Isobutane, Isopentane, Butane, and Propane

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Abstract

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the safety of Isobutane, Isopentane, Butane, and Propane in 1982. The Panel previously 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. The Panel reviewed update frequency and concentration of use data again in 2023, in addition to newly 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.

Keywords

Cosmetic Ingredient Review, Expert Panel for Cosmetic Ingredient Safety, Safety, Cosmetics, Isobutane, Isopentane, n-Butane, Butane, 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 had been at least 15 years since the prior rereview 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 re-review 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.⁶⁻¹⁸ Notably, Butane and Isobutane are listed in Annex II of the European Union (prohibited), but only if they contain \geq .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 newly 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

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		Summarized by likely dura	tion and	exposu	re**													
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		Rinse-Off	146	126	0.53-4.5	0.6-38	46	27	0.036-2.5	37 0.05- 35	44	45	1.4-39.9	1-52	98	06	0.65-1	0.4-13
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		Hair Preparations (Non-C	oloring)															

Table 1. Frequency (2023/2001)^{2,5} and Concentration (2022/2001)^{2,4} of Use According to Likely Duration and Exposure and by Product Category.

$\# d \ [like \$				lsobutane			_	lsopentane				Butane				Propane	
		#	of Uses	Max Conc	of Use (%)	lo #	r Uses	Max Conc of l	Jse (%)	# of	Uses	Max Conc ol	f Use (%)	# of	· Uses	Max Conc of Use (%)	of Use (%)
		2023			2001 ²	2023 <mark>5</mark>			2001 <mark>2</mark>	2023 ⁵			2001 ²				2001 ²
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30 NR 1 NR 31 NR 31 NR 51 NR NR 51 NR NR 51 NR NR 51 NR NR 51 13 16 NR NR 13 16 NR	Hair Spray (aerosol fixatives)	46	107	0.26-71.9 (aerosol)		_	R	NR	15	4	47	22-54.6 (aerosol)	12-14	31	72	0.045-25.5 (aerosol)	6-20
50 37 41 NR 1 NR 1 NR 1 N 51 19 2.6 NR 51 19 1 N 51 19 1 1 N 1 1 N 1 1 N 1 1 N N 1 1 N 1 1 N 1 1 N 1 1 N N 1 N	Shampoos (non-coloring)	52	R	I.3 (serocol)						31	R	(1000-000) 39.9 (aerosol)	NR	51	R	.84 (aerosol)	R
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NR 17 NR NR <td< td=""><td>requiring caution statements and patch tests)</td><td>~</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>	requiring caution statements and patch tests)	~															
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		_	lsobutane			sl	lsopentane				Butane			-	Propane	
	o #	# of Uses	Max Conc of	of Use (%)	# of	# of Uses	Max Conc of Use (%)	Use (%)	‡o #	# of Uses	Max Conc of Use (%)	⁻ Use (%)	# of Uses	Uses	Max Conc of Use (%)	f Use (%)
	2023 <mark>5</mark>	2001 <mark>2</mark>	2022 ⁴	2001 ²	2023 ⁵	2001 ²	2022 ⁴	2001 ²	2023 <mark>5</mark>	2001 <mark>2</mark>	20224	2001 <mark>2</mark>	2023 ⁵	2001 <mark>2</mark>	2022 ⁴	2001 ²
Shaving Soap	m	R	R	NR	m	NR	R	R								
Other Shaving Preparations	=	61	R	5	=	61	NR	R					R	NR	NR	0.8
Skin Care Preparations																
Cleansing	٣	7	NR	0.9	R	_	NR	R	e	NR	NR	NR	9	_	0.8	2
Depilatories	٣	R	NR	4					_	NR	NR	NR	٣	R	NR	_
Face and Neck (exc shave)	_	_	NR	5	_	NR	NR	RR								2
Body and Hand (exc shave)	2	_	8-9.2	I-75	R	NR	0.55 (spray)	R	2	NR	I 3.8-30	4-29	2	NR	8.3-10.4	0.5-9
			(spray)								(spray)				(spray)	
Foot Powders and Sprays	NR	2	NR	26-82					NR	NR	43.2 (spray)	NR	R	NR	18.9 (spray)	RR
Moisturizing	28	_	NR	0.5-6					16	NR	NR	NR	4	_	NR	0.2-0.4
Skin Fresheners	2	R	NR	21					2	NR	NR	NR	_	NR	NR	0.8
Other Skin Care Preparations	2	R	NR	2-24					_	NR	NR	55	2	NR	NR	2-7
Suntan Preparations																
Suntan Gels, Creams, and	_	R	30	NR	R	NR	30 (aerosol)	NR	_	NR	19.4-40	NR	R	RR	8.1 (spray)	R
Liquids			(aerosol)								(aerosol)					
Indoor Tanning Preparations	7	2	NR	NR					2	_	NR	NR	2	2	NR	RR
Other Suntan Preparations	7	R	R	NR					7	NR	NR	RR	_	NR	NR	_
NR – not reported.																
*Because each ingredient may be used in cosmetics with multiple	be used in	1 cosmetic	s with multic	ole exposure	types. t	he sum (exposure types. the sum of all exposure types may not equal the sum of total uses.	types m	iv not eq	ual the s	um of total use	es.				
**[[kelv duration and exposure are derived based on product category (see] (see Categorization https://www.cit-cafery.org/in-finations)	are deriv	- hased he	no product	ategory (see	Ilse Ca	tegorizat	-ion https://www	w cir-cafe	tv ora/cii	findings						
and the possible these products are sprave but it is not specified whether the reported lises are sprave		but it is r	on product c	whether the	renorte	in the all		M.CII - 3010		20						

^alt is possible these products are sprays, but it is not specified whether the reported uses are sprays. ^bIt is possible these products are powders, but it is not specified whether the reported uses are powders. ^cNot 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.

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 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.

Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 555 13th Street, NW, Suite 300W, Washington, DC 20004, USA.

Author Contributions

The articles in this supplement were sponsored by the Cosmetic Ingredient Review.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient Review. The Cosmetic Ingredient Review is financially supported by the Personal Care Products Council.

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