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Amyl Acetate and Isoamyl Acetate

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1988, along with updated information regarding product types and concentrations of use, and confirmed that Amyl Acetate and Isoamyl Acetate are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Cosmetics, Safety, Amyl Acetate, Isoamyl Acetate

The Expert Panel for Cosmetic Ingredient Safety first published a Final Report on the Safety Assessment of Amyl Acetate and Isoamyl Acetate in 1988. The Expert Panel concluded that these ingredients are safe as used as described in that safety assessment.[1]

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review Procedures, the Expert Panel determined whether the safety assessment should be reopened. At the June 2022 meeting, the Expert Panel 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,[2] and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council).[3] The frequency and concentration of use for Amyl Acetate has decreased from 18 to 4 uses, and from <10% to ≤.09%, respectively.[1,3] In 1987, Isoamyl Acetate was not reported to be in use; however, according to 2022 VCRP data, this ingredient is now used in 1 formulation at up to .22%. The cumulative frequency and concentration of use data are presented in Table 1.

An extensive search of the world's literature was performed for studies dated 1982 forward, and new data were found.[4-9] These data include subchronic inhalation toxicity data, developmental inhalation toxicity data, in vitro and in vivo genotoxicity data, and Research Institute for Fragrance Materials, Inc. safety assessments. The Expert Panel agreed, however, that the published literature did not reveal toxicity or other data that warrant re-evaluation of the safety of these ingredients in cosmetic products.

After reviewing updated frequency and concentration of use data and toxicity and safety data, the Expert Panel determined to not reopen this safety assessment on Amyl Acetate and Isoamyl Acetate and reaffirmed the original conclusion.

Author Notes

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

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Declaration of Conflicting Interest

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

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Amyl Acetate				Isoamyl Acetate			
	2022[2]	1987[1]	2021[3]	1987[1]	2022[2]	1987[1]	2021[3]	1987[1]
Totals*	4	18	.000000025–.09	> .1–≤10	1	NR	.002–.22	NR
Duration of use								
Leave-on	*2*	*18*	*.000000025–.05*	*>.1–>10*	*1*	*NR*	*.002–.075*	*NR*
Rinse-off	*2*	*NR*	*.00004–.09*	*NR*	*NR*	*NR*	*.027–.22*	*NR*
Diluted for (bath) use	*NR*	*NR*	*.0078*	*NR*	*NR*	*NR*	*.048*	*NR*
Exposure type								
Eye area	NR	NR	.000000025	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	NR	NR	.05; .03[a]	NR	1[a]	NR	.0037–.016	NR
Incidental inhalation-powder	NR	NR	.026[b]	NR	NR	NR	.019	NR
Dermal contact	NR	NR	.000000025–.09	NR	1	NR	.22	NR
Deodorant (underarm)	NR	NR	Not spray: .0075–.023; spray: .0032	NR	NR	NR	Not spray: .0062–.013; spray: .0065	NR
Hair – non-coloring	NR	NR	.0012	NR	NR	NR	.0037–.082	NR
Hair-coloring	NR	NR	.0012–.065	NR	NR	NR	NR	NR
Nail	4	18	NR	>.1–>10	NR	NR	NR	NR
Mucous membrane	NR	NR	.0031–.09	NR	NR	NR	.048–.22	NR
Baby products	NR	NR	NR	NR	NR	NR	.008–.075	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.
NR, no reported use.

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