

3573-54

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 10, 2007

Mary Joy Stuart
Regulatory Affairs
The Procter & Gamble Company
P&G Household Care
5299 Spring Grove Avenue
Cincinnati, Ohio 45217

Subject: Name of Product: Comet Disinfecting Bathroom Cleaner
 EPA Registration No.: 3573-54
 Application Date: 19-Dec-2006
 Receipt Date: 27-Dec-2006

Dear Ms. Stuart:

The following labeling, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable under the conditions of the labeling comments listed below :

Proposed Action:

- Add claim for Avian Influenza A: Claim support by efficacy data.

General Comments

The submitted data (MRID 470160-01) support the use of the product, Comet Disinfecting Bathroom Cleaner, as a disinfectant with virucidal activity against Avian Influenza A virus (H3N2) on hard, non-porous surfaces at full strength with a contact time of 10 minutes in the presence of 5% organic soil.

Note the following Agency's Label Guidance for Antimicrobial pesticides Used against Avian Influenza A as it applies to this product.

Ready-to-Use and Coarse Spray Products – Commercial, Industrial, Institutional, Agricultural and Residential Uses

Avian influenza A label claims will be accepted for these types of products provided efficacy data has been submitted and accepted to support the label claim. It should

be clear that the use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs, and similar "high touch" surfaces.) For uses in hospital/medical/health facilities, the directions for use for hospital disinfection should be followed. For all other use sites, general disinfection directions for use should be followed.

[This applies to the ready-to-use spray form of the product.]

Labeling comments:

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.

[Currently, it is understood that you have not made such claims/statements on the proposed label, however, you should be aware of this policy for future label revisions.]

The following additional changes must be made to the proposed label.

- A) On pages 1 and 4 of the proposed label, delete the terms "Hospital Grade" and "Hospital Level." The product is approved for use in hospital or medical environments, however the terms grade and level imply heightened efficacy which is misleading. This policy is outlined in Subsection 156.10 of 40 CFR under *False or misleading statements* and also in PR Notice 93-06.
- B) On page 2 of the proposed label, add detailed instructions for the method of application of the product under the "To Clean and Disinfect" and the "To Clean and Sanitize" sections. For example, "Thoroughly wet surfaces by cloth, mop, immersion, or spray..."
- C) On page 4 of the proposed label, delete the claim "...prevents the spread of...." From the left column. This claim is misleading. If you wish, you may use the following label language: "Prevents cross contamination of..."
- D) On page 5 of the proposed label, delete the claim "Safely cleans..." from the left and right panels under "Cleaning and Deodorizing Claims." Claims as to the safety of a product are not allowed; this is also outlined in Subsection 156.10 of 40 CFR under *False or misleading statements*.

Other comments:

For detailed information and consideration, refer to the enclosed copy of the EPA AD/PSB Efficacy review dated March 8, 2007.

Submit three (3) copies of the final printed labeling bearing the revisions as stated above. A copy will be stamped and returned for your record.

A stamped copy of the label is enclosed for your records.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6422 or by email at heyward.adam@epa.gov. or Stacey Grigsby by telephone at (703) 305-6442 or by email at: grigsby.stacey@epa.gov.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosures: Stamped label and Efficacy memo

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FRONT LABEL

COMET DISINFECTING BATHROOM CLEANER \ alternate brand name \ product name

ACTIVE INGREDIENTS: Citric acid.....6.0%
INERT INGREDIENTS:.....*94.0%
TOTAL.....100.0%
*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

Virucide\Virucidal

Sanitizer

Institutional

Commercial

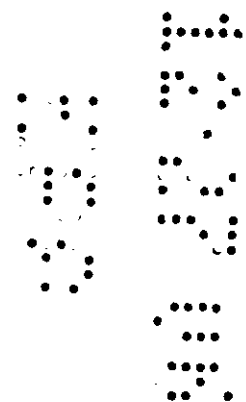
P&G ProLine \ Procter & Gamble Professional [or logo]

For Institutional Use \ For Industrial and Institutional Use

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 10 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 3573-54



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BACKSIDE 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.

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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

™

®

©

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

[Call Toll-Free] X-XXX-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 ink-jetted 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.

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

DISINFECTION	
<p>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 <i>list of and/or options:</i></p> <ul style="list-style-type: none"> • Salmonella choleraesuis (Salmonella) • Staphylococcus aureus (Staph) • Pseudomonas aeruginosa (Pseudomonas) • Proteus mirabilis (Proteus) • Escherichia coli \ E. coli <p>and virus <i>list of options:</i></p> <ul style="list-style-type: none"> • Avian Influenza A [virus] \ Avian Influenza A (H3N2) [virus] <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 (Staph) • Pseudomonas aeruginosa (Pseudomonas) • Proteus mirabilis (Proteus) • Escherichia coli \ E. coli • Avian Influenza A [virus] \ Avian Influenza A (H3N2) [virus] <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 (Staph) • Pseudomonas aeruginosa (Pseudomonas) • Proteus mirabilis (Proteus) • Escherichia coli \ E. coli • Avian Influenza A [virus] \ Avian Influenza A (H3N2) [virus] 	<ul style="list-style-type: none"> • 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 <i>For use on commercial product only</i> • Bactericide \ Bactericidal • Virucide \ Virucidal • 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

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Additional claims (front, back or side label):

SANITIZING	
<ul style="list-style-type: none"> Kills \ Eliminates \ Destroys \ Removes [and prevents the spread of] 99.9% of Staphylococcus aureus (Staph) and Enterobacter aerogenes (Enterobac) (<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]. Kills \ Eliminates \ Destroys \ Removes [and prevents the spread of] 99.9% of bacteria (<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]. Cleans and kills \ eliminates \ destroys \ removes 99.9% of bacteria (<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]. 	<ul style="list-style-type: none"> Sanitizer Antibacterial Cleaner Cleaner / sanitizer Sanitizing cleaner Cleans and sanitizes Sanitizes non-food contact surfaces Leaves surfaces [clean and] sanitized

CLEANING AND DEODORIZING CLAIMS	
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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

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Additional claims (front, back or side label):

NON-PESTICIDAL CLAIMS	
<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• A clean you can trust• Fresh \ pleasant scent <p><i>For closed chemical container only:</i></p> <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 <p><i>For gallon size refill container and closed chemical container:</i></p> <ul style="list-style-type: none">• Concentrate <p><i>For gallon size refill container and closed chemical container that display dilution instructions to achieve sanitizing benefits:</i></p> <ul style="list-style-type: none">• 5X Concentrate <p><i>For spray container only:</i></p> <ul style="list-style-type: none">• For household use

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Additional claims (front, back or side label):

WHERE TO USE	
<p>This product may be used on [washable] hard non-porous [non-food contact] [exterior] surfaces in <i>(list of and/or options)</i></p> <ul style="list-style-type: none"> • Foodservice establishments • Restaurants • Bars • Cafeterias • [institutional] kitchen exteriors \ exterior surfaces • 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 • supermarkets • convenience stores • dressing rooms • laundries • laundromats • office buildings • funeral homes 	<ul style="list-style-type: none"> • laboratories • recreational facilities • health clubs • household areas • kitchen exteriors \ exterior surfaces • bathrooms \ restrooms • basements • household garages • automotive garages • boats • ships • campers • RVs • Trailers • Mobile homes • Cars • Buses • Trains • Taxis • Airplanes • Transportation terminals • Veterinary clinics • Kennels • Breeding and grooming establishments • Pet \ animal quarters • Zoos • Pet shops • Churches • Manufacturing facilities • Military installations • Factories • Motels • hotels

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TASK AREAS	
<p>Task areas:</p> <ul style="list-style-type: none"> • Restroom \ bathroom surfaces • Glazed Porcelain • Fiberglass • Glazed Ceramic • Stainless steel • [Glazed] [Ceramic] Tile • Synthetic \ Cultured marble • Formica • Chrome <p>**Formica is a registered trademark of the Formica Corporation.</p>	<ul style="list-style-type: none"> • Toilet exteriors • Urinal exteriors • Countertops • Sinks • Fixtures • Showers/Tubs • Shower walls and doors • Laminated surfaces[s] • Plastic laminate • Sealed granite • Enamel <p>For all other surfaces, test on a small area before use.</p> <p>Do not use on NATURAL MARBLE.</p>

Picture Icons

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