

71654-2

10-16-2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 16 2001

Nancy B. Lomax  
DuPont Belle Plant  
901 W. DuPont Avenue  
Belle, WV 25314

Subject: DuPont Organic Bowl Cleaner  
EPA Registration No. 71654-2  
Submission Dated July 17, 2001

Dear Ms. Lomax:

This letter is in response to the proposed rationale submitted by E.I. DuPont De Nemours, Inc. with regards to requested Agency changes outlined in the May 31, 2001 conditional registration for this product.

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments outlined below.

Positive Responses to Proposed Amendment for Glycolic Acid:

1. The placement of the **Keep Out of Reach of Children** statement on the label is acceptable.
2. The revised **First Aid Heading** and **First Aid** statements which include the **Note to Physician** are acceptable.
3. The addition of an **EPA Establishment Number** is acceptable.
4. The producers name change to **E.I. duPont de Nemours and Company**, is acceptable.
5. The elimination of the phrases "and skin burns" "and on skin" under the **Hazards to Humans statement** are acceptable.

CONCURRENCES

SYMBOL	7570C						
SURNAME	Mitchell						
DATE	10-16-01						

- 6. *The addition of "safety glasses" as part of the Personal Protective Equipment for this product is acceptable.*
- 7. *The elimination of the phrase "May be fatal if absorbed through skin" has been found acceptable based on the fact that the product as a toilet bowl cleanser would probably be formulated in an aqueous media that would not enhance the dermal absorption of the compounds as would be found in oil-based cosmetics. Additionally, precautions to wear gloves and protective gear appear on the label, limiting the risk from absorption through the skin. Comparative LD50 values for oral and dermal exposure, based on highly conservative estimates indicate that given the dermal absorption of the glycolic acid in an aqueous solution would result in a dermal LD50 of greater than 2000 mg/kg. This dermal LD50, based on laboratory studies and conservative calculations would not support a label statement that the 13.6% glycolic acid would be fatal if absorbed through the skin.*

*An additional consideration in removing or altering the label statement that the product would not be fatal if absorbed through the skin, would be that the exposure in a household setting would probably involve no more than the skin surface area that would be the result of a skin splash.*

- 8. *The inclusion of the sentence "Do not use with chlorine or any other chemical product" is acceptable.*
- 9. *The revised language to include the complete nomenclature of each organism and ATTC designations are acceptable. The replacement of the phrase "such as" with "including" under the claims section is acceptable.*

**Labeling Requirements**

- 1. *The primary brand name change "DuPont™Organic Bowl Cleaner is unacceptable. "Organic" is considered an implied safety claim under the terms of 40 CFR §156.10 (5)(ix), therefore it can not appear as part of the name of the product.*
- 2. *The inclusion of the Environmental Hazards statement is required for this toilet bowl cleaner, because it includes all end use products that may be discharged to the municipal sewer systems. You may however delete the following phrase.*

*"This product is toxic to wildlife, fish, and aquatic invertebrates. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or effluents.*

- 3. *The directions for use for this product must include the statement "Empty toilet bowl water" or use dilution data must be provided. The use directions include the whole toilet including under the rim, and since this product must remain on the surface for 10 minutes it will be diluted into the water.*
- 4. *Delete the marketing safety claim "Made with Organic Acid Disinfectant" from the label.*

*A stamped copy of your labeling is enclosed for your records. Submit one copy of the final printed label prior to release of the product for shipment.*

*If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 308-6345.*

Sincerely,

*Wanda Mitchell*  
for

Robert S. Brennis  
Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510C)66

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**FRONT PANEL**

**DUPONT™ ORGANIC BOWL CLEANER**

ACTIVE INGREDIENT: Glycolic acid _____	13.6%
OTHER INGREDIENTS: _____	86.4%
TOTAL:	100%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**FIRST AID STATEMENTS**

**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 ON SKIN OR CLOTHING:**

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call poison control center or doctor for treatment advice

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

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

**71654-2**

**IF SWALLOWED:**

- Call poison control center or doctor immediately for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

**NOTE TO PHYSICIAN:**

Probable mucosal damage may contraindicate the use of gastric lavage.

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FRONT PANEL, Cont'd.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

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EPA Registration No. 71654-2  
EPA Establishment No. 352-WV-1

E.I. duPont de Nemours and Company

Belle, West Virginia 25015

Net Contents: \_\_\_\_\_

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**SIDE PANEL**

**PRECAUTIONARY STATEMENTS**

**HAZARD TO HUMANS**

**DANGER**

Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear safety glasses, protective clothing, and rubber or chemical resistant gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed. Do not use with chlorine bleach or any other chemical product.

CLEANS & DEODORIZES  
 KILLS GERMS  
 ANTI-BACTERIAL  
 DISINFECTANT  
 DISINFECTING TOILET BOWL CLEANER  
 DISINFECTS THE TOILET BOWL AS IT CLEANS  
 KILLS HOUSEHOLD GERMS INCLUDING STAPHYLOCOCCUS AUREUS ATCC 6538 (STAPH),  
 SALMONELLA CHOLERAESUIS, ATCC 10708 (SALMONELLA), PSEUDOMONAS AERUGINOSA,  
 ATCC 15442 (PSEUDOMONAS), HUMAN IMMUNODIFICIENCY VIRUS TYPE 1 (HIV 1),  
 ESCHERICHIA COLI, ATCC 11229 (E-COLI)  
 CLEANS, DISINFECTS AND DEODORIZES EVEN UNDER THE RIM  
 REMOVES THE STAINS YOU SEE, KILLS THE GERMS YOU DON'T!  
 QUICKLY ELIMINATES TOILET RINGS, HARD WATER STAINS, MINERAL DEPOSITS, AND RUST STAINS  
 HEAVY DUTY CLEANING  
 SAFE FOR WHITE OR COLORED BOWLS  
 DEODORIZES-LEAVES A FRESH, CLEAN SCENT  
 THICK LIQUID  
 REMOVES STUBBORN RUST & HARD WATER STAINS  
 CONTAINS NO PHOSPHATES  
 MADE WITH ORGANIC ACID DISINFECTANT  
 CONTAINS BIODEGRADABLE CLEANING AGENTS  
 BOTTLE MADE OF 25% POST-CONSUMER RECYCLED PLASTIC  
 THICK LIQUID COATS ABOVE AND BELOW THE WATERLINE AND STARTS CLEANING ON CONTACT  
 ERGONOMIC GRIP FOR ULTIMATE CONTROL  
 CLEANS AND DESTROYS LIMESCALE  
 DISINFECTS WITHOUT HARSH CHEMICALS  
 CONTAINS NEUTRAL ODOR\* TO ELIMINATE OFFENSIVE ODORS  
 WILL NOT HARM PLUMBING OR SEPTIC SYSTEMS  
 NON-STAINING FORMULA^

^When in contact with hard, non-porous surfaces or synthetic fibers

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SIDE PANEL, Cont'd.

**DIRECTIONS FOR USE**

**IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT  
IN A MANNER INCONSISTENT WITH ITS LABELING**

**Read the entire label before using this product**

**TO CLEAN AND DISINFECT:**

To use, unscrew cap. Raise toilet seat. Aim **directional** spout under the bowl rim. Squeeze gently, directing at least 2 ounces of product (squeeze **approximately** 12 seconds) evenly to exposed surfaces above the water line and below the rim of the bowl, **not** to the bowl water. Do not dilute with water. Let stand for at least 10 minutes. Brush the entire bowl **and** flush. Replace cap. Rinse brush in fresh bowl water after ease use. If bowl is heavily soiled, **flush and** remove excess dirt and grime before cleaning and disinfecting. Never use with chlorine bleach or **any** other chemical product.

**EFFECTIVE AGAINST HIV-1 (AIDS VIRUS):** Product was evaluated and found to be an effective virucide in the presence of 5% serum **against** the virus HIV-1 (Human Immuno deficiency Virus 1, commonly referred to as "AIDS VIRUS") on inanimate surfaces.

**STORAGE AND DISPOSAL**

Store out of **reach** of children

Do not reuse **empty** container

Wrap empty bottle **and** put in trash or recycle

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