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**EPA-OTS**  
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 **Gelman Sciences**

OTS DOCUMENT CONTROL  
OFFICE

January 14, 1989

*8EHQ-0189-0761 SUPP.  
PCN 88-89000006  
89-890000081*

Document Processing Center (TS-709)  
Attn: Section 8 (e) Coordinator  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 "M" Street, S.W.  
Washington, D.C. 20460

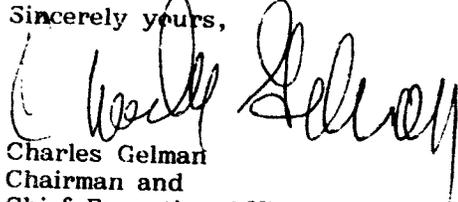
Re: EPA Documentation Control Number: 8EHQ-1088-0761

Gentlemen:

Enclosed are the following documents:

1. A notice we received from Union Carbide Corporation with respect to 1,4-dioxane and polyethylene glycol, dated December 1988.
2. Progress Report on the Analysis of Cosmetic Raw Materials and Finished Cosmetic Products for 1,4-Dioxane, dated September 30, 1981.
3. Progress Report on the Analyses of Ethoxylated Ingredients for 1,4-Dioxane, dated March 31, 1980.

Sincerely yours,

  
Charles Gelman  
Chairman and  
Chief Executive Officer

/dms/EPACon  
Enclosures



**UNION CARBIDE CORPORATION** 38 OLD ROOSEVELT ROAD, DANBURY, CT 06817-0001  
INDUSTRIAL CHEMICALS DIVISION

December, 1988

Dear Union Carbide Customer,

The purpose of this letter is to advise you that our CARBONAX® Polyethylene Glycols above the molecular weight of 200 do not contain toxic chemicals in quantities subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA) and 40 CFR Part 372. However, our CARBONAX® Polyethylene Glycols do contain trace amounts of materials which are included on the State of California's list of carcinogens and reproductive toxicants under the provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65.

The following chart outlines the CARBONAX® Polyethylene Glycols manufactured by Union Carbide and the typical maximum levels of the trace "Proposition 65" materials contained within each product.

	TYPICAL MAXIMUM LEVELS (PPM)			
	ETHYLENE OXIDE	DIOXANE	FORMALDEHYDE	ACETALDEHYDE
CARBONAX® Methoxy Polyethylene Glycols 200 to 2000	5		4	6
CARBONAX® Polyethylene Glycols 200 to 2000	5		4	6
CARBONAX® Polyethylene Glycols 200 to 2000	5		4	6
Polyethylene glycol Carbocel 200	5		4	6
CARBONAX® 1725 990	5		4	6

Please be aware that Ethylene Oxide has been listed by the State of California as a carcinogen and reproductive toxicant. Dioxane, Formaldehyde, and Acetaldehyde have been listed as carcinogens.

We are in the process of updating our Material Safety Data Sheets (MSDSs) to reflect this (and other) right-to-know information, and plan to have these available and distributed within the first quarter of 1989. In the meantime, please add a copy of this letter to each of the MSDSs for those products listed which you have received from us.

Should you have any questions on this information we would be happy to address them. Thank you for your continued business.

Very truly yours,  
Union Carbide Corporation  
Industrial Chemicals Division

*Patricia L. Cody*  
Patricia L. Cody  
Product Safety Manager

PLC/cw  
22380  
MS-0009

September 30, 1981

Progress Report on the Analysis  
of Cosmetic Raw Materials and  
Finished Cosmetic Products  
for 1,4-Dioxane

Division of Cosmetics Technology  
Food and Drug Administration  
200 "C" Street, S.W.  
Washington, DC 20204

This report contains the results of the analyses of the ethoxylated cosmetic raw materials and finished cosmetic products obtained since the March 31, 1980 report. These results were obtained using an atmospheric distillation technique for isolation followed by gas chromatographic determination of 1,4-dioxane (see attached method). The report also contains separate overall summaries of results obtained for both raw materials and finished products as of September 30, 1981, and a summary of all results obtained (raw materials and finished products) from March 31, 1980 to September 30, 1981.

Summary of FDA 1,4-Dioxane  
Analyses of Ethoxylated Cosmetic  
Raw materials\* As of  
September 30, 1981

Samples Found to Contain 1,4-Dioxane at	Number	% of Total
Levels above 100 ppm	22	22
Levels between 10 and 100 ppm	36	36
Levels between 0.5 and 10 ppm	23	23
None detected	<u>19</u>	<u>19</u>
Total number of samples analyzed	100	100

Summary of FDA 1,4-Dioxane  
Analyses of Finished Cosmetic  
Products\* As of  
September 30, 1981

Samples Found to Contain 1,4-Dioxane at	Number	% of Total
Levels above 100 ppm	2	18
Levels between 10 and 100 ppm	5	46
Levels between 0.5 and 10 ppm	1	9
None detected	<u>3</u>	<u>27</u>
Total number of samples analyzed	11	100

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Summary of FDA 1,4-Dioxane  
Analyses of Ethoxylated Cosmetic  
Raw Materials and  
Finished Cosmetic Products\*  
from March 31, 1980 to  
September 30, 1981

Samples Found to Contain 1,4-Dioxane at	Number	% of Total
Levels above 100 ppm	16	39
Levels between 10 and 100 ppm	18	44
Levels between 0.5 and 10 ppm	2	5
None Detected	<u>5</u>	<u>12</u>
Total number of samples analyzed	41	100

\*Samples analyzed by the Division of Cosmetics Technology,  
Food and Drug Administration

Results of Analyses of  
Ethoxylated Cosmetic  
Ingredients for 1,4-Dioxane

Division of Cosmetics Technology  
Food and Drug Administration  
200 "C" Street, S.W.  
Washington, DC 20204

September 30, 1981

Ingredient/Trade Name (Lot No.)	Manufacturer	1,4-Dioxane PPM
Ammonium Laureth Sulfate		
Carsonol SES-A (13879-1)	Quad Chemical	1282*
Conco Sulfate WEM-60 (E160)	Continental Chemical	465
Steol CA-460 (51286)	Stepan	288
Sodium Laureth Sulfate		
Carsonol SES-S (7939)	Quad Chemical	340
Steol 4N (79944)	Stepan	315
Conco Sulfate WE (K209)	Continental Chemical	277
Steol CS-460 (51285)	Stepan	255
Maprofix ESY (480-304)	Onyx	187
Genapol LRO	American Hoechst	158
Maprofix ES (480-432)	Onyx	89
Steol CS-125 (L-01102)	Stepan	69

\*Confirmed by GC-MS

Ingredient/Trade Name (Lot No.)	Manufacturer	1,4-Dioxane PPM
Ammonium Laureth-12 Sulfate		
Standapol 230-E (Y-8024)	Henkel	23
Sodium Laureth-12 Sulfate		
Standapol 130-E (Y-8967)	Henkel	6
Ammonium Myreth Sulfate		
Standapol EA-40 (Y-9306)	Henkel	62
Sodium Myreth Sulfate		
Standapol ES-40 (Y-9321)	Henkel	60
Ammonium Pareth-25 Sulfate		
Ultra Sulfate AE-3 (U-3093)	Witco	238
Sodium Pareth-25 Sulfate		
Witcolate 1050 (K0931)	Witco	74
Sodium Octoxynol-3 Sulfonate		
Triton X-200 (6-1576; L-2-8681)	Rohm and Haas	70
Amphoteric-5		
Miranol 2MCT (6754D80)	Miranol	115
Amphoteric-6		
Miranol 2MCA (6842D80)	Miranol	ND

Ingredient/Trade Name (Lot No.)	Manufacturer	1,4-Dioxane PPM
<b>Amphoteric-14</b>		
Miranol 2MHT (6861D80)	Miranol	62
<b>Amphoteric-17</b>		
Miranol MHT (6770D80)	Miranol	63
<b>PEG-3 Cocamide</b>		
Amidex C-2 (51297)	Stepan	72
<b>PEG-8 Oleate</b>		
Sponso H-44C (4161)	Witco	234
<b>Trilaureth-4 Phosphate</b>		
Hostaphat KL-340	American Hoechst	60
<b>Disodium Monolaureth Sulfosuccinate</b>		
Emcol 4300 (WS-1420)	Witco	ND
<b>No CTFA Adopted Name</b>		
Varonic LI-48 (8347-K; Code 184375)	Sherex	353
<b>No CTFA Adopted Name</b>		
Varonic LI-63 (9331-K; Code 659270)	Sherex	180
<b>No CTFA Adopted Name</b>		
Varonic LI-67 (027-K; Code 659275)	Sherex	20
<b>No CTFA Adopted Name</b>		
Miranol BT (6226D80)	Miranol	58

ND = None detected

Results of Analyses of  
Finished Cosmetic Products  
for 1,4-Dioxane

Product FDA Sample # Manufacturing Code	Manufacturer or Distributor	Amount of 1,4-Dioxane PPM	Date of Analysis
Azuree Single Application Natural Shampoo DCST 81-1812 Lot # A90B	Estee Lauder New York, NY	66*	3/29/81
Jean Nate Bath Gel DCST 81-1819 Lot # 0973	Charles of the Ritz Group, Ltd. New York, NY	36*	4/7/81
Phisoderm Skin Cleanser and Conditioner DCST 81-1820 Lot # 918TE	Winthrop Labs New York, NY	140*	4/7/81
Aramis Malt-Enriched Shampoo Concentrate DCST 81-1821 Lot # D50B	Aramis, Inc.	279*	4/7/81
Peoples Peach Concentrated Foam Bath DCST 81-1822 Lot # 415KO	Peoples Drug Store, Inc. Alexandria, VA	64	4/15/81
Liquid Jojoba Foundation INV 81-219-278 Lot # A5	Cosmetic Sciences, Inc. Rancho Cucamonga, CA	ND	4/15/81
Avido Hair Dressing 81-280-216 Lot # 1149	Hub States, Corp. Indianapolis, IN	2	4/15/81
Fresh 'n Fancy Disco Red Cream and Fresh 'n Fancy White Mixing Cream 81-159-051 Lot # Red Cream 1121 White Cream 1122	Hasbro Ind., Inc. Pawtucket, RI	White ND Red ND	5/8/81

\*Confirmed by GC-MS

Product FDA Sample # Manufacturing Code	Manufacturer or Distributor	Amount of 1,4-Dioxane PPM	Date of Analysis
Pro-Line Curly Kit Detangling Shampoo 81-266-163 Lot # None	Pro-Line Corp. Dallas, TX	33	5/6/81
Keri Lotion for Hands, Face, Body DCST 80-1698 Lot # 46P124	Westwood Pharamaceuticals inc. Buffalo, NY	ND	6/18/81
Skin Quencher Hand and Body Lotion DCST 80-1699 Lot #77290	Miller-Morton, Co. Richmond, VA	30	6/25/81

ND = None Detected

MARCH 31, 1980

PROGRESS REPORT ON THE ANALYSES OF  
ETHOXYLATED INGREDIENTS FOR 1,4-DIOXANE

Division of Cosmetics Technology  
Food and Drug Administration  
200 "C" Street, S.W.  
Washington, D.C. 20204

SUMMARY OF FDA 1,4-DIOXANE ANALYSES OF  
ETHOXYLATED COSMETIC RAW MATERIALS\*  
March 31, 1980

<u>Samples Found to Contain 1,4-Dioxane at:</u>	<u>Number</u>	<u>% of Total</u>
Levels above 100 ppm	8	11
Levels between 10 and 100 ppm	23	33
Levels between 0.5 and 10 ppm	22	32
None detected	<u>17</u>	
Total	70	

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\* Samples analyzed by the Division of Cosmetics Technology, FDA.

**RESULTS OF ANALYSES OF ETHOXYLATED  
COSMETIC INGREDIENTS FOR 1,4-DIOXANE**

DIVISION OF COSMETICS TECHNOLOGY  
FOOD AND DRUG ADMINISTRATION  
200 C ST., S.W.  
WASHINGTON, D.C. 20204

MARCH 31, 1980

<u>Ingredient/Trade Name<sup>(c)</sup></u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm)<sup>(a)</sup><sup>(b)</sup></u>
<b>Polysorbate 60</b>		
Emsorb 6905 (E-698)	Emery Industries	84
Glycosperse S-20 (818483)	Glyco	6
Tween 60 (7252CL)	ICI America	ND
<b>Laneth-5</b>		
Solulan 5 (135)	Amerchol	1
Polychol 5 (167)	Croda	ND
<b>Laneth-10 Acetate</b>		
Crodalan AWS (37)	Croda	20
Solulan 98 (391)	Amerchol	1
<b>Oleth-20</b>		
Volpo 20 (8019)	Croda	5
Standamul 020 (1-478-M)	Henkel	2

(a) The method used was developed by T.J. Birkel, C.R. Warner and T. Fazio of FDA, J. Assoc. Off. Anal. Chem. 62 930 (1979)

(b) ND, Non-Detected - The sensitivity of the method was 0.5 ppm.

(c) All raw materials tested were ethoxylated substances, i.e. derived from the polymerization of ethylene oxide. Under some conditions 1,4-dioxane is formed as a by-product of the polymerization reaction.

\* Confirmed by GC-MS

<u>Ingredient/Trade Name (c)</u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
Brij 99 (4256 B)	ICI America	1
PEG-75 Lanolin		
Ethoxylan 50 (14258)	Emery Industries	52
Solulan L-575 (154)	Amerchol	ND
Octoxynol-3		
Triton X-35 (Code 6-5721)	Rohm and Haas	18
Igepal CA-420 (82)	GAF Corporation	6
Oleth-2		
Ameroxol OE-2 (112)	Amerchol	3
Brij 92 (6423 B)	ICI America	0.6
PEG-8 Stearate		
Pegospere 400 MS (718230)	Glyco	152*
Kessco PEG 400 Monostearate (2815901)	Armak	23
Cerasynt 600 (5357)	Van Dyk	16
PEG-2 Stearate		
Cerasynt SP (5099)	Van Dyk	5
Kessco Diethylene Glycol Monostearate (2906002)	Armak	ND

<u>Ingredient/Trade Name (c)</u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
<b>Polysorbate 20</b>		
Emorb 6915 (H-786)	Emery Industries	31
Glycosperse L-20 (818733)	Glyco	5
<b>Ammonium Laureth Sulfate</b>		
Standapol EA-3 (9813)	Henkel	207
Sipon EA (A534C7)	Alcolac	405*
<b>Sodium Laureth Sulfate</b>		
Standapol ES-2 (Y-6064)	Henkel	97*
Maprofix 60S	Onyx	71*
<b>Coceth-6</b>		
Promulgen D (2019-D)	Robinson Wagner	ND
Promulgen G (2003-G)	Robinson Wagner	ND
<b>Polysorbate 85</b>		
Emorb 6903 (E-733)	Emery Industries	194
<b>PEG-12 Stearate</b>		
Pegosperse 600 MS (919053)	Glyco	3
<b>PEG-75 Lanolin Oil</b>		
Lantrol AWS (E-384 Code 1692)	Emery Industries	72

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<u>Ingredient/Trade Name (c)</u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
PEG-8 Laurate (and) PEG-4 Oleate		
Emulsynt 2400 (5079)	Van Dyk	31
PEG-150 Distearate		
Kessco PEG 6000 Distearate (2909301)	Arnak	ND
Polysorbate 81		
Glycosperse 0-5 (717967)	Glyco	2
PEG-20 Stearate		
Cerasynt 840 (5437)	Van Dyk	3
Steareth-20		
Brij 78 (6212 B)	ICI America	ND
PEG-6 Cocamide		
Amidox C-5 (79804)	Stepan	133
Oleth-3		
Volpo 3 (644)	Croda	18
Laneth-16		
Solulan 16 (164)	Amerchol	ND
Polysorbate 80		
Glycosperse 0-20 (919030)	Glyco	17

<u>Ingredient/Trade Name<sup>(c)</sup></u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
PEG-8 Dioleate		
Emerest 2648 (G-789)	Emery Industries	11
PEG-3 Lauramide		
Amidox L-2 (51104)	Stepan	44
Laureth-23		
Brij 35 (6433 B)	ICI America	5
Oleth-20 and Methoxydiglycol		
Emery 6802 (E-070-M)	Emery Industries	ND
PEG-40 Sorbitan Peroleate		
Arlatone T (116)	ICI America	3
PEG-6 Lauramide		
Amidox L-5 (79428)	Stepan	636*
PEG-40 Lanolin		
Ethoxygel 50 (2232-20E Code 1684)	Emery Industries	246*
PEG-20 Lanolin		
Atlas G-1790 (6616 D)	ICI America	18*
PEG-100 Stearate		
Myrj 59 (6223 C)	ICI America	32*

<u>Ingredient/Trade Name (c)</u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
Oleth-5		
Volvo 5 (509)	Croda	10*
Octoxynol-1		
Triton X-15 (Code 6-5721)	Rohm and Haas	1*
Nonoxynol-10		
Igepal CO-660 (81)	GAF Corporation	4*
Sodium Nonoxynol-4 Sulfate		
Alipal CO-433 (82)	GAF Corporation	16*
Octoxynol-5		
Triton X-45 (Code 6-1571)	Rohm and Haas	42*
Oleth-25		
Siponic Y-500-70 (B-472 P7)	Alcolac	ND
PEG-2 Cocoamine		
Ethomeen C/12 (1812801)	Armak	4*
PEG-50 Tallow Amide		
Ethomid HT/60 (1507401)	Armak	28
Octoxynol-9		
Triton X-100 (Code 6-1572)	Rohm and Haas	23*

<u>Ingredient/Trade Name (c)</u> <u>(Lot No.)</u>	<u>Manufacturer</u>	<u>1,4-Dioxane</u> <u>(ppm) (a) (b)</u>
<b>Ceteareth-10</b>		
Siponic E-5 (B880F7)	Alcolac	0.8
<b>Nonoxynol-15</b>		
Igepal CO-730	GAF Corporation	4
<b>Nonoxynol-50</b>		
Igepal CO-970 (81)	GAF Corporation	1
<b>PEG-2 Oleyl Quaternium-4</b>		
Ethoquad O/12 (1815504)	Armak	ND
<b>Ammonium Nonoxynol-4 Sulfate</b>		
Alipal CO-436 (82)	GAF Corporation	580 *
<b>PEG-15 Cocamine</b>		
Ethomeen C/25 (1901903)	Armak	35 *
<b>PEG-75</b>		
Carbowax 4000 (221825)	Union Carbide	ND
<b>Pareth 25-3</b>		
Neodol 25-3 (14200-24-18A)	Shell Chemical	ND
<b>Pareth 25-7</b>		
Neodol 25-7 (14200-25-19A)	Shell Chemical	ND

Ingredient/Trade Name (c)  
(Lot No.)

Manufacturer

1,4-Dioxane  
(ppm) (a) (b)

No CTFA Adopted Name

Neodol 25-9  
(14200-26-20A)

Shell Chemical

ND

No CTFA Adopted Name

Atpeg 400  
(111)

ICI Americas

ND