

71654-1

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: Glycolic Acid
EPA Registration No. 71654-1
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 primary brand name change to "DuPont™ Glyclean™AM is acceptable. You must submit a notification for the proposed alternate brand name.
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.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Mitchell						
DATE	10-16-01						

5. *The addition of the phrase "and skin burns" under the Hazards to Humans statement is acceptable.*
6. *The inclusion of the following requested two sentences under the Environmental Hazards statement are acceptable.*

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

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.

Labeling Requirements

1. *Revise the heading under the Precautionary Statements to read: Hazards To Humans And Domestic Animals.*
2. *The word "DANGER:" should precede "Corrosive." under the Hazards to Humans and Domestic Animals statement.*
3. *There was no argument provided for the elimination of the phrase "Harmful if swallowed." Therefore, it should be returned to the label as the last sentence under the "Hazards to Humans and Domestic Animals statement.*

- 4. *The phrase and other surfaces which can found under the Direction For Use is too general. This phrase must be replace every where it appears on the label to read as follows "and other hard non-porous surfaces.*

- 5. *Only the first sentence of the Warranty statement is acceptable all other language must be deleted. Our label review manual specifically indicates that claims which are overly broad are unacceptable. The lines which are unacceptable from your label are, 1) The manufacturer makes no other express or implied warranties either of merchantability or fitness for a particular use. 2) Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow directions will be assumed by the buyer or user. And 3) In no case will the manufacturer or seller be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product. These lines must be either substantially revised or eliminated from your label before this product may be marketed.*

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,



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

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FRONT PANEL

DUPONT™ GLYCLEAN™ AM

ACTIVE INGREDIENT: Glycolic acid _____	70%
OTHER INGREDIENTS: _____	30%
TOTAL:	100%

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

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 16 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 71654-1

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FRONT PANEL, Cont'd.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 71654-1
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 and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed or if absorbed through the skin. Wear protective eyewear (goggles or face shield). Wear protective clothing and rubber or chemical resistant gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to wildlife, fish and aquatic invertebrates. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or effluents. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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SIDE PANEL, Cont'd.

OCT 16 2001
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DIRECTIONS FOR USE

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

**THIS PRODUCT MUST NOT BE USED IN A MANNER THAT COULD RESULT IN THE DIRECT OR INDIRECT
CONTAMINATION OF FOOD PRODUCTS. IF USED ON FOOD PREPARATION SURFACES, ALL FOOD MUST
BE REMOVED PRIOR TO APPLICATION AND THE APPLICATION OF THE END-USE FORMULATIONS MUST
BE FOLLOWED BY A POTABLE WATER RINSE.**

**ONLY FOR USE IN THE FORMULATION OF THE FOLLOWING TYPES
OF LIQUID ANTIMICROBIAL CLEANING PRODUCTS:**

- (1) Household disinfecting cleaners for use in cleaning toilet bowls, bathrooms, floors, and other surfaces.
- (2) Industrial disinfecting cleaners for use in cleaning toilet bowls, bathrooms, floors, walls, ceilings, equipment, piping, and other surfaces.
- (3) Institutional and commercial premises disinfecting cleaners for use in cleaning toilet bowls, bathrooms, floors, walls, ceilings, and other surfaces.
- (4) Disinfecting cleaners for use in agricultural premises and food processing facilities and on food processing equipment. However, label directions must specify that all food, feed, and animals be removed prior to application and that application of the end-use formulation must be followed by a potable water rinse.
- (5) Any use for which U.S.E.P.A. has accepted the required data and/or citation of data that a formulator has submitted in support of registration.
- (6) Uses for experimental purposes that are in compliance with U.S.E.P.A. requirements.

**NOTE: MANUFACTURERS USING THIS PRODUCT TO FORMULATE PESTICIDES ARE RESPONSIBLE
FOR OBTAINING EPA REGISTRATION FOR THEIR FORMULATED PRODUCTS.**

**For formulation of antimicrobial cleaners for use in household, industrial,
institutional, commercial, & agricultural premises, and on food processing facilities
and equipment; use up to 20% Glycolic Acid by weight (100% basis) in an aqueous
solution. Formulation should be performed using a closed system. Labeling on end-use
formulations may direct that end-use product be applied by spraying, mopping, or flooding.**

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SIDE PANEL, Cont'd.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Keep product dry in tightly closed original container when not in use. Use protective clothing, eyewear and chemical resistant gloves when handling damaged or leaking containers or spilled product.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

CONTAINER DISPOSAL: (Metal Containers) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(Plastic Containers) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. **The manufacturer makes no other express or implied warranties either of merchantability or fitness for a particular use.** Handling, storage and use of the product by buyer or user are beyond the control of the manufacturer and seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow directions will be assumed by the buyer or user. **In no case will the manufacturer or seller be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product.**

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**ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 16 2001**

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 171654-1