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Phytantriol

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 2007, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that Phytantriol is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Phytantriol, Safety

The Expert Panel for Cosmetic Ingredient Safety published the Final Report on the Safety Assessment of Phytantriol in 2007.[1] The Expert Panel concluded that Phytantriol is safe as a cosmetic ingredient in the practices of use and concentration 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 Expert Panel considered whether the safety assessment should be reopened. At its December 2022 meeting, the Expert Panel reviewed updated (2022) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database[2] and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.[3] Since the original report was issued, the frequency of use has decreased, from 94 uses reported in 2002 to 82 uses reported in 2022. In 2022, the maximum concentration of use was reported to be .54%; the maximum use concentration reported by industry in 2003 was .1%. However, it should be noted that personal communication submitted to CIR in 2004 indicated that the expected use concentration in products under development was 3%; accordingly, the conclusion that was reached in the original report considered use up to 3%. The frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

In September 2022, an extensive search of the world's literature was performed for studies dated 2000 forward, and one case report was found.[4] The Expert Panel agreed, however, that the published data did not reveal toxicity or other data that warrant re-evaluation of the safety of this ingredient in cosmetic products.

In summary, the Expert Panel reviewed 2022 frequency and concentration of use data and noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Expert Panel reaffirmed the 2007 conclusion for Phytantriol.

Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Author Contributions

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Table 1. Frequency (2022; 2002) and Concentration (2022; 2003) of Use According to Likely Duration and Exposure and Product Category.

	# of Uses		Max Conc of Use (%)	
	2022[2]	**2002[1]**	**2022[3]**	**2003[1]**
Totals[d]	**82**	**94**	**.001-.54**	**.0001-1; ≤3.0[f]**
Summarized by likely duration and exposure[e]				
Duration of use				
Leave-on	46	42	.001-.54	.0001-1; ≤ 3.0[f]
Rinse-off	36	52	.01-.05	.002-.1; ≤ 3.0[f]
Diluted for (bath) use	NR	NR	NR	.05; ≤ 3.0[f]
Exposure type				
Eye area	10	NR	NR	NR
Incidental ingestion	1	6	.25	0.1
Incidental inhalation-spray	5; 14[a]; 2[b]	4; 16[a]; 1[b]	.018-.54; .1-0.2[a]	.0001-.1; .0001[a]; .1-0.2[b]; ≤3.0[f,a,b]
Incidental inhalation-powder	2[b]	1[b]	0.1[c]	.1-0.2[b]; ≤3.0[f,b]
Dermal contact	13	3	.01-0.2	.05-.5; ≤3.0[f]
Deodorant (underarm)	NR	NR	NR	0.5[a]
Hair – non-coloring	58	80	.01-.54	.0001-.1; ≤3.0[f]
Hair-coloring	NR	NR	NR	NR
Nail	1	5	.001-.25	1; ≤3.0[f]
Mucous membrane	2	6	.25	.05-.1; ≤3.0[f]
Baby products	NR	NR	NR	NR
As reported by product category[e]				
Bath preparations (diluted for use)				
Other bath preparations	NR	NR	NR	.05, ≤3.0[f]
Eye makeup preparations				
Eye lotion	1	NR	NR	NR
Mascara	9	NR	NR	NR
Fragrance preparations				
Other fragrance preparation	1	NR	NR	NR
Hair preparations (non-coloring)				
Hair conditioner	15	30	.01-0.5	.002-.1, ≤3.0[f]
Hair spray (aerosol fixatives)	4	4	.15-.54 (aerosol) .018 (pump spray)	.0001-0.1
Rinses (non-coloring)	2	NR	NR	NR
Shampoos (non-coloring)	18	22	.01-.05	.002-.1, ≤3.0[f]
Tonics, dressings, and other hair grooming aids	12	15	0.1	.0001, ≤3.0[f]
Other hair preparations	7	9	.025-.05	NR
Makeup preparations				
Foundations	5	NR	NR	NR
Lipstick	1	6	.25	0.1
Rouges	NR	NR	NR	0.1
Other makeup preparations	NR	1	NR	NR
Manicuring preparations (nail)				
Basecoats and undercoats	NR	2	NR	≤3.0[f]
Nail creams and lotions	NR	NR	.25	NR
Nail polish and enamel	NR	2	.001	≤3.0[f]
Other manicuring preparations	1	1	NR	1, ≤3.0[f]
Personal cleanliness products				
Deodorants (underarm)	NR	NR	NR	0.5
Other personal cleanliness products	1	NR	NR	.05

(continued)

Table 1. (continued)

	# of Uses		Max Conc of Use (%)	
	2022[2]	**2002**[1]	**2022**[3]	**2003**[1]
Shaving preparations				
Aftershave lotion	NR	NR	.01	.05, ≤3.0[f]
Shaving cream	NR	NR	.01	NR
Skin care preparations				
Face and neck (exc shave)	2	1	.1 (not spray)	.1-.2, ≤3.0[f]
Moisturizing	2	1	.2 (not spray)	≤3.0[f]
Other skin care preparations	1	NR	NR	NR
Suntan preparations				
Other suntan preparations	NR	NR	0.2	NR

NR, not reported.
[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.
[d]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.
[e]Likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings).
[f]Presented as anticipated use concentration; the conclusion that was reached considered use as up to 3%.

Declaration of Conflicting Interest

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