Rereview Summaries

Acid Orange 3

Chloroxylenol

Erythrobic Acid

Glyceryl Diesters

Hexamidine

Mink Oil

Sodium Lauryl Sulfoacetate

EXPERT PANEL MEETING
December 5-6, 2022

ACID ORANGE 3

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Acid Orange 3 in 2000.[1] The Panel concluded that this ingredient is safe for use in hair dye formulations at concentrations ≤ 0.2%.

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the 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, and the maximum use concentrations provided by the Personal Care Products Council (Council). According to 2022 VCRP survey data, Acid Orange 3 is used in one formulation; it is reported to be used in a nail polish and enamel.[2] The results of the concentration of use survey provided by the Council in 2022 reported no uses for this ingredient.[3] When the original safety assessment was published in 2000, Acid Orange 3 was reported to be used in 4 hair dye formulations (data acquired in 1997).[1] At that time, concentrations of use were no longer reported by the FDA; however, data available from the FDA in 1984 indicated that Acid Orange 3 was used in one hair dye formulation at a concentration between 10% and 25%,and 33 hair dye formulations at ≤ 1%.

An exhaustive search of the world's literature was performed for studies dated 1997 forward, and new data were found.[4-7] The Panel agreed that an updated search of the published literature did not reveal toxicity data that warrant re-evaluation of the safety of this ingredient in cosmetic products. The Panel did note that the European Union has banned Acid Orange 3 for use in cosmetic products; however, this ban is due to a lack of safety test data and not because of any toxicological findings.

The Panel noted that Acid Orange 3 has been reported to be used in a non-coloring cosmetic product (nail polish and enamel). The Federal Food, Drug and Cosmetic Act (FD&C Act) mandates that color additives must be approved by FDA for their intended use before they are used. Acid Orange 3 is an unapproved color additive in cosmetics products, and thereby, such use is not permitted. This use is not within the purview of this Panel.

However, due to the "coal-tar hair dye exemption" of the FD&C Act, hair dye products labeled with the following caution statement do not require FDA approval prior to use:

> *Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.*

Thus, use of this ingredient in hair dye products is permitted and is within the purview of this Panel.

Finally, Acid Orange 3 is a secondary aryl amine; the Panel cautions that this ingredient should not be used in cosmetic products in which *N*-nitroso compounds can be formed. After reviewing data on ingredient use frequencies and concentrations and safety data, the Panel determined to not reopen this safety assessment on Acid Orange 3, and reaffirmed the original conclusion.

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CHLOROXYLENOL

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Chloroxylenol in 1985.[1] The Panel concluded that Chloroxylenol is safe as used in cosmetics, as described in the safety assessment. Upon re-review, the Panel reaffirmed the original conclusion, as published in 2006.[2]

Because it has been at least 15 years since the original re-review was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the 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, and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council). The frequency of use of Chloroxylenol increased slightly. In 2002, Chloroxylenol was reported to be used in 43 formulations.[2] According to 2022 VCRP data, Chloroxylenol is now reported to be used in 51 formulations.[3] The maximum reported concentration of use, 0.05%, has not changed since the last review.[2,4] The cumulative frequency and concentration of use data are presented in Table 1.

An exhaustive search of the world's literature was performed for studies dated 2000 forward, and new data were found.[5-17] The Panel agreed, however, that the published literature did not reveal toxicity or other data that warrant re-evaluation of the safety of this ingredient in cosmetic products. The Panel noted depigmentation following dermal exposure to undiluted Chloroxylenol and an antiseptic formulation containing predominantly Chloroxylenol. However, depigmentation/skin lightening is considered a drug effect, and therefore, these effects would not be within the purview of the Panel to be evaluated. In addition, concern for this endpoint was mitigated as the concentrations the subjects were exposed to in these cases were much higher than what would be used in cosmetics.

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

Table 1. Current and historical frequency and concentration of use according to duration and exposure for Chloroxylenol

	# of Uses		*Max Conc of Use (%)*	
	2022[3]	**2002[2]**	**2022[4]**	**2003[2]**
Totals*	**51**	**43**	**0.1 – 0.5**	**0.1 – 0.5**
Duration of Use				
Leave-On	*40*	*20*	*0.1 – 0.3*	*0.1 – 0.2*
Rinse-Off	*10*	*23*	*0.2 – 0.5*	*0.4 – 0.5*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*
Exposure Type				
Eye Area	8	1	NR	NR
Incidental Ingestion	NR	NR	NR	0.4
Incidental Inhalation-Spray	20[a]; 5[b]	7[a]; 2[b]	NR	0.1[s]; 0.2[b]
Incidental Inhalation-Powder	5[b]	2[b]	0.1 – 0.3[c]	0.2[b]; 0.1[c]
Dermal Contact	40	31	0.1 – 0.5	0.1 – 0.5
Deodorant (underarm)	NR	1[a]	NR	NR
Hair - Non-Coloring	4	12	0.3	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	4	12	0.2 – 0.5	0.4
Baby Products	NR	NR	0.1 – 0.3	0.1

*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] 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
[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.
NR – not reported

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ERYTHORBIC ACID and SODIUM ERYTHORBATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of Erythorbic Acid and Sodium Erythorbate, as part of a larger group of ingredients, in 1999.[1] The Panel concluded that these ingredients are safe for use as cosmetic ingredients in the present practices of use described in the safety assessment. Subsequently, Ascorbyl Palmitate, Ascorbyl Dipalmitate, and Ascorbyl Stearate, which were a part of the original review, were added to a grouping of ethers and esters of ascorbic acid for which a safety assessment was published in 2017, and therefore, are not included as part of this rereview.

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the 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) in 2022.[3] In the original 1999 report, there were 727 reported uses for Erythorbic Acid which has since decreased to 300 reported uses in 2022. Similarly, the overall reported concentrations of use have decreased for both ingredients. In both the historical and current data, the bulk of reported uses are for non-coloring hair preparations. Sodium Erythorbate, which was reported to be used in hair coloring preparations at > 50% in 1984, is reported to be used at up to 0.3% in hair dyes and colors in 2022. Updated and historical frequency and concentration of use data are presented in Table 1.

An exhaustive search of the world's literature was performed for studies dated 1994 forward, and minimal new published data was found. One notable finding included a local lymph node assay performed in female mice using Sodium Erythorbate at up to 25% in propylene glycol. After considering the low reported concentrations of use and the lack of new safety data of concern, the Panel determined to not reopen this safety assessment on Erythorbic Acid and Sodium Erythorbate, and reaffirmed the original conclusion.

Table 1. Current and historical frequency and concentration of use of Erythorbic Acid and Sodium Erythorbate according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Erythorbic Acid				**Sodium Erythorbate**			
	2022[2]	**1996[1]**	**2022[3]**	**1984[1]**	**2022[2]**	**1996[1]**	**2022[3]**	**1984[1]**
Totals*	**300**	**727**	**0.1-0.7**	**1****	**6**	**19**	**0.3**	**> 50****
Duration of Use								
Leave-On	*2*	*1*	*0.1*	**	*NR*	*NR*	*NR*	**
Rinse-Off	*298*	*726*	*0.2-0.7*	**	*6*	*19*	*0.3*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	1	NR	0.1	**	NR	NR	NR	**
Incidental Ingestion	NR	1	NR	**	NR	NR	NR	**
Incidental Inhalation-Spray	1[a]	1[a]	0.1[a]; 0.1[b]	**	NR	NR	NR	**
Incidental Inhalation-Powder	NR	NR	0.1[b]	**	NR	NR	NR	**
Dermal Contact	2	NR	0.1	**	NR	NR	NR	**
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	**
Hair - Non-Coloring	NR	4	NR	**	NR	NR	NR	**
Hair-Coloring	298	721	0.2-0.7	**	6	19	0.3	>50**
Nail	NR	1	NR	**	NR	NR	NR	**
Mucous Membrane	NR	1	NR	**	NR	NR	NR	**
Baby Products	NR	NR	NR	**	NR	NR	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.
**At the time of the 1999 safety assessment, concentration of use data were not reported. However, data provided to the FDA in 1984 data were presented; use categories were not indicated.
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] 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
NR – not reported

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GLYCERYL DIESTERS

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of these 17 glyceryl diester ingredients (listed below) in 2007, with the conclusion that these ingredients are safe as cosmetics in the present practices of use and concentrations described in the safety assessment provided that the content of 1,2-diesters is not high enough to induce epidermal hyperplasia. Glyceryl Dimyristate was originally a part of this group, but has since been reviewed with Myristic Acid ingredients, and is therefore not included in this rereview.

Glyceryl Dilaurate
Glyceryl Diarachidate
Glyceryl Dibehenate
Glyceryl Dierucate
Glyceryl Dihydroxystearate
Glyceryl Diisopalmitate
Glyceryl Diisostearate
Glyceryl Dilinoleate
Glyceryl Dioleate
Glyceryl Diricinoleate
Glyceryl Dipalmitate
Glyceryl Dipalmitoleate
Glyceryl Distearate
Glyceryl Palmitate Lactate
Glyceryl Stearate Citrate
Glyceryl Stearate Lactate
Glyceryl Stearate Succinate

Because it has been at least 15 years since the final amended report was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the Panel considered updated information regarding product types and ingredient use frequencies as reported by the US Food and Drug Administration Voluntary Cosmetic Registration Program database in 2022,[1] and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2020.[2] Generally, there has been an increase in frequency of use since the last review in 2007. As of 2022, Glyceryl Distearate and Glyceryl Stearate Citrate were reported to be used in baby products, when there were no reported uses for glyceryl diesters in this product category previously. Glyceryl Stearate Citrate, which had no reported uses in the original report, was reported to have164 reported uses and to be used at up to 4% in non-spray moisturizing products. Additionally, although the number of reported uses of Glyceryl Diisostearate in lipstick increased, the maximum reported concentrations of use for this product category significantly decreased, from 43% in 1999 to 0.54% in 2022. The cumulative frequency and concentration of use data are presented in Table 1. Ingredients with no reported use are listed in Table 2.

An exhaustive search of the world's literature was performed for studies dated 2002 forward. The Panel considered new chronic toxicity, developmental and reproductive toxicity, and carcinogenicity/tumor promotion studies. Aside from these studies having negative results, the FDA-approved use of Glyceryl Dibehenate and Glyceryl Distearate as inactive ingredients in oral capsule formulations as well as the approved use of diacylglycerol oil and diglycerides as food additives reassured the Panel of safety.

After reviewing updated frequency and concentration of use data, and considering the lack of new toxicological data of concern, the Panel determined to not reopen this safety assessment on glyceryl diesters, and reaffirmed the conclusion published in 2007.

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 (%)*	
	Glyceryl Dibehenate				**Glyceryl Diisostearate**			
	2022[1]	**2002[3]**	**2022[2]**	**1999[3]**	**2022[1]**	**2002[3]**	**2022[2]**	**1999[3]**
Totals*	**32**	**NR**	**1**	**NR**	**139**	**97**	**0.54**	**18-43**
Duration of Use								
Leave-On	*32*	*NR*	*1*	*NR*	*138*	*97*	*0.54*	*18-43*
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*1*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	8	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	NR	124	93	0.54	43
Incidental Inhalation-Spray	5[a]; 12[b]	NR	1[a]	NR	3[a]; 3[b]	1; 1[a]; 1[b]	NR	18
Incidental Inhalation-Powder	12[b]	NR	NR	NR	3[b]	1[b]	NR	NR
Dermal Contact	26	NR	1	NR	15	3	NR	18
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	1	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	2	NR	NR	NR	NR	1	NR	NR
Mucous Membrane	1	NR	NR	NR	124	93	0.54	43
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	Glyceryl Dilaurate				**Glyceryl Dioleate**			
	2022[1]	**2002[3]**	**2022[2]**	**1999[3]**	**2022[1]**	**2002[3]**	**2022[2]**	**1999[3]**
Totals*	**27**	**35**	**1-4**	**0.02-5**	**10**	**1**	**NR**	**0.8-2**
Duration of Use								
Leave-On	*26*	*27*	*1-4*	*2-5*	*10*	*1*	*NR*	*0.8-2*
Rinse-Off	*1*	*8*	*NR*	*0.02-5*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR	NR	NR	2	1	NR	NR	NR
Incidental Ingestion	NR	1	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	22[a]; 4[b]	8[a]; 13[b]	NR	5[a]; 2-4[b]	5[a]; 1[b]	NR	NR	2[a]; 0.8[b]
Incidental Inhalation-Powder	4[b]	13[b]	1.5[c]	2-4[b]	1; 1[b]	NR	NR	0.8[b]
Dermal Contact	27	34	1-4	0.02-5	10	1	NR	0.8-2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	4	NR	0.02	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	Glyceryl Dipalmitate				**Glyceryl Distearate**			
	2022[1]	**2002[3]**	**2022[2]**	**1999[3]**	**2022[1]**	**2002**	**2022[2]**	**1999[3]**
Totals*	**NR**	**NR**	**1.1**	**NR**	**16**	**NR**	**0.05-4.4**	**0.00003-7**
Duration of Use								
Leave-On	*NR*	*NR*	*1.1*	*NR*	*14*	*NR*	*0.05-4.4*	*0.00003-7*
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*2*	*NR*	*0.3-2.2*	*0.0003-6*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR	NR	NR	NR	2	NR	2.3	0.003-0.5
Incidental Ingestion	NR	NR	NR	NR	1	NR	NR	7
Incidental Inhalation-Spray	NR	NR	NR	NR	6[a]; 2[b]	NR	2.9[a]	0.00003-7[a]; 0.2-7[b]
Incidental Inhalation-Powder	NR	NR	1.1[c]	NR	2[b]	NR	0.22-4.4[b]	0.2-7[b]
Dermal Contact	NR	NR	1.1	NR	12	NR	0.05-4.4	0.00003-7
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	3	NR	0.3-0.55	6
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	0.02
Mucous Membrane	NR	NR	NR	NR	1	NR	NR	7
Baby Products	NR	NR	NR	NR	NR	NR	0.55-1.1	NR

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 (%)*	
	Glyceryl Stearate Citrate				**Glyceryl Stearate Lactate**			
	2022[1]	**2002[3]**	**2022[2]**	**1999[3]**	**2022[1]**	**2002[3]**	**2022[2]**	**1999[3]**
Totals*	164	NR	0.5-4	NR	NR	NR	NR	5
Duration of Use								
Leave-On	*142*	*NR*	*0.5-4*	*NR*	*NR*	*NR*	*NR*	*5*
Rinse-Off	*21*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	6	NR	1.2	NR	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1;53[a]; 61[b]	NR	NR	NR	NR	NR	NR	5[a]; 5[b]
Incidental Inhalation-Powder	61[b]; 4[c]	NR	0.5-2[c]	NR	NR	NR	NR	5[b]
Dermal Contact	157	NR	0.5-4	NR	NR	NR	NR	5
Deodorant (underarm)	4[a]	NR	NR	NR	NR	NR	NR	5[a]
Hair - Non-Coloring	6	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	6	NR	NR	NR	NR	NR	NR	NR
Baby Products	5	NR	2	NR	NR	NR	NR	NR
	Glyceryl Stearate Succinate							
	2022[1]	**2002[3]**	**2022[2]**	**1999[3]**				
Totals*	1	NR	NR	NR				
Duration of Use								
Leave-On	*1*	*NR*	*NR*	*NR*				
Rinse-Off	*NR*	*NR*	*NR*	*NR*				
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*				
Exposure Type								
Eye Area	NR	NR	NR	NR				
Incidental Ingestion	NR	NR	NR	NR				
Incidental Inhalation-Spray	NR	NR	NR	NR				
Incidental Inhalation-Powder	NR	NR	NR	NR				
Dermal Contact	1	NR	NR	NR				
Deodorant (underarm)	NR	NR	NR	NR				
Hair - Non-Coloring	NR	NR	NR	NR				
Hair-Coloring	NR	NR	NR	NR				
Nail	NR	NR	NR	NR				
Mucous Membrane	NR	NR	NR	NR				
Baby Products	NR	NR	NR	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] 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

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

NR – not reported

Table 2. Glyceryl Diesters not reported to be in use[1,2]

Glyceryl Diarachidate
Glyceryl Dierucate
Glyceryl Dihydroxystearate
Glyceryl Diisopalmitate
Glyceryl Dilinoleate
Glyceryl Diricinoleate
Glyceryl Dipalmitoleate
Glyceryl Palmitate Lactate

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HEXAMIDINE AND HEXAMIDINE DIISETHIONATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Hexamidine and Hexamidine Diisethionate in 2007.[1] The Panel concluded that Hexamidine and Hexamidine Diisethionate are safe in the practices and concentrations of use as described in the safety assessment if used at concentrations less than or equal to 0.10%.

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the 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, and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council). The frequency of use of Hexamidine Diisethionate has increased from 38 uses in 2002[1] to 52 uses in 2022.[2] The concentration of use of this ingredient has remained the same (≤ 0.1%).[1,3] There were previously, and are currently, no reported uses for Hexamidine. The cumulative frequency and concentration of use data are presented in Table 1.

An exhaustive search of the world's literature was performed for studies dated 2000 forward, and new data were found.[4-9] The 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. The Panel noted the clinical studies in which hypersensitivity was observed; however, these studies were performed in previously determined atopic individuals; therefore, concern for this endpoint was mitigated.

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

Table 1. Current and historical frequency and concentration of use of Hexamidine Diisethionate according to duration and exposure

	# of Uses		*Max Conc of Use (%)*	
	Hexamidine Diisethionate			
	2022[2]	**2002[1]**	**2022[3]**	**2004[1]**
Totals*	**52**	**38**	**0.036 – 0.1**	**0.03 – 0.1**
Duration of Use				
Leave-On	*34*	*23*	*0.036 – 0.1*	*0.03 – 0.1*
Rinse-Off	*18*	*15*	*NR*	*0.05 – 0.06*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*
Exposure Type				
Eye Area	2	1	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	9[a]; 8[b]	9[a]; 5[b]	NR	0.1[a]; 0.05[b]
Incidental Inhalation-Powder	1; 8[b]; 3[c]	5[b]; 3[c]	0.036[c]	0.05[b]
Dermal Contact	37	32	0.036 – 0.1	0.04 – 0.1
Deodorant (underarm)	3[a]	NR	0.05	0.1[a]
Hair - Non-Coloring	14	5	NR	NR
Hair-Coloring	1	NR	NR	NR
Nail	NR	NR	NR	0.03
Mucous Membrane	1	NR	NR	NR
Baby Products	5	5	0.036	NR

[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] 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
[c] 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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MINK OIL

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review on the safety of Mink Oil in 1998, with an insufficient data conclusion.[1] Subsequently, the Panel's data needs were met, and in 2005, a final amended report was published with the conclusion that Mink Oil is safe as a cosmetic ingredient in the practices of use and concentration described in the safety assessment.[2]

Because it has been at least 15 years since the previous report was published, in accordance with CIR Procedures, the Panel again considered whether the safety assessment should be reopened. At the September 2022 meeting, the 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,[3] and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council).[4] Since the final amended report was issued, there is one new use category reported in 2022 (hair-coloring). The frequency of use has decreased, from 100 reported uses in 2001 to 32 uses in 2022, and the maximum concentration of use for Mink Oil has decreased from 3% in 2001 to 0.1% in 2022. The cumulative frequency and concentration of use data are presented in Table 1.

An exhaustive search of the world's literature was performed for studies dated 2000 forward. No new toxicity or safety data were found.

After reviewing updated frequency and concentration of use data and considering the lack of new toxicological and safety data, the Panel determined to not reopen this safety assessment on Mink Oil, and reaffirmed the conclusion stated in the final amended report that was published in 2005.

Current and historical frequency and concentration of use according to duration and exposure of Mink Oil

	# of Uses		*Max Conc of Use (%)*	
	2022[3]	**2001[2]**	**2022[4]**	**2001[2]**
Totals*	**32**	**100**	**0.1**	**0.001-3**
Duration of Use				
Leave-On	*22*	*63*	*0.1*	*0.001-2*
Rinse-Off	*5*	*36*	*NR*	*3*
Diluted for (Bath) Use	*5*	*1*	*NR*	*0.1*
Exposure Type				
Eye Area	NR	2	NR	0.1-1
Incidental Ingestion	11	12	NR	0.001
Incidental Inhalation-Spray	5[a];3[c]	3;23[a];12[c]	NR	1;0.2-2[a];0.1-0.5[c]
Incidental Inhalation-Powder	1;3[c]	1;12[c]	NR	0.1;1[b];0.1-0.5[c]
Dermal Contact	19	48	0.1	0.1-2
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	1	39	NR	3
Hair-Coloring	1	NR	NR	NR
Nail	NR	NR	NR	0.001-0.1
Mucous Membrane	16	13	NR	NR
Baby Products	NR	NR	NR	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.

[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

NR – no reported use

References

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SODIUM LAURYL SULFOACETATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Sodium Lauryl Sulfoacetate in 1987 with the conclusion that this ingredient is safe as a cosmetic ingredient in the present practices of use and concentration.[1] The Panel reaffirmed this conclusion in a previous re-review that was published in 2006.[2]

Because it has been at least 15 years since the original re-review was published, in accordance with CIR Procedures, the Panel determined whether the safety assessment should be reopened. At the September 2022 meeting, the 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, and the maximum use concentrations provided by the Personal Care Products Council (Council). The cumulative frequency and concentration of use data are presented in Table 1. Since the initial re-review was considered, the frequency of use has increased slightly, from 68 to 97 uses.[2,3] In 2004, the maximum concentration of use for this ingredient was reported to be 4% in leave-on products, 5% in rinse-off products, and 21% in products diluted for use.[2] Concentration of use provided by the Council in 2022 indicate that Sodium Lauryl Sulfoacetate is used at up to 2.5% in leave-on products (foot powders), up to 10.2% in rinse-off products (preshave lotions), and up to 8.4% in products diluted for use (bubble baths).[4]

An exhaustive search of the world's literature was performed for studies dated 2004 forward, when the last re-review was initiated. The Panel agreed, however, that that the published literature did not reveal toxicity or other data that warrant re-evaluation of the safety of this ingredient in cosmetic products. After reviewing data on ingredient use frequencies and concentrations and safety data, the Panel determined to not reopen this safety assessment on Sodium Lauryl Sulfoacetate and reaffirmed the original conclusion.

Current and historical frequency and concentration of use according to duration and exposure for Sodium Lauryl Sulfoacetate

	# of Uses		*Max Conc of Use (%)*	
	2022[3]	**2002[2]**	**2022[4]**	**2004[2]**
Totals*	**87**	**68**	**0.00028-10.2**	**0.6-21**
Duration of Use				
Leave-On	*5*	*1*	*0.8-2.5*	*4*
Rinse-Off	*52*	*6*	*0.00028-10.2*	*5*
Diluted for (Bath) Use	*30*	*61*	*3-8.4*	*21*
Exposure Type				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	1	0.74	0.7
Incidental Inhalation-Spray	1[a]	1	1.5	2; 2[a]
Incidental Inhalation-Powder	1[a]	NR	2.5	1[b]; 2[a]
Dermal Contact	53	64	0.00028-10.2	0.6-21
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	33	1	0.53-4.4	1-5
Hair-Coloring	1	2	3	NR
Nail	NR	NR	NR	4
Mucous Membrane	42	62	0.00028-10	0.6-21
Baby Products	1	NR	0.53	1

*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] 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 powders, but it is not specified whether the reported uses are powders.

NR – no reported use

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