

ADMIN

ReReview Summaries

Benzaldehyde

Polyquaternium-11

EXPERT PANEL MEETING

September 11-12, 2023

Safety Assessment of Benzaldehyde as Used in Cosmetics

Status: Re-Review Summary for Panel Consideration
Release Date: August 18, 2023
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History

Original Safety Assessment – published [2006]

Most Recent Action – new data considered at the June 2023 Panel meeting; not re-opened

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This summary was prepared by Preethi Raj, M.Sc., Senior Scientific Analyst/Writer, CIR.

BENZALDEHYDE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Benzaldehyde in 2006.¹ On the basis of the data presented in that report, the Panel concluded that Benzaldehyde is safe as used in cosmetic products.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At the June 2023 meeting, the Panel reviewed 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) database² and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2022.³ In 2023, 8 uses were reported in the VCRP for Benzaldehyde, a minor change from the 7 reported uses in 2001. Reported use categories have not changed significantly, and concentrations of use have remained constant over time. In 2023, the maximum reported concentration of use for Benzaldehyde is 0.2% in non-spray face and neck products; in 2001, Benzaldehyde was reported to be used at a maximum concentration of 0.5% in perfumes. The cumulative frequency and concentration of use data are presented in Table 1.

In April 2023, an extensive search of the world's literature was performed for studies dated 2001 forward, and new data were found.⁴⁻²⁶ Most notably, Benzaldehyde has been identified by the Research Institute for Fragrance Materials (RIFM) as a weak sensitizer with a defined no expected sensitization induction level (NESIL) of 590 $\mu\text{g}/\text{cm}^2$.⁸ The Panel remarked that methods of determining sensitization potential have changed considerably since the safety of Benzaldehyde was originally reviewed, and standards for maximum acceptable concentrations in finished products are set based on use categories and areas of application. Concern for sensitization potential with the use of Benzaldehyde in cosmetic products was mitigated by the fact that the maximum concentrations of use reported in response to the Council survey fall within the standards for the maximum acceptable concentrations in finished products for Benzaldehyde that have been set by the International Fragrance Association (IFRA).

In summary, the Panel reviewed 2023 frequency and 2022 concentration of use data, in addition to new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2006 conclusion for Benzaldehyde. The Panel discussed the possibility for this ingredient 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>.

Table 1. Frequency (2023/2001) and concentration (2022/2001) of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)	
	2023 ²	2001 ¹	2022 ³	2001 ¹
Totals*	6	7	0.000001 - 0.2	0.0001-0.5
summarized by likely duration and exposure**				
Duration of Use				
Leave-On	3	1	0.000001 - 0.2	0.0002 - 0.5
Rinse-Off	3	4	0.00033 - 0.068	0.0001 - 0.003
Diluted for (Bath) Use	NR	2	0.015 - 0.05	NR
Exposure Type				
Eye Area	1	NR	NR	NR
Incidental Ingestion	NR	NR	0.04	NR
Incidental Inhalation-Spray	1; 1 ^a	NR	0.00008 - 0.1; 0.000003 - 0.0055 ^b	0.5; 0.0002 ^b
Incidental Inhalation-Powder	1 ^a	NR	0.0003 - 0.2 ^c	NR
Dermal Contact	6	5	0.000001 - 0.2	0.0001 - 0.5
Deodorant (underarm)	NR	NR	spray: 0.00008; not spray: 0.0002	0.001 ^b
Hair-Non-Coloring	NR	2	0.00008 - 0.012	0.0006 - 0.003
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	NR	2	0.0016 - 0.068	0.0001 - 0.003
Baby Products	NR	NR	NR	NR
as reported by product category				
Bath Preparations (diluted for use)				
Bath Oils, Tablets, and Salts	NR	2	NR	NR
Bubble Baths	NR	NR	0.015	NR
Other Bath Preparations	NR	NR	0.05	NR
Eye Makeup Preparations				
Eye Lotion	1	NR	NR	NR
Fragrance Preparations				
Perfumes	NR	NR	NR	0.5
Other Fragrance Preparation	1	NR	NR	NR
Hair Preparations (non-coloring)				
Hair Conditioner	NR	NR	0.00033 - 0.012	0.0006
Hair Spray (aerosol fixatives)	NR	NR	0.00008 - 0.00042	NR
Shampoos (non-coloring)	NR	1	0.001 - 0.01	0.003
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	0.005 - 0.0055	NR
Other Hair Preparations	NR	1	NR	NR
Makeup Preparations				
Lipstick	NR	NR	0.04	NR
Personal Cleanliness Products				
Bath Soaps and Detergents	NR	NR	0.0016 - 0.068	0.0001
Deodorants (underarm)	NR	NR	spray: 0.00008 not spray: 0.0002	0.001
Other Personal Cleanliness Products	NR	NR	0.02	0.003
Shaving Preparations				
Aftershave Lotion	NR	NR	0.006	NR
Other Shaving Preparations	1	NR	0.0091	NR
Skin Care Preparations				
Cleansing	NR	1	NR	NR
Face and Neck (exc shave)	1	NR	not spray: 0.0003 - 0.2	NR
Body and Hand (exc shave)	NR	NR	not spray: 0.025	NR
Foot Powders and Sprays	NR	NR	spray: 0.1	NR
Night	NR	NR	NR	0.0002
Paste Masks (mud packs)	2	2	NR	NR
Other Skin Care Preparations	NR	NR	0.075	0.004
Suntan Preparations				
Suntan Gels, Creams, and Liquids	NR	NR	not spray: < 0.000001	NR
Indoor Tanning Preparations	NR	NR	0.000003	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>)^a Not 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^b It is possible these products are sprays, but it is not specified whether the reported uses are sprays.^c It is possible these products are powders, but it is not specified whether the reported uses are powders.

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Safety Assessment of Polyquaternium-11 as Used in Cosmetics

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History

Original Safety Assessment – published 1983

Original Re-Review – published 2005

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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen; Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This summary was prepared by Regina Tucker, M.S., Scientific Analyst/Writer, CIR.

POLYQUATERNIUM-11

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report of the safety of Polyquaternium-11 in 1983.¹ The Panel concluded that Polyquaternium-11 is safe as a cosmetic ingredient in the present practices of use as described in that safety assessment. Upon re-review in 2001, the Panel reaffirmed the original conclusion, as published in 2005.²

Because it has 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 its June 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 these data, the frequency and concentrations of use of Polyquaternium-11 have decreased. In 2023, Polyquaternium-11 is used in 192 formulations at up to 2.9% in leave-on products; in 2001, Polyquaternium-11 was reported to be used in 254 formulations at up to 12% in rinse-off products and up to 10% in leave-on products. The cumulative frequency and concentration of use data are presented in Table 1.

In June 2023, an extensive search of the world's literature was performed for studies dated 2000 forward. No relevant new data were found.

In summary, the Panel reviewed 2023 frequency and concentration of use data and noted the lack of any new, 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 1983 conclusion. The Panel discussed the possibility for Polyquaternium-11 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>.

Table 1. Frequency and concentration of use (2003/2001) according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)	
	2023 ³	2001 ²	2023 ⁴	2001 ²
Totals*	192	254	0.05 – 2.9	0.05 - 12
summarized by likely duration and exposure**				
Duration of Use				
Leave-On	108	127	0.05-2.9	0.05-10
Rinse-Off	84	126	0.08-0.6	0.05-12
Diluted for (Bath) Use	NR	1	NR	NR
Exposure Type				
Eye Area	1	1	0.1-1.2	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	7;74 ^a	89 ^a	0.2-2.9;0.05-2.3 ^a	2;0.05-10 ^a ;0.05 ^c
Incidental Inhalation-Powder	NR	NR	NR	0.05 ^c
Dermal Contact	1	5	NR	0.05-12
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	172	241	0.05-2.9	0.05-10
Hair-Coloring	18	7	NR	0.3
Nail	NR	NR	NR	NR
Mucous Membrane	1	2	NR	12
Baby Products	NR	NR	NR	NR
as reported by product category				
Bath Preparations (diluted for use)				
Other Bath Preparations	NR	1	NR	NR
Eye Makeup Preparations				
Mascara	1	1	0.1-1.2	NR
Hair Preparations (non-coloring)				
Hair Conditioner	22	69	0.08-0.6	0.8-3
Hair Spray (aerosol fixatives)	7	NR	0.2-2.9	2
Permanent Waves	4	14	NR	NR
Rinses (non-coloring)	NR	1	NR	0.8
Shampoos (non-coloring)	39	24	0.15	0.05-4
Tonics, Dressings, and Other Hair Grooming Aids	74	88	0.05-2.3	0.05-10
Wave Sets	NR	8	NR	2-3
Other Hair Preparations	26	37	0.08	0.1-4
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	11	NR	NR	NR
Hair Tints	NR	4	NR	NR
Hair Shampoos (coloring)	1	NR	NR	NR
Hair Bleaches	NR	3	NR	NR

Table 1. Frequency and concentration of use (2003/2001) according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)	
	2023 ³	2001 ²	2023 ⁴	2001 ²
Other Hair Coloring Preparation	6	NR	NR	0.3
Personal Cleanliness Products				
Bath Soaps and Detergents	1	NR	NR	NR
Other Personal Cleanliness Products	NR	1	NR	12
Shaving Preparations				
Shaving Cream	NR	2	NR	NR
Skin Care Preparations				
Cleansing	NR	NR	NR	0.4
Face and Neck (exc shave)	NR	NR	NR	0.05
Night	NR	NR	NR	0.05
Paste Masks (mud packs)	NR	NR	NR	4
Skin Fresheners	NR	1	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>)

^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.

^c Not 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

References

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