Acetyl Trialkyl Citrates

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 2002, along with updated information regarding product types and concentrations of use, and confirmed that Acetyl Triethyl Citrate, Acetyl Tributyl Citrate, Acetyl Tributyl Citrate, Acetyl Tributyl Citrate, and Acetyl Trihexyl Citrate are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

Safety, Cosmetics, Acetyl Trialkyl Citrates

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of Acetyl Trialkyl Citrates in 2002.¹ The Panel concluded that Acetyl Triethyl Citrate, Acetyl Tributyl Citrate, Acetyl Triethylhexyl Citrate (previously known as Acetyl Trioctyl Citrate), and Acetyl Trihexyl Citrate are safe as cosmetic ingredients in the present practices of use and concentration, as described in that report. Data identified in the published literature²⁻¹⁶ that have become available since the Final Report was issued support the conclusion that was reached by the Panel in the original review. The Panel also 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,¹⁷ and the maximum use concentrations provided by the Personal Care Products Council (Council).¹⁸ The Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that Acetyl Triethyl Citrate, Acetyl Tributyl Citrate, Acetyl Triethylhexyl Citrate (previously known as Acetyl Trioctyl Citrate), and Acetyl Trihexyl Citrate are safe as cosmetic ingredients in the present practices of use and concentration, as given in Table 1.

The data indicate that only Acetyl Triethyl Citrate and Acetyl Tributyl Citrate are currently reported to be used in cosmetic products.^{17,18} The frequency of use has increased for both of these ingredients since the initial assessment. According to VCRP data, Acetyl Triethyl Citrate and Acetyl Tributyl Citrate were reported to be used in 9 and 27 formulations, respectively, in 1998.¹ In 2019, VCRP data indicate that Acetyl Triethyl Citrate is used in 22 formulations, and

Acetyl Tributyl Citrate is used in 438 formulations.¹⁷ There were no reported uses of Acetyl Trihexyl Citrate or Acetyl Triethylhexyl Citrate (formerly Acetyl Trioctyl Citrate) in 1998 or in 2019. For Acetyl Triethyl Citrate, the maximum concentration of use was 7% in nail products in 1999¹; however, according to a recent survey provided by the Council, current use concentration data on this ingredient were not submitted.¹⁸ For Acetyl Tributyl Citrate, the maximum concentrations of use have increased slightly since the original report was issued. In 1999, Acetyl Tributyl Citrate was used at up to 7% in nail products and up to 3% in products that resulted in dermal contact (i.e., eyeliners)¹; data collected in 2018 indicate that the maximum concentrations of use are 8.9% in nail products and 7% in products that result in dermal contact.¹⁸ Though increases in use concentrations are noted when the two years are compared, the higher use concentrations were not considered to be dissimilar to the values that were reported initially and do not warrant any safety concerns.

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	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Acetyl Triethyl Citrate				Acetyl Tributyl Citrate			
	2019 ¹⁷	1998 ¹	2018 ¹⁸	1999 ¹	2019 ¹⁷	1998 ¹	2018 ¹⁸	1999 ¹
Totals ^a	22	9	NR	4-7	438	27	.0015-8.9	.8-7
Duration of use								
Leave-on	21	9	NR	4-7	437	26	5.8-8.9	.8-7
Rinse-off	I	NR	NR	NR	I	Ι	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	5	3	7.5	3
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation-spray	10	NR	NR	NR	I	NR	.001509	NR
Incidental inhalation-powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	5	3	.0015-7.5	3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	11	I	NR	NR	3	I	.09	NR
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	11	8	NR	4-7	428	23	6-8.9	.8-7
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR

Table I. Current and Historical Frequency and Concentration of Use of Acetyl Trialkyl Citrates According to Duration and Exposure.

NR, not reported. The use of bold that indicates readability, panel preference.

^aBecause 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.

Author's Note

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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