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Sulfites

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1998, along with updated information regarding product types and concentrations of use, and confirmed that Sodium Sulfite, Potassium Sulfite, Ammonium Sulfite, Sodium Bisulfite, Ammonium Bisulfite, Sodium Metabisulfite, and Potassium Metabisulfite are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Safety, Sulfites

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of Sulfites in 2003.[1] The Expert Panel concluded that Sodium Sulfite, Potassium Sulfite, Ammonium Sulfite, Sodium Bisulfite, Ammonium Bisulfite, Sodium Metabisulfite, and Potassium Metabisulfite are safe as used in cosmetic formulations. At the September 2019 meeting, the Expert Panel reviewed data identified in the published literature since 1998.[2-62] The Expert Panel also considered 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,[10] and the maximum use concentrations provided by the Personal Care Products Council (Council).[11] Upon review, the Expert Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that these ingredients are safe as used in cosmetic formulations, as given in Table 1.

Frequency of use has increased substantially for Sodium Sulfite since the original review; in the 2003 report, 911 uses were reported, and in 2020, this ingredient was reported to have 1713 uses.[10] Sodium Metabisulfite also had a substantial increase in reported use frequency, from 348 uses in 2003 to 916 uses in 2020. The maximum concentration of use reported for this family of ingredient has decreased; in the 2003 report, Sodium Metabisulfite had the highest use concentration (14% in rinse-off products)[1]; in 2019, this ingredient was reported being used at substantially lower concentrations of up to .6% in rinse-off products.[11] The sulfite with the highest reported use concentration in 2019 was Sodium Sulfite, at concentrations up to 3% in rinse-off products. (This is the same use concentration reported for this ingredient in the 2003 report.[1])

The Expert Panel's concern about sulfite-induced contact sensitization, following a review of patient studies, was allayed after considering negative results from two human repeated insult patch tests on Sodium Sulfite at concentrations greater than .25% (highest reported use concentration in leave-on products) in normal subjects.[1] The Expert Panel noted that results from a patient population are difficult to interpret in terms of their relevance to the general population, and, also, that few reactions to sulfites on standard panels used by dermatologists are being reported.[42] However, they acknowledged that sulfites can cause hypersensitivity, as evidenced by the enhancement of allergic sensitization in dust mite allergen-sensitized BALB/c mice.[36] Additionally, the Expert Panel noted that sulfites are associated with IgE-mediated allergic reactions in some individuals, and that individuals with sulfite allergies should exercise caution in using products containing sulfites that may be incidentally inhaled.[38] The lack of awareness of asthmatic responses to topical cosmetics was also acknowledged by the Expert Panel.[35]

After considering that positive genotoxicity results (sister chromatid exchanges) were observed at the highest dose tested, the Expert Panel agreed that such a high dose would not be achieved in the current reported concentrations of use in cosmetics. Furthermore, the Expert Panel noted that the weight of

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Table 1. Current and Historical Frequency and Concentration of Use of Sulfites According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Ammonium Bisulfite				Potassium Metabisulfite			
	2020[10]	2003[1]	2019[11]	2003[1]	2020[10]	2003[1]	2019[11]	2003[1]
Totals[a]	1	NR	NR	32	NR	1	.35	NR
Duration of use								
Leave-on	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Rinse-off	*1*	*NR*	*NR*	*32*	*NR*	*1*	*.35*	*NR*
Diluted for (bath) use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	1	NR	NR	32	NR	1	.35	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	Potassium Sulfite				Sodium Bisulfite			
	2020[10]	2003[1]	2019[11]	2003[1]	2020[10]	2003[1]	2019[11]	2003[1]
Totals[a]	2	1	NR	NR	74	58	.0013-0.1	.03-0.7
Duration of use								
Leave-on	*2*	*NR*	*NR*	*NR*	*50*	*6*	*.0013-0.1*	*.03-0.3*
Rinse-off	*NR*	*1*	*NR*	*NR*	*24*	*51*	*.013*	*.1-0.7*
Diluted for (bath) use	*NR*	*NR*	*NR*	*NR*	*NR*	*1*	*NR*	*NR*
Exposure type								
Eye area	NR	NR	NR	NR	8	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	1[b]	NR	NR	NR	11[b]; 24[d]	1[b]	.0013[b]	.03[b]; 0.05[d]
Incidental inhalation-powder	NR	NR	NR	NR	24[d]	NR	.02[c]	.05[d]
Dermal contact	2	NR	NR	NR	69	7	.02	.05-0.3
Deodorant (underarm)	1[b]	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	1	NR	NR	5	2	.0013-0.1	.03
Hair-coloring	NR	NR	NR	NR	NR	49	NR	0.7
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	15	1	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	Sodium Metabisulfite				Sodium Sulfite			
	2020[10]	2003[1]	2019[11]	2003[1]	2020[10]	2003[1]	2019[11]	2003[1]
Totals[a]	916	348	.000005-0.6	.003-14	1713	911	.000001-3	.01-3
Duration of use								
Leave-on	*326*	*28*	*.0001-.25*	*.003-0.4*	*129*	*3*	*.0000051-.12*	*.1-0.4*
Rinse-off	*590*	*312*	*.000005-0.6*	*.1-14*	*1583*	*906*	*.000001-3*	*.01-3*
Diluted for (bath) use	*NR*	*8*	*NR*	*NR*	*1*	*2*	*NR*	*NR*

(continued)

Table 1. (continued)

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Sodium Metabisulfite				Sodium Sulfite			
	2020[10]	2003[1]	2019[11]	2003[1]	2020[10]	2003[1]	2019[11]	2003[1]
Exposure type								
Eye area	28	1	.003-.03	NR	12	NR	.03	NR
Incidental ingestion	NR	NR	.003	NR	NR	NR	.0015	NR
Incidental inhalation-spray	125[b]; 115[d]	12[b]; 2[d]	.02-.25	.003-0.3[b]; 0.003[d]	45[b]; 41[d]	NR	.0000051-.002[b]	0.1[b]
Incidental inhalation-powder	115[d]	2[d]	.0001;0.001-.12[c]	.003[d]	41[d]	NR	.00001-.12[c]	NR
Dermal contact	324	34	.0001-.25	.003-0.4	170	5	.00001-3	.1-0.4
Deodorant (underarm)	NR	7[b]	.04	0.1[b]	6	NR	NR	NR
Hair – non-coloring	8	3	.000005-.00011	.1-14	16	12	.000001-.35	.01
Hair-coloring	537	310	.29-0.6	NR	1525	893	.05-1.1	.5-3
Nail	1	1	NR	NR	1	1	NR	NR
Mucous membrane	24	8	.00041-0.1	NR	40	3	.00005-.0015	0.2
Baby products	1	NR	NR	NR	NR	NR	.00001	NR

NR, no reported use.
[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]It is possible these products are powders, but it is not specified whether the reported uses are powders.
[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.

evidence for sulfite-induced carcinogenicity in animal models is negative, and that the International Agency for Research on Cancer has concluded that there is inadequate evidence for the carcinogenicity of sulfites, bisulfites, and metabisulfites in experimental animals and humans. The minimal concern by the Expert Panel over the potential toxicity of sulfites from cosmetic exposure is further mitigated by the use of these ingredients at low concentrations and the low potential for absorption.

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Author's Note

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