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Quaternium-18 and Quaternium-18 Bentonite

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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 Quaternium-18 and Quaternium-18 Bentonite are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Safety, Quaternium-18, Quaternium-18 Bentonite

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the safety assessment of Quaternium-18, Quaternium-18 Bentonite, and Quaternium-18 Hectorite in 1982 and concluded that these ingredients were safe as used.[1] In 2003, after considering new studies and updated use data on these ingredients, the Panel determined to not re-open the safety assessment.[2] In 2019, Quaternium-18 and Quaternium-18 Bentonite were again re-reviewed, and it was determined to re-open the safety assessment to evaluate the sufficiency of inhalation data on Quaternium-18 Bentonite. Additionally, an exhaustive search of the world's literature was performed for studies dated 1995 forward. No relevant published data were found; however, unpublished data provided by the Personal Care Products Council regarding Quaternium-18 Bentonite were provided.[3] (Some of the data provided were already included in the original report.)

However, at the June 2020 meeting, the Panel determined the data on Quaternium-18 and Quaternium-18 Bentonite was sufficient to re-affirm the original conclusion that these ingredients are safe as cosmetic ingredients in the present practices of use and concentration as given in Table 1. The Panel concluded that the acute inhalation toxicity study was sufficient to support the use of Quaternium-18 Bentonite in cosmetics, as no toxic effects were observed when animals were exposed to a high concentration of the test substance for a prolonged period of time. In cosmetics, exposure to Quaternium-18 Bentonite in potentially inhaled products would be short, and of a low concentration. In addition, the concentrations and number of uses for both Quaternium-18 and Quaternium-18 Bentonite have decreased since 2001. Quaternium-18 Bentonite was previously reported to be used at up to 9% in leave-on products; however, according to 2018 concentration of use data, Quaternium-18 Bentonite is reported to be used at up to 2.5% in leave-on products. The Panel also mitigated the concern for developmental/reproductive toxicity or genotoxicity, as these ingredients would not result in dermal penetration and have shown no evidence of chronic oral or dermal toxicity.

It should be noted that Quaternium-18 Hectorite was also included in the 1982 safety assessment and 2001 re-review. However, Quaternium-18 Hectorite is not included in the current assessment because it was recently (2013) part of a separate assessment (Safety Assessment of Ammonium Hectorites as Used in Cosmetics).[4] In that assessment, Quaternium-18 Hectorite was determined to be safe as used in cosmetics in the present practices of use and concentration.

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Table 1. Current and Historical Frequency and Concentration of Use of Quaternium-18 and Quaternium-18 Bentonite.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Quaternium-18				Quaternium-18 Bentonite			
	2020[5]	2001[2]	2018[6]	2001[2]	2020[5]	2001[2]	2018[6]	2001[2]
Totals*	**70**	**90**	**.46–.95**	**.1-2**	**200**	**221**	**.15–2.5**	**.8-9**
Duration of use								
Leave-on	*18*	*27*	*.46*	*.1–2*	*200*	*218*	*.15–2.5*	*.8–9*
Rinse-off	*53*	*63*	*.76–.95*	*1–2*	*NR*	*3*	*NR*	*NR*
Diluted for bath) use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure type								
Eye area	NR	1	NR	NR	72	70	NR	4–9
Incidental ingestion	2	NR	NR	0.7	108	138	NR	5
Incidental inhalation-spray	15[a]	1; 3[a]	.46[a]	.1–2[a]	3[a]; 1[c]	1[a]	2.5[a]	5[a]
Incidental inhalation-powder	NR	NR	NR	NR	2	NR	.29[b]	NR
Dermal contact	1	16	NR	NR	87	79	.29–1	.8–6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	0.6[d]	NR
Hair – non-coloring	66	68	.46–.95	.1–2	3	NR	2.5	NR
Hair-coloring	1	1	NR	NR	NR	NR	NR	NR
Nail	NR	5	NR	NR	2	NR	.15–.25	NR
Mucous membrane	2	1	NR	0.7	108	141	NR	5
Baby products	NR	NR	NR	NR	NR	NR	NR	NR

*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.
[a]It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b]It is possible these products are powders, but it is not specified whether the reported uses are powders.
[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]Formulated as a spray.
NR, no reported use.

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Author's Note

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