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Dioscorea Villosa (Wild Yam) Root Extract

Preethi S. Raj*, Wilma F. Bergfeld, Donald V. Belsito**, David E. Cohen**, Curtis D. Klaassen**, Allan E Rettie**, David Ross**, Thomas J. Slaga**, Paul W. Snyder**, Susan Tilton**, Monice Fiume†, and Bart Heldreth‡**

Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed updated information that has become available since their original assessment from 2004, along with updated information regarding product types, and frequency and concentrations of use, and reaffirmed their original conclusion that Dioscorea Villosa (Wild Yam) Root Extract is safe as a cosmetic ingredient in the practices of use and concentration as described in this report.

Keywords

Safety, Cosmetics, 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 included 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 (ie, 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) database[2] 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% (.5% maximum solids from wild yam) in moisturizing formulations; in 2022, it was reported to be used at .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 2 short-term oral toxicity studies and a 13-week 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.

*Cosmetic Ingredient Review Senior Scientific Analyst/Writer
**Expert Panel for Cosmetic Ingredient Safety Member
†Cosmetic Ingredient Review Senior Director
‡Cosmetic Ingredient Review Executive Director

Corresponding Author:
Bart Heldreth, Executive Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.
Email: cirinfo@cir-safety.org

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[a]	43	1	.3	.00001-15
Summarized by likely duration and exposure[b]				
Duration of use				
Leave-on	*39*	*1*	*0.3*	*.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[c]; 10[d]	1[d]	NR	15[c]; .00001[d]
Incidental inhalation-powder	10[d]	1[d]	NR	.00001[d]
Dermal contact	42	1	0.3	.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	.00001 (.000002% maximum solids from wild yam)
Moisturizing	23	NR	.3 (not spray)	15 (.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.

[a]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.

[b]Likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings).

[c]It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

[d]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.

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.

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.

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References

1. Andersen FA, ed. Final report of the amended safety assessment of Dioscorea Villosa (Wild Yam) root extract. *Int J Toxicol*. 2004; 23(Suppl 2):49-54.
2. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition (CFSAN). Voluntary cosmetic registration Program - frequency of use of cosmetic ingredients (VCRP). (Obtained under the freedom of information act from CFSAN; requested as "frequency of use data". 2022. (January 4, 2022; received January 11, 2022).
3. Personal Care Products Council. Concentration of use by FDA product category: Dioscorea Villosa (Wild Yam) root extract. 2022. (Unpublished data submitted by the Personal Care Products Council on October 31, 2022).
4. Lima CM, Lima AK, Melo MG, et al. Bioassay-guided evaluation of Dioscorea Villosa - an acute and subchronic toxicity, antinociceptive and anti-inflammatory approach. *BMC Compl Alternative Med*. 2013;13:195.
5. Wojcikowski K, Wohlmuth H, Johnson DW, Gobe G. Dioscorea Villosa (Wild Yam) induces chronic kidney injury via pro-fibrotic pathways. *Food Chem Toxicol*. 2008;46(9):3122-3131.
6. Cha SB, Kim HS, Bae JS, Song SW, Lim JO, Kim JC. A 13-week subchronic toxicity study of a Dioscorea Rhizome water extract in rats. *Regul Toxicol Pharmacol*. 2021;120:104844.
7. Mazzio E, Almalki A, Darling-Reed SF, Soliman KFA. Effects of Wild Yam root (Dioscorea Villosa) extract on the gene expression profile of triple-negative breast cancer cells. *Cancer Genomics Proteomics*. 2021;18(6):735-755.
8. Aumsuwan P, Khan SI, Khan IA, et al. Evaluation of Wild Yam (Dioscorea Villosa) root extract as a potential epigenetic agent in breast cancer cells. *In Vitro Cell Dev Biol Anim*. 2015;51(1):59-71.
9. Komesaroff PA, Black CV, Cable V, Sudhir K. Effects of Wild Yam extract on menopausal symptoms, lipids and sex hormones in healthy menopausal women. *Climacteric*. 2001;4(2): 144-150.