MSDS?] [A Material Safety Data Sheet (MSDS) is available upon request from your supplier.]

[Call Toll-Free] X-XXX-XXXX pgbrands.com [or www.pgproline.com]

MADE IN USA. Distributed by PROCTER & GAMBLE Cincinnati, OH 45202.

EPA Reg. No. 3573-54

EPA Est. No. 3573-MO-1 [or 52379-MI-002] [or a blank box in which the appropriate establishment number is inkjetted at the manufacturing site. This option allows the flexibility to use one supply of product labels for product manufactured at multiple sites. The establishment number ink-jetted into this box would be 3573-MO-1 or 52379-MI-002 depending on where the product is manufactured.]

Patent statement

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

August 10, 2005 Page 4 of 8

Claims for Containers with Disinfecting Instructions (front, back or side label):

DISINFECTION

This product is a hospital use \ hospital grade \ hospital level \ medical environment disinfectant that kills \ eliminates \ destroys \ removes a broad \ wide range \ spectrum of bacteria list of and/or options:

- Salmonella choleraesuis (Salmonella)
- Staphylococcus aureus (Staph)
- Pseudomonas aeruginosa (Pseudomonas)
- Proteus mirabilis (Proteus)
- Escherichia coli \ E. coli

Kills \ eliminates \ destroys \ removes and prevents the spread of *list of and/or options:*

- Salmonella choleraesuis (Salmonella)
- Staphylococcus aureus (Staph)
- Pseudomonas aeruginosa (Pseudomonas)
- Proteus mirabilis (Proteus)
- Escherichia coli \ E. coli

Cleans and kills \ eliminates \ destroys \ removes *list* of and/or options:

- Salmonella choleraesuis (Salmonella)
- Staphylococcus aureus (Staph)
- Pseudomonas aeruginosa (Pseudomonas)
- Proteus mirabilis (Proteus)
- Escherichia coli \ E. coli

- Clean and disinfects
- Disinfects as it cleans
- One step cleaner and disinfectant
- Disinfects [and deodorizes]
- Restroom \ Bathroom disinfectant
- Combines cleaning, disinfecting
- Disinfecting cleaner
- Disinfectant
- Hospital Use \ Hospital Grade \ Hospital Level
 Medical Environment Disinfectant For use on commercial product only
- Bactericide \ Bactericidal
- Disinfects and deodorizes by killing bacteria [and controlling odors]
- Cleans [and] [shines] [and] disinfects [and] [deodorizes] [washable] [restroom \ bathroom] [surfaces] [and] [fixtures]
- One step cleaner & disinfectant

August 10, 2005 Page 5 of 8

Additional claims (front, back or side label):

		ANITIZ	II	٧G
•	Kills \ Eliminates \ Destroys \ Removes [and prevents the spread of] 99.9% of Staphylococcus aureus (Staph) and Enterobacter aerogenes (Enterobac) (For))	Sa Ar Cl
	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].		,	Sa Cle Sa Le

- Kills \ Eliminates \ Destroys \ Removes fand prevents the spread of] 99.9% of bacteria (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].
- Cleans and kills \ eliminates \ destroys \ removes 99.9% of bacteria (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].

- Sanitizer
 - Antibacterial Cleaner
 - Cleaner / sanitizer
 - Sanitizing cleaner
 - Cleans and sanitizes
 - Sanitizes non-food contact surfaces
 - Leaves surfaces [clean and] sanitized

CLEANING AND DEODORIZING CLAIMS

- Cuts through \ Eliminates \ Removes \ Cleans \ Dissolves tough soap scum [and hard water stains] [from bathtubs] [and] [showers] [and] [shower stalls]
- Dissolves \ Cleans \ Cuts through tough [stains] [soap scum] [and] [hard water stains]
- Removes \ Eliminates \ Cleans tough [stains] [soap scum] [and] [hard water stains]
- Cleans [and] [shines] [and] [deodorizes] [washable] [restroom \ bathroom] [surfaces] [and] [fixtures]
- Safely cleans restroom \ bathroom surfaces. such as counters, sinks, tubs, toilet exteriors, showers, floors, etc.
- Cleans without scrubbing
- Restrooms great all-around restroom \ bathroom cleaner
- Makes employee tasks simple, cutting through soap scum [and] [hard water stains]
- Designed to help improve cleaning productivity
- Saves time little to no scrubbing needed!
- Minimizes training time

- Deodorizer
- **Deodorizes**
- Freshens
- Freshens \ Deodorizes as you clean
- Powerful restroom \ bathroom cleaner
- Penetrates [and dissolves] tough soap scum and hard water stains [without scrubbing]
- Penetrates tough restroom \ bathroom soils without scrubbing
- Non-abrasive
- Safely cleans most surfaces
- Designed to improve cleaning productivity
- No scrubbing
- Minimizes training time
- Fewer products no need for separate deodorizer
- Non-abrasive [formula] [won't scratch surfaces]
- Rinses away easily
- Eliminates \ Removes odors caused by bacteria
- Scum buster formula
- Heavy duty formula
- A clean you can trust
- Makes employee tasks \ job \ life simple \ easy
- Powers away soap scum and hard water stains in one step

August 10, 2005 Page 6 of 8

Additional claims (front, back or side label):

NON-PESTICIDAL CLAIMS

- Institutional [size] [use]
- Professional Line \ Pro-Line
- Commercial
- Contains biodegradable ingredients \ cleaning agents
- Not harmful to \ will not harm septic tanks
- Suitable for septic tank systems [and] [wastewater systems] [and] [treatment plants]
- Developed \ Formulated \ Designed for [institutional] [restroom \ bathroom] use
- This product \ Product name complies with consumer volatile organic compound (VOC) \ VOC laws
- [Contains] no bleach

- A clean you can trust
- Fresh \ pleasant scent

For 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

For gallon size refill container and closed chemical container:

Concentrate

For gallon size refill container and closed chemical container that display dilution instructions to achieve sanitizing benefits:

5X Concentrate

For spray container only:

For household use

August 10, 2005 Page 7 of 8

Additional claims (front, back or side label):

	WHERE TO USE						
	is product may be used on [washable] hard non-	•	laboratories				
porous [non-food contact] [exterior] surfaces in (list		•	recreational facilities				
of and/or options)		•	health clubs				
•	Foodservice establishments	•	household areas				
•	Restaurants	•	kitchen exteriors \ exterior surfaces				
•	Bars	•	bathrooms \ restrooms				
•	Cafeterias	•	basements				
•	[institutional] kitchen exteriors \ exterior	•	household garages				
	surfaces	•	automotive garages				
•	fast food operations	•	boats				
•	food storage areas	•	ships				
•	medical environments	•	campers				
•	hospitals	•	RVs				
•	nursing homes	•	Trailers				
•	medical and dental offices and clinics	•	Mobile homes				
•	operation rooms	•	Cars				
•	isolation wards	•	Buses				
•	medical research centers	•	Trains				
•	ambulance	•	Taxis				
•	schools	•	Airplanes				
•	colleges	•	Transportation terminals				
•	dormitories	•	Veterinary clinics				
•	classrooms	•	Kennels				
•	athletic facilities	•	Breeding and grooming establishments				
•	gymnasiums	•	Pet \ animal quarters				
•	locker rooms	•	Zoos				
•	day care centers	•	Pet shops				
•	nurseries	•	Churches				
•	retail establishments	•	Manufacturing facilities				
•	supermarkets	•	Military installations				
•	convenience stores	•	Factories				
•	dressing rooms	•	Motels				
•	laundries	•	hotels				
•	laundromats						
•	office buildings						
•	funeral homes						

August 10, 2005 Page 8 of 8

TASK AREAS						
Task areas:	Toilet exteriors					
Restroom \ bathroom surfaces	Urinal exteriors					
Glazed Porcelain	Countertops					
Fiberglass	• Sinks					
Glazed Ceramic	• Fixtures					
Stainless steel	Showers/Tubs					
[Glazed] [Ceramic] Tile	Shower walls and doors					
Synthetic \ Cultured marble	Laminated surfaces[s]					
Formica	Plastic laminate					
Chrome	Sealed granite					
	Enamel					
**Formica is a registered trademark of the Formica Corporation.	For all other surfaces, test on a small area before use.					
	Do not use on NATURAL MARBLE.					

Picture Icons

Restroom \ Bathroom	Kitchen surfaces	Kitchen appliance	Floor surfaces
surfaces		exteriors	}
(bathtub, shower, sink,			
toilet exterior)			