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

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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 (%)											
	Hydrogenated Castor Oil								Ricinoleic 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	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																				
Perfumes	NR	NR	NR	5					1	NR	NR	0.3 – 1																				

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	# 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				Ricinoleic 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
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				
Feminine Deodorants	1	NR	NR	2												
Other Personal Cleanliness Products	6	65	3.5	NR					5	1	NR	0.003				

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	Hydrogenated Castor Oil				Ricinoleic 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
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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