

ISOBUTANE, ISOPENTANE, BUTANE, and PROPANE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the safety of Isobutane, Isopentane, n-Butane (now known as Butane), and Propane in 1982.¹ The Panel concluded that these ingredients are considered safe as cosmetic ingredients under the present conditions of concentration and use, as described in that safety assessment. Upon re-review in 2002, the Panel reaffirmed the original conclusion, as published in 2005.²

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 its September 2023 meeting, the Panel 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 in 2023³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2022.⁴ The frequency and concentrations of use have increased for all ingredients since the rereview was published. According to 2023 frequency of use and 2022 concentration of use data, Isobutane has the greatest frequency and concentration of use, and is used in 392 formulations at up to 98% in other manicuring preparations; in 2001, it was reported to be used in 338 formulations at up to 83% in powder fragrance preparations. The cumulative frequency and concentration of use data for all 4 ingredients are presented in Table 1.

In July 2023, an extensive search of the world's literature was performed for studies dated 2000 forward, and new data were found.⁵⁻¹⁷ Notably, Butane and Isobutane are listed in Annex II of the European Union (prohibited), but only if they contain $\geq 0.1\%$ butadiene. No evidence of developmental or reproductive toxicity was observed for Isobutane, Butane, or Propane, and genotoxicity studies were all negative. Irritation and sensitization studies on Isopentane were also negative.

In summary, the Panel reviewed 2023 frequency and 2022 concentration of use data, in addition to 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 1982 conclusion for Isobutane, Isopentane, Butane, and Propane. The Panel discussed that these ingredients are propellants and used in cosmetic products which may be incidentally inhaled; however, the Panel noted that despite the very high concentrations reported for leave-on products, these ingredients are completely volatile and therefore they are expected to dissipate and not remain on the skin. 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)^{2,18} and concentration (2022/2001)^{2,4} of use according to likely duration and exposure and by product category

	Isobutane				Isopentane				Butane				Propane			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ¹⁸	2001 ²	2022 ⁴	2001 ²	2023 ¹⁸	2001 ²	2022 ⁴	2001 ²	2023 ¹⁸	2001 ²	2022 ⁴	2001 ²	2023 ¹⁸	2001 ²	2022 ⁴	2001 ²
Totals*	392	338	0.26-98	0.5-83	53	29	0.036-66.7	0.05-37	272	173	1.4-84	1-92	269	248	0.045-25.5	0.2-24
summarized by likely duration and exposure**																
Duration of Use																
<i>Leave-On</i>	246	212	0.26-98	0.5-83	6	2	0.041-66.7	0.05-37	228	128	2.6-84	4-92	171	158	0.045-25.5	0.2-24
<i>Rinse-Off</i>	146	126	0.53-4.5	0.6-38	46	27	0.036-2.5	0.05-35	44	45	1.4-39.9	1-52	98	90	0.65-1	0.4-13
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	1	NR	NR	NR	0	NR	NR	NR	NR	NR	NR	NR
Exposure Type																
Eye Area	NR	NR	NR	NR	NR	NR	66.7	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	5	NR	38	NR	NR	NR	35	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	88; 88 ^a ; 5 ^c	122; 45 ^a , 4 ^c	0.26-95, 4.1 ^a	13-82, 0.5-38 ^a , 1-82 ^c	1;1 ^a ;1 ^c	1 ^c	0.041-30	15; 35 ^a	113, 55 ^a ; 8 ^c	79, 20 ^b	13.8-54.6; 2.6 ^a	12-54; 4-29 ^c	42;69 ^a , 4 ^c	95; 22 ^a	0.045-25.5; 1.8-12.2 ^a ,	6-21; 0.2-9 ^a ; 0.5-9 ^c
Incidental Inhalation-Powder	3, 5 ^c	4 ^c	NR	83, 1-82 ^c	3, 1 ^b ,	1 ^c	NR	NR	8 ^c	NR	NR	4-29 ^c	4 ^c	NR	NR	0.5-9 ^c
Dermal Contact	205	157	3.4-51	0.5-83	51	27	0.036-30	0.05-37	122	74	1.9-60.6	1-92	109	130	0.75-22.9	0.2-21
Deodorant (underarm)	38 ^a	20 ^a	35-51 (aerosol)	25-70 ^a	NR	2 ^a	0.95 (aerosol)	0.5-37 ^a	37 ^a	5 ^a	24.8-60.6 (aerosol)	17-92 ^a	38 ^a	NR	8.3-22.9 (aerosol)	14-16 ^a
Hair - Non-Coloring	182	158	0.26-71.9	8-32	2	NR	NR	15	120	96	2.6-54.6	12-21	159	114	0.045-25.5	3-20
Hair-Coloring	4	18	0.53-95	NR	NR	NR	NR	NR	30	3	1.4-47.5	NR	NR	4	0.65	NR
Nail	1	NR	81.8-98	30	NR	NR	NR	NR	NR	NR	84	NR	1	NR	15	24
Mucous Membrane	44	20	4.5	2-38	25	1	0.036	0.05-35	10	12	NR	52	20	12	NR	13
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
as reported by product category																
Bath Preparations																
Other Bath Preparations					1	NR	NR	NR								
Eye Makeup Preparations																
Mascara					NR	NR	66.7	NR								
Fragrance Preparations																
Cologne and Toilet Water	2	12	NR	54					2	26	19.2	29	1	17	7.8	11
Perfumes	1	NR	NR	NR					1	5	NR	NR				
Powders (dusting/talcum, excl aftershave talc)	NR	NR	NR	83												
Sachets	NR	4	NR	32									NR	4	NR	NR
Other Fragrance Preparation	35	6	NR	51-60	NR	NR	0.041	NR	39	1	NR	54	10	5	17.4	7-21
Hair Preparations (non-coloring)																
Hair Conditioner	17	2	NR	NR					4	6	NR	21	13	6	NR	3
Hair Spray (aerosol fixatives)	46	107	0.26-71.9 (aerosol)	13-32	1	NR	NR	15	41	47	22-54.6 (aerosol)	12-14	31	72	0.045-25.5 (aerosol)	6-20
Shampoos (non-coloring)	52	NR	1.3 (aerosol)	NR					31	NR	39.9 (aerosol)	NR	51	NR	0.84 (aerosol)	NR
Tonics, Dressings, and Other Hair Grooming Aids	50	37	4.1 (mousse)	8-20	1	1	NR	NR	32	19	2.6	NR	51	19	1.8-12.2	3-9
Wave Sets	NR	1	NR	NR									NR	1	NR	NR
Other Hair Preparations	17	11	NR	NR	NR	1	NR	NR	12	24	48	NR	13	16	8.8	NR
Hair Coloring Preparations																
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	NR	0.53	NR					NR	NR	1.4	NR	NR	NR	0.65	NR
Hair Tints	NR	17	NR	NR					NR	3	NR	NR	NR	3	NR	NR
Hair Color Sprays (aerosol)	4	1	95 (aerosol)	NR					30	NR	18.4-47.5	NR	NR	1	NR	NR

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Makeup Preparations																
Face Powders	3	NR	NR	NR	3	NR	NR	NR								
Foundations	3	NR	NR	3					1	NR	NR	NR	1	NR	NR	2-3
Leg and Body Paints	2	NR	NR	NR												
Makeup Fixatives	1	NR	NR	NR					1	NR	NR	NR	1	NR	NR	NR
Other Makeup Preparations	1	NR	NR	NR												
Manicuring Preparations (Nail)																
Basecoats and Undercoats	NR	NR	NR	30									NR	NR	NR	24
Other Manicuring Preparations	1	NR	98; 81.8 (spray)	NR					NR	NR	84	NR	1	NR	15	NR
Oral Hygiene Products																
Mouthwashes and Breath Fresheners	NR	5	NR	38	NR	NR	NR	35								
Personal Cleanliness Products																
Bath Soaps and Detergents	36	NR	4.5	NR	24	NR	0.036	NR	1	NR	NR	NR	13	NR	NR	NR
Deodorants (underarm)	38	20	35-51 (aerosol)	25-70	NR	NR	0.95 (aerosol)	0.5-37	37	5	24.8-60.6 (aerosol)	17-92	38	21	8.3-22.9 (aerosol)	14-16
Feminine Deodorants	2	2	NR	NR					6	NR	NR	NR	2	NR	NR	NR
Other Personal Cleanliness Products	6	13	NR	2-16	NR	1	NR	0.05	3	12	NR	52	5	12	NR	13
Shaving Preparations																
Aftershave Lotion	NR	6	NR	NR												
Mens Talcum									NR	NR	1.9-2.3	NR				
Shaving Cream	15	67	3-4.2	0.6-5	8	6	2.5	1-5	1	24	NR	1-5	7	66	0.75-1	0.4-4
Shaving Soap	3	NR	NR	NR	3	NR	NR	NR								
Other Shaving Preparations	11	19	NR	5	11	19	NR	NR					NR	NR	NR	0.8
Skin Care Preparations																
Cleansing	3	2	NR	0.9	NR	1	NR	NR	3	NR	NR	NR	6	1	0.8	2
Depilatories	3	NR	NR	4					1	NR	NR	NR	3	NR	NR	1
Face and Neck (exc shave)	1	1	NR	5	1	NR	NR	NR								2
Body and Hand (exc shave)	2	1	8-9.2 (spray)	1-75	NR	NR	0.55 (spray)	NR	2	NR	13.8-30 (spray)	4-29	2	NR	8.3-10.4 (spray)	0.5-9
Foot Powders and Sprays	NR	2	NR	26-82					NR	NR	43.2 (spray)	NR	NR	NR	18.9 (spray)	NR
Moisturizing	28	1	NR	0.5-6					16	NR	NR	NR	14	1	NR	0.2-0.4
Skin Fresheners	2	NR	NR	21					2	NR	NR	NR	1	NR	NR	0.8
Other Skin Care Preparations	2	NR	NR	2-24					1	NR	NR	55	2	NR	NR	2-7
Suntan Preparations																
Suntan Gels, Creams, and Liquids	1	NR	30 (aerosol)	NR	NR	NR	30 (aerosol)	NR	1	NR	19.4-40 (aerosol)	NR	NR	NR	8.1 (spray)	NR
Indoor Tanning Preparations	2	2	NR	NR					2	1	NR	NR	2	2	NR	NR
Other Suntan Preparations	2	NR	NR	NR					2	NR	NR	NR	1	NR	NR	1

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>)

^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

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