

ReReview Summaries

Castor Oil

PEG Stearates

EXPERT PANEL MEETING

December 2 - 3, 2024

Safety Assessment of Ricinus Communis (Castor) Seed Oil and Ricinoleates as Used in Cosmetics

Status: Re-Review Summary for Panel Approval
Release Date: November 8, 2024
Panel Meeting Date: December 2 – 3, 2024

History

Original Safety Assessment – published 2007

Most Recent Action – new data considered at the September 2024 Panel meeting; not re-opened

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.; 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.

RICINUS COMMUNIS (CASTOR) SEED OIL AND RICINOLEATES

The Expert Panel for Cosmetic Ingredient Safety (Panel) first reviewed the safety of Ricinus Communis (Castor) Seed Oil and Ricinoleates in 2007.¹ The Panel concluded that Ethyl Ricinoleate, Glycol Ricinoleate, Hydrogenated Castor Oil, Methyl Ricinoleate, Potassium Ricinoleate, Ricinoleic Acid, Ricinus Communis (Castor) Seed Oil and Sodium Ricinoleate are safe as cosmetic ingredients in the practices of use and concentrations as described in the safety assessment.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At the September 2024 meeting, the Panel reviewed updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database in 2023² and maximum use concentrations provided in response to the survey conducted in 2022 by the Personal Care Products Council.³ Reported frequency of use has significantly increased for both Hydrogenated Castor Oil (202 uses in 2002 to 501 uses in 2023) and Ricinus Communis (Castor) Seed Oil (769 uses in 2002 to 1018 uses in 2023). Maximum reported concentrations of use have decreased for Hydrogenated Castor Oil from a maximum of 39% in other eye makeup preparations in 2002 to a maximum of 21% in eyebrow pencils in 2023. Ricinoleic Acid and Sodium Ricinoleate did not have reported concentrations of use in the previous or present review. Ethyl Ricinoleate, Glycol Ricinoleate, Methyl Ricinoleate, and Potassium Ricinoleate continue to not have reported frequencies or concentrations of use. The cumulative frequency and concentration of use data are presented in Table 1.

In August 2024, an extensive search of the world's literature was performed for studies dated 2002 forward, and new data were found.⁴⁻¹⁵ These data included FDA-approved uses in food contact surfaces and as inactive ingredients in drugs, a dermal absorption study of Ricinoleic Acid, and dermal and oral absorption studies of Ricinus Communis (Castor) Seed Oil in humans. Additionally, the effect of Ricinoleic Acid and Ricinus Communis (Castor) Seed Oil upon the induction of labor, a retrospective study of allergic contact cheilitis in patients exposed to Ricinus Communis (Castor) Seed Oil in personal cosmetics, and several case reports of subjects that patch tested positive to Hydrogenated Castor Oil, Ricinoleic Acid, and Ricinus Communis (Castor) Seed Oil were found.

In summary, the Panel reviewed 2023 frequency and 2022 concentration of use data and new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2007 conclusion for Ricinus Communis (Castor) Seed Oil and Ricinoleates. The Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.]

Tsable 1. Frequency (2023/2002) and concentration (2022/2004) of use 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 (%)	
	Hydrogenated Castor Oil				Ricinoic Acid				Ricinus Communis (Castor) Seed Oil				Sodium Ricinoleate			
	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹
Totals*	501	202	0.043 – 21	0.0003-39	2	6	NR	NR	1018	769	0.0002–77.8	0.00004– 81	3	12	NR	NR
summarized by likely duration and exposure**																
Duration of Use																
Leave-On	423	131	0.05 – 21	0.0003–39	2	5	NR	NR	791	668	0.0002 – 77.8	0.00004 - 81	NR	1	NR	NR
Rinse-Off	52	70	0.043 – 12.6	0.0003 – 7	NR	NR	NR	NR	212	90	0.0002 – 73.5	0.0002 - 19	3	11	NR	NR
Diluted for (Bath) Use	26	1	NR	3 - 19	NR	1	NR	NR	15	11	NR	22	NR	NR	NR	NR
Exposure Type																
Eye Area	70	57	0.42 – 21	0.5 – 39	NR	NR	NR	NR	75	58	0.002 – 43.6	0.4 – 13	NR	NR	NR	NR
Incidental Ingestion	74	20	3.6 – 8	0.5 – 33	NR	NR	NR	NR	199	492	0.0029 – 75	15 – 81	NR	NR	NR	NR
Incidental Inhalation-Spray	1; 67 ^a ; 37 ^b	7 ^a ; 3 ^b	0.05 ^a	0.0003 – 7; 0.8 – 5 ^a ; 0.0003 – 8 ^b	2 ^a	5	NR	NR	16; 161 ^a ; 71 ^b	1; 44 ^a ; 4 ^b	0.0002 – 0.01; 0.005 – 10 ^a	0.004 – 1; 0.00004 - 52 ^a ; 0.02 – 55 ^b	NR	NR	NR	NR
Incidental Inhalation-Powder	8; 37 ^b ; 4 ^c	3 ^b	2.8 – 13 ^b	0.0003 – 8 ^b	NR	NR	NR	NR	7; 71 ^b ; 12 ^c	1; 4 ^b ; 1 ^c	3.5 – 7.9; 0.1 – 24 ^c	1; 0.02 – 55 ^b	NR	NR	NR	NR
Dermal Contact	398	180	0.043 – 21	0.0003 - 39	2	6	NR	NR	625	154	0.0002 – 77.8	0.00004 - 55	3	11	NR	NR
Deodorant (underarm)	80 ^a	2 ^a	3 – 8.7	2 – 8	NR	NR	NR	NR	3 ^a	NR	0.14 (spray) 1.4 (not spray)	0.01 – 3 ^a	NR	NR	NR	NR
Hair - Non-Coloring	23	1	0.05 – 4	0.02 – 3	NR	NR	NR	NR	158	66	0.0002 – 73.5	0.0002 – 52	NR	1	NR	NR
Hair-Coloring	NR	NR	0.6	NR	NR	NR	NR	NR	8	28	NR	0.0005 – 2	NR	NR	NR	NR
Nail	NR	1	NR	NR	NR	NR	NR	NR	3	13	1 – 12.2	69	NR	NR	NR	NR
Mucous Membrane	115	87	0.043 – 12.6	0.0003 - 33	NR	1	NR	NR	275	522	0.0002 – 75	0.003 - 81	1	10	NR	NR
Baby Products	5	NR	2	5	NR	NR	NR	NR	13	3	NR	NR	NR	1	NR	NR
as reported by product category																
Baby Products																
Baby Lotions/Oils/Powders/Creams	4	NR	2 (lotions/oils/cream)	NR					12	1	NR	NR				
Other Baby Products	1	NR	NR	5					1	2	NR	NR	NR	1	NR	NR
Bath Preparations (diluted for use)																
Bath Oils, Tablets, and Salts	22	1	NR	19	NR	1	NR	NR	13	1	NR	22				
Bubble Baths	1	NR	NR	4												
Other Bath Preparations	3	NR	NR	3					2	10	NR	NR				
Eye Makeup Preparations																
Eyebrow Pencil	34	11	6 – 21	4 – 26					8	10	11.4	3				
Eyeliner	12	25	5 – 11	3 – 39					12	11	39	4 – 8				
Eye Shadow	8	6	0.42 – 18.2	2 – 19					3	9	3.8 – 43.6	2 – 5				
Eye Lotion	1	NR	NR	0.5					6	NR	0.002 – 1.5	NR				
Eye Makeup Remover	NR	1	NR	7					NR	1	NR	NR				
Mascara	6	NR	NR	5					25	16	0.1 - 1	0.4 – 3				
Other Eye Makeup Preparations	9	14	NR	22 – 39					21	11	42.8	13				
Fragrance Preparations																
Cologne and Toilet Water	NR	NR	NR	0.0003	NR	1	NR	NR	NR	NR	NR	0.1				

Tsable 1. Frequency (2023/2002) and concentration (2022/2004) of use 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 (%)	
	Hydrogenated Castor Oil				Ricinoletic Acid				Ricinus Communis (Castor) Seed Oil				Sodium Ricinolete			
	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹
Perfumes	NR	NR	NR	5					1	NR	NR	0.3 – 1				
Other Fragrance Preparation	1	NR	NR	7	NR	4	NR	NR	15	NR	NR	NR				
Hair Preparations (non-coloring)																
Hair Conditioner	3	NR	4	NR					42	20	0.0002 – 73.5	0.0002 – 5				
Hair Spray (aerosol fixatives)									NR	1	0.0002 – 0.01	NR				
Hair Straighteners	1	NR	NR	NR					3	NR	NR	NR				
Rinses (non-coloring)	1	NR	NR	NR					1	5	NR	19				
Shampoos (non-coloring)	6	NR	NR	0.02					30	NR	0.01 – 1.2	0.005	NR	1	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	7	NR	0.05	3					52	34	0.005 – 10	0.005 – 52				
Wave Sets									NR	NR	NR	16				
Other Hair Preparations	5	1	NR	NR					30	6	63	NR				
Hair Coloring Preparations																
Hair Dyes and Colors (all types requiring caution statements and patch tests)									1	27	NR	2				
Hair Tints									2	NR	NR	NR				
Hair Rinses (coloring)									NR	NR	NR	0.0005				
Hair Lighteners with Color									1	NR	NR	NR				
Hair Bleaches	NR	NR	0.6	NR					NR	1	NR	0.04				
Other Hair Coloring Preparation									4	NR	NR	NR				
Makeup Preparations																
Blushers (all types)	11	2	0.36	3					14	10	3.3 – 27.6	0.08 – 45				
Face Powders	8	NR	NR	NR					7	1	3.5 – 7.9	1				
Foundations	3	4	NR	0.9 – 5					5	5	4.5 – 30.4	0.05 – 6				
Leg and Body Paints	NR	NR	NR	1					1	NR	NR	NR				
Lipstick	73	20	3.6 – 8	0.5 – 33					199	492	12.5 – 75	15 – 81				
Makeup Bases	2	NR	NR	NR					5	4	14.9	0.002 – 20				
Rouges									1	1	33	38 – 48				
Makeup Fixatives	NR	NR	NR	3 – 7					1	NR	NR	NR				
Other Makeup Preparations	14	24	12.1	0.04 – 13					85	25	41.1	40 – 49				
Manicuring Preparations (Nail)																
Cuticle Softeners									1	1	12.2	NR				
Nail Creams and Lotions	NR	1	NR	NR					NR	1	NR	NR				
Nail Polish and Enamel									2	NR	NR	69				
Nail Polish and Enamel Removers									NR	8	1 – 2	NR				
Other Manicuring Preparations									NR	3	NR	NR				
Oral Hygiene Products																
Mouthwashes and Breath Fresheners	1	NR	NR	NR												
Other Oral Hygiene Products	NR	NR	NR	1 – 5					NR	NR	0.0029 – 4.9	NR				
Personal Cleanliness Products																
Bath Soaps and Detergents	8	1	0.043 – 12.6	0.0003 – 0.7					56	18	0.0002 – 0.4	0.008	1	10	NR	NR
Deodorants (underarm)	80	2	not spray: 3 – 8.7	2 – 8					3	NR	aerosol: 0.14 not spray: 1.4	0.01 – 3				

Tsable 1. Frequency (2023/2002) and concentration (2022/2004) of use 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 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹	2023 ²	2002 ¹	2022 ³	2004 ¹
	Hydrogenated Castor Oil				Ricinoleic Acid				Ricinus Communis (Castor) Seed Oil				Sodium Ricinoleate			
Feminine Deodorants	1	NR	NR	2												
Other Personal Cleanliness Products	6	65	3.5	NR					5	1	NR	0.003				
Shaving Preparations																
Aftershave Lotion	NR	2	NR	NR					NR	2	NR	0.004 – 0.03				
Beard Softeners	1	NR	NR	NR					7	NR	17.5	NR				
Preshave Lotions (all types)									5	NR	73.5	NR				
Shaving Cream									1	NR	0.0024	NR				
Other Shaving Preparations	1	NR	NR	NR					2	1	NR	0.03				
Skin Care Preparations																
Cleansing	24	3	1 – 3.2	1					49	4	0.005 – 10	0.004	2	NR	NR	NR
Depilatories									8	2	0.33 – 30.3	NR				
Face and Neck (exc shave)	27	NR	not spray: 13	1 – 2					40	1	not spray: 12.7	1 – 7				
Body and Hand (exc shave)	9	3	not spray: 2.8	0.0003 – 1					31	3	not spray: 0.1 – 24	0.02 – 55 spray: 0.004				
Foot Powders and Sprays	NR	NR	NR	8												
Moisturizing	51	3	not spray: 0.089 – 2	1 – 5	2	NR	NR	NR	105	8	not spray: 0.01 – 77.8	7				
Night	1	1	NR	1 – 3					2	NR	NR	0.00004				
Paste Masks (mud packs)	1	NR	0.9	NR					2	2	1	NR				
Skin Fresheners	7	NR	NR	NR					2	NR	NR	NR				
Other Skin Care Preparations	47	9	NR	0.1 – 1					94	8	11.5 – 14	NR				
Suntan Preparations																
Suntan Gels, Creams, and Liquids	NR	1	NR	0.8 – 3					NR	1	NR	6				
Other Suntan Preparations	NR	2	NR	NR					NR	1	NR	10				

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Safety Assessment of PEG Stearates as Used in Cosmetics

Status: Re-Review Summary for Panel Approval
Release Date: November 8, 2024
Panel Meeting Date: December 2 – 3, 2024

History

Original Safety Assessment – published 1983

Original Re-Review – published 2005

Most Recent Action – new data considered at the September 2024 Panel meeting; not re-opened

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.; 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.

PEG STEARATES

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearates in 1983.¹ The Panel concluded, on the basis of the available information presented in the report, that these 10 PEG Stearates are safe as cosmetic ingredients in the present practices of concentration and use. Upon re-review in November 2002, the Panel reaffirmed the original conclusion and included 20 additional PEG Stearates in this group, as published in 2005.²

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At the September 2024 meeting, the Panel considered updated (2023) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.⁴ Reported frequency and concentrations of use mostly decreased or remained constant for these ingredients, with a few exceptions. Frequency of use increased notably for PEG-75 (97 uses reported in 2023 compared to 6 uses in 2002) and PEG-100 Stearate (1844 uses reported in 2023 compared to 424 uses in 2002). 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. New uses were reported in baby products for some ingredients. The cumulative frequency and concentration of use data are presented in Table 1.

In August 2024, an extensive search of the world's literature was performed for studies dated 2000 forward, and new data were found.⁵⁻⁷ These data included 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.

In summary, the Panel reviewed 2023 frequency and concentration of use data and new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1983 conclusion. The Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.)

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²
Hair Coloring Preparations																
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				
Makeup Preparations																
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												
Manicuring Preparations (Nail)																
Cuticle Softeners																
Nail Creams and Lotions																
Other Manicuring Preparations																
Personal Cleanliness Products																
Bath Soaps and Detergents																
Deodorants (underarm)																
Other Personal Cleanliness Products																
Shaving Preparations																
Aftershave Lotion	NR	3	NR	0.4												
Beard Softeners																
Shaving Cream																
Other Shaving Preparations	NR	NR	0.11	NR												
Skin Care Preparations																
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
Suntan Preparations																
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

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²
	PEG-8 Stearate				PEG-10 Stearate				PEG-12 Stearate				PEG-20 Stearate			
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																
Leave-On	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
Rinse-Off	1	6	2	2	NR	3	NR	NR	NR	13	1.2	NR	6	16	0.1 – 0.45	2
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	1	NR	NR
Exposure Type																
Eye Area	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	2	1	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	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
Incidental Inhalation-Powder	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
Dermal Contact	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
Deodorant (underarm)	NR	NR	0.49	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	1	3	0.5 – 2	NR	NR	2	NR	NR	NR	NR	NR	NR	4	2	0.1 – 10.1	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1	4	NR	NR
Baby Products	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

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²
	PEG-25 Stearate				PEG-30 Stearate				PEG-32 Stearate				PEG-40 Stearate			
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																
Leave-On	2	NR	NR	NR	9	2	0.2	NR	3	7	NR	2-6	136	138	0.0001-3	0.5-5
Rinse-Off	NR	NR	NR	NR	NR	NR	0.2	NR	1	4	NR	1-3	6	32	0.6-4	0.01-7
Diluted for (Bath) Use	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

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	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
<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
<i>Skin Care Preparations</i>																
Cleansing										1	1	1	1	4	9	1 – 2.5
Depilatories																
Face and Neck (exc shave)										1	NR	NR	3	23	8	not spray: 0.079 – 2.6
Body and Hand (exc shave)										1	1	1	2	36	27	not spray: 0.5 – 3
Foot Powders and Sprays										NR	NR	1	NR	NR	1	NR
Moisturizing	2	NR	NR	NR	3	1	NR	NR	NR	NR	5	NR	6	32	34	not spray: 0.033 – 1.6
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
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

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	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**																
Duration of Use																
<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
Exposure Type																
Eye Area	3	NR	3.2	NR	NR	NR	NR	NR	NR	1	NR	NR	3	NR	0.6 – 1	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	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
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	1 ^b	NR	NR	2 ^b	NR	NR	NR	21 ^b	3 ^b	0.15 – 1.2 ^c	NR
Dermal Contact	3	NR	NR	NR	NR	11	NR	NR	2	1	2.3	NR	95	NR	0.15 – 1.2	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	6	1.2	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	NR	2	NR	NR	NR	2	NR	0.15	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	8.5	9	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.5 – 0.75	NR
as reported by product category																
Baby Products																
Baby Shampoos																
Baby Lotions/Oils/Powders/Creams													NR	NR	0.5 – 0.75	NR
Other Baby Products																
Bath Preparations (diluted for use)																
Bubble Baths																
Other Bath Preparations																
Eye Makeup Preparations																
Eye Brow Pencil																
Eyeliner	3	NR	NR	NR					NR	1	NR	NR				
Eye Shadow																
Eye Lotion													3	NR	0.6 – 1	NR
Eye Makeup Remover																
Mascara	NR	NR	3.2	NR												
Other Eye Makeup Preparations																
Fragrance Preparations																
Cologne and Toilet Water																
Perfumes																
Sachets																
Other Fragrance Preparation																
Hair Preparations (non-coloring)																
Hair Conditioner																
Hair Straighteners																
Rinses (non-coloring)																
Shampoos (non-coloring)									2	NR	NR	NR				
Tonics, Dressings, and Other Hair Grooming Aids																
Other Hair Preparations													2	NR	0.15	NR

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	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

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²
Indoor Tanning Preparations																
Other Suntan Preparations																
	PEG-90 Stearate				PEG-100 Stearate				PEG-150 Stearate							
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																
Leave-On	NR	NR	NR	NR	1675	299	0.0075 - 6	0.01 - 25	NR	14	0.1 - 0.95	0.4 - 6				
Rinse-Off	NR	1	NR	NR	168	125	0.00033 - 2.5	0.2 - 6	NR	9	0.088 - 6	0.2 - 3				
Diluted for (Bath) Use	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																
Baby Products																
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								
Bath Preparations (diluted for use)																
Bubble Baths									NR	NR	0.75	NR				
Other Bath Preparations					1	NR	1	3	NR	NR	0.15	NR				
Eye Makeup Preparations																
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								
Fragrance Preparations																
Cologne and Toilet Water					NR	NR	0.25	NR								
Perfumes					10	1	NR	3								

Table 1. 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 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ³	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²	2023 ³	2002 ²	2023 ⁴	2002 ²
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				
Body and Hand (exc shave)					140	34	not spray: 0.25 – 3.3	3	NR	3	not spray: 0.15 – 0.95	0.8				

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