

SODIUM SESQUICARBONATE, SODIUM CARBONATE, AND SODIUM BICARBONATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Sodium Sesquicarbonate, Sodium Bicarbonate, and Sodium Carbonate in 1987.¹ The Panel concluded that these 3 ingredients were “safe as presently used” in cosmetics. Upon re-review in March 2005, the Panel reaffirmed the original conclusion, as published in 2006.²

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At the December 2023 meeting, the Panel considered updated (2023) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.⁴ The frequencies of use for both Sodium Bicarbonate and Sodium Carbonate have increased since the previous rereview was conducted; of note, the frequency of use of Sodium Bicarbonate increased from 66 uses in 2002 to 571 reported uses in 2023. The frequency of use of Sodium Sesquicarbonate has decreased. Additionally, the maximum reported concentrations of use of all 3 ingredients have decreased since the previous re-review. The cumulative frequency and concentration of use data are presented in Table 1.

In October 2023, an extensive search of the world’s literature was performed for studies dated 2000 forward, and new data were found.⁵⁻²⁰ Toxicology, genotoxicity, carcinogenicity, anti-carcinogenicity, dermal irritation, ocular irritation, and clinical studies were considered by the Panel. The Panel remarked that although a considerable amount of new data were available, no findings were noted that would change the existing conclusion.

In summary, the Panel reviewed 2023 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 and the prior re-review document, the Panel reaffirmed the 1987 conclusion. The Panel discussed the possibility for these ingredients 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 (2023/2001)^{2,3} and concentration (2023/2004)^{2,4} of use according to likely duration and exposure and by product category

	Sodium Sesquicarbonate				Sodium Bicarbonate				Sodium Carbonate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ³	2002 ²	2023 ⁴	2004 ²	2023 ³	2002 ²	2023 ⁴	2004 ²	2023 ³	2002 ²	2023 ⁴	2004 ²
Totals*	9	24	0.5-69.1	2-90	571	66***	0.00001-67.6	0.006-95	76	21	0.0002-48.7	0.000002-51
summarized by likely duration and exposure**												
Duration of Use												
<i>Leave-On</i>	2	1	35	35-59	142	26	0.0003-55.1	0.01-56	22	7	0.0002-0.044	0.000002-0.6
<i>Rinse-Off</i>	1	3	34.9	NR	132	33	0.00001-66.4	0.006-95	16	10	0.0002-2.3	0.01-32
<i>Diluted for (Bath) Use</i>	6	20	0.5-69.1	2-90	297	7	63.2-67.6	1-64	38	4	0.0012-48.7	0.009-51
Exposure Type												
Eye Area	NR	NR	NR	NR	NR	8	0.012	0.04-0.2	4	NR	0.00068	0.004-0.3
Incidental Ingestion	NR	1	NR	NR	69	13***	0.35-66.4	0.03-95	6	3	0.0009-2	2***
Incidental Inhalation-Spray	NR	1	35 ^a	35-59 ^a	34 ^a ,18 ^b	6 ^a ,4 ^b	0.001;1-55.1 ^a	0.1,0.2-0.4 ^a , 0.01-56 ^b	1; 6 ^a ; 11 ^b	1 ^a ; 2 ^b	0.0009-0.19 ^b	0.03; 0.008 ^a ; 0.000002-0.01 ^b
Incidental Inhalation-Powder	NR	NR	35 ^a	35-59 ^a	18b,1 ^c	9; 6 ^a ;1 ^c	20;1-55.1 ^a ; 0.0003-7 ^c	20,0.01-56b,5 ^c	6 ^a	1 ^a	0.0004 ^a	0.008 ^a
Dermal Contact	8	23	0.5-69.1	2-90	495	34	0.00001-67.6	0.006-64	69	12	0.0002-48.7	0.002-51
Deodorant (underarm)	NR	NR	NR	NR	80 ^b	NR	0.05-15 (not spray)	0.01-15 ^b	NR	NR	0.012-0.016 (not spray)	0.002 ^b
Hair - Non-Coloring	NR	NR	NR	NR	5	3	0.05-3.4	0.09-10	NR	4	0.0002-2.3	0.000002-1
Hair-Coloring	NR	NR	NR	NR	NR	8	6	0.1-10	1	2	1-2	0.02-25
Nail	1	NR	NR	NR	2	NR	35.5	39	NR	NR	NR	0.6
Mucous Membrane	7	23	0.5-69.1	2-90	393	33	0.00001-67.6	0.03-95	52	10	0.0009-48.7	0.009-51
Baby Products	NR	NR	NR	NR	1	1	0.001	5	NR	NR	0.044	NR
as reported by product category												
Baby Products												
Baby Lotions/Oils/Powders/Creams					1	1	NR	5				
Other Baby Products					NR	NR	0.001 (wipes, leave-on)	NR	NR	NR	0.044	NR
Bath Preparations (diluted for use)												
Bath Oils, Tablets, and Salts	2	16	0.5-69.1	2-90	261	7	63.2-67.6	30-64	36	4	13.5-48.7	40-51
Bubble Baths	NR	2	50	18	15	NR	NR	5-52	1	NR	NR	7-39
Bath Capsules					1	NR	NR	49				
Other Bath Preparations	4	2	NR	10-35	20	NR	63.3	1-64	1	NR	0.0012-42.3	0.009-39
Eye Makeup Preparations												
Eyebrow Pencil					NR	NR	NR	0.2	NR	NR	0.00068	0.2
Eyeliners					NR	1	NR	0.04-0.1	1	NR	NR	NR
Eye Shadow									NR	NR	NR	0.3
Eye Lotion									NR	NR	NR	0.004
Mascara					NR	6	0.012	0.2	1	NR	NR	0.2
Other Eye Makeup Preparations					NR	1	NR	NR	2	NR	NR	NR
Fragrance Preparations												
Cologne and Toilet water Spray					NR	NR	0.001	NR	1	NR	NR	0.03
Powders (dusting/talcum, excl aftershave talc)					NR	9	20	20				
Other Fragrances	NR	1	NR	NR								
Hair Preparations (non-coloring)												
Hair Conditioner					NR	NR	0.05	5	NR	2	0.0002	0.01
Hair Straighteners									NR	NR	2.3	NR
Permanent Waves					NR	3	0.8	10	NR	1	NR	NR
Rinses (non-coloring)												
Shampoos (non-coloring)					4	NR	3.4	0.09	NR	1	0.0053-0.41	0.08

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	Sodium Sesquicarbonate				Sodium Bicarbonate				Sodium Carbonate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ³	2002 ²	2023 ⁴	2004 ²	2023 ³	2002 ²	2023 ⁴	2004 ²	2023 ³	2002 ²	2023 ⁴	2004 ²
Tonics, Dressings, and Other Hair Grooming Aids									NR	NR	NR	0.000002-0.01
Wave Sets												1
Other Hair Preparations					1	NR	NR	NR				
Hair Coloring Preparations												
Hair Dyes and Colors					NR	8	6	NR	NR	2	1	0.1-0.6
Hair Rinses (coloring)									NR	NR	NR	0.02
Hair Color Sprays (aerosol)												
Hair Bleaches					NR	NR	NR	0.1-10	1	NR	NR	25
Other Hair Coloring Preparation									NR	NR	2	1
Makeup Preparations												
Blushers (all types)									NR	NR	NR	0.03
Foundations					NR	NR	NR	0.09	NR	1	NR	0.3
Lipstick					NR	NR	NR	0.03-1	NR	3	NR	NR
Other Makeup Preparations					1	NR	NR	NR				
Manicuring Preparations (Nail)												
Other Manicuring Preparations	1	NR	NR	NR	2	NR	35.5	39	NR	NR	NR	0.6
Oral Hygiene Products												
Dentifrices					42	10	0.35-66.4	3-95	2	NR	0.65-2	2
Mouthwashes and Breath Fresheners					9	2	NR	0.1	1	NR	0.0009	NR
Other Oral Hygiene Products					18	1	NR	0.5	2	NR	NR	22 ^d
Personal Cleanliness Products												
Bath Soaps and Detergents	NR	2	NR	NR	20	2	0.00001-43.5	25-54	3	1	0.0074-0.4	3-32
Deodorants (underarm)					80	NR	0.05-15 (not spray)	0.01-15	NR	NR	0.012-0.016 (not spray)	0.002
Douches					NR	2	NR	NR				
Feminine Deodorants					2	2	1	NR				
Other Personal Cleanliness Products	1	1	34.9 (rinse-off)	NR	5	3	1	0.07-56	6	2	NR	NR
Shaving Preparations												
Preshave Lotions (all types)					1	NR	NR	NR				
Shaving Cream					1	NR	NR	0.006	NR	NR	0.0051	NR
Other Shaving Preparations					1	1	1.3	NR	NR	NR	0.0053	NR
Skin Care Preparations												
Cleansing					29	NR	0.01-43.5	0.04-26	1	1	0.003-0.93	0.02-0.2
Face and Neck (exc shave)					11	NR	NR	0.01-7	4	NR	NR	0.008
Body and Hand (exc shave)					5	NR	0.0003-7 (not spray)	10	2	1	0.0004 (not spray)	NR
Foot Powders and Sprays	NR	NR	35	35-59	NR	4	55.1	25-56				
Moisturizing					20	NR	11.8 (not spray)	0.4	7	2	0.0002 (not spray)	NR
Night (Spray)									1	NR	NR	NR
Paste Masks (mud packs)					2	1	0.02-4	61				
Skin Fresheners					4	2	NR	NR	2	NR	0.019	NR
Other Skin Care Preparations	1	NR	NR	NR	14	4	0.005-30.8	2-5 ^d	1	NR	NR	NR
Suntan Preparations												
Suntan Gels, Creams, and Liquids					NR	NR	NR	0.2				
Other Suntan Preparations					1	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 are derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

*** frequency and concentration of use of a denture cleaner were reported in 2002/2004; because this is not currently a product category, these data were omitted from the table

^a 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.

^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.

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