
Safety Assessment of PEG Stearates as Used in Cosmetics

Status: Re-Review for Panel Consideration
Release Date: September 6, 2024
Panel Meeting Date: September 30 – October 1, 2024

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Preethi Raj, M.Sc., Senior Scientific Analyst/Writer, CIR.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Preethi S. Raj, M.Sc.,
Senior Scientific Analyst/Writer, CIR
Date: September 6, 2024
Subject: Re-Review of the Safety Assessment of PEG Stearates as Used in Cosmetics

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of 10 PEG Stearates in 1983 (identified as *originalreport_PEGStearates_092024* in the pdf). The Panel concluded, on the basis of the available information presented in the report, that PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates are safe as cosmetic ingredients in the present practices of concentration and use. The Panel previously considered a re-review of this report in November 2002 and re-affirmed the 1983 conclusion, as published in 2005 (*rereview2005_PEGStearates_092024*). At that time, 20 more PEG Stearate ingredients were added to this group (PEG-3, -4, -5, -6-32, -7, -9, -10, -14, -15, -18, -23, -25, -30, -35, -36, -45, -55, -75, -90, and -120 Stearates).

Because it has been at least 15 years since the previous re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel should consider whether the safety assessment of PEG Stearates should be re-opened. In August 2024, an extensive search of the world's literature was performed for studies dated 2000 forward. An historical overview, comparison of original and new use data, the search strategy used, and a synopsis of notable new data are enclosed herein (*newdata_PEGStearates_092024*). Non-cosmetic uses for multiple PEG Stearates, an in vitro study evaluating the effect of PEG-8, -12, and -40 Stearate on penetration enhancement, and an in vitro ocular irritation study on PEG-2 Stearate were found.

Also included for your review are current and historical use data (*usetable_PEGStearates_092024*). Reported frequency and concentrations of use mostly decreased or remained constant for these ingredients, with a few exceptions. Frequency of use significantly increased for PEG-75 and PEG-100 Stearate, which were reported to be used in 1844 and 97 formulations in 2023, respectively, compared to 424 and 6 reported uses in 2002, respectively. The maximum reported concentration of use increased for PEG-20 Stearate, from 4% (in body and hand and in moisturizing products) in 2002 to 10.1% (in tonics, dressings, and other hair grooming aids) in 2023. Several exposure type categories were newly reported in 2023; namely, PEG-2 Stearate was reported to be used in 5 lipstick formulations. In 2023, newly reported uses near the eye included PEG-45 Stearate in 3 eyeliner formulations and at up to 3.2% in mascara and PEG-75 Stearate was reported to be used in 3 eye shadow formulations (concentration of use not reported) and at up to 1% in eye lotions. PEG-40, PEG-75, and PEG-100 Stearate were reported to be used at up to 0.6, 0.75, and 1.4% in the baby lotions, oils, powders, and creams category, respectively; PEG-8 Stearate was reported to have 3 uses in baby lotions, powders, and creams (concentrations of use not reported). PEG-30 Stearate and PEG-150 Stearate were reported to be used at 0.2 and 0.7%, respectively in baby shampoos.

If upon review of the new studies and updated use data the Panel determines that a re-review is warranted, a full Draft Amended Report will be presented at an upcoming meeting.

Re-Review - PEG Stearates - History and New Data

(Preethi Raj – September 2024 Panel meeting)

Ingredients (30)	Citation	Conclusion	Use - New Data	Results	Use - Existing Data	Results	Notes	
PEG-2 Stearate* PEG-3 Stearate PEG-4 Stearate PEG-5 Stearate PEG-6 Stearate* PEG-6-32 Stearate PEG-7 Stearate PEG-8 Stearate* PEG-9 Stearate PEG-10 Stearate PEG-12 Stearate* PEG-14 Stearate PEG-15 Stearate PEG-18 Stearate PEG-20 Stearate* PEG-23 Stearate PEG-25 Stearate PEG-30 Stearate PEG-32 Stearate* PEG-35 Stearate PEG-36 Stearate PEG-40 Stearate* PEG-45 Stearate PEG-50 Stearate* PEG-55 Stearate PEG-75 Stearate PEG-90 Stearate PEG-100 Stearate* PEG-120 Stearate PEG-150 Stearate*	JACT 2(7):17-34, 1983 IJT 24(S1): 74-80, 2005	safe as used not re-opened	<u>PEG-2 Stearate</u> frequency of use (2023) conc of use (2023)	23 uses ≤ 1.5%	<u>PEG-2 Stearate</u> frequency of use (2002) conc of use (2002)	64 uses ≤ 2%	<p>The following 11 ingredients were not reported to be in use in the re-review summary published in 2005 or as of 2023:</p> <ul style="list-style-type: none"> • PEG-3 Stearate • PEG-4 Stearate • PEG-7 Stearate • PEG-9 Stearate • PEG-14 Stearate • PEG-15 Stearate • PEG-18 Stearate • PEG-23 Stearate • PEG-35 Stearate • PEG-36 Stearate • PEG-120 Stearate <p>Reported frequencies and concentrations of use have mostly decreased, or remained constant, with a few exceptions:</p> <ul style="list-style-type: none"> - Frequency of use has significantly increased for PEG-75 Stearate and PEG-100 Stearate <p>New categories/uses as of 2023</p> <ul style="list-style-type: none"> - PEG-2 Stearate had 5 uses in lipstick - PEG-40 Stearate had 3 uses in baby lotions, oils, powders, and creams at ≤ 0.6% - PEG-45 and PEG-75 Stearate were used in 3 formulations near the eye, at up to 3.2 and 1%, respectively <p>Increased concentrations of use</p> <ul style="list-style-type: none"> - PEG-20 concentration of use has increased from ≤ 4% in body and hand products to ≤ 10.1% in hair tonics <p>Newly reported conc of use in 2023</p> <ul style="list-style-type: none"> - PEG-12 Stearate: ≤ 1.8% in non-spray suntan products, - PEG-30 Stearate: ≤ 0.2% in baby shampoos and other baby products - PEG-45 Stearate: 3.2% in mascara - PEG-55 Stearate: 2.3% in non-spray suntan products - PEG-75 Stearate: ≤ 1.2% in non-spray deodorants and non-spray face and neck products 	
			<u>PEG-5 Stearate</u> frequency of use (2023) conc of use (2023)	not reported not reported	<u>PEG-5 Stearate</u> frequency of use (2002) conc of use (2002)	8 uses not reported		
			<u>PEG-6 Stearate</u> frequency of use (2023) conc of use (2023)	10 uses not reported	<u>PEG-6 Stearate</u> frequency of use (2002) conc of use (2002)	22 uses ≤ 6%		
			<u>PEG 6-32 Stearate</u> frequency of use (2023) conc of use (2023)	not reported not reported	<u>PEG 6-32 Stearate</u> frequency of use (2002) conc of use (2002)	34 uses not reported		
			<u>PEG-8 Stearate</u> frequency of use (2023) conc of use (2023)	17 uses ≤ 4%	<u>PEG-8 Stearate</u> frequency of use (2002) conc of use (2002)	18 uses ≤ 3%		
			<u>PEG-10 Stearate</u> frequency of use (2023) conc of use (2023)	not reported not reported	<u>PEG-10 Stearate</u> frequency of use (2002) conc of use (2002)	3 uses not reported		
			<u>PEG-12 Stearate</u> frequency of use (2023) conc of use (2023)	not reported ≤ 1.8%	<u>PEG-12 Stearate</u> frequency of use (2002) conc of use (2002)	19 uses not reported		
			<u>PEG-20 Stearate</u> frequency of use (2023) conc of use (2023)	40 uses ≤ 10.1%	<u>PEG-20 Stearate</u> frequency of use (2002) conc of use (2002)	42 uses ≤ 4%		
			<u>PEG-25 Stearate</u> frequency of use (2023) conc of use (2023)	2 uses not reported	<u>PEG-25 Stearate</u> frequency of use (2002) conc of use (2002)	not reported not reported		
			<u>PEG-30 Stearate</u> frequency of use (2023) conc of use (2023)	9 uses 0.2%	<u>PEG-30 Stearate</u> frequency of use (2002) conc of use (2002)	2 uses not reported		
			<u>PEG-32 Stearate</u> frequency of use (2023) conc of use (2023)	4 uses not reported	<u>PEG-32 Stearate</u> frequency of use (2002) conc of use (2002)	11 uses ≤ 6%		
			<u>PEG-40 Stearate</u> frequency of use (2023) conc of use (2023)	142 uses ≤ 4%	<u>PEG-40 Stearate</u> frequency of use (2002) conc of use (2002)	170 uses ≤ 7%		
<u>Changes to Original List</u>								
*original 1983 report had these 10 ingredients; 20 more were added during the 2005 re-review								

Ingredients (30)	Citation	Conclusion	Use - New Data	Results	Use - Existing Data	Results	Notes
			<u>PEG-45 Stearate</u> frequency of use (2023) conc of use (2023)	3 uses 3.2%	<u>PEG-45 Stearate</u> frequency of use (2002) conc of use (2002)	not reported not reported	
			<u>PEG-50 Stearate</u> frequency of use (2023) conc of use (2023)	not reported 8.5%	<u>PEG-50 Stearate</u> frequency of use (2002) conc of use (2002)	11 uses 9%	
			<u>PEG-55 Stearate</u> frequency of use (2023) conc of use (2023)	4 uses 2.3%	<u>PEG-55 Stearate</u> frequency of use (2002) conc of use (2002)	1 use not reported	
			<u>PEG-75 Stearate</u> frequency of use (2023) conc of use (2023)	97 uses ≤ 1.2%	<u>PEG-75 Stearate</u> frequency of use (2002) conc of use (2002)	6 uses not reported	
			<u>PEG-90 Stearate</u> frequency of use (2023) conc of use (2023)	not reported not reported	<u>PEG-90 Stearate</u> frequency of use (2002) conc of use (2002)	1 use not reported	
			<u>PEG-100 Stearate</u> frequency of use (2023) conc of use (2023)	1844 uses ≤ 6%	<u>PEG-100 Stearate</u> frequency of use (2002) conc of use (2002)	424 uses ≤ 25%	
			<u>PEG-150 Stearate</u> frequency of use (2023) conc of use (2023)	not reported ≤ 6%	<u>PEG-150 Stearate</u> frequency of use (2002) conc of use (2002)	23 uses ≤ 6%	

NOTABLE NEW DATA

Publication	Study Type	Results – Brief Overview	Different from Existing Data?
CHEMISTRY			
USE			
Non-Cosmetic			
https://www.ecfr.gov/ (CFRs cited in: Nikitakis J, Kowcz A. 2024. <i>wINCI: International Cosmetic Ingredient Dictionary and Handbook.</i> http://webdictionary.personalcarecouncil.org/jsp/Home.jsp .)	non-cosmetic use	<ul style="list-style-type: none"> • 21CFR173.340 – safe use as a defoaming agent in food processing <ul style="list-style-type: none"> ○ PEG-40 Stearate • 21CFR175.105 – safe use as adhesive components in food packaging and transport <ul style="list-style-type: none"> ○ PEG-4, -5, -6, -7, -8, -9, -10, -12, -14, -40 Stearate • 21CFR176.170 – safe use as paper components which come in contact with aqueous and fatty foods <ul style="list-style-type: none"> ○ PEG -8, -12 Stearate • 21CFR176.200 - safe use as defoaming agents in coatings related to food packaging and transport <ul style="list-style-type: none"> ○ PEG-2, -8, -40 Stearate • 21CFR176.210 - safe use as defoaming agents used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food <ul style="list-style-type: none"> ○ PEG-2, -4, -6, -8, -12, 20, -32, 40, -100 Stearate • 21CFR177.1200 – safe use in cellophane used for packaging of food <ul style="list-style-type: none"> ○ PEG-8, -12 Stearate 	no CFRs are listed in the original report

NOTABLE NEW DATA

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		<ul style="list-style-type: none"> 21CFR177.1210 – safe use as substance employed in the manufacture of closure-sealing gaskets for food containers (1% limit, expressed as percent by weight of closure-sealing gasket composition) <ul style="list-style-type: none"> PEG-8 Stearate 21CFR177.2260 – safe use as substance employed in the fiber finishing of producing resin-bonded filters used in the producing, manufacturing, processing, and preparing of food <ul style="list-style-type: none"> PEG-8, -9, -10, -12, -14, -18, -20, -25, -30, -32, -35, -36, -40, -45, -50 Stearate 21CFR177.2800 – safe use as substances employed in the production of or added to textiles and textile fibers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food <ul style="list-style-type: none"> PEG-2, -8, -9, -10, -12, -14, -18, -20, -25, -30, -32, -35, -36, -40, -45, -50 Stearate 21CFR178.3910 – safe use as substance used in surface lubricants employed in the manufacture of metallic articles that contact food <ul style="list-style-type: none"> PEG-8 Stearate 																																																																																																																																																																																																																																																			
		<table border="1"> <thead> <tr> <th>PEG Stearate-</th> <th>2</th> <th>4</th> <th>5</th> <th>6</th> <th>7</th> <th>8</th> <th>9</th> <th>10</th> <th>12</th> <th>14</th> <th>18</th> <th>20</th> <th>25</th> <th>30</th> <th>32</th> <th>35</th> <th>36</th> <th>40</th> <th>45</th> <th>50</th> <th>100</th> </tr> </thead> <tbody> <tr> <td>21CFR173.340</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR175.105</td> <td></td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR176.170</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR176.200</td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR176.210</td> <td>♦</td> <td>♦</td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td>♦</td> </tr> <tr> <td>21CFR177.1200</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR177.1210</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>21CFR177.2260</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> </tr> <tr> <td>21CFR177.2800</td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> <td>♦</td> </tr> <tr> <td>21CFR178.3910</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>♦</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	PEG Stearate-	2	4	5	6	7	8	9	10	12	14	18	20	25	30	32	35	36	40	45	50	100	21CFR173.340																		♦				21CFR175.105		♦	♦	♦	♦	♦	♦	♦	♦	♦								♦				21CFR176.170						♦			♦													21CFR176.200	♦					♦												♦				21CFR176.210	♦	♦		♦					♦			♦						♦			♦	21CFR177.1200						♦			♦													21CFR177.1210						♦																21CFR177.2260						♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	21CFR177.2800	♦					♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	21CFR178.3910						♦																
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TOXICOKINETICS STUDIES

Absorption, Distribution, Metabolism, Excretion – Penetration Enhancement

Casiraghi et al. The influence of the polar head and the hydrophobic chain on the skin penetration enhancement effect of poly(ethylene glycol) derivatives. <i>AAPS PharmSciTech.</i> 2012; 13(1): 247 – 253.	Penetration enhancement, in vitro	The effect of PEG-8 Stearate, PEG-12 Stearate, and PEG-40 Stearate upon the permeability of ketoprofen was evaluated in hairless mouse skin. Ketoprofen (10%) was added with either 5, 10, or 20% of each test substance to Franz diffusion cells and dermal penetration was evaluated using ATR-FTIR spectroscopy. A skin membrane tested with only ketoprofen was used as the control. Ketoprofen fluxes and dermal penetration obtained in cells treated with formulations containing PEG-8 Stearate or PEG-12 Stearate were statistically significantly higher than the control. PEG-40 Stearate did not increase ketoprofen flux or penetration at any tested concentration, compared to the control.	the original report does not have penetration enhancement data
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OCULAR IRRITATION STUDIES

https://chem.echa.europa.eu/100.077.74/5/dossier-view/46eb062e-c364-4ac4-badf-302259669ec3/8f160641-cd60-40a7-8be8-d9583624d33d_8f160641-cd60-40a7-8be8-d9583624d33d?searchText=85116-97-8	Ocular irritation, in vitro	An unspecified amount of PEG-2 Stearate was applied (undiluted) to the SkinEthic reconstructed human corneal epithelial model for 10 min. Appropriate negative and positive controls were used and the test was performed in triplicate. At the end of the exposure period, tissues were rinsed with Dulbecco’s phosphate buffered saline and cell viability was measured in an MTT assay. The relative mean viability of tissues treated with PEG-2 Stearate was 95.7%, compared to 38.1% in tissues treated with the positive control. The predicted ocular irritation potential of PEG-2 Stearate was inconclusive.	there is no in vitro ocular irritation data in the original report
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DPS)) OR (Lanoxide-52)) OR (Lipopeg 39-S)) OR (Lumulse POE (40) MS KP)) OR (Myrj S40)) OR (Myrs S40)) OR (Nikkol MYS-40MV)) OR (Nikkol MYS-40V)) OR (Pegosperse 1750 MS)) OR (Protamate 1540 DPS)) OR (Protamate 2000 DPS)) OR (Ritox 52)) OR (ROL 52)) OR (Sabowax SE 40)) OR (Simulsol M 52)) OR (Sympatens-BS/400)) OR (Tego Acid S 40 P)) OR (Unipeg-S-40)) OR (AF 9030E)) OR (Ceral ML)) OR (Ritachol 5000)) OR (SAG 720 antifoam emulsion)) OR (SAG 730 antifoam emulsion)) OR (Silsoft E-Pearl emulsion)) OR (Silsoft E-Pearl PF emulsion)) OR (Silsoft E-Pearl PMF emulsion)) OR (Silsoft Simethicone Emulsion)) OR (Velvesil E-Gel PrF emulsion)) OR (PEG-45 Stearate)) OR (Polyethylene Glycol (45) Monostearate)) OR (Polyoxyethylene (45) Monostearate)) OR (AEC PEG-45 Stearate)) OR (Nikkol MYS-45V)) OR (PEG-50 Stearate)) OR (Polyethylene Glycol (50) Monostearate)) OR (Polyoxyethylene (50) Monostearate)) OR (AEC PEG-50 Stearate)) OR (Lanoxide-53)) OR (Myrj S50)) OR (Ritox 53)) OR (ROL 53)) OR (PEG-55 Stearate)) OR (Polyethylene Glycol (55) Monostearate)) OR (Polyoxyethylene (55) Monostearate)) OR (Nikkol MYS-55V)) OR (Silsoft EMU 103N emulsion)) OR (Silsoft EMU 121N emulsion)) OR (Silsoft EMU 122N emulsion)) OR (Silsoft EMU 8105N emulsion)) OR (Silsoft EMU 8105N PMF emulsion)) OR (Silsoft EMU 8110N PMF emulsion)) OR (Silsoft EMU 9101N emulsion)) OR (Silsoft EMU 9101N PF emulsion)) OR (Silsoft EMU121-NS)) OR (Silsoft HD 689 emulsion)) OR (Silsoft XK-688 emulsion)) OR (Silsoft XS65-C3494 emulsion)) OR (Silsoft XS65-C3494 PF emulsion)) OR (XS65-B3803)) OR (XS65-B3804)) OR (XS65-B4280)) OR (XS65-C5189)) OR (PEG-75 Stearate)) OR (Polyethylene Glycol 4000 Monostearate)) OR (Polyoxyethylene (75) Monostearate)) OR (AEC PEG-75 Stearate)) OR (Prodhybase 4000)) OR (Protamate 4000 DPS)) OR (Unipeg-4000 MS)) OR (Emulium Delta)) OR (Gelot 64)) OR (PEG-90 Stearate)) OR (Polyethylene Glycol (90) Monostearate)) OR (Polyoxyethylene (90) Monostearate)) OR (AEC PEG-90 Stearate)) OR (PEG-100 Stearate)) OR (Polyethylene Glycol 100 Monostearate)) OR (Polyoxyethylene (100) Monostearate)) OR (AEC PEG-100 Stearate)) OR (Botanimulse 100-S)) OR (Hetoxamate SA-100)) OR (Jeemate 4400-DPS)) OR (Lanoxide-59)) OR (Lipopeg-100-S)) OR (Myrj S100)) OR (Protamate 4400 DPS)) OR (Ritox 59)) OR (ROL 59)) OR (Sabowax SE 100)) OR (Simulsol M 59)) OR (Sympatens-BS/1000)) OR (AEC Glyceryl Stearate (& PEG-100 Stearate)) OR (Arlacel 165)) OR (Arlacel 170)) OR (Belsil DADM 3050 E)) OR (Botanimulse 165)) OR (Ceral 165)) OR (Customulse 165)) OR (Dracorin 100 S.E.P. 618240)) OR (Endimulse 165V)) OR (Extan-GMS)) OR (HallStar GMS SE/AS)) OR (Jeechem GMS-165)) OR (Jessperse CPW-GCS)) OR (Lexemul(r) 561 MB)) OR (Lipomulse 165)) OR (Lipowax R-2)) OR (Lonzest MSA)) OR (Megasperse Z)) OR (Mulsifan CGM 165)) OR (Nano Emulsion Concentrate)) OR (Nano Emulsion Concentrate Conditioning)) OR (Nano Emulsion Concentrate DHA)) OR (Nano Emulsion Concentrate J)) OR (Nano Emulsion Concentrate Shine)) OR (Nano Emulsion Concentrate Sun)) OR (Protachem GMS-165)) OR (Ritapro 165)) OR (Sabowax AOG)) OR (Sabowax FL 65/K)) OR (Simulsol 165)) OR (SNP - Nonawax)) OR (Suncaps 664)) OR (Suncaps 903)) OR (Tego Care 165)) OR (Tewax TC 65)) OR (Unitolate 165-C)) OR (PEG-120 Stearate)) OR (Polyethylene Glycol (120) Monostearate)) OR (Polyoxyethylene (120) Monostearate)) OR (AEC PEG-120 Stearate)) OR (PEG-150 Stearate)) OR (Polyethylene Glycol 6000 Monostearate)) OR (Polyoxyethylene (150) Monostearate)) OR (AEC PEG-150 Stearate)) OR (HallStar PEG 6000 MS)) OR (Jeemate 6000 DPS)) OR (Prodhybase 6000)) OR (Unipeg-6000 MS)) OR (Jeecol P)) OR (Procol P)) OR (Ritachol 1000)) OR (Ritachol 5000)) OR (Unicol CPS)) OR (Viscolene)) AND (toxicity) AND (2000:2024[pat])

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
<i>Hair Coloring Preparations</i>																
Hair Dyes and Colors (all types requiring caution statements and patch tests)																
Hair Tints																
Hair Color Sprays (aerosol)																
Hair Lighteners with Color																
Hair Bleaches																
Other Hair Coloring Preparation									NR	1	NR	NR				
<i>Makeup Preparations</i>																
Blushers (all types)																
Face Powders																
Foundations	NR	4	NR	0.2 - 1					NR	1	NR	NR	NR	1	NR	NR
Lipstick	5	NR	NR	NR												
Makeup Bases	NR	1	NR	NR												
Rouges																
Makeup Fixatives																
Other Makeup Preparations	NR	NR	NR	2												
<i>Manicuring Preparations (Nail)</i>																
Cuticle Softeners																
Nail Creams and Lotions																
Other Manicuring Preparations																
<i>Personal Cleanliness Products</i>																
Bath Soaps and Detergents																
Deodorants (underarm)																
Other Personal Cleanliness Products																
<i>Shaving Preparations</i>																
Aftershave Lotion	NR	3	NR	0.4												
Beard Softeners																
Shaving Cream																
Other Shaving Preparations	NR	NR	0.11	NR												
<i>Skin Care Preparations</i>																
Cleansing	NR	6	NR	2					1	1	NR	NR	NR	2	NR	NR
Depilatories																
Face and Neck (exc shave)	NR	1	not spray: 1.5	NR					3	NR	NR	3	NR	1	NR	NR
Body and Hand (exc shave)	8	7	NR	NR	NR	5	NR	NR	2	2	NR	NR	NR	1	NR	NR
Foot Powders and Sprays																
Moisturizing	10	13	NR	NR					1	3	NR	6	NR	6	NR	NR
Night	NR	9	NR	NR					1	3	NR	NR	NR	2	NR	NR
Paste Masks (mud packs)	NR	4	NR	NR	NR	1	NR	NR	NR	1	NR	2 - 3				
Skin Fresheners																
Other Skin Care Preparations	NR	8	NR	NR	NR	2	NR	NR	2	8	NR	NR	NR	5	NR	NR
<i>Suntan Preparations</i>																
Suntan Gels, Creams, and Liquids	NR	2	NR	2									NR	11	NR	NR
Indoor Tanning Preparations	NR	1	NR	1									NR	4	NR	NR
Other Suntan Preparations	NR	1	NR	NR									NR	1	NR	NR

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Totals*	17	18	0.49 – 4	0.5 – 3	NR	3	NR	NR	NR	19	1.2 – 1.8	NR	40	42	0.1 – 10.1	0.2 – 4
summarized by likely duration and exposure**																
Duration of Use																
<i>Leave-On</i>	16	12	0.49 – 4	0.5 – 3	NR	NR	NR	NR	NR	6	1.8	NR	33	25	0.1 – 10.1	0.2 – 4
<i>Rinse-Off</i>	1	6	2	2	NR	3	NR	NR	NR	13	1.2	NR	6	16	0.1 – 0.45	2
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	1	NR	NR
Exposure Type																
<i>Eye Area</i>	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	2	1	NR	NR
<i>Incidental Ingestion</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Incidental Inhalation-Spray</i>	7 ^a ; 7 ^b	6 ^a ; 2 ^b	0.5 ^a	3 ^a ; 0.5 ^b	NR	NR	NR	NR	NR	1 ^a ; 5 ^b	NR	NR	16 ^a ; 9 ^b	2; 13 ^a ; 8 ^b	1.2; 0.1 – 10.1 ^a	3 – 4 ^a ; 0.2 – 4 ^b
<i>Incidental Inhalation-Powder</i>	7 ^b	2 ^b	1.1 – 3 ^c	0.5 ^b	NR	NR	NR	NR	NR	5 ^b	NR	NR	9 ^b	8 ^b	1.1; 2.3 ^c	0.2 – 4 ^b
<i>Dermal Contact</i>	16	14	0.49 – 4	0.5 – 3	NR	1	NR	NR	NR	19	1.2 – 1.8	NR	35	40	1.1 – 2.3	0.2 – 4
<i>Deodorant (underarm)</i>	NR	NR	0.49	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Hair - Non-Coloring</i>	1	3	0.5 – 2	NR	NR	2	NR	NR	NR	NR	NR	NR	4	2	0.1 – 10.1	NR
<i>Hair-Coloring</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Nail</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	NR	NR	NR
<i>Mucous Membrane</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	4	NR	NR
<i>Baby Products</i>	NR	NR	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
as reported by product category																
Baby Products																
Baby Shampoos																
Baby Lotions/Oils/Powders/Creams	NR	NR	3	NR												
Other Baby Products																
Bath Preparations (diluted for use)																
Bubble Baths																
Other Bath Preparations													1	1	NR	NR
Eye Makeup Preparations																
Eyebrow Pencil																
Eyeliners																
Eye Shadow																
Eye Lotion													1	NR	NR	NR
Eye Makeup Remover													NR	1	NR	NR
Mascara	NR	1	NR	NR												
Other Eye Makeup Preparations													1	NR	NR	NR
Fragrance Preparations																
Cologne and Toilet Water																
Perfumes																
Sachets																
Other Fragrance Preparations													NR	2	1.2	NR
Hair Preparations (non-coloring)																
Hair Conditioner	NR	3	2	NR									2	2	0.1 – 0.45	NR
Hair Straighteners																
Rinses (non-coloring)																
Shampoos (non-coloring)					NR	2	NR	NR								
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	0.5	NR									1	NR	0.1 – 10.1	NR
Other Hair Preparations	1	NR	NR	NR									1	NR	NR	NR

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Totals*	2	NR	NR	NR	9	2	0.2	NR	4	11	NR	1 – 6	142	170	0.0001 – 4	0.01 – 7
summarized by likely duration and exposure**																
Duration of Use																
<i>Leave-On</i>	2	NR	NR	NR	9	2	0.2	NR	3	7	NR	2 – 6	136	138	0.0001 – 3	0.5 – 5
<i>Rinse-Off</i>	NR	NR	NR	NR	NR	NR	0.2	NR	1	4	NR	1 – 3	6	32	0.6 – 4	0.01 – 7
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4
Exposure Type																
Eye Area	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	24	6	0.0001 – 2.5	0.8 – 5
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	6	NR	2	2
Incidental Inhalation-Spray	2 ^a	NR	NR	NR	4 ^a	2 ^a	NR	NR	1 ^a ; 2 ^b	5 ^a ; 1 ^b	NR	6 ^a ; 2 – 3 ^b	4; 36 ^a ; 59 ^b	12; 46 ^a ; 36 ^b	2.5; 0.1 – 2.4 ^a	2; 0.5 – 3 ^a ; 0.8 – 5 ^b
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	NR	2 ^b	1 ^b	NR	2 – 3 ^b	59 ^b ; 3 ^c	36 ^b	0.079 – 3 ^c	0.8 – 5 ^b
Dermal Contact	2	NR	NR	NR	9	2	0.2	NR	4	11	NR	1 – 6	132	157	0.0001 – 4	0.01 – 7
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	3 ^a
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	0.2	NR	NR	NR	NR	NR	2	7	0.1	0.5 – 2
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	2	0.6 – 0.9	0.07
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	NR	3
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	NR	NR	6	4	2 – 4	0.01 – 4
Baby Products	NR	NR	NR	NR	NR	NR	0.2	NR	NR	NR	NR	NR	3	NR	0.6	NR
as reported by product category																
Baby Products																
Baby Shampoos					NR	NR	0.2	NR								
Baby Lotions/Oils/Powders/Creams													3	NR	0.6	NR
Other Baby Products					NR	NR	0.2	NR								
Bath Preparations (diluted for use)																
Bubble Baths																
Other Bath Preparations													NR	NR	NR	4
Eye Makeup Preparations																
Eyebrow Pencil													1	NR	NR	5
Eyeliners													2	NR	0.0001 – 2	NR
Eye Shadow													1	NR	0.002	2
Eye Lotion													6	NR	1 – 2.5	1 – 2
Eye Makeup Remover													NR	1	NR	0.8 – 2
Mascara													2	3	0.22 – 1	1
Other Eye Makeup Preparations													12	2	0.98 – 1.8	3 – 4
Fragrance Preparations																
Cologne and Toilet Water																
Perfumes													NR	8	NR	NR
Sachets																
Other Fragrance Preparation													4	4	2.5	2
Hair Preparations (non-coloring)																
Hair Conditioner													NR	4	NR	0.5 – 2
Hair Spray (aerosol fixatives)																
Hair Straighteners													NR	2	NR	NR
Shampoos (non-coloring)																
Tonics, Dressings, and Other Hair Grooming Aids													2	1	0.1	2

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Other Hair Preparations																
<i>Hair Coloring Preparations</i>																
Hair Dyes and Colors (all types requiring caution statements and patch tests)													NR	NR	0.9	NR
Hair Tints																
Hair Color Sprays (aerosol)																
Hair Lighteners with Color													NR	NR	NR	0.07
Hair Bleaches													NR	1	0.6	NR
Other Hair Coloring Preparation													NR	1	NR	NR
<i>Makeup Preparations</i>																
Blushers (all types)													NR	NR	NR	2
Face Powders																
Foundations													NR	6	0.5	2 – 3
Lipstick													6	NR	2	2
Makeup Bases													NR	1	NR	2 – 3
Rouges																
Makeup Fixatives																
Other Makeup Preparations													NR	1	NR	3
<i>Manicuring Preparations (Nail)</i>																
Cuticle Softeners																
Nail Creams and Lotions																
Other Manicuring Preparations													NR	1	NR	3
<i>Personal Cleanliness Products</i>																
Bath Soaps and Detergents													NR	1	4	0.01
Deodorants (underarm)													NR	NR	NR	3
Other Personal Cleanliness Products									NR	1	NR	NR	NR	3	NR	NR
<i>Shaving Preparations</i>																
Aftershave Lotion													NR	15	3	NR
Beard Softeners																
Shaving Cream													NR	1	NR	NR
Other Shaving Preparations									NR	1	NR	NR	NR	2	3	3
<i>Skin Care Preparations</i>																
Cleansing									1	1	1	1	4	9	1 – 2.5	0.8 – 7
Depilatories																
Face and Neck (exc shave)									1	NR	NR	3	23	8	not spray: 0.079 – 2.6	0.8 – 3
Body and Hand (exc shave)									1	1	1	2	36	27	not spray: 0.5 – 3	0.8 – 5
Foot Powders and Sprays									NR	NR	1	NR	NR	1	NR	NR
Moisturizing	2	NR	NR	NR	3	1	NR	NR	NR	5	NR	6	32	34	not spray: 0.033 – 1.6	2 – 3
Night					NR	1	NR	NR	1	NR	1	NR	2	6	not spray: 0.75	2 – 3
Paste Masks (mud packs)									NR	1	NR	3	2	7	2.5	0.8
Skin Fresheners					1	NR	NR	NR								
Other Skin Care Preparations					5	NR	NR	NR	NR	1	NR	NR	4	15	2.8	1 – 2
<i>Suntan Preparations</i>																
Suntan Gels, Creams, and Liquids													NR	1	NR	0.5 – 2
Indoor Tanning Preparations													NR	3	2.4	2
Other Suntan Preparations													NR	1	2	2

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
	PEG-45 Stearate				PEG-50 Stearate				PEG-55 Stearate				PEG-75 Stearate			
Totals*	3	NR	3.2	NR	NR	11	8.5	9	4	1	2.3	NR	97	6	0.15 – 1.2	NR
summarized by likely duration and exposure**																
<i>Duration of Use</i>																
<i>Leave-On</i>	3	NR	3.2	NR	NR	11	8.5	9	2	1	2.3	NR	92	6	0.15 – 1.2	NR
<i>Rinse-Off</i>	NR	NR	NR	NR	NR	NR	NR	NR	2	NR	NR	NR	5	NR	0.3 – 0.68	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>																
<i>Eye Area</i>	3	NR	3.2	NR	NR	NR	NR	NR	NR	1	NR	NR	3	NR	0.6 – 1	NR
<i>Incidental Ingestion</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Incidental Inhalation-Spray</i>	NR	NR	NR	NR	NR	9 ^a ; 1 ^b	NR	NR	2 ^b	NR	NR	NR	58 ^a ; 21 ^b	3 ^a ; 3 ^b	NR	NR
<i>Incidental Inhalation-Powder</i>	NR	NR	NR	NR	NR	1 ^b	NR	NR	2 ^b	NR	NR	NR	21 ^b	3 ^b	0.15 – 1.2 ^c	NR
<i>Dermal Contact</i>	3	NR	NR	NR	NR	11	NR	NR	2	1	2.3	NR	95	NR	0.15 – 1.2	NR
<i>Deodorant (underarm)</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	6	1.2	NR
<i>Hair - Non-Coloring</i>	NR	NR	NR	NR	NR	NR	NR	NR	2	NR	NR	NR	2	NR	0.15	NR
<i>Hair-Coloring</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Nail</i>	NR	NR	NR	NR	NR	NR	8.5	9	NR	NR	NR	NR	NR	NR	NR	NR
<i>Mucous Membrane</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
<i>Baby Products</i>	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.5 – 0.75	NR
as reported by product category																
<i>Baby Products</i>																
<i>Baby Shampoos</i>																
<i>Baby Lotions/Oils/Powders/Creams</i>													NR	NR	0.5 – 0.75	NR
<i>Other Baby Products</i>																
<i>Bath Preparations (diluted for use)</i>																
<i>Bubble Baths</i>																
<i>Other Bath Preparations</i>																
<i>Eye Makeup Preparations</i>																
<i>Eyebrow Pencil</i>																
<i>Eyeliner</i>	3	NR	NR	NR					NR	1	NR	NR				
<i>Eye Shadow</i>																
<i>Eye Lotion</i>													3	NR	0.6 – 1	NR
<i>Eye Makeup Remover</i>																
<i>Mascara</i>	NR	NR	3.2	NR												
<i>Other Eye Makeup Preparations</i>																
<i>Fragrance Preparations</i>																
<i>Cologne and Toilet Water</i>																
<i>Perfumes</i>																
<i>Sachets</i>																
<i>Other Fragrance Preparation</i>																
<i>Hair Preparations (non-coloring)</i>																
<i>Hair Conditioner</i>																
<i>Hair Straighteners</i>																
<i>Rinses (non-coloring)</i>																
<i>Shampoos (non-coloring)</i>									2	NR	NR	NR				
<i>Tonics, Dressings, and Other Hair Grooming Aids</i>																
<i>Other Hair Preparations</i>													2	NR	0.15	NR

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
<i>Hair Coloring Preparations</i>																
Hair Dyes and Colors (all types requiring caution statements and patch tests)																
Hair Tints																
Hair Color Sprays (aerosol)																
Hair Lighteners with Color																
Hair Bleaches																
Other Hair Coloring Preparation																
<i>Makeup Preparations</i>																
Blushers (all types)													2	NR	NR	NR
Face Powders																
Foundations													NR	NR	0.68	NR
Lipstick																
Makeup Bases																
Rouges																
Makeup Fixatives																
Other Makeup Preparations																
<i>Manicuring Preparations (Nail)</i>																
Cuticle Softeners																
Nail Creams and Lotions																
Other Manicuring Preparations					NR	NR	8.5	9								
<i>Personal Cleanliness Products</i>																
Bath Soaps and Detergents																
Deodorants (underarm)													NR	NR	not spray: 1.2	NR
Other Personal Cleanliness Products																
<i>Shaving Preparations</i>																
Aftershave Lotion					NR	1	NR	NR								
Beard Softeners																
Shaving Cream																
Other Shaving Preparations																
<i>Skin Care Preparations</i>																
Cleansing													1	NR	0.3 – 0.68	NR
Depilatories																
Face and Neck (exc shave)					NR	1	NR	NR					15	2	not spray: 0.45 – 1.2 spray: 0.38	NR
Body and Hand (exc shave)									2	NR	NR	NR	6	1	not spray: 0.15 – 0.9	NR
Foot Powders and Sprays																
Moisturizing					NR	8	NR	NR					50	1	not spray: 0.28 – 0.75	NR
Night					NR	1	NR	NR					8	1	NR	NR
Paste Masks (mud packs)													4	NR	0.45 – 0.5	NR
Skin Fresheners																
Other Skin Care Preparations													6	1	0.24 – 0.27	NR
<i>Suntan Preparations</i>																
Suntan Gels, Creams, and Liquids									NR	NR	not spray: 2.3	NR	NR	NR	not spray: 0.45	NR

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Indoor Tanning Preparations																
Other Suntan Preparations																
	PEG-90 Stearate				PEG-100 Stearate				PEG-150 Stearate							
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²				
Totals*	NR	1	NR	NR	1844	424	0.00033 - 6	0.01 - 25	NR	23	0.088 - 6	0.2 - 6				

summarized by likely duration and exposure*****Duration of Use***

<i>Leave-On</i>	NR	NR	NR	NR	1675	299	0.0075 - 6	0.01 - 25	NR	14	0.1 - 0.95	0.4 - 6				
<i>Rinse-Off</i>	NR	1	NR	NR	168	125	0.00033 - 2.5	0.2 - 6	NR	9	0.088 - 6	0.2 - 3				
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	1	NR	1	3	NR	NR	0.15 - 0.75	NR				

Exposure Type

Eye Area	NR	NR	NR	NR	84	19	0.5 - 2.5	0.5 - 4	NR	1	NR	2 - 3				
Incidental Ingestion	NR	NR	NR	NR	7	NR	NR	0.3 - 5	NR	NR	NR	NR				
Incidental Inhalation-Spray	NR	NR	NR	NR	20; 1110 ^a ; 347 ^b	16; 141 ^a ; 60 ^b	0.25 - 1.8; 0.25 - 4.5 ^a	3; 0.01 - 4 ^a ; 0.3 - 5 ^b	NR	1; 7 ^a ; 4 ^b	NR	0.5 - 1 ^a ; 0.8 - 2 ^b				
Incidental Inhalation-Powder	NR	NR	NR	NR	1; 347 ^b ; 7 ^c	60 ^b ; 5 ^c	1.5; 0.25 - 3.3 ^c	0.3 - 5 ^b ; 1 ^c	NR	4 ^b	0.15 - 0.95 ^c	0.8 - 2 ^b				
Dermal Contact	NR	1	NR	NR	1737	365	0.0003 - 3.8	0.01 - 25	NR	14	0.15 - 6	0.5 - 6				
Deodorant (underarm)	NR	NR	NR	NR	NR	3 ^a	2.5 - 3.8	0.5 - 25 ^a	NR	NR	NR	NR				
Hair - Non-Coloring	NR	NR	NR	NR	56	39	0.0065 - 4.5	0.2 - 4	NR	8	0.088 - 0.75	0.2 - 0.4				
Hair-Coloring	NR	NR	NR	NR	23	9	0.98	NR	NR	NR	0.18	NR				
Nail	NR	NR	NR	NR	6	3	2.5 - 6	3	NR	1	NR	NR				
Mucous Membrane	NR	NR	NR	NR	20	24	0.00033 - 2	0.3 - 5	NR	NR	0.15 - 2.3	0.5				
Baby Products	NR	NR	NR	NR	8	5	1 - 1.4	1	NR	NR	0.7	NR				

as reported by product category

<i>Baby Products</i>																
Baby Shampoos									NR	NR	0.7	NR				
Baby Lotions/Oils/Powders/Creams					7	5	1 - 1.4	1								
Other Baby Products					1	NR	NR	NR								
<i>Bath Preparations (diluted for use)</i>																
Bubble Baths									NR	NR	0.75	NR				
Other Bath Preparations					1	NR	1	3	NR	NR	0.15	NR				
<i>Eye Makeup Preparations</i>																
Eyebrow Pencil					1	1	0.5	NR								
Eyeliner					NR	2	NR	1	NR	NR	NR	3				
Eye Shadow					2	NR	NR	NR								
Eye Lotion					50	3	0.57 - 2.5	0.5 - 4	NR	1	NR	NR				
Eye Makeup Remover									NR	NR	NR	2				
Mascara					15	8	0.5 - 2.5	2 - 3								
Other Eye Makeup Preparations					16	5	NR	1 - 3								
<i>Fragrance Preparations</i>																
Cologne and Toilet Water					NR	NR	0.25	NR								

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Perfumes					10	1	NR	3								
Sachets																
Other Fragrance Preparation					10	14	1.2 – 1.8	NR	NR	1	NR	NR				
<i>Hair Preparations (non-coloring)</i>																
Hair Conditioner					15	30	0.023 – 2.5	0.2 – 4	NR	3	NR	NR				
Hair Straighteners					2	NR	NR	NR	NR	2	NR	NR				
Rinses (non-coloring)					1	2	NR	0.6								
Shampoos (non-coloring)					6	NR	0.0065 – 2.1	NR	NR	3	0.088 – 0.75	0.2				
Tonics, Dressings, and Other Hair Grooming Aids					29	2	0.25 – 4.5	NR			0.1					
Other Hair Preparations					3	5	NR	3	NR	NR	NR	0.4				
<i>Hair Coloring Preparations</i>																
Hair Dyes and Colors (all types requiring caution statements and patch tests)					21	2	0.98	NR	NR	NR	0.18	NR				
Hair Tints					NR	1	NR	NR								
Hair Color Sprays (aerosol)					NR	1	NR	NR								
Hair Lighteners with Color					NR	1	NR	NR								
Hair Bleaches					NR	2	NR	NR								
Other Hair Coloring Preparation					2	2	NR	NR								
<i>Makeup Preparations</i>																
Blushers (all types)					NR	NR	1	NR	NR	NR	NR	1				
Face Powders					1	NR	1.5	NR								
Foundations					NR	6	NR	0.5 – 2								
Lipstick					7	NR	NR	0.3 – 5								
Makeup Bases					4	1	NR	NR								
Rouges									NR	NR	NR	0.6				
Makeup Fixatives					1	1	NR	NR								
Other Makeup Preparations					3	NR	NR	4	NR	NR	NR	3				
<i>Manicuring Preparations (Nail)</i>																
Cuticle Softeners					NR	2	2.5	3								
Nail Creams and Lotions					4	1	6	NR								
Other Manicuring Preparations					2	NR	NR	NR	NR	1	NR	NR				
<i>Personal Cleanliness Products</i>																
Bath Soaps and Detergents					7	NR	0.00033 - 2	0.8	NR	NR	0.7	0.5				
Deodorants (underarm)					NR	3	not spray: 2.5 – 3.8	0.5 – 25								
Other Personal Cleanliness Products					5	24	NR	2	NR	NR	2.3	NR				
<i>Shaving Preparations</i>																
Aftershave Lotion					5	1	1.2	0.8 – 2								
Beard Softeners					1	NR	NR	NR								
Shaving Cream					3	NR	2.1	NR								
Other Shaving Preparations					1	1	NR	0.8								
<i>Skin Care Preparations</i>																
Cleansing					80	38	1 – 2	1 – 5	NR	NR	0.5 – 6	2 – 3				
Depilatories					2	NR	NR	NR								
Face and Neck (exc shave)					207	25	not spray: 0.5 – 2.5	0.3 – 5	NR	NR	not spray: 0.4	2				

Frequency (2023/2002) and concentration (2023/2002) of use of PEG Stearates according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²	2023 ¹	2002 ²	2023 ³	2002 ²
Body and Hand (exc shave)					140	34	not spray: 0.25 – 3.3	3	NR	3	not spray: 0.15 – 0.95	0.8				
Foot Powders and Sprays					NR	1	NR	NR	NR	1	NR	NR				
Moisturizing					1010	85	not spray: 0.0075 – 3.2	1 – 3	R	4	NR	0.8 – 1				
Night					56	20	not spray: 0.32 – 1	0.01 – 3	NR	2	not spray: 0.3	0.5 – 1				
Paste Masks (mud packs)	NR	1	NR	NR	23	22	0.0075 – 1.5	2 – 6	NR	1	NR	NR				
Skin Fresheners					5	2	NR	NR	NR	1	NR	NR				
Other Skin Care Preparations					75	38	2.5	0.9 – 3	NR	NR	NR	6				
<i>Suntan Preparations</i>																
Suntan Gels, Creams, and Liquids					5	14	not spray: 1.5	3								
Indoor Tanning Preparations					3	18	1.3	2 – 4								
Other Suntan Preparations					2	NR	NR	NR								

NR – not reported

*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

likely duration and exposure are derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)^a It is possible these products are sprays, but it is not specified whether the reported uses are sprays.^b Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories^c It is possible these products are powders, but it is not specified whether the reported uses are powders.Ingredients not reported to be in use¹⁻³**

PEG-3 Stearate
PEG-4 Stearate
PEG-7 Stearate
PEG-9 Stearate
PEG-14 Stearate
PEG-15 Stearate
PEG-18 Stearate
PEG-23 Stearate
PEG-35 Stearate
PEG-36 Stearate
PEG-120 Stearate

REFERENCES

1. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD [Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023].
2. Andersen FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. *Int J Toxicol*. 2005;24(S1):74-80.
3. Personal Care Products Council. 2024. Updated concentration of use by FDA product category: PEG Stearates. [Unpublished data submitted by Personal Care Products Council on June 18, 2024].

2

Final Report on the Safety Assessment of PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates

The PEG Stearates are the polyethylene glycol esters of stearic acid. These nonionic surfactants are used mainly in cosmetic products as surfactants and emollients at concentrations up to 25%. The PEG Stearates, whose average number of ethylene oxide monomers range from 2 to 150, were nonlethal to test animals up to 10 g/kg. They gave evidence of only low-level skin irritation and minimal eye irritation when tested at 100% concentrations in test animals. PEG-8, -40, and -100 Stearates produced no significant changes in growth mortality rates, histopathologic observations or hematologic values in long-term feeding studies. Multiple generation studies of PEG-8 and -40 Stearates were negative for effects on reproduction; the presence or absence of a carcinogenic effect was not reported.

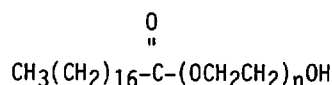
Clinical studies on the PEG Stearates indicated that these ingredients are neither irritants nor sensitizers at concentrations of $\geq 25\%$. There was no evidence of phototoxicity or photosensitization of PEG-2 or -8 Stearates.

It is concluded that PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates are safe as cosmetic ingredients in the present practices of concentration and use.

CHEMICAL AND PHYSICAL PROPERTIES

Structure

The PEG Stearates are the polyethylene glycol esters of stearic acid that conform to the following formula:



The n value corresponds to the average number of ethylene oxide monomers in the polyether chain and is expressed as the identifier for the various PEG Stearates used in cosmetic products. Because the n value is the average value of ethylene oxide monomers, any given PEG Stearate will not have a single chain length, but will contain shorter and longer chain lengths whose average is expressed as the chemical identifier.^(1,2)

Method of Manufacture

The PEG Stearates may be prepared in one of three ways:⁽²⁾

1. PEG-n Stearate is made by esterification of stearic acid and PEG-n under acid catalysis. The catalyst is neutralized following esterification.
2. Stearic acid can undergo direct ethoxylation under alkaline catalysis. The base is neutralized following ethoxylation.
3. Methyl stearate can be catalytically transesterified to polyethylene glycol. After preparation, the product is refined by vacuum stripping and/or filtration.

Properties

The PEG Stearates are soft to waxy solids, white to tan in color, and most have a faint odor. In general, the monoesters are soluble in water and alcohol but not in mineral oil; the diesters are soluble in isopropyl alcohol and toluene, and dispersible or soluble in hot water.

The PEG Stearates are nonionic surfactants.^(3,4) The monostearates are highly amphiphatic compounds. The long, 18-carbon stearate chain is lipophilic; the polyether chain is hydrophilic. Each ether oxygen atom carries a partial negative charge which attracts polar water molecules, thus potentiating water solubility of the monostearate. The longer the polyether chain (greater n value), the greater is the hydrophilicity of the ingredient. The hydrophile-lipophile balance (HLB) value is used to describe the PEG Stearates and facilitate the selection of an ingredient for a particular use. Typical HLB values are 4.3 for PEG-2 Stearate and 18.8 for PEG-150 Stearate.⁽²⁾ As any surfactant interacting at an oil-water interface, PEG Stearates align themselves with the hydrophilic polyether part of the molecule dissolved in the aqueous phase and the lipophilic stearate part of the molecule dissolved in the oil phase. The amphoteric nature of these compounds affords them many of their physical properties and, thus, many of their uses in cosmetic and noncosmetic formulations.^(4,5)

Reactivity

PEG Stearates are relatively stable compounds.⁽⁶⁾ Nevertheless, the ether oxygens are potentially reactive and the ester bonds are potentially vulnerable to enzymatic cleavage.

Impurities

Traces of the reactants, stearic acid and ethylene oxide, and of the catalytic agents used, may remain in the finished product. The addition of antioxidants or other additives has not been reported.⁽²⁾ A reaction product of ethoxylation,

1,4-dioxane, may also be present in trace amounts; industry is aware of this possible impurity and thus uses additional purification steps to remove it from the ingredient before blending into cosmetic formulations.⁽⁷⁾

USE

Noncosmetic Uses

Drugs

There are numerous references for the use of the PEG Stearates in drugs as emulsifiers, carriers and stabilizers. They are used to solubilize salicylic acid and barbital and for dissolution of other poorly soluble pharmaceuticals.^(5,8)

PEG Stearates make excellent emulsifying agents because of their dual solubility in both water and oil. A variety of emulsions and ointments containing these ingredients has been described as, for example, a benzoic acid emulsion and a zinc sulfadiazine topical burn ointment.⁽⁹⁻¹³⁾ PEG Stearates provide ointment bases with stability to heat and cold.⁽¹²⁾ One PEG Stearate emulsion has been found to be stable for over two years.⁽¹³⁾

Foods

The Food and Drug Administration (FDA) has approved without limits the use of PEG-40 Stearate as a defoaming agent used in coating food packaging materials.⁽¹⁴⁾

PEG Stearates are used in the bakery industry as bread softeners and antistaling agents.⁽¹⁵⁻¹⁹⁾

Purpose and Frequency of Use in Cosmetics

PEG Stearates are used as surfactants in skin creams, emollients and conditioners, shampoos, body cleansers, and soapless detergents.^(10-12,20)

PEG Stearate-containing formulations may be applied to the face (creams, emollients, cleansers), axillae (antiperspirants), hair and scalp (shampoos), skin in general (body cleansers, detergents) and the oral and gingival mucosae (toothpastes, dentifrices).

The frequency of application of PEG Stearate products may vary from daily (toothpastes, antiperspirants, skin creams) to occasional use (emollients, shampoos, skin conditioners). Duration of application can range from seconds (shampoos, toothpastes, body cleansers) to all day (skin conditioners and emollients, antiperspirants). This occasional or daily use may extend over a period of years.

PEG Stearates are used in over 500 cosmetic formulations. Most are used at concentrations from less than 0.1% to 10%.⁽²⁰⁾ Two products list concentrations in the >10%–25% range (Table 1).⁽²¹⁾ The cosmetic product formulation computer printout which is made available by the FDA is a database compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.⁽¹⁴⁾ Ingredients are listed in prescribed concentra-

TABLE 1. Product Formulation Data.

Product category	Total no. containing ingredient	No. of product formulations within each concentration range (%)			
		>10-25	>5-10	>1-5	>0.1-1
<i>PEG-2 Stearate</i>					
Bath preparations	1	—	—	—	1
Fragrance preparations	11	—	9	2	—
Hair preparations (noncoloring)	4	—	1	2	1
Hair coloring preparations	1	—	—	—	1
Makeup preparations (not eye)	16	—	1	5	10
Manicuring preparations	1	—	—	1	—
Personal cleanliness products	1	—	—	—	1
Shaving preparations	6	—	—	—	6
Skin care preparations	20	—	5	13	2
Suntan and sunscreen preparations	1	—	—	1	—
1976 TOTALS	62	—	16	24	22
1979 TOTALS	103	2	8	2	91
<i>PEG-6 Stearate</i>					
Hair preparations (noncoloring)	1	—	—	1	—
Skin care preparations	3	—	—	3	—
1976 TOTALS	4	—	—	4	—
1979 TOTALS	3	—	—	3	—
<i>PEG-8 Stearate</i>					
Eye makeup preparations	1	—	—	—	1
Fragrance preparations	3	—	—	3	—
Hair preparations (noncoloring)	13	—	2	10	1
Makeup preparations (not eye)	5	—	—	4	1
Shaving preparations	1	—	—	1	—
Skin care preparations	3	—	—	1	2
Suntan and sunscreen preparations	1	—	—	1	—
1976 TOTALS	27	—	2	20	5
1979 TOTALS	37	—	7	25	5
<i>PEG-12 Stearate</i>					
Eye makeup preparations	1	—	—	—	1
1976 TOTALS	1	—	—	—	1
1979 TOTALS	2	—	—	1	1
<i>PEG-20 Stearate</i>					
Eye makeup preparations	4	—	1	2	1
Fragrance preparations	4	—	—	4	—
Hair preparations (noncoloring)	8	1	1	3	3
Hair coloring preparations	1	—	—	1	—
Makeup preparations (not eye)	3	—	—	—	3
Personal cleanliness products	3	—	—	1	2
Shaving preparations	2	—	—	2	—
Skin care preparations	10	—	—	4	6
1976 TOTALS	35	1	2	17	15
1979 TOTALS	23	1	2	11	9

TABLE 1. (Continued.)

Product category	Total no. containing ingredient	No. of product formulations within each concentration range (%)			
		>10-25	>5-10	>1-5	>0.1-1
<i>PEG-32 Stearate</i>					
Eye makeup preparations	3	—	3	—	—
Personal cleanliness products	1	—	1	—	—
Shaving preparations	1	—	—	1	—
Skin care preparations	4	—	3	1	—
1976 TOTALS	9	—	7	2	—
1979 TOTALS	8	—	7	1	—
<i>PEG-40 Stearate</i>					
Bath preparations	1	—	1	—	—
Eye makeup preparations	4	—	2	2	—
Fragrance preparations	9	—	5	4	—
Hair preparations (noncoloring)	5	—	5	—	—
Makeup preparations (not eye)	42	—	39	3	—
Manicuring preparations	2	—	2	—	—
Personal cleanliness products	11	—	11	—	—
Shaving preparations	2	—	1	1	—
Skin care preparations	19	—	12	7	—
Suntan and sunscreen preparations	5	—	5	—	—
1976 TOTALS	100	—	83	17	—
1979 TOTALS	179	2	110	67	—
<i>PEG-50 Stearate</i>					
Eye makeup preparations	13	—	13	—	—
Hair preparations (noncoloring)	1	—	—	1	—
Skin care preparations	3	—	3	—	—
1976 TOTALS	17	—	16	1	—
1979 TOTALS	15	—	12	1	2
<i>PEG-100 Stearate</i>					
Hair preparations (noncoloring)	7	—	3	4	—
Personal cleanliness products	2	1	1	—	—
1976 TOTALS	9	1	4	4	—
1979 TOTALS	—	2	7	16	5
<i>PEG-150 Stearate</i>					
Hair preparations (noncoloring)	1	—	—	—	1
Skin care preparations	2	—	2	—	—
1976 TOTALS	3	—	2	—	1
1979 TOTALS	4	—	3	—	1

Data from Refs. 20, 21.

tion ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the concentration in such a case would be a fraction of that reported to the FDA. The fact that data are submitted only within the framework of preset concentration ranges also provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to 10-fold error in the assumed ingredient concentration.⁽²⁰⁾

BIOLOGICAL PROPERTIES

General Effects

PEG-40 Stearate produced no significant interference with oxygen uptake by kidney tissue preparations.⁽²²⁾ PEG-20, -30, and -40 Stearates were reported to activate the cytochrome oxidase enzyme system in heart muscle preparations up to a concentration of 150 mg/ml.⁽²³⁾

PEG-40 Stearate is hydrolyzed *in vitro* by pancreatic lipase.^(24,25)

Krantz et al.⁽²²⁾ hydrolyzed PEG-40 Stearate with alkali and examined the polyoxyethylene hydrolysate. In a concentration range of 5–1000 mg percent, the hydrolysate was found to have no hemolytic effect on defibrinated human blood when tested at 37 °C for 18 h. The hydrolysate was injected intravenously (5 ml, 5% solution) into dogs; there were no resultant changes in blood pressure.

Weanling hamsters were fed a diet containing 5% or 15% PEG Monostearate or lard for 2–10 weeks. The animals were sacrificed, and a variety of tissues were examined microscopically. Pronounced changes were found in the duodenum, ileum, liver, kidney, and testes. Severe erosion of the ileal mucosa was observed along with necrosis of the liver. There was decreased spermatogenic activity and tubular degeneration of the kidney.⁽²⁶⁾

Hamsters were fed 5%, 10%, or 15% dietary levels of PEG Monostearate for 28–39 weeks. For all concentrations used, the observations included a very high mortality rate, chronic diarrhea, atrophic testes, enlarged kidneys, thickened bladder walls, striking hepatic, cecal and splenic hemosiderosis, enlarged ceca, and obstructive nephropathy. Six large calculi (4–6 mm in diameter, 50–95 mg in weight) were found in the urinary bladders of hamsters fed PEG Stearates for periods ranging from 74 to 260 days.⁽²⁷⁾

PEG-2 Stearate

Animal Toxicology

Acute oral

A 50% w/v suspension of PEG-2 Stearate in corn oil was given orally to five groups of five rats each in a dosage range of 0.464–10.0 g/kg. There were no

deaths during the two week observation period. Body weight gains were normal; no abnormal gross lesions.⁽²⁸⁾

Groups of 10 rats each were administered varying doses of PEG-2 Stearate orally. The 72-h LD50 was reported as > 10 g/kg.⁽²⁹⁾

Primary skin irritation

PEG-2 Stearate (0.5 ml) was applied to intact and abraded skin sites on the back of each of six rabbits. Following 24 h of exposure, the sites were scored and again at 72 h according to the Federal Hazardous Substances Labeling Act (FHSLA) scale. The primary irritation index (PII) was found to be 0.08/8.00 indicating that the ingredient has a potential for slight irritation.⁽²⁹⁾ The same protocol and scoring procedure were used in another experiment. The resulting PII was 0.17/8.00 indicating the same low level of skin irritation potential for PEG-2 Stearate.⁽²⁸⁾

Eye irritation

One hundred mg of PEG-2 Stearate were instilled into one eye of each of six rabbits according to the Draize procedure. The 24, 48, and 72 h ocular irritation scores were 6.3, 1.5, and 0.0/110, respectively. PEG-2 Stearate is a minimal eye irritant.⁽²⁹⁾

Skin sensitization

The Landsteiner and Jacobs sensitization procedure was used on two guinea pigs to evaluate the effects of a 0.1% suspension of PEG-2 Stearate. Intracutaneous injections were made thrice weekly for a total of 10 exposures. The first induction injection was 0.05 ml while the remaining nine were 0.1 ml each. After two weeks, a challenge injection of 0.05 ml was made. The exposure sites were scored 24 h after each injection. The average score for the 10 sensitizing injections was compared with the score for the challenge. PEG-2 Stearate was considered to be a nonsensitizer.⁽²⁹⁾

Clinical Studies

Irritation and sensitization

A repeated insult patch test was performed on 168 subjects (115F, 53M) using 0.1 ml of a 25% water solution of PEG-2 Stearate. The test material was applied at 48 h intervals, three times per week for three weeks on the backs of the subjects. The test area was occluded for 24 h before removal, and washed with distilled water. The test sites were read at 48 h, after which fresh test material and the occlusive patch were reapplied. After a three-week rest period, the test area, as well as an untreated site, were challenged using the same procedure as previously noted. The sites were scored for sensitization at 24, 48, and 72 h. The investigator noted that only transient reactions were observed during the test and that PEG-2 Stearate was neither an irritant nor a sensitizer.⁽³⁰⁾

Phototoxicity and photosensitization

Twenty-eight of the 168 subjects tested for irritation and sensitization discussed above were randomly selected to test the ability of PEG-2 Stearate to in-

duce a phototoxic or photosensitive reaction following ultraviolet exposure. The test protocols were the same except that the forearm was used as a test site. The 28 subjects were divided into two groups; 19 received only UVA and nine received both UVA and UVB. The UVA (320–400 nm) light was applied for 15 min to the 19 subjects ($4.4 \mu\text{W}/\text{cm}^2$ at the skin surface measured at a 360 nm wave length peak). The UVB was applied at two times Mean Erythema Dose (MED) to nine subjects from a 150 watt Xenon Arc Solar Simulator emitting at 280–320 nm. The subjects receiving the UVB exposure were also exposed for 5 min to UVA as previously described. The investigator noted that only transient reactions were observed, and that PEG-2 Stearate was not a photosensitizer.⁽³⁰⁾

PEG-6 Stearate

Animal Toxicology

Acute oral

A hair cream preparation containing 1.5% PEG-6 Stearate was tested for acute oral toxicity on four groups of four rats each at 10.2, 15.4, 23.1, or 34.6 g/kg. There were no deaths or gross pathologic alterations. The LD50 was reported to be $> 34.6 \text{ g/kg}$.⁽³¹⁾

Primary skin irritation

The 1.5% PEG Stearate hair cream formulation was tested for primary skin irritancy on abraded and intact skin sites on each of four rabbits. The sites were exposed under occlusion for 24 h and then scored according to the Draize system. The PII was reported as 0.4/8.0.⁽³¹⁾

Eye irritation

The 1.5% PEG-6 Stearate hair cream formulation was tested for potential eye irritancy on two groups of five rabbits each. In the nonirrigated group, the Draize scores were 19.2, 9.8, and 2.6 at 1, 24, and 48 hours, respectively, postinstillation, and zero thereafter. In the group with eyes irrigated for 4 sec after instillation, the scores were 13.0 and 3.8 at 1 and 24 hours, respectively, and zero thereafter.⁽³¹⁾

Subchronic dermal toxicity

Three groups of 10 rabbits each were exposed topically for 20 days to 0.5, 1.0, or 2.0 g/kg of the 1.5% PEG-6 Stearate hair cream product. No significant adverse findings were noted; mortality, body weights, hematologic parameters, blood studies, urinalyses, and gross and micropathologic studies were negative. Erythema, dryness, wrinkling, desquamation and hyperkeratosis were found at the application sites of both experimental and control groups.⁽³¹⁾

Clinical Studies

The 1.5% PEG-6 Stearate hair cream was tested on 48 subjects for potential skin irritancy/sensitization. Four occlusive patches per week for two weeks were applied for 18–24 h each after which the patch was removed and the sites scored

on a scale of 0 to 8. Two weeks after the last induction patch, a challenge patch was applied to an adjacent area of the arm. These sites were scored 24 and 48 h later. All irritation scores were zero following the first five exposures. For insults 6, 7, and 8 there were 1, 4, and 7 reactors, respectively. All challenge scores were zero.⁽³¹⁾

PEG-8 Stearate

Animal Toxicology

General studies

Acute Oral: In two different tests, a 50% suspension of PEG-8 Stearate in corn oil was administered orally to five groups of five rats each in a dosage range of 0.464–10.0 g/kg. The LD50s were reported to be > 10 g/kg. There were no gross abnormalities.^(28,32)

Ten ml/kg of a hair cream product containing 15% PEG-8 Stearate was given by gastric intubation to 10 rats. There were no deaths or gross lesions. The LD50 was reported as > 10 ml/kg.⁽³¹⁾

Groups of 10 rats each were orally administered varying doses of PEG-8 Stearate up to 10 g/kg. There were no deaths. The LD50 was estimated to be in excess of 10 g/kg.⁽²⁹⁾

PEG-8 Stearate was given orally to nine rats; all animals survived. The LD50 was > 11.1 ml/kg.⁽³³⁾ The ingredient as a 50% w/v aqueous suspension was administered per os to groups of 10 rats. The LD50 was reported as > 31.6 g/kg. The compound was designated as "relatively harmless."⁽³³⁾

Subchronic and Chronic Oral: Several PEG-8 Stearate feeding studies were conducted in rats, dogs, mice, rabbits, and monkeys (Table 2).⁽³³⁾

Acute Intraperitoneal: Ten rats were injected intraperitoneally with 2 ml of PEG-8 Stearate. The IP LD50 was estimated to be > 9.0 ml/kg.⁽³³⁾

Acute Dermal: Ten ml/kg of an undiluted hair cream product containing 15% PEG-8 Stearate was applied topically for 24 h to four rabbits. The acute dermal LD50 was reported to be > 10 ml/kg. There was moderate erythema at the exposure sites at 24 h which cleared by Day 3.⁽³¹⁾

Primary Skin Irritation: The PII was determined in rabbits in four studies on undiluted PEG-8 Stearate according to the protocol described for PEG-2 Stearate. The resulting indices were 3.29, 0.293, 3.42, and 0.5 out of 8 maximum. The irritation was primarily the result of erythema. The variability of test results between studies was most likely caused by the variation in abrading skin techniques, and not the ingredient used.^(28,29,32,33)

An undiluted hair product containing 15% PEG-8 Stearate was tested for skin irritation potential in four rabbits according to the Draize protocol. The resulting PII was 0.81/8.00.⁽³¹⁾

Skin Sensitization: PEG-8 Stearate was tested for skin sensitization in the guinea pig according to the procedure described for PEG-2 Stearate. The ingredient was considered to be a nonsensitizer with all scores being 0.0.⁽²⁹⁾

Eye Irritation: The Draize ocular irritation test was used to evaluate two samples of undiluted PEG-8 Stearate in rabbits. The maximum average scores at 24 h were 2.0 and 0.0/110, and zero thereafter.^(28,32)

TABLE 2. PEG-8 Stearate Feeding Studies.

<i>Duration</i>	<i>Species</i>	<i>Number</i>	<i>Normal weight gain</i>	<i>Tissue changes</i>	<i>Hematology</i>	<i>Diet (%)</i>
9 Weeks	Rat	15	Yes	Normal	Normal	4
8 Weeks	Rat	15	Yes	Normal	Normal	2
2 Years	Rat	15	Yes	Normal	Normal	4
8 Weeks	Monkey	1	—	Normal	Normal	1 g/day
6 Weeks	Mouse	10	Yes	Normal	Normal	4
9 Weeks	Dog	2	—	Normal	Normal	2 g/day
19 Weeks	Rabbit	2	—	Normal	Normal	5
4 Months	Rabbit	11	Yes	Normal	Normal	4

Data from Ref. 33.

An undiluted hair cream formulation containing 15% PEG-8 Stearate was tested for ocular irritancy in 10 rabbits according to the Draize method. For nonirrigated eyes, the scores were 11, 7, 2, and 0.8/110 at 1, 24, 48, and 72 h, respectively, and zero thereafter. For irrigated eyes, the scores were 7 and 0.4/110 at 1 and 24 h, respectively, and zero thereafter.⁽³¹⁾

Special studies

Multiple Generation: Feeding of 4% PEG-8 Stearate in the diet of young rats for three successive generations did not affect growth or fecundity. No micropathological changes were observed in the livers or kidneys of first generation rats after 11 weeks on the diet, after 16 weeks in the second generation, and after 16 months in the third generation. The ratios of liver/body weight and kidneys/body weight were comparable for third generation and control animals.⁽³³⁾

Another three-generation study was carried out on rats fed diets containing 5%, 10%, or 20% PEG-8 Stearate. In both control and experimental groups, seven of ten matings were successful. The reproduction and lactation responses for the 5% group were not different from control responses. At the 10% and 20% levels, newborn litter survival times were diminished probably as a result of maternal neglect. In the 20% group, there was some impairment of lactation efficiency as evidenced by lower weanling weights. In the 20% group, there was also a greater mortality rate of the nurslings. In the F₂ and F₃ generations, similar responses were reported. The overall level of reproductive performance was lower in the F₃ generation for the animals fed the 20% PEG-8 Stearate diet.⁽³⁴⁾

Clinical Studies

Oral toxicity

PEG Stearates have been used in the bakery industry as antistaling and bread softening agents suggesting that these ingredients are probably not toxic in those concentrations used.^(17-19,35) More specifically, the Food Protection Committee of the National Research Council has reported that there is no consistent indication of toxic action of PEG-8 Stearate at animal dietary levels of less than 5%.

They have also stated that PEG-8 Stearate, at levels no greater than 0.05% in the human diet, would be considered safe.⁽³⁶⁾

PEG-8 Stearate was fed to two children at a rate of 4 g/day for 14 or 16 days. No deleterious effects were reported with respect to behavior, general health, appetite, frequency or consistency of stools, or weight gain.⁽³⁷⁾

Skin irritation/sensitization

An undiluted hair cream preparation containing 15% PEG-8 Stearate was applied topically to the upper arm of each of 48 males subjects. The patches containing 0.5 ml of sample were applied on the same sites on Days 1–4 and 6–9. The reactions were scored on Days 2–5 and 7–10. Following a two-week nontreatment period, challenge patches were applied and reactions read at 24, 72, and 96 h. All induction and challenge scores were zero for all subjects tested.⁽³¹⁾

A repeated insult patch test was performed on 168 subjects (115F, 53M) using 0.1 ml of a 25% water solution of PEG-8 Stearate. The test material was applied at 48 h intervals, three times per week for three weeks on the backs of the subjects. The test area was occluded for 24 h before removal, and washed with distilled water. The test sites were read at 48 h, after which fresh test material and the occlusive patch were reapplied. After a three-week nontreatment period, the test area, as well as an untreated site, were challenged using the same procedure as previously noted. The sites were scored for sensitization at 24, 48 and 72 h. The investigator noted that only transient reactions were observed during the test and that PEG-8 Stearate was neither an irritant nor a sensitizer.⁽³⁰⁾

Phototoxicity and photosensitization

Twenty-eight of the 168 subjects tested for irritation and sensitization discussed above were randomly selected to test the ability of PEG-8 Stearate to induce a phototoxic or photosensitive reaction following ultraviolet exposure. The test protocols were the same except that the forearm was used as a test site. The 28 subjects were divided into two groups, 19 received only UVA and 9 received both UVA and UVB. The UVA (320–400 nm) light was applied for 15 min to the 19 subjects (4.4 $\mu\text{W}/\text{cm}^2$ at the skin surface measured at a 360 nm wave length peak). The UVB was applied at two times Mean Erythema Dose (MED) to nine subjects from a 150 watt Xenon Arc Solar Simulator emitting at 280–320 nm. The subjects receiving the UVB exposure were also exposed for 5 min to UVA as previously described. The investigator noted that only transient reactions were observed, and that PEG-8 Stearate was not a photosensitizer.⁽³⁰⁾

PEG-12 Stearate

Animal Toxicology

Acute oral

Five groups of five rats each were dosed by gavage with 0.464, 1.00, 2.15, 4.64, or 10.0 g/kg of PEG-12 Stearate. There were no deaths.⁽²⁸⁾

Primary skin irritation

The PII in rabbits for undiluted PEG-12 Stearate was obtained according to

the procedure described for PEG-2 Stearate. The index was reported to be 2.42/8.00. Most of the irritancy score was the result of erythema.⁽²⁸⁾

Eye irritation

The Draize eye irritation test was used to evaluate the effects of undiluted PEG-12 Stearate in rabbits. All scores were zero. The ingredient was considered to be nonirritating to the eye.⁽²⁸⁾

PEG-20 Stearate

Animal Toxicology

Acute oral

A 50% w/v suspension of PEG-20 Stearate in corn oil was given orally to five groups of five rats each in two studies. The ingredient was equally toxic to males and females and caused no significant gross lesions. The LD50s were reported as 19.85 and > 10 g/kg.⁽³⁸⁾

Primary skin irritation

Undiluted PEG-20 Stearate was tested for potential skin irritancy in rabbits in three tests according to the protocols of FHSLA and DOT as well as that stated previously for PEG-2 Stearate. The PII scores were reported as 0.00, 0.00, and 0.04/8.00, respectively. All scoring was according to the Draize standards.^(28,39)

Eye irritation

The Draize rabbit eye irritation procedure was used to evaluate the ocular irritancy of undiluted PEG-20 Stearate in two studies. The maximum average scores were 2.0, 0.0, and 0.0/110 for unrinsed eyes, eyes rinsed 2 sec, and eyes rinsed 4 sec, respectively, with no corneal involvement.⁽³⁹⁾ In the second study, all scores were zero.⁽²⁸⁾

PEG-32 Stearate

Animal Toxicology

Acute oral

A 50% w/v suspension of PEG-32 Stearate in corn oil was administered orally to five groups of five rats each up to a maximum dose of 10 g/kg. There were no deaths during the 14-day observation period. Normal body-weight gains and no gross lesions were reported.⁽²⁸⁾

Primary skin irritation

The PII was determined for PEG-32 Stearate using the procedure described previously for PEG-2 Stearate. The PII in rabbits was calculated to be 0.32/8.00.⁽²⁸⁾

Eye irritation

The Draize eye irritation procedure was used to evaluate undiluted PEG-32 Stearate in rabbits. The maximum average score was 2.0/110 with no corneal involvement.⁽²⁸⁾

PEG-40 Stearate**Animal Toxicology***General studies*

Acute Oral: A 50% w/v suspension of PEG-40 Stearate was given orally to six groups of five rats each. The LD50 was estimated to be 32 g/kg.⁽³⁹⁾

Twenty rats were given 34.8 g/kg of undiluted PEG-40 Stearate by gastric intubation. The LD50 was reported as > 34.8 g/kg.⁽³³⁾

Subchronic and Chronic Oral: Several PEG-40 Stearate feeding studies were conducted in rats and monkeys (Table 3).⁽³³⁾

Acute Injection Studies: Five ml of 5% PEG-40 Stearate was injected into the lumen of the jejunum of a dog. There was no effect on blood pressure. In the same day, an intravenous injection produced a prolonged hypotensive response. It was stated that this response is a "characteristic reaction" of the dog to a variety of polyoxyethylene compounds.⁽³³⁾

Primary Skin Irritation: PIIs in the rabbit were determined for PEG-40 Stearate according to the protocol used for PEG-2 Stearate. In two tests, the scores were reported as 0.09 and 0.0/8.0.^(33,39)

In skin tests on the guinea pig, PEG-40 Stearate was applied to intact, shaven sites on the back. The PII scores ranged from 0.0 to 1.39/8.00 for the various batches tested.⁽⁴⁰⁾

Skin Sensitization: Guinea pigs (unspecified number) received induction and challenge intradermal injections of 0.1 ml of a 0.1% PEG-40 Stearate solution in saline. No evidence of sensitization was reported.⁽³³⁾

Eye Irritation: The Draize procedure was used to evaluate the ocular irritancy in the rabbit of undiluted PEG-40 Stearate. In two studies, the maximum average scores for eyes not rinsed following instillation were 2.7 and 1.33/110.

TABLE 3. PEG-40 Stearate Feeding Studies.

<i>Duration</i>	<i>Species</i>	<i>Diet (%)</i>	<i>Results</i>
24 h	Rat	Entire diet for one day (2.4 g/rat)	No toxic signs
9 Weeks	Rat	2	No effect on growth, no lesions
9 Weeks	Rat	4	No effect on growth, no lesions
8 Weeks	Monkey	1 g/day	No effect on growth, no lesions
2 Years	Rat	2	No effect on growth or mortality rate, no lesions and hematologic value normal

Data from Ref. 33.

For eyes rinsed at 2 or 4 sec after instillation, all scores were 0.0/110 in both tests.^(33,38)

In another series of tests, 0.1 ml of the ingredient was instilled in rabbit eyes without subsequent washout. The maximum average scores ranged from 0.0 to 2.0/110 for the various batches tested.⁽⁴⁰⁾

Special studies

Multiple Generation: Rats were fed diets containing 5%, 10%, or 20% PEG-40 Stearate in a three-generation study. For all groups including control, an average of seven out of 10 matings were successful. The lactation and reproduction responses for the 5% group were the same as for the control group. Survival of the newborn was slightly diminished for the 20% group. In the same group, there was an impairment of lactation. Similar lactation and survival responses were found for the two succeeding generations.⁽³⁴⁾

Clinical Studies

Skin irritation/sensitization

Schwartz prophetic patch tests on 60% and 30% PEG-40 Stearate were conducted on 50 and 10 volunteers, respectively. The test consisted of a 72 h occluded patch, scoring of skin site, seven-day nontreatment period, a second 72 h patch at the same site, and scoring the site again. There were no reactors following either exposure for both concentrations used. It was concluded that PEG-40 Stearate is "neither a primary irritant to human skin nor a skin sensitizer."⁽³³⁾

Undiluted PEG-40 Stearate was evaluated in 147 subjects in a single insult, 24 h occlusive patch test. There were 4, 2, and 2 reactions graded as 1/2, 1, and 2, respectively. All other scores were zero.⁽⁴⁰⁾ When 10% PEG-40 Stearate in 5% glycine/95% water vehicle was similarly tested on 60 subjects, all skin irritation scores were zero.⁽⁴⁰⁾

PEG-50 Stearate

Animal toxicology

Acute oral

A 50% w/v aqueous solution of PEG-50 Stearate was given orally to 20 rats. There were no deaths at doses up to 25 g/kg.⁽⁴¹⁾

Subchronic oral

A diet containing 4% PEG-50 Stearate was fed to 10 rats for nine weeks. No deleterious effects were reported.⁽⁴¹⁾

Acute intraperitoneal

Ten rats were injected intraperitoneally with 2.5 g/kg of PEG-50 Stearate. No signs of toxicity were noted throughout the five-day observation period.⁽⁴¹⁾

Eye irritation

The Draize procedure was used to evaluate the ocular irritancy of a 50% w/v aqueous solution of PEG-50 Stearate. The maximum average scores were 0.67

and 0.33/110 at 1 and 24 h, respectively, and zero thereafter for eyes unrinsed. All scores were zero for eyes washed two seconds after exposure.⁽⁴¹⁾

Clinical Studies

Skin irritation/sensitization

The Schwartz patch test on 50% PEG-50 Stearate was conducted on 50 individuals. There was no irritation or sensitization. A 30% solution was similarly tested but with 48 h patches on 10 subjects resulting in identical findings.⁽⁴²⁾

PEG-100 Stearate

Animal Toxicology

Acute oral

A 50% w/v aqueous suspension of PEG-100 Stearate was given orally to 20 rats. The LD50 was reported to be in excess of 25.1 g/kg.⁽⁴²⁾

Dosages of 2.5 g/kg of a 25% aqueous dispersion of PEG-100 Stearate or 10.0 g/kg of a 50% aqueous dispersion of the ingredient were given to two groups of 10 rats each. There were no deaths or signs of intoxication.⁽⁴²⁾

Subchronic and chronic oral

Two groups of 10 rats each were fed diets containing either 2% or 5% PEG-100 Stearate for eight weeks. There were no differences from control with respect to mortality, growth, hematologic values and histopathologic observations.⁽⁴²⁾

Thirty rats were fed diets containing 2% PEG-100 Stearate for over two years. There were no differences from control with respect to growth, mortality, histopathologic observations, and hematologic values.⁽⁴²⁾

Acute intraperitoneal

Ten rats were injected intraperitoneally with 2.5 g of PEG-100 Stearate. No signs of toxicity were observed during the subsequent 5-day period.⁽⁴²⁾

Subchronic and chronic dermal

A 28-day abraded skin study and a 91-day intact skin percutaneous toxicity study were conducted on a skin conditioner containing 1%–3% PEG-100 Stearate. A dose of 2 ml/kg/day of undiluted product was applied topically to the shaven backs of rabbits. In both studies, mild to moderate skin erythema developed. Necropsy and histopathologic observations were unremarkable.⁽²⁾

Clinical Studies

Skin irritation/sensitization

Undiluted PEG-100 Stearate was patch-tested on 10 individuals. Two 48 h patches were applied with one week between applications. There were no reactions following either exposure.⁽²⁾

A repeated insult patch test on a skin conditioner containing 1%–3% PEG-100 Stearate (without fragrance) was conducted on 188 individuals. The in-

duction phase was followed by a 24 h challenge patch. There were 0/188 reactors to the challenge.⁽²⁾

Phototoxicity

A skin conditioner containing 1%–3% PEG-100 Stearate was phototested on humans. Exposure sites were irradiated with UV light with no adverse effects.⁽²⁾

PEG-150 Stearate

Animal Toxicology

Acute oral

A 50% w/v suspension of PEG-150 Stearate in corn oil was given orally to five groups of five rats each. The LD₅₀ was reported to be >10 g/kg. Body weight gains were normal and necropsy findings were negative.⁽²⁸⁾

Skin irritation

The PII was determined for PEG-150 Stearate using the protocol described for PEG-2 Stearate. The value reported was 0.34/8.0.⁽²⁸⁾

Eye irritation

The Draize procedure was used to evaluate the ocular irritancy in rabbits of undiluted PEG-150 Stearate. A maximum average score of 2.0/110 was reported for eyes that were unrinsed following instillation of sample.⁽²⁸⁾

SUMMARY

The PEG Stearates are the polyethylene glycol esters of stearic acid. The identifying number of each PEG Stearate corresponds to the average number of ethylene oxide monomers in the polyether chain. These nonionic surfactants are used mainly in cosmetic products as surfactants and emollients at concentrations up to 25%.

The PEG Stearates, whose average number of ethylene oxide monomers range from 2 to 150, were nonlethal to test animals up to 10 g/kg. They gave evidence of only low-level skin irritation and minimal eye irritation when tested at 100% concentrations in experimental test animals.

PEG-8, -40, and -100 Stearates produced no significant changes in growth, mortality rates, histopathologic observations, or hematologic values in long-term feeding studies. Multiple generation studies of PEG-8 and -40 Stearates were negative for effects on reproduction; the presence or absence of a carcinogenic effect was not reported in these long-term studies.

Clinical studies on PEG-2, -8, -40, -50, and -100 Stearates indicated that these ingredients are neither irritants nor sensitizers at concentrations of ≥ 25 percent. There was no evidence of phototoxicity or photosensitization of PEG-2 or -8 Stearate, nor in a formulation containing 1%–3% PEG-100 Stearate.

DISCUSSION

Although the clinical data on certain PEG Stearates may be marginal, the Panel concludes that the total available data on all PEG Stearates are sufficient for a rational decision regarding the safety of the entire group. This is particularly true in the areas of phototoxicity and photosensitivity. With increasing ethoxylation, the fatty-acid components of Stearic Acid moiety have less potential to produce phototoxicity and photosensitivity in humans and animals. Since there were no phototoxicity or photosensitivity reactions in subjects tested with PEG-2 Stearate and PEG-8 Stearate, the Panel concludes it is reasonable to extrapolate these data to the higher molecular weight species (e.g., PEG-20, -32, -40, -50, -100, -150 Stearates). The converse of this latter statement, that is, the extrapolation of high molecular weight species to lower molecular weight species, may or may not be true.

CONCLUSION

On the basis of the available information presented in this report, the Panel concludes that PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates are safe as cosmetic ingredients in the present practices of concentration and use.

REFERENCES

1. ESTRIN, N.F. (ed.). (1977). *CTFA Cosmetic Ingredient Dictionary*. 2nd ed. Washington, DC. Cosmetic, Toiletry and Fragrance Ass'n.
2. COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION (CTFA). (Nov. 15, 1979). Summary of unpublished safety data on PEG Stearates.*
3. ICI UNITED STATES, INC. (1976). The HLB system edited and reprinted from Chemmunique. Wilmington, Delaware.*
- ✓ 4. TURAKKA, L. and KROGERUS, V.E. (1974). Effect of some nonionic surface active agents on the rate of release of drugs from suppositories. II. Effect of the HLB (Hydrophile-lipophile balance) value of the surface active agent. *Farm. Aikak.* **83**(3), 105-10.
- ✓ 5. ISMAIL, A.A., GOUDAH, M.W., and MOTAWI, M.M. (1974). Effect of pH, temperature, and electrolyte concentration on solubilization of barbiturates. *Pharma. Ind.* **36**(10), 735-7.
- ✓ 6. NAGAI, M. and KOZAWA, T. (1977). Cosmetics containing alkyloxyacetic acid alkyl esters. Japan Pat. 7757336.
7. ICI UNITED STATES (April 7, 1980). Personal Communication.*
- ✓ 8. COLLETT, J.H., WITHINGTON, R., and KOO, L. (1975). Effects of surfactant structure on the solubilization of salicylic acid. *J. Pharm. Pharmacol.* **27**(1), 46-8.
- ✓ 9. MINKOV, E., OVCHAROV, R., MIKHAILOVA, D., BOGDANOVA, S., KASAROVA, M., and KOBUROVA, K. (1974). Biopharmaceutical studies of emulsions of the oil-water type. *Pharm. Ind.* **36**(6), 446-9.
- ✓ 10. MUNZEL, K. and AMMANN, R. (1954). Washable fat-in-water ointments. III. Emulsifying agents in washable ointments. *Pharm. Acta Helv.* **29**, 1-2.
- ✓ 11. FIERO, G.W. and DUTCHER, M.W. (1945). Glycol esters in ointment bases. *J. Am. Pharm. Assoc.* **34**, 56-9.

*Available on request: Administrator, Cosmetic Ingredient Review, 1110 Vermont Ave., N.W., Suite 810, Washington, DC. 20005.

- ✓ 12. IKTSAMOV, SH.A. and BLAGOVIDOVA, YU A. (1971). Characteristics of emulsion ointment bases containing diethylene glycol stearate. *Farmatsiya (Moscow)* **21**(4), 10-3.
- ✓ 13. KAZAROVA, I.L., VOLFENZON, I.I., and KORCHAGINA, T.N. (1969). Use of esters of diethylene glycol and fatty acids in cosmetics. I. Diethylene glycol oleate and stearate. *Maslo-Zhir. Prom.* **35**(12), 25-7.
14. CODE OF FEDERAL REGULATIONS (CFR). (1979). Title 21 CFR 176.200.
- ✓ 15. BRADLEY, W.B., GASE, W.T., and LUCKA, L.O. (1948). Bread softeners. *Open forum. Proc. Am. Soc. Bakery Engineers* **24**, 53-63.
- ✓ 16. BRADLEY, W.B., GASE, W.T., and LUCKA, L.O. (1949). Bread softness and bread quality. *Bakers Digest* **23**(1), 29-31.
- ✓ 17. FAVOR, H.H. and JOHNSTON, N.F. (1947). Effect of polyoxyethylene stearate on the crumb softness of bread. *Cereal Chem.* **24**(5), 346-55.
- ✓ 18. FAVOR, H.H. and JOHNSTON, N.F. (1947). A new anti-staling agent. Effect of polyoxyethylene stearate on the crumb softness of bread. *Bakers Digest* **21**(6), 124-5, 127.
- ✓ 19. JOHNSTON, N.F. (1950). Retarding stiffening of bread. U.S. Pat. 2,509,926.
20. FOOD AND DRUG ADMINISTRATION (FDA). (Aug. 31, 1976). Cosmetic product formulation data. FDA Computer Printout.
21. FDA. (1979). Cosmetic product formulation data, computer printout.
- ✓ 22. KRANTZ, Jr., J.C., MUSSER, R.D., and KNAPP, N.J. (1952). Sugar alcohols. XXIX. Sorbitan polyoxyethylene fatty acid esters and polyoxyethylene monostearate and respiration of kidney. *Proc. Soc. Exp. Biol. Med.* **81**(3), 640-2.
- ✓ 23. WAINIO, W.W. and ARONOFF, M. (1955). Effect of some surface-active agents on cytochrome oxidase. *Arch. Biochem. Biophys.* **57**(1), 115-23.
24. KRANTZ, Jr., J.C. (1947). Submission of unpublished safety data by CTFA on PEG Stearate.*
25. HARRISSON, J.W.E. (Sept. 19, 1949). Testimony in hearings on the definition and standards for bread, FDC Docket No. 31(b), et. seq.
- ✓ 26. WANG, H., McBRIDE, B.H., and SCHWEIGERT, B.S. (1950). Histological manifestations of feeding polyoxyethylene monostearates to weanling hamsters. *Proc. Soc. Exp. Biol. Med.* **75**(2), 342-8.29.
27. EAGLE, E. and POLING, C.E. (1956). The oral toxicity and pathology of polyoxyethylene derivatives in rats and hamsters. *Food Res.* **21**(3), 348-61.
28. ARMAK. (1972). Submission of unpublished safety data by CTFA on PEG Stearate.*
29. INOLEX. (1975). Submission of unpublished safety data by CTFA on PEG Stearate.*
30. FOOD AND DRUG RESEARCH LABS (FDRL). (March 31, 1982). CTFA submission of unpublished safety data on PEG-2 and -8 Stearate.*
31. CTFA. (December 26, 1979). Submission of unpublished safety data. Additional cosmetic products containing PEG Stearate.*
32. HILL TOP RESEARCH, INC. (June 13, 1969). Submission of unpublished safety data by CTFA. Acute oral toxicity of PEG-6 Stearate.*
33. ICI UNITED STATES. (September 19, 1977). Submission of unpublished safety data by CTFA on PEG Stearates.*
- 34. OSER, B.L. and OSER, M. (1956). Nutritional studies on rats on diets containing high levels of partial ester emulsifiers. 2. Reproduction and lactation. *J. Nutr.* **60**, 489-505.
- ✓ 35. FAVOR, H.H. and JOHNSTON, N.F. (1948). Additional data on effect of polyoxyethylene stearate on the crumb softness of bread. *Cereal Chem.* **25**(6), 424-5.
- ✓ 36. NATIONAL RESEARCH COUNCIL. (1958). Food Protection Committee. The safety of polyoxyethylene (8) stearate for use in foods. *Natl. Acad. Sci. Natl. Res. Counc. Publ.* **646**, 1-19.
- ✓ 37. PRESTON, III, E., HUNT, Jr., A.D., SCOTT, T.F. MCN., and SPUR, B. (1953). Short-term feeding studies in infants and children with certain surface-active agents used in food technology. *J. Clin. Nutr.* **1**(7), 539-50.
38. BIO-TOXICOLOGY LABORATORIES (BTL). (October 10, 1975). Submission of unpublished safety data by CTFA on PEG-20 Stearate.*
39. BTL. (May 8, 1975). Submission of unpublished safety data by CTFA on PEG Stearate.*
40. AVON PRODUCTS, INC. (1976). Submission of unpublished safety data by CTFA, on PEG Stearates.*
41. ICI UNITED STATES, INC. (1973). Submission of unpublished safety data by CTFA on PEG Stearates.*
42. ICI UNITED STATES, INC. (1975). Submission of unpublished safety data on PEG Stearates.*

Pepe, R. C., J. A. Wenninger, and G. N. McEwen, Jr. 2002. *International cosmetic ingredient dictionary and handbook*. 9th ed. Washington, DC: CTFA.

Smith, J. H., A. K. Mallett, A. J. Preston, et al. 1996. Ninety-day feeding study in Fischer-344 rats of highly refined petroleum-derived food-grade white oils and waxes. *Toxicol. Pathol.* 24:214–230.

Vigneswaran, W. T., and S. S. Ramasastry. 1996. Paraffin plompage of the chest revisited. *Ann. Thorac. Surg.* 62:1837–1839.

Witschel, H., and K. Geiger. 1994. Paraffin induced sclerosing lipogranuloma of eyelids and anterior orbit following endonasal sinus surgery. *Br. J. Ophthalmol.* 78:61–65.

PEG-2, -3, -4, -5, -6, -6-32, -7, -8, -9, -10, -12, -14, -15, -18, -20, -23, -25, -30, -32, -35, -36, -40, -45, -50, -55, -75, -90, -100, -120, AND -150 STEARATES

A safety assessment of PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates was published in 1983 with the conclusion “safe as cosmetic ingredients in the present practices of

concentration and use” (Elder 1983). Studies available since that safety assessment was completed, along with updated information regarding use concentrations, were considered by the CIR Expert Panel. The Panel determined not to reopen this safety assessment.

In 1979, PEG Stearates were used in 374 cosmetic products, typically at concentrations ranging from >0.1% to 10%. Currently, there are uses reported in 1459 products, typically at concentrations <4%. Table 18 presents the available use information.

REFERENCES

Barany, E., M. Lindberg, and M. Loden. 2000. Unexpected skin barrier influence from nonionic emulsifiers. *Int. J. Pharm.* 195:189–195.

Bryan, A. J., R. Kaur, G. Robinson, N. W. Thomas, and C. G. Wilson. 1980. Histological and physiological studies on the intestine of the rat exposed to solutions of Myrj 52 and PEG 2000. *Int. J. Pharm.* 7:145–156.

TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
<i>PEG-2 Stearate</i>				
Bath preparations (other)	1	—	>0.1–1	—
Eye makeup (other)	—	—	—	2
Sachets	—	1	—	—
Fragrance preparations	11	—	>0.1–1	—
Shampoos (noncoloring)	—	2	—	—
Hair tonics, dressings, etc.	—	1	—	—
Hair preparations (other noncoloring)	4	—	>0.1–10	—
Hair-coloring preparations (other)	1	—	>0.1–1	—
Foundations	—	4	—	0.2–1
Makeup bases	—	1	—	—
Makeup (other)	16	—	>0.1–10	2
Manicuring preparations (other)	1	—	>1–5	—
Personal cleanliness products (other)	1	—	>0.1–1	—
Aftershave lotion	—	3	—	0.4
Shaving preparations (other)	6	—	>0.1–1	—
Skin-cleansing creams, lotions, liquids, and pads	—	6	—	2
Face and neck skin care preparations	—	1	—	—
Body and hand skin care preparations	—*	7	—*	—
Moisturizers	—	13	—	—
Night skin care preparations	—	9	—	—
Paste masks/mud packs	—	4	—	—
Skin care preparations (other)	20	8	>0.1–10	—
Suntan gels, creams, and liquids	1	2	>1–5	2
Indoor tanning preparations	—	1	—	1
Suntan preparations (other)	—	1	—	—
Total uses/ranges for PEG-2 Stearate	62	64	>0.1–10	0.2–2
Body and hand skin care preparations	—	5	—	—

(Continued on next page)

TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates (*Continued*)

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
Paste masks/mud packs	—	1	—	—
Skin care preparations (other)	—	2	—	—
Total uses/ranges for PEG-5 Stearate	—	8	—	—
<i>PEG-6 Stearate</i>				
Eyeliner	—	—	2–2.5	—
Mascara	—	1	—	—
Eye makeup (other)	—	—	3	—
Hair conditioners	—	1	—	—
Hair preparations (other noncoloring)	1	—	>1–5	—
Hair-coloring preparations (other)	—	1	—	—
Foundations	—	1	—	—
Skin-cleansing creams, lotions, liquids, and pads	—	1	—	—
Face and neck skin care preparations	—	—	—	3
Body and hand skin care preparations	—*	2	—*	—
Moisturizers	—	3	—	6
Night skin care preparations	—	3	—	—
Paste masks (mud packs)	—	1	—	2–3
Skin care preparations (other)	3	8	>1–5	—
Total uses/ranges for PEG-6 Stearate	4	22	>1–5	2–6
<i>PEG-6-32 Stearate</i>				
Foundations	—	1	—	—
Skin-cleansing creams, lotions, liquids, and pads	—	2	—	—
Face and neck skin care preparations	—	1	—	—
Body and hand skin care preparations	—*	1	—*	—
Moisturizers	—	6	—	—
Night skin care preparations	—	2	—	—
Skin care preparations (other)	—	5	—	—
Suntan gels, creams, and liquids	—	11	—	—
Indoor tanning preparations	—	4	—	—
Suntan preparations (other)	—	1	—	—
Total uses/ranges for PEG-6-32 Stearate	—	34	—	—
<i>PEG-8 Stearate</i>				
Mascara	—	1	—	—
Eye makeup (other)	1	—	>0.1–1	—
Fragrance preparations (other)	3	—	>1–5	—
Hair conditioners	—	3	—	—
Hair preparations (other noncoloring)	13	—	>0.1–10	—
Foundations	—	1	—	—
Makeup (other)	5	1	>0.1–5	—
Shaving cream	—	1	—	—
Shaving preparations (other)	1	—	>1–5	—
Skin-cleansing creams, lotions, liquids, and pads	—	1	—	2
Depilatories	—	1	—	—
Face and neck skin care preparations	—	—	—	0.5
Body and hand skin care preparations	—*	2	—*	—
Moisturizers	—	5	—	3

(Continued on next page)

TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates (*Continued*)

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
Other skin care preparations	3	1	>0.1–5	—
Suntan gels, creams, and liquids	1	1	>1–5	—
Total uses/ranges for PEG-8 Stearate	27	17	>0.1–5	0.5–3
<i>PEG-10 Stearate</i>				
Shampoos (noncoloring)	—	2	—	—
Skin-cleansing creams, lotions, liquids, and pads	—	1	—	—
Total uses/ranges for PEG-10 Stearate	—	3	—	—
<i>PEG-12 Stearate</i>				
Eye makeup (other)	1	—	>0.1–1	—
Shaving cream	—	12	—	—
Skin-cleansing creams, lotions, liquids, and pads	—	1	—	—
Face and neck skin care preparations	—	2	—	—
Body and hand skin care preparations	—*	3	—*	—
Suntan gels, creams, and liquids	—	1	—	—
Total uses/ranges for PEG-12 Stearate	1	19	>0.1–1	—
<i>PEG-20 Stearate</i>				
Bath preparations (other)	—	1	—	—
Eye makeup remover	—	1	—	—
Eye makeup (other)	4	—	>0.1–10	—
Fragrance preparations (other)	4	2	>1–5	—
Hair conditioners	—	2	—	—
Hair preparations (other noncoloring)	8	—	>0.1–25	—
Hair-coloring preparations (other)	1	—	>1–5	—
Foundations	—	1	—	—
Makeup (other)	3	—	>0.1–1	—
Personal cleanliness products (other)	3	3	>0.1–5	—
Aftershave lotions	—	1	—	—
Shaving preparations (other)	2	1	>1–5	—
Skin-cleansing creams, lotions, liquids, and pads	—	6	—	2
Face and neck skin care preparations	—	2	—	0.5–2
Body and hand skin care preparations	—	6	—	0.2–4
Moisturizers	—	8	—	4
Night skin care preparations	—	1	—	3
Paste masks/mud packs	—	3	—	—
Suntan gels, creams, and liquids	10	4	>0.1–5	—
Total uses/ranges for PEG-20 Stearate	35	42	>0.1–10	0.2–4
<i>PEG-30 Stearate</i>				
Moisturizers	—	1	—	—
Night skin care preparations	—	1	—	—
Total uses/ranges for PEG-30 Stearate	—	2	—	—
<i>PEG-32 Stearate</i>				
Eye makeup preparations (other)	3	—	>5–10	—
Personal cleanliness products (other)	1	1	>5–10	—
Shaving preparation products (other)	1	1	>1–5	—
Skin-cleansing creams, lotions, liquids and pads	—	1	—	1
Face and neck skin care preparations	—	—	—	3

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TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates (*Continued*)

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
Body and hand skin care preparations	—*	1	—*	2
Moisturizers	—	5	—	6
Paste masks (mud packs)	—	1	—	3
Skin care preparations (other)	4	1	>1–10	—
Total uses/ranges for PEG-32 Stearate	9	11	>1–10	1–6
<i>PEG-40 Stearate</i>				
Bath preparations (other)	1	—	>5–10	4
Eyebrow pencil	—	—	—	5
Eye shadow	—	—	—	2
Eye lotion	—	—	—	1–2
Eye makeup remover	—	1	—	0.8–2
Mascara	—	3	—	1
Eye makeup (other)	4	2	>1–10	3–4
Perfumes	—	8	—	—
Fragrance preparations (other)	9	4	>1–10	2
Hair conditioners	—	4	—	0.5–2
Hair straighteners	—	2	—	—
Hair tonics, dressings, etc.	—	1	—	2
Hair preparations (other noncoloring)	5	—	>5–10	—
Hair lighteners with color	—	—	—	0.07
Hair bleaches	—	1	—	—
Hair-coloring preparations (other)	—	1	—	—
Blushers (all types)	—	—	—	2
Foundations	—	6	—	2–3
Lipstick	—	—	—	2
Makeup bases	—	1	—	2–3
Makeup (other)	42	1	>1–10	3
Manicuring preparations (other)	2	1	>5–10	3
Bath soaps and detergents	—	1	—	0.01
Underarm deodorants	—	—	—	3
Personal cleanliness products (other)	11	3	>5–10	—
Aftershave lotion	—	15	—	—
Shaving cream	—	1	—	—
Shaving preparations (other)	2	2	>1–10	3
Skin-cleansing creams, lotions, liquids, and pads	—	9	—	0.8–7
Face and neck skin care preparations	—	8	—	0.8–3
Body and hand skin care preparations	—*	27	—*	0.8–5
Foot powders and sprays	—	1	—	—
Moisturizers	—	34	—	2–3
Night skin care preparations	—	6	—	2–3
Paste masks (mud packs)	—	7	—	0.8
Skin care preparations (other)	19	15	>1–10	1–2
Suntan gels, creams, and liquids	5	1	>5–10	0.5–2
Indoor tanning preparations	—	3	—	2
Suntan preparations (other)	—	1	—	2
Total uses/ranges for PEG-40 Stearate	100	170	>1–10	0.07–7

(Continued on next page)

TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates (*Continued*)

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
<i>PEG-50 Stearate</i>				
Eye makeup preparations (other)	13	—	>5–10	—
Hair preparations (other)	1	—	>1–5	—
Manicuring preparations (other)	—	—	—	9
Aftershave lotion	—	1	—	—
Face and neck skin care preparations	—	1	—	—
Moisturizers	—	8	—	—
Night skin care preparations	—	1	—	—
Skin care preparations (other)	3	—	>5–10	—
Total uses/ranges for PEG-50 Stearate	17	11	>1–10	9
<i>PEG-55 Stearate</i>				
Eyeliners	—	1	—	—
Total uses/ranges for PEG-55 Stearate	—	1	—	—
<i>PEG-75 Stearate</i>				
Face and neck skin care preparations	—*	2	—*	—
Body and hand skin care preparations	—	1	—	—
Moisturizers	—	1	—	—
Night skin care preparations	—	1	—	—
Skin care preparations (other)	—	1	—	—
Total uses/ranges for PEG-75 Stearate	—	6	—	—
<i>PEG-90 Stearate</i>				
Paste masks/mud packs	—	1	—	—
Total uses/ranges for PEG-90 Stearate	—	1	—	—
<i>PEG-100 Stearate</i>				
Baby lotions, oils, powders, and creams	—	5	—	1
Baby products (other)	—	—	—	—
Bath preparations (other)	—	—	—	3
Eyebrow pencil	—	1	—	—
Eyeliners	—	2	—	1
Eye Lotion	—	3	—	0.5–4
Mascara	—	8	—	2–3
Eye makeup (other)	—	5	—	1–3
Perfumes	—	1	—	3
Fragrance preparations (other)	—	14	—	—
Hair conditioners	—	30	—	0.2–4
Rinses (noncoloring)	—	2	—	0.6
Hair tonics, dressings, etc.	—	2	—	—
Hair preparations (other noncoloring)	7	5	>1–10	3
Hair dyes and colors	—	2	—	—
Hair tints	—	1	—	—
Hair color sprays (aerosol)	—	1	—	—
Hair lighteners with color	—	1	—	—
Hair bleaches	—	2	—	—
Hair-coloring preparations (other)	—	2	—	—
Foundations	—	6	—	0.5–2
Lipstick	—	—	—	0.3–5

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TABLE 18
Historical and current cosmetic product uses and concentrations for PEG Stearates (*Continued*)

Product type	1976 uses (Elder 1983)	2002 uses (FDA 2002)	1976 use concentrations (Elder 1983) (%)	2002 use concentrations (CTFA 2002) (%)
Makeup bases	—	1	—	—
Makeup fixatives	—	1	—	—
Makeup (other)	—	—	—	4
Cuticle softeners	—	2	—	3
Nail creams and lotions	—	1	—	—
Bath soaps and detergents	—	—	—	0.8
Underarm deodorants	—	3	—	0.5–25
Personal cleanliness products (other)	2	24	>5–25	2
Aftershave lotion	—	1	—	0.8–2
Shaving preparations (other)	—	1	—	0.8
Skin-cleansing creams, lotions, liquids, and pads	—	38	—	1–5
Face and neck skin care preparations	—*	25	—*	0.3–5
Body and hand skin care preparations	—	34	—	3
Foot powders and sprays	—	1	—	—
Moisturizers	—	85	—	1–3
Night skin care preparations	—	20	—	0.01–3
Paste masks/mud packs	—	22	—	2–6
Skin fresheners	—	2	—	—
Skin care preparations (other)	—	38	—	0.9–3
Suntan gels, creams, and liquids	—	14	—	3
Indoor tanning preparations	—	18	—	2–4
Total uses/ranges for PEG-100 Stearate	9	431	>1–25	0.01–25
<i>PEG-150 Stearate</i>				
Eyeliner	—	—	—	3
Eye lotion	—	1	—	—
Eye makeup remover	—	—	—	2
Fragrance preparations (other)	—	1	—	—
Hair conditioners	—	3	—	—
Hair straighteners	—	2	—	—
Shampoos (noncoloring)	—	3	—	0.2
Hair preparations (other noncoloring)	1	—	>0.1–1	0.4
Blushers (all types)	—	—	—	1
Rouges	—	—	—	0.6
Makeup (other)	—	—	—	3
Manicuring preparations (other)	—	1	—	—
Bath soaps and detergents	—	—	—	0.5
Skin-cleansing creams, lotions, liquids, and pads	—	—	—	2–3
Face and neck skin care preparations	—	—	—	2
Body and hand skin care preparations	—*	3	—*	0.8
Foot powders and sprays	—	1	—	—
Moisturizers	—	4	—	0.8–1
Night skin care preparations	—	2	—	0.5–1
Paste masks/mud packs	—	1	—	—
Skin fresheners	—	1	—	—
Skin care preparations (other)	2	—	>5–10	6
Total uses/ranges for PEG-150 Stearate	3	23	>0.1–10	0.2–6

*These categories were combined when the original safety assessment was performed and are now two separate categories.

- Cosmetic, Toiletry, and Fragrance Association (CTFA). 2002. Use concentration data on peg stearates from industry survey. Unpublished data submitted by CTFA, September 13, 2002. 5 pages.¹⁹
- Cutler, R. R., P. Wilson, and F. V. Clarke. 1987. The effect of polyoxyethylene stearate (POES) on the growth of mycobacteria in radiometric 7H12 Middlebrook TB medium. *Tubercle*. 68:209–220.
- Dahlgren, C., and K. E. Magnusson. 1980. Modulation of polymorphonuclear leukocyte locomotion by synthetic amphiphiles. *Scand. J. Infect. Dis. Suppl.* 24:44–47.
- Dahlgren, C., I. Rundqvist, O. Stendahl, and K. E. Magnusson. 1980. Modulation of polymorphonuclear leukocyte locomotion by synthetic amphiphiles: Effect of saturated fatty acid esters (C2-C18) of poly(ethyleneglycol) 6000. *Cell Biophys.* 2:253–267.
- Elder, R. L., ed. 1983. Final report on the safety assessment of PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates. *J. Am. Col. Toxicol.* 2:17–34.
- Gowan, W. G., F. Tio, K. Lamp, C. Gowan, and S. Stavchansky. 1986. The effects of Tween 80 MYRJ-52 and polyethylene glycol 8000 on the rate of pentobarbital disappearance cumulative water flux and histological changes in the rat small intestine. *Int. J. Pharm.* 29:169–176.
- Hachiya, N. 1987. Evaluation of chemical genotoxicity by a series of short-term tests. *Akita. Igaku.* 14:269–292.
- Ismail, S., A. A. Mohamed, and M. G. Abd El-Mohsen. 1989. Modifying effects of polyoxyethylene stearates on the rate of acid-catalyzed hydrolysis of acetylsalicylic acid. *Bull. Pharm. Sci.* 12:52–67.
- Ivanchenko, O. B., O. N. I'inskaya, A. N. Fattakhova, I. M. Skipina, and IE. Cherepneva. 1992. Assessment of genotoxicity of non-ionogenic surfactants. *Biol. Nauki.* 10:75–80.
- Kaur, R., D. J. W. Grant, and T. Eaves. 1980. Comparison of polyethylene glycol and polyoxyethylene stearate as excipients for solid dispersion systems of griseofulvin and tolbutamide. Part 1. Phase equilibria. Part 2. Dissolution and solubility studies. *J. Pharm. Sci.* 69:1317–1326.
- Kilbanov, A. L., K. Maruyama, V. P. Torchilin, and L. Huang. 1990. Ampipathic polyethyleneglycols effectively prolong the circulation time of liposomes. *FEBS Lett.* 268:235–237.
- Kobayashi, I. 1989. The screening test for mutagenesis of surfactants, detergents and fluorescent whitening agents. *Gosei Senzai Kenkyukaiishi* 12:19–28.
- Lee, M. H., C. D. Kim, and H. J. Ahn. 1994. Evaluation of surfactant cytotoxicity potential by neutral red uptake assay, MTT assay and cell protein assay. *Korean J. Toxicol.* 10:215–220.
- Lewis, R. W., J. C. McCall, P. A. Botham, and R. Trebilcock. 1994. A comparison of two cytotoxicity tests for predicting the ocular irritancy of surfactants. *Toxicol. In Vitro* 8:867–869.
- Margarit, M. V., I. C. Rodriguez, and A. Cerezo. 1992. Myrj 51 as a suppository excipient in fluence on pharmaceutical availability and bioavailability of sodium valproate. *Int. J. Pharm.* 81:67–73.
- Miller, M. A., L. Thibert, F. Desjardins, S. H. Siddiqi, and A. Dascal. 1996. Growth inhibition of *Mycobacterium tuberculosis* by polyoxyethylene stearate present in the BACTEC pyrazinamide susceptibility test. *J. Clin. Microbiol.* 34:84–86.
- Pepe, R. C., J. A. Wenninger, and G. N. McEwen Jr., eds. 2002. *International cosmetic ingredient dictionary and handbook*, 9th ed., 1201–1207. Washington, DC: CTFA.
- Pienaar, E. W., N. P. Kriek, B. Boneschans, and H. A. Koelman. 1994. Adverse effects of polyethylene glycol and phenytoin on the rectal mucosa of the rat. *Drug Dev. Ind. Pharm.* 20:1493–1502.
- Realini, L., P. Van Der Stuyf, K. De Ridder, B. Hirschel, and F. Portaels. 1997. Inhibitory effects of polyoxyethylene stearate, PANTA, and neutral pH on growth of *Mycobacterium genavense* in BACTEC[®] primary cultures. *J. Clin. Microbiol.* 35:2791–2794.
- Salminen, S., and E. Salminen. 1987. Urinary excretion of orally administered oxalic acid in MYRJ-45-treated NMRI mice. *Toxicol. Lett.* 37:91–94.
- Satoh, S., Y. Horiguchi, K. Ito, N. Nambu, and T. Nagai. 1985. Irritative effects of suppository bases on the rectal membranes in rabbits. *Arch. Pract. Pharm.* 45:298–303.
- Shen, W.-W., A. G. Danti, and F. N. Bruscatto. 1976. Effect of nonionic surfactants on percutaneous absorption of salicylic acid and sodium salicylate in the presence of dimethyl sulfoxide. *J. Pharm. Sci.* 65:1780–1783.
- Tassett, C., V. Preat, A. Bernard, and M. Roland. 1992. Comparison of nephrotoxicities of different polyoxyethylene formulations of amphotericin B in rats. *Antimicrob. Agent Chemother.* 36:1525–1531.
- Tassett, C., V. Preat, and M. Roland. 1991. The influence of Myrj 59 on the solubility, toxicity and activity of amphotericin B. *J. Pharm. Pharmacol.* 43:297–302.
- Tatsumi, H., and H. Ritsuko. 1991. A study on the relation between the result of guinea-pig skin irritation test and human patch test with cosmetic ingredients. *Hifu* 33:31–38.
- Uraizee, S. A., A. M. McPhillips, A. A. Sakr, and W. A. Ritschel. 1999. Evaluation of absorption enhancers and enzyme inhibitors for the protection of human insulin: screening study. *Pharm. Ind.* 61:259–262.

POLYAMINO SUGAR CONDENSATE

A safety assessment of Polyamino Sugar Condensate was published in 1982 (Elder 1982). New studies since then (listed at the end of this review), along with the updated information below regarding types and concentrations of use, were considered by the CIR Expert Panel. The Panel determined not to reopen this safety assessment.

In 1976 Polyamino Sugar Condensate was reported to be used in 111 cosmetic preparations with the largest single use occurring in moisturizers at concentrations of $\leq 0.1\%$ to 1%. As reported to the FDA (FDA 2001), Polyamino Sugar Condensate is currently used in 25 cosmetic preparations; however, according to an industry survey (CTFA 2001), Polyamino Sugar Condensate is not currently used in cosmetic preparations. Table 19 presents the available use information.

A study by Peterson et al. (1986) demonstrated that Polyamino Sugar Condensate was absorbed into the stratum corneum and epidermis of athymic nude mice grafted with human skin. Although this information was new, the Expert Panel noted that Polyamino Sugar Condensate is a sugar–amino acid expected to be metabolized to sugars and amino acids. Because the original safety assessment fully discussed the potential production of nitrosamines during the manufacture of Polyamino Sugar Condensate, no further discussion was warranted.

REFERENCES

- CTFA. 2002. Product use concentration information for Polyamino Sugar Condensate; memorandum dated January 22. Unpublished data.²⁰
- Baker, C. G., R. D. Berg, and E. S. Curtis. 1987. Formulating with NMF (normal moisturizing factor). *Drug Cosmet. Ind.* 140:32–39.
- Elder, R. L., ed., 1982. Final report on the safety assessment of Polyamino Sugar Condensate. *J. Am. Col. Toxicol.* 1:25–32.

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²⁰Available from the Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.