8/10/1998

SUBJECT: PRODUCT CHEMISTRY REVIEW – Antimicrobials Division
DP Barcode D246354 Reg. No. or File Symbol 71654-R
Manufacturing-Use [✓] OR End-Use Product [ ]

TO: Robert Brennis / Delores Williams
PM Team No. 32

FROM: Anna Skapars, Chemist
Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief
Efficacy and Science Support Branch

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product for use in formulation of liquid antibacterial cleaning products.

A. Confidential Statement of Formula dated 4-15-98 is not in compliance with PR Notice 91-2 and it should be revised and resubmitted.

Submit revised Confidential Statement of Formula and revise lower certified limit for the active ingredient, it should be lower than the nominal concentration and the label claim.

B. Provided product chemistry data in MRID No. 445560-01 provides data for Guideline series 61, 62 and 63. These data are in compliance with 40 CFR part 158.155 through 158.190 and it satisfies product chemistry data for this product.

C. Note to PM:
This product is not cleared by FDA for use on food contact surfaces as terminal sanitizing rinse.

Label should have note that formulators for the end use products for use as food contact surfaces sanitizer must obtain clearance from EPA to use this product as terminal sanitizing rinse.

Anna Skapars
8-10-98

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT [ ] MANUFACTURING-USE PRODUCT [✓]
EPA Reg. No. (or File Symbol No.) 71654-R

Registration [✓] Reregistration [ ]
Case No.: _____

D246354
DP Barcode/Chemist: Anna Skapars

1) 3)

2) 4)

1. Product Name: Glycolic Acid

2. Company: E.I. DuPont De Nemours Co., Inc.

3. Type of Submission: New [✓] Resubmission [ ] Amendment [ ]
"ME-TOO" [ ] Alternate Formulation [ ] REPACK [ ]
Expt Use Permit [ ] Other (Specify)_____

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4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [ ]
  - Are all TGAIs used registered • yes [ ] • no [ ]
- Integrated formulation system [✓]
- If "ME-TOO", specify EPA Reg. No. of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40CFR§180.1001:
• yes [ ] • no [ ]. If yes: • c[ ] • d[ ] • e [ ]
Cleared for non-food use: • yes [✓] • no [ ]

4c. Physical state of product: Liquid

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes [✓] • no [ ]

4e. Density (or bulk density for solids): at •C. 10.6 lb/gal

4f. pH (if dissolved or dispersed in water): 0.1

4g. Flash point and/or flame extension: N/A

4h. NCs and CLs are acceptable: • [✓] • not acceptable [ ]

4i. Active ingredient(s)

	NC	LCL	UCL
A. Hydroxyacetic acid (Glycolic acid)	70%	69%	72%
B.			
C.			
D.			

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have an UCL: • yes [ ] • no [ ] • not applicable [✓]
- All impurities ≥ 0.1% in the product have been identified: • yes [✓] • no [ ] • not applicable [ ]

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5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [✓] • no [ ]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: • yes [ ] • no [✓]
- 1% or more of methyl alcohol: • yes [ ] • no [✓]
- sodium nitrite at any level: • yes [ ] • no [✓]
- a toxic List 1 inert at any level: • yes [ ] • no [✓]
- arsenic in any form: • yes [ ] • no [✓]

5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
• yes [ ] • no [ ] • not applicable [✓]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
• yes [✓] • no [ ] • not applicable [ ]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses: • yes [ ] • no [ ]

6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):
• yes [ ] • no [ ]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/Analytical Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix)[1]	A	445560-01
61-2a Manufacturing Process[2]	A	445560-01
61-2b Formulation Method[3]		
61-3 Discussion of Impurities[4]	A	445560-01
62-1 Analysis[5]	A	
62-2 Certified Limits[6]	A	CSF
62-3 Analytical Method for AIs[7]	A	445560-01

6b. Physical/Chemical Properties		Accept of Data	Value or qualitat descrip[8]	MRID No.
63-3	Physical State	A	Liquid	445560-01
63-7	Density/Bulk Density (g/cc)	A	10.6 lb/gal	
63-12	pH of product [9]	A	0.1	
63-14	Oxid/Red Action	A		
67-15a	Flash Point(°C)[10]	N/A		
63-15b	Flame Extension	N/A		
63-16	Explodability	N/A		
63-17	Storage Stability (% degradation of AIs at 20-30°C for ≥ 1 year)	2 years	A	
63-18	Viscosity	A	11.28 mPa/s 68°F	
63-19	Miscibility (with hydrocarbon solvents)[11]	N/A		
63-20	Corrosivity (specify metals/conditions)	A	Corrosive	
63-21	Dielectric Breakdown Voltage[12]	N/A		

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

Footnotes: 1 See Confidential appendix A for additional information; [2] For MP/EP products produced by an integrated formulation system; [3] For products produced from a TGAI or MP; [4] May be waived unless actual/possible impurities are of tox concern; [5] Five batch analysis required for products produced by an integrated formulation system; [6] If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A; [7] Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc. [8] Provide brief description, e.g., color - yellow or property value, e.g. density 1.25 g/cc. Unless otherwise indicated, the property should be at 25 C ; [9] If product is a water solution or dispersion; [10] Not required for aerosols; [11] Emulsifiable liquids only; [12] For end-use products used near electrical equipment.

Attachment: Confidential Appendix A (page 5).

H7505W:RD:RSB:PCRS:CS-1

cc: Reviewer's Name and Central File (Reg. No. or Rereg Case No.)
1:Rxxxx:Reviewer's Name:Typist Initials:xx/xx/94:703-308-xxxx:Code (Reg or Rereg No).
<PCFORM>

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[redacted]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

GLR #	TITLES		
	Series 61-Product Identity and Composition (40CFR§158.155, 160, 162, 165 & 167)		
61-1	Product Identity & Disclosure of Ingredients	A	445560-01
61-2	Description of Starting Materials & Manufacturing Process	A	445560-01
61-3	Discussion of Formation of Impurities	A	445560-01
	Series 62-Analysis and Certification of Product Ingredients (40CFR§158.170, 175 & 180)		
62-1	Preliminary Analysis of Product Samples	A	445560-01
62-2	Certification of Ingredient Limits		
62-3	Analytical Methods to Verify Certified Limits	A	445560-01
	Series 63-Physical and Chemical Characteristics (40CFR§158.190)		
63-2	Color Light amber	A	
63-3	Physical State Liquid	A	
63-4	Odor Mild - burned sugar	A	
63-5	Melting Point	N/A	
63-6	Boiling Point 112°C (with)	A	
63-7	Density, Bulk Density, or Specific Gravity 10.6 lb/gal	A	
63-8	Solubility	A	
63-9	Vapor Pressure	A	
63-10	Dissociation Constant in Water 1.5×10^{-4} (at 25°C)	A	
63-11	Octanol/Water Partition Coefficient		
63-12	pH		
63-13	Stability to normal + elevated temp.	A	
63-14	Oxidizing or Reducing Action reacts with active metals sodium or potassium to release hydrogen gas	A	
63-15	Flammability	N/A	
63-16	Explodability	N/A	
63-17	Storage stability Stable for 2 years	A	
63-18	Viscosity 11.28 mPa/s at 60°F	A	
63-19	Miscibility miscible with water	A	
63-20	Corrosion Characteristics low corrosivity to common materials	A	
63-21	Dielectric Breakdown Voltage	N/A	

A - Acceptable
W - Waived
NA - Not Applicable
DG - Data Gap

Reviewer: _____

Section Head _____

Date: _____