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Squalane and Squalene

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1982, along with updated information regarding product types and concentrations of use, and confirmed that Squalane and Squalene are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Safety, Squalane, Squalene

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Squalane and Squalene in 1982.[1] The Panel concluded that "both Squalane and Squalene are safe as cosmetic ingredients in the present practices of use and concentration," as described in that report. In 2001, after considering new studies and updated use data on these two ingredients, the Panel determined to not re-open the safety assessment.[2] Data identified in the published literature[3–13] that have become available since the 2001 re-review was issued support the conclusion reached by the Panel in the original review. The Panel also 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,[14] and the maximum use concentrations provided by the Personal Care Products Council.[15] The Panel determined to not re-open this safety assessment and reaffirmed the original conclusion that Squalane and Squalene are safe as cosmetic ingredients in the present practices of use and concentration, as given in Table 1.

The reported frequency of use has increased significantly for both ingredients since the initial re-review was considered. According to VCRP data, Squalane and Squalene were reported to be used in 595 and 29 formulations, respectively, in 2001.[2] In 2019, the VCRP indicates that Squalane is used in 2785 formulations, and Squalene is used in 527 formulations.[14] For Squalane, the current maximum concentration of use (96.8%)[14] is the same as that reported in 2001 (97%);[2] however, the maximum concentrations of use by exposure type (e.g., eye area and nails) have increased for some categories. The opposite is true for Squalene; the maximum concentration of use has decreased since the previous re-review. In 2001, Squalene was used at up to 10%;[2] data received in 2018 report that the maximum concentration of use is 1.2%.[15]

Squalane and Squalene are natural components of human sebum. Although new studies indicated there could be sensitization potential, there is no significant clinical evidence of sensitization. The Panel stated the lack of case reports, in spite of the increased frequency of use, and the Panel's clinical experience with these ingredients support the safety of these ingredients for use in cosmetics.

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. Current and Historical Frequency and Concentration of Use of Squalane and Squalene According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)	
	2019[14]	2001[2]	2018[15]	2001[2]
	Squalane			
Totals[a]	**2785**	**595**	**.0001-96.8**	**.01-97**
Duration of use				
Leave-on	*2608*	*541*	*.0001-96.8*	*.01-97*
Rinse-off	*171*	*54*	*.0001-34.9*	*.1-5*
Diluted for (bath) use	*6*	*NR*	*.14*	*NR*
Exposure type				
Eye area	366	42	.0001-38	.01-15
Incidental ingestion	253	52	.001-22.8	3-17
Incidental inhalation-spray	Spray: 12 Possible: 772[b]; 656[c]	Spray: 12 Possible: 170[b]; 68[c]	Spray: .048-.15 Possible: .005-12[b]	Possible: .3-36[b] .1-97[c]
Incidental inhalation-powder	Powder: 107 Possible: 656[c]; 11[d]	Powder: 28 Possible: 68[c]; 2[d]	Powder: 1-3.4 Possible: .01-40.1	Powder: 3-9 Possible: .1-97[c]
Dermal contact	2447	510	.0001-85.4	.1-97
Deodorant (underarm)	3[b]	NR	.18-4	NR
Hair – non-coloring	69	17	.001-2.3	.8-5
Hair-coloring	NR	NR	NR	NR
Nail	4	6	.0001-96.8	NR
Mucous membrane	277	63	.001-22.8	.1-17
Baby products	11	2	.03-2	NR
	Squalene			
Totals[a]	**527**	**29**	**.004-1.2**	**.01-10**
Duration of use				
Leave-on	*300*	*26*	*.0045-.7*	*.02-10*
Rinse-off	*215*	*2*	*.004-1.2*	*.01-.5*
Diluted for (bath) use	*12*	*1*	*NR*	*.2*
Exposure type				
Eye area	19	NR	.0046-.07	.5-.7
Incidental ingestion	71	NR	.0045-.09	.7
Incidental inhalation-spray	Spray: 1 Possible: 102[b]; 67[c]	Possible: 9[b]; 13[c]	Possible: .07[b]	Possible: .06-.5[b] .08-.5[c]
Incidental inhalation-powder	Powder: 2 Possible: 67[c]; 2[b]	Possible: 13[c]	Possible: .05-.7	Powder: 10 Possible: .08-.5[c]
Dermal contact	453	29	.004-.7	.02-10
Deodorant (underarm)	NR	NR	.06	NR
Hair – non-coloring	3	NR	.07-1.2	.01
Hair-coloring	NR	NR	0.2	NR
Nail	NR	NR	NR	NR
Mucous membrane	288	1	.004-.09	.2-.7
Baby products	2	NR	NR	NR

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

Declaration of Conflicting Interests

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