

PEG Soy Sterols

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in year 2000, along with updated information regarding product types and concentrations of use, and confirmed that PEG-5, -10, -16, -25, -30, and -40 Soy Sterol are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

PEG Soy Sterols, Safety, Cosmetics

The Expert Panel for Cosmetic Ingredient Safety first published a Final Report on the Safety Assessment of PEG-5, -10, -16, -25, -30, and -40 Soy Sterol in 2000, with the conclusion that the data were insufficient to support the safety of this ingredient group.¹ Subsequently, additional data were received, and in 2004, the Expert Panel published an Amended Safety Assessment of PEG-5, -10, -16, -25, -30, and -40 Soy Sterol, with the conclusion that these six PEG Soy Sterol ingredients are safe as used in cosmetics, as described in the safety assessment.²

Because it has been at least 15 years since the final amended report was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel determined whether the safety assessment should be reopened. At the June 2022 meeting, the Expert Panel considered updated 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 the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council⁴ (Council). The frequency of use has decreased for all ingredients that were reported to be in use, with the exception that PEG-30 Soy Sterol, which was not previously reported to be used, is now used in 11 formulations.^{2,3} In 2000, the maximum concentration of use for this ingredient group was reported to be 2% in leave-on products for PEG-5 Soy Sterol, PEG-10 Soy Sterol, and PEG-25 Soy Sterol. Recent (2020) concentration of use data indicate that PEG-10 Soy Sterol is used at up to 2.6% in rinse-off products, and up to 2.1% in leave-on products.⁴ The cumulative frequency and concentration of use data are presented in Table 1.

An extensive search of the world's literature was performed for studies dated 1998 forward. No new toxicity or safety data were found. After reviewing updated frequency and concentration of use data, and considering the lack of new toxicological or safety data, the Expert Panel determined to not reopen this safety assessment on the PEG Soy Sterol ingredients and reaffirmed the conclusion published in 2004.

Author's Note

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Table 1. Current and Historical Frequency and Concentration of Use according to Duration and Exposure.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	PEG-5 Soy Sterol				PEG-10 Soy Sterol			
	1996 ¹	2022 ³	2000 ²	2020 ⁴	1996 ²	2022 ³	2000 ²	2020 ⁴
Totals ^a	41	7	.2–2	0.5	35	9	.05–2	.1–2.6
Duration of use								
Leave-on	36	7	.2–2	NR	17	6	.05–2	.1–2.1
Rinse-off	5	NR	NR	0.5	18	3	2	.1–2.6
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	6	1	2	NR	1	NR	.1–2	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	0.5
Incidental inhalation-spray	10 ^b ; 9 ^c	3 ^b ; 2 ^d	.2–2 ^d	NR	9 ^b ; 3 ^d	4 ^b ; 1 ^d	.4–2 ^b ; 2 ^d	2.1 ^b
Incidental inhalation-powder	9 ^c	2 ^c	.2–2 ^d	NR	3 ^d	1 ^d	2 ^d	.1–1 ^c
Dermal contact	33	7	.2–2 ^d	NR	33	8	.05–2	.1–2.6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	3	NR	NR	0.5	2	2	.4–2	2.1
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	0.5
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	PEG-16 Soy Sterol				PEG-25 Soy Sterol			
	1996 ²	2022 ³	2000 ²	2020 ⁴	1996 ²	2022 ³	2000 ²	2020 ⁴
Totals ^a	8	3	.2–0.5	.01–1	5	2	.5–2	NR
Duration of use								
Leave-on	5	NR	.2–0.5	.01–.25	2	1	.5–2	NR
Rinse-off	3	3	0.5	1	3	1	0.5	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	3	NR	0.2	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	1 ^b	NR	.2–0.5 ^c	NR	NR	NR	0.5 ^d	NR
Incidental inhalation-powder	NR	NR	NR	.25 ^b	NR	1 ^c	0.5 ^d	NR
Dermal contact	8	3	0.2	.01–1	5	2	.5–2	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	0.5	NR	NR	NR	0.5	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	1	NR	NR
Baby products	NR	NR	NR	NR	NR	1	NR	NR
	PEG-30 Soy Sterol				PEG-40 Soy Sterol			
	1996 ²	2022 ³	2000 ²	2020 ⁴	1996 ²	2022 ³	2000 ²	2020 ⁴
Totals ^a	NR	11	NR	.35	1	NR	NR	NR
Duration of use								
Leave-on	NR	11	NR	.35	NR	NR	NR	NR
Rinse-off	NR	NR	NR	NR	1	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR

(continued)

Table 1. (continued)

	PEG-30 Soy Sterol				PEG-40 Soy Sterol			
	1996 ²	2022 ³	2000 ²	2020 ⁴	1996 ²	2022 ³	2000 ²	2020 ⁴
<i>Exposure type</i>								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	NR	5 ^b ; 6 ^d	NR	NR	NR	NR	NR	NR
Incidental inhalation-powder	NR	6 ^d	NR	NR	NR	NR	NR	NR
Dermal contact	NR	I I	NR	.35	I	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR

^aBecause 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.

^bIt is possible these products are sprays, but it is not specified whether the reported uses are sprays.

^cIt is possible these products are powders, but it is not specified whether the reported uses are powders.

^dNot 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. NR, no reported use.

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