

EDTA and Salts

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 1998, along with updated information regarding product types and concentrations of use and confirmed that EDTA and certain salts are safe as cosmetic ingredients in the practices of use and concentration as described in this report.

Keywords

safety, cosmetics, EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, HEDTA, TEA-EDTA, Tetrasodium EDTA, Tripotassium EDTA, Trisodium EDTA, Trisodium HEDTA

The Expert Panel for Cosmetic Ingredient Safety first published a final report on the Safety Assessment of EDTA and Salts in 1998.¹ The Expert Panel concluded that EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, triethanolamine (TEA)-EDTA, Tetrasodium EDTA, Tripotassium EDTA, Trisodium EDTA, hydroxyethyl ethylenediamine triacetic acid (HEDTA), and Trisodium HEDTA are safe as used in cosmetic formulations as described in that report. Because it has been at least 15 years since the report was published, in accord with Cosmetic Ingredient Review Procedures, an updated search was performed, and the Expert Panel considered whether the safety assessment of EDTA and the related salts should be reopened. Data identified in the published literature^{2–9} that have become available since the original report was issued support the original conclusion. The Expert Panel also 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,¹⁰ and the maximum use concentrations provided by the Personal Care Products Council.¹¹ The Expert Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that EDTA and salts of EDTA are safe as cosmetic ingredients in the present practices of use and concentration, as given in Table 1.

According to VCRP data from 2019, Disodium and Tetrasodium EDTA are reported to be used in 12,509 and 7691 formulations, respectively, while in 1998 they were reported to be used in 1165 and 1285 formulations.^{1,10} In addition, in 1998, Calcium Disodium EDTA and Tripotassium EDTA were not reported to be in use. According to 2019 VCRP data,

these ingredients are reported to be used in 25 and 1 formulation, respectively. In 1998, the maximum concentrations of use were reported for EDTA (2% in hair products; rinse-off) and Trisodium EDTA (2% in bath soaps and detergents; rinse-off).¹ According to 2019 concentration of use data, the ingredient with the highest maximum concentration of use is Disodium EDTA, which is used at 3% in “other hair coloring preparations.”¹¹ This ingredient was previously reported to be used at a maximum of 1% in bath products. Disodium EDTA is also reported to have the highest concentration of use in leave-on products (.85%; hair color sprays) and in products which would come in contact with the skin (.6%; skin cleansing). All other in-use ingredients are reported to be used at 2% or less.

Although a substantial increase in frequency of use was reported, the lack of evidence of genotoxic and clinical effects continues to support the safety of this ingredient group. According to the Expert Panel, EDTA and its salts did not pose a toxicological risk as used in cosmetics; and therefore, the original conclusion was reaffirmed.

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Table I. Current and Historical Frequency and Concentration of Use of EDTA and Salts According to Duration and Exposure.

Exposure type	# of Uses	Calcium Disodium EDTA		Max Conc of Use (%)		# of Uses	Max Conc of Use (%)
		1998 ¹	2019 ¹⁰	1998, 1999 ¹	2019 ¹⁰		
		NR	.000098-.025	NR	17		
Duration of use							
Leave-on	1	NR	.025	NR	7	16	NR .09
Rinse-off	24	NR	.000098-.00059	NR	10	5	.054 .09
Diluted for (Bath) use	NR	NR	NR	NR	NR	NR	NR
Eye area	1	NR	NR	NR	8	1	NR
Incidental ingestion	22	NR	.000098-.00059	NR	NR	NR	NR
Incidental inhalation-spray	2 ^a	NR	.000098 ^a	NR	5 ^c	9 ^{a, c}	.09
Incidental inhalation-powder	NR	NR	NR	NR	5 ^c	NR	NR
Dermal contact	2	NR	.025	NR	17	21	.054 .05-.09
Deodorant (underarm)	NR	NR	.025	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR
Hair-coloring	1	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	22	NR	.000098-.00059	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR
Disodium EDTA							
Duration of use							
Leave-on	1998 ¹	2019 ¹⁰	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹⁰	1998, 1999 ¹
Totals*	12509	1165	.00002-3	.001-1	1011	923	.000004-2 -.02-2
Disodium EDTA						EDTA	
Duration of use							
Leave-on	8455	590	.000075-.85	.001-0.6	210	85	.0000055-.01 .03-0.5
Rinse-off	3931	498	.00002-3	.005-0.8	794	835	.000004-2 .02-2
Diluted for (bath) use	123	77	.05	.1-1	7	3	NR
Eye area	755	33	.05-.33	.1-0.6	28	5	.0001-0.05 .03-.05
Incidental ingestion	39	NR	.00033-0.1	.05-0.1	25	NR	NR
Incidental inhalation-spray	150; 3986 ^a ; 33; 271 ^a ; 125 ^c	.001-85; .00075-.12 ^a ; .1-0.2 ^c	.05-2; .02-.05 ^a ; .05-.6 ^c	2; 58 ^a ; 52 ^c 2; 38 ^a	.0000055-.00055; .0033-0.1 ^a .00001-0. ^b	.05-0.1 ^a .03-0.5 ^c	
Incidental inhalation-powder	2292 ^c	125 ^c	.1; .00045-.35 ^b ; .1-0.2 ^c	.02-.05; .05-.6 ^c	3; 2 ^b ; 52 ^c 2; 15 ^c	.00001-0. ^b .1; .03-0.5 ^c	
Dermal contact	9988	783	.000075-0.6	.01 - 1	284	122	.000004-0.1 .03-0.5

(continued)

Table I. (continued)

Disodium EDTA										EDTA			
	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹		
Totals*	12509	1165	.00002-3	.001-1	1011	923	.000004-2					.02-2	
Deodorant (underarm)	57 ^a	2 ^a	NR	.02 ^a	26 ^a	3 ^a	NR					.1-0.5 ^a	
Hair – non-coloring	1664	303	.00002-.95	.005-0.8	175	72	.0000055-.22					.05-0.3	
Hair-coloring	631	76	.016-3	.05-0.4	506	725	.000055-.2					.02-2	
Nail	20	1	NR	.001-0.02	11	3	NR					NR	
Mucous membrane	1377	130	.000075-.25	.05-1	111	19	.02-0.052					.05-0.3	
Baby products	45	5	.2-35	NR	4	NR	NR					.03	
HEDTA													
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹		
Totals*	1	1	NR	NR	7691	1285	.000002-1.9					.004-1.3	
Tetrasodium EDTA													
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹		
Totals*	1	1	NR	NR	7691	1285	.000002-1.9					.004-1.3	
Trisodium EDTA													
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹		
Totals*	1	1	.01	NR	507	616	.00000045-.35					.00001-2	
Tripotassium EDTA													
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	2019 ¹¹	1998, 1999 ¹		
Totals*	1	1	.01	NR	507	616	.00000045-.35					.00001-2	
Duration of use													
Leave-on	NR	NR	.01	NR	368	479	.0000045-.24					.00001-0.5	
Rinse-off	1	1	NR	NR	137	130	.00000045-.35					.03-2	
Diluted for (bath) use	NR	NR	NR	NR	2	7	NR					.01-0.4	

(continued)

Table I. (continued)

Exposure type	Tripotassium EDTA				Trisodium EDTA			
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹
	Totals*	1	1	.01	NR	507	616	.00000045–35
Eye area	NR	—	NR	NR	137	128	.0005–0.2	.3
Incidental ingestion	NR	NR	NR	NR	NR	4	0.2	NR
Incidental inhalation-spray	NR	NR	NR	NR	5; 76 ^a ; 82 ^c	11; 117 ^a ; 65 ^c	.05; .0000045 ^a	.00001–0.1; .01–0.5 ^a ; .02–0.2 ^c
Incidental inhalation-powder	NR	NR	NR	NR	8; 82 ^c	11; 65 ^c	.1; .002–.24 ^c	.07–.2; .021–0.2 ^c
Dermal contact	1	—	.01	NR	415	531	.0005–.24	.00001–2
Deodorant (underarm)	NR	NR	NR	NR	NR	1 ^a	NR	.02 ^a
Hair – non-coloring	NR	NR	NR	NR	5	29	.00000045–.0000045	.01–0.4
Hair-coloring	NR	NR	NR	NR	28	18	.35	.1–0.5
Nail	NR	NR	NR	NR	2	10	NR	.1–0.2
Mucous membrane	NR	NR	NR	NR	52	27	.01–2	NR
Baby products	NR	NR	NR	NR	1	1	NR	NR
Trisodium HEDTA								
Exposure type	Tripotassium HEDTA				Trisodium HEDTA			
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹
	Totals*	124	124	159	159	159	.000017–0.3	.1–0.7
Duration of use								
Leave-on	24	—	13	—	.004–0.1	.004–0.1	.02–0.3	.1–0.3
Rinse-off	97	—	144	—	.000017	.000017	.000017	.1–0.7
Diluted for (both) use	3	3	2	2	NR	NR	NR	NR
Exposure type	Tripotassium HEDTA				Trisodium HEDTA			
	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹	2019 ¹⁰	1998 ¹	2019 ¹¹	1998, 1999 ¹
	Totals*	124	124	159	159	159	.000017–0.3	.1–0.7
Duration of use	24	—	13	—	.004–0.1	.004–0.1	.02–0.3	.1–0.3
Leave-on	97	—	144	—	.000017	.000017	.000017	.1–0.7
Rinse-off	3	3	2	2	NR	NR	NR	NR
Diluted for (both) use	NR	NR	NR	NR	NR	NR	NR	NR
Eye area	3	—	—	—	.004 ^a	.004 ^a	.021–0.1 ^b	.01 ^c
Incidental ingestion	5 ^a ; 2 ^c	—	3 ^a	—	NR	NR	.000017–0.1	.1–0.3 ^a , 0.1 ^c
Incidental inhalation-spray	2 ^c	—	NR	—	NR	NR	.000017–0.1	.1–0.5
Incidental inhalation-powder	92	—	35	—	NR	NR	.000017–0.1	.1–0.3 ^a
Dermal contact	NR	—	6 ^a	—	NR	NR	.000017–0.1	.1–0.3 ^a
Deodorant (underarm)	32	—	23	—	NR	NR	.004–.13	.1–0.3
Hair – non-coloring	NR	—	98	—	NR	NR	.01	0.1
Hair-coloring	NR	—	2	—	NR	NR	.000017–.084	.2–0.5
Nail	62	—	22	—	NR	NR	.000017–.084	NR
Mucous membrane	NR	—	NR	—	NR	NR	.000017–.084	NR
Baby products	NR	—	NR	—	NR	NR	.000017–.084	NR

^aIt 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.

NR, No reported use.

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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