

DIOSCOREA VILLOSA (WILD YAM) ROOT EXTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the Amended Safety Assessment of Dioscorea Villosa (Wild Yam) Root Extract in 2004.¹ The Panel concluded that based on the chemical and animal data include in the safety assessment, Dioscorea Villosa (Wild Yam) Root Extract is safe for use in cosmetic products. In the Discussion of that report, the Panel further clarified that this conclusion is valid only for extracts prepared in a manner that produces a similar chemical profile as that described in the safety assessment, particularly in regard to diosgenin (i.e., an expected upper limit of 3.5%). Additionally, the Panel stated that extracts not prepared in a manner that produces a similar chemical profile would be considered safe if they have a similar safety test profile.

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 March 2023 meeting, the Panel reviewed 2022 information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database² and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.³ The frequency of use increased. Dioscorea Villosa (Wild Yam) Root Extract had 1 reported use in the original review, and 43 reported uses in 2022;² total reported uses and use categories did not significantly change. However, the reported concentrations of use decreased. The maximum reported use concentration of Dioscorea Villosa (Wild Yam) Root Extract in 1999 was 15% (0.5% maximum solids from wild yam) in moisturizing formulations; in 2022, it was reported to be used at 0.3% in non-spray moisturizing products. The cumulative frequency and concentration of use data are presented in Table 1.

In January 2023, an extensive search of the world's literature was performed for studies dated 1999 forward, and new data were found.⁴⁻⁹ Notable findings include two short-term oral toxicity studies and a 13-wk oral toxicity study in which the no-observed-adverse-effect-level (NOAEL) for rats of both sexes was determined to be the maximum received dose of 5000 mg/kg/d. Additionally, studies demonstrating the potential cytotoxicity of *Dioscorea villosa* (wild yam) root extract against breast cancer cell lines, a study of anti-inflammatory effects, and a clinical study in which no significant side effects or metabolic/endocrinal changes were seen in healthy premenopausal women following 3 mo of topical application of wild yam cream, were found.

In summary, the Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2004 conclusion for Dioscorea Villosa (Wild Yam) Root Extract. The Panel discussed the possibility for this ingredient 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 (2022/1998) and concentration (2022/1999) of use according to likely duration and exposure by product category

	# of Uses		Max Conc of Use (%)	
	2022 ²	1998 ¹	2022 ³	1999 ¹
Totals*	43	1	0.3	0.00001-15
summarized by likely duration and exposure**				
Duration of Use				
Leave-On	39	1	0.3	0.00001-15
Rinse-Off	4	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type				
Eye Area	2	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	25 ^a ; 10 ^b	1 ^b	NR	15 ^a ; 0.00001 ^b
Incidental Inhalation-Powder	10 ^b	1 ^b	NR	0.00001 ^b
Dermal Contact	42	1	0.3	0.00001-15
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	1	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR
Baby Products	NR	NR	NR	NR
as reported by product category				
Eye Makeup Preparations				
Eye Lotion	2	NR	NR	NR
Hair Preparations (non-coloring)				
Tonics, Dressings, and Other Hair Grooming Aids	1	NR	NR	NR
Personal Cleanliness Products				
Other Personal Cleanliness Products	1	NR	NR	NR
Skin Care Preparations				
Cleansing	2	NR	NR	NR
Face and Neck (exc shave)	6	NR	NR	NR
Body and Hand (exc shave)	4	1	NR	0.00001 (0.000002% maximum solids from wild yam)
Moisturizing	23	NR	0.3 (not spray)	15 (0.5% maximum solids from wild yam)
Night	1	NR	NR	NR
Paste Masks (mud packs)	1	NR	NR	NR
Other Skin Care 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 is 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

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