

Sodium Dehydroacetate and Dehydroacetic Acid

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Priya Cherian*, **Wilma F. Bergfeld****, **Donald V. Belsito****,
David E. Cohen**, **Curtis D. Klaassen****, **Allan E. Rettie****,
David Ross**, **Thomas J. Slaga****, **Paul W. Snyder****, **Susan Tilton****,
Monice Fiume†, and **Bart Heldreth††**

Abstract

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a safety assessment of Sodium Dehydroacetate and Dehydroacetic Acid in 1985. The Panel previously concluded that Sodium Dehydroacetate and Dehydroacetic Acid are safe as used in the present practices of use and concentration, as stated in that report. Upon re-review in 2003, the Panel reaffirmed the original conclusion, as published in 2006. The Panel reviewed updated frequency and concentration of use data again in 2023, in addition to any 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 1985 conclusion.

Keywords

Cosmetic Ingredient Review, Expert Panel for Cosmetic Ingredient Safety, Ingredients, Safety, Cosmetics, Sodium Dehydroacetate

Sodium Dehydroacetate and Dehydroacetic Acid

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Sodium Dehydroacetate and Dehydroacetic Acid in 1985.¹ The Panel concluded that Sodium Dehydroacetate and Dehydroacetic Acid are safe as used in the present practices of use and concentration, as stated in that report. Upon re-review in 2003, the Panel reaffirmed the original conclusion, as published in 2006.²

Because it had 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 the September 2023 meeting, the Panel considered updated 2023 information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.⁴ According to 2023 FDA VCRP data, the number of uses of both Sodium Dehydroacetate and Dehydroacetic Acid have increased significantly since the previous re-review. Sodium Dehydroacetate and Dehydroacetic Acid were previously reported to be used in 325 and 88 formulations in 2002, respectively, and are now reported to be used in 1233

and 833 formulations, respectively. The 2023 reported concentrations of use for both ingredients (maximum concentrations of 0.6% for Sodium Dehydroacetate and 0.7% for Dehydroacetic Acid) are the same maximum concentrations as reported in 2003. The cumulative frequency and concentrations of use data 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 The Panel noted the cases of hypersensitivity followed by topical application of creams containing Sodium Dehydroacetate (test article cream reported to contain 3% Sodium Dehydroacetate in one study). Concern was mitigated due to the minimal number of case reports, in comparison to the widespread use of these ingredients, and low concentrations of use. In addition, the Panel noted the photoisomerization study, and determined that these ingredients are not likely to cause

*Cosmetic Ingredient Review Senior Scientific Analyst/Writer

**Expert Panel for Cosmetic Ingredient Safety Member

†Cosmetic Ingredient Review Senior Director

††Cosmetic Ingredient Review Executive Director

Corresponding Author:

Bart Heldreth, Executive Director, Cosmetic Ingredient Review, 555 13th St., NW, Suite 300W, Washington, DC 20004, USA.

Email: cirinfo@cir-safety.org

Table 1. Frequency (2023/2002) and Concentration (2023/2003) of Use According to Likely Duration and Exposure and by Product Category.

	Sodium Dehydroacetate				Dehydroacetic Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ³	2002 ²	2023 ⁴	2003 ²	2023 ³	2002 ²	2023 ⁴	2003 ²
Totals*	1233	325	0.000005–0.6	0.00003–0.6	833	88	0.0000029–0.7	0.007–0.7
summarized by likely duration and exposure**								
Duration of Use								
Leave-On	1191	293	0.000005–0.6	0.00003–0.6	637	68	0.0000029–0.5	0.01–0.7
Rinse-Off	42	32	0.00003–0.2	0.0001–0.3	190	19	0.0000042–0.7	0.007–0.1
Diluted for (Bath) Use	NR	NR	NR	NR	6	1	NR	NR
Exposure Type								
Eye Area	331	110	0.0015–0.6	0.0006–0.5	145	9	0.015–0.5	0.1–0.3
Incidental Ingestion	5	1	0.2–0.5	0.3–0.5	61	NR	0.064	NR
Incidental Inhalation-Spray	3; 469 ^a ; 96 ^b	52 ^a ; 24 ^b	0.000005 ^a	0.001–0.5 ^a ; 0.0001–0.5 ^a ; 0.00003–0.5 ^b	4; 131 ^a ; 166 ^b	18 ^a ; 20 ^b	0.0000029–0.000008; 0.0000042–0.64 ^a ; 0.062 ^b	0.03–0.2 ^a ; 0.01–0.08 ^b
Incidental Inhalation-Powder	83; 96 ^b ; 2 ^c	34; 24 ^b	0.2–0.5; 0.0005–0.6 ^c	0.05–0.4; 0.00003–0.5 ^b ; 0.6 ^c	24; 166 ^b ; 2 ^c	3; 20 ^b	0.0019–0.5; 0.062 ^b ; 0.00008–0.048 ^c	0.7; 0.01– 0.08 ^b
Dermal Contact	1152	293	0.00004–0.6	0.00003–0.6	690	85	0.000021–0.7	0.007–0.7
Deodorant (underarm)	NR	2 ^a	0.00004	NR	5 ^a	NR	NR	NR
Hair - Non-Coloring	31	7	0.000005–0.05	0.2	76	1	0.0000029–0.08	0.02–0.03
Hair-Coloring	NR	3	0.1	NR	NR	NR	0.00003	NR
Nail	2	5	NR	0.02–0.2	NR	2	NR	NR
Mucous Membrane	9	3	0.00058–0.5	0.0001–0.3	99	1	0.000043–0.85	0.03
Baby Products	2	NR	0.05–0.5	0.6	7	NR	0.048–0.071	NR
as reported by product category								
Baby Products								
Baby Shampoos	NR	NR	0.05	NR	3	NR	NR	NR
Baby Lotions/Oils/ Powders/Creams	2	NR	NR	0.6	2	NR	0.048	NR
Other Baby Products	NR	NR	0.5	NR	2	NR	0.071	NR
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts	NR	NR	NR	NR	NR	1	NR	NR
Bubble Baths	NR	NR	NR	NR	5	NR	NR	NR
Other Bath Preparations	NR	NR	NR	NR	1	NR	NR	NR
Eye Makeup Preparations								
Eyebrow Pencil	3	NR	NR	0.2–0.3	3	NR	NR	NR
Eyeliners	36	4	0.34–0.51	0.05–0.5	3	NR	0.15	0.1
Eye Shadow	204	74	0.3–0.6	0.05–0.3	99	4	0.05–0.5	0.3
Eye Lotion	8	3	0.0015–0.2	NR	16	NR	0.1	0.2
Eye Makeup Remover	1	1	NR	0.05	4	5	0.084	0.1
Mascara	43	16	0.3–0.5	0.001–0.4	5	NR	0.015–0.02	0.2
Other Eye Makeup Preparations	36	12	0.32–0.45	0.0006–0.4	15	NR	NR	NR
Fragrance Preparations								
Cologne and Toilet Water	1	NR	NR	0.001–0.5	NR	NR	NR	NR
Powders (dusting/ talcum, excl aftershave talc)	NR	3	NR	NR	NR	NR	NR	NR
Other Fragrance Preparation	2	NR	NR	NR	3	NR	NR	NR

(continued)

Table I. (continued)

	Sodium Dehydroacetate				Dehydroacetic Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ³	2002 ²	2023 ⁴	2003 ²	2023 ³	2002 ²	2023 ⁴	2003 ²
Hair Preparations (non-coloring)								
Hair Conditioner	10	NR	0.00003–0.015	0.2	27	NR	0.0000042–0.08	NR
Hair Spray (aerosol fixatives)	NR	NR	NR	NR	1	NR	0.0000029–0.000008	NR
Shampoos (non-coloring)	8	2	0.00003–0.0005	0.2	33	NR	0.000007–0.079	0.02–0.03
Tonics, Dressings, and Other Hair Grooming Aids	5	1	0.000005	NR	5	1	0.0000042–0.064	NR
Other Hair Preparations	2	4	NR	NR	6	NR	0.048–0.08	NR
Hair Coloring Preparations								
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	NR	0.1	NR	NR	NR	0.00003	NR
Hair Tints	NR	12	NR	NR	NR	1	NR	NR
Other Hair Coloring Preparation	NR	2	NR	NR	NR	2	NR	NR
Makeup Preparations								
Blushers (all types)	69	15	0.3–0.45	0.1–0.4	31	1	NR	0.05–0.2
Face Powders	83	31	0.2–0.5	0.05–0.4	24	3	0.5	0.7
Foundations	70	10	0.00049–0.5	0.0001–0.4	1	3	NR	0.1
Leg and Body Paints	NR	NR	NR	0.1	NR	NR	NR	NR
Lipstick	5	1	0.2–0.5	0.3	60	NR	0.064	NR
Makeup Bases	5	6	0.00049	0.1	2	NR	NR	NR
Rouges	1	NR	0.35	NR	NR	1	NR	NR
Makeup Fixatives	NR	1	NR	NR	1	NR	NR	NR
Other Makeup Preparations	15	4	0.45	0.0003–0.2	27	NR	NR	0.07
Manicuring Preparations (Nail)								
Basecoats and Undercoats	NR	NR	NR	0.02	NR	NR	NR	NR
Cuticle Softeners	NR	2	NR	NR	NR	1	NR	NR
Nail Creams and Lotions	NR	3	NR	NR	NR	NR	NR	NR
Nail Polish and Enamel	1	NR	NR	0.2	NR	1	NR	NR
Other Manicuring Preparations	1	NR	NR	0.2	NR	NR	NR	NR
Oral Hygiene Products								
Other Oral Hygiene Products	NR	NR	NR	NR	1	NR	NR	NR
Personal Cleanliness Products								
Bath Soaps and Detergents	2	2	0.00058	0.0001	16	NR	0.000043–0.07	0.03
Deodorants (underarm)	NR	2	0.00004	NR	5	NR	NR	NR
Douches	NR	NR	NR	NR	1	NR	NR	NR
Feminine Deodorants	NR	NR	NR	NR	NR	NR	0.062	NR
Other Personal Cleanliness Products	2	NR	NR	NR	15	NR	0.064–0.085	0.03

(continued)

Table 1. (continued)

	Sodium Dehydroacetate				Dehydroacetic Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023 ³	2002 ²	2023 ⁴	2003 ²	2023 ³	2002 ²	2023 ⁴	2003 ²
Shaving Preparations								
Aftershave Lotion	5	1	NR	0.0003	1	NR	0.000066	NR
Beard Softeners	NR	NR	NR	NR	2	NR	NR	NR
Shaving Cream	4	4	NR	NR	1	NR	0.000024–0.003	NR
Other Shaving Preparations	NR	1	NR	NR	NR	NR	NR	NR
Skin Care Preparations								
Cleansing	8	13	0.0003–0.2	0.0003–0.3	65	8	NR	0.007–0.02
Face and Neck (excluding shave)	96	4	0.0005–0.5	0.008–0.2	102	11	NR	0.01–0.08
Body and Hand (excluding shave)	19	20	0.3–0.6	0.00003–0.5	64	9	NR	0.03–0.05
Moisturizing	455	39	0.1	0.001–0.3	96	10	NR	NR
Night	5	5	NR	0.003–0.2	20	20	NR	0.03
Paste Masks (mud packs)	1	6	0.00027–0.1	0.03–0.2	23	6	NR	NR
Skin Fresheners	4	2	NR	NR	7	NR	NR	NR
Other Skin Care Preparations	15	25	NR	0.00003–0.1	31	16	NR	0.03
Suntan Preparations								
Suntan Gels, Creams, and Liquids	NR	1	0.01–0.05	0.2	2	NR	0.05	0.2
Indoor Tanning Preparations	NR	2	NR	0.4	NR	5	NR	NR
Other Suntan Preparations	NR	2	0.5	0.1	1	NR	NR	NR

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>).^aIt is possible these products are sprays, but it is not specified whether the reported uses are sprays.^bNot 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.^cIt is possible these products are powders, but it is not specified whether the reported uses are powders.

phototoxicity/photosensitization at concentrations used in cosmetics, as supported by the existing negative phototoxicity/ photosensitization data present in the original report.

In summary, the Panel reviewed 2023 frequency and concentration of use data, in addition to any 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 1985 conclusion. The Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. 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 St., NW, Suite 300W, Washington, DC 20004, USA.

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