Rereview Summaries

Amyl Acetate

Cottonseed Glyceride

Glycol Stearate

N,N-Bis(2-Hydroxyethyl-p-Phenylenediamine Sulfate

PEGs Soy Sterol

Polyacrylamide

PPGs Stearyl Ether

EXPERT PANEL MEETING
September 26-27, 2022

AMYL ACETATE AND ISOAMYL ACETATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of Amyl Acetate and Isoamyl Acetate in 1988. The Panel concluded that these ingredients are safe as presently used, as described in that safety assessment.[1]

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 June 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).[3] The frequency and concentration of use for Amyl Acetate has decreased from 18 to 4 uses, and from < 10% to ≤ 0.09%, respectively.[1,3] In 1987 Isoamyl Acetate was not reported to be in use; however, according to 2022 FDA VCRP data, this ingredient in now used in 1 formulation at up to 0.22%. 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 1982 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.

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

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 (%)*	
	Amyl Acetate				**Isoamyl Acetate**			
	2022[2]	**1987[1]**	**2021[3]**	**1987[1]**	**2022[2]**	**1987[1]**	**2021[3]**	**1987[1]**
Totals*	**4**	**18**	**0.000000025 – 0.09**	**> 0.1 - ≤10**	**1**	**NR**	**0.002 – 0.22**	**NR**
Duration of Use								
Leave-On	*2*	*18*	*0.000000025 – 0.05*	*>0.1 - >10*	*1*	*NR*	*0.002 – 0.075*	*NR*
Rinse-Off	*2*	*NR*	*0.00004 – 0.09*	*NR*	*NR*	*NR*	*0.027 – 0.22*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*0.0078*	*NR*	*NR*	*NR*	*0.048*	*NR*
Exposure Type								
Eye Area	NR	NR	0.000000025	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	0.05; 0.03[a]	NR	1[a]	NR	0.0037 – 0.016	NR
Incidental Inhalation-Powder	NR	NR	0.026[b]	NR	NR	NR	0.019	NR
Dermal Contact	NR	NR	0.000000025 – 0.09	NR	1	NR	0.22	NR
Deodorant (underarm)	NR	NR	not spray: 0.0075 – 0.023; spray: 0.0032	NR	NR	NR	not spray: 0.0062 – 0.013; spray: 0.0065	NR
Hair - Non-Coloring	NR	NR	0.0012	NR	NR	NR	0.0037 – 0.082	NR
Hair-Coloring	NR	NR	0.0012 – 0.065	NR	NR	NR	NR	NR
Nail	4	18	NR	>0.1 - >10	NR	NR	NR	NR
Mucous Membrane	NR	NR	0.0031 – 0.09	NR	NR	NR	0.048 – 0.22	NR
Baby Products	NR	NR	NR	NR	NR	NR	0.008 – 0.075	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.

NR – no reported use

REFERENCES

1. Elder RL. Final Report on the Safety Assessment of Amyl Acetate and lsoamyl Acetate. *J Am Coll Toxicol.* 1988;7(6).

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COTTONSEED GLYCERIDE and HYDROGENATED COTTONSEED GLYCERIDE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of Cottonseed Glyceride and Hydrogenated Cottonseed Glyceride, as part of a larger group of ingredients, in 2001.[1] The Panel concluded that these ingredients are safe as used in cosmetic products, provided that established and imposed limits on gossypol, heavy metals, and pesticide concentrations are not exceeded.

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 June 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 2001 report, there was 1 reported use for Cottonseed Glyceride in hair conditioners and 5 reported uses for Hydrogenated Cottonseed Glyceride. At that time, Cottonseed Glyceride was reported to be used at up to 5% in unspecified cosmetic formulations; no concentrations of use were reported for Hydrogenated Cottonseed Glyceride. In 2022, there are no reported uses in FDA VCRP or reported concentrations of use from Council for either ingredient. 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 1996 forward, and no new published data were found specific to these 2 ingredients. All studies that were found pertained to cottonseed oil.

After considering the absence of use data and lack of new toxicological and safety data, the Panel determined to not reopen this safety assessment on Cottonseed Glyceride and Hydrogenated Cottonseed Glyceride, and reaffirmed the original conclusion.

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 (%)*	
	Cottonseed Glyceride				**Hydrogenated Cottonseed Glyceride**			
	2022[2]	**1998[1]**	**2022[3]**	**1984[1]**	**2022[2]**	**1998[1]**	**2022[3]**	**1984[1]**
Totals*	**NR**	**1**	**NR**	**1-5****	**NR**	**5**	**NR**	***
Duration of Use								
Leave-On	*NR*	*NR*	*NR*	*NR*	*NR*	*5*	*NR*	***
Rinse-Off	*NR*	*1*	*NR*	*NR*	*NR*	*NR*	*NR*	***
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	***
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	1	NR	***
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	***
Incidental Inhalation-Spray	NR	NR	NR	NR	NR	2; 1[a]	NR	***
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	***
Dermal Contact	NR	NR	NR	NR	NR	5	NR	***
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	***
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	***
Hair-Coloring	NR	1	NR	NR	NR	NR	NR	***
Nail	NR	NR	NR	NR	NR	NR	NR	***
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	***
Baby Products	NR	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 original 2001 safety assessment, concentration of use data were not reported. However, data provided to the FDA in 1984 were presented; use categories were not indicated.
***Concentration of use data were not provided in the original safety assessment.
a It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
NR – none reported

References

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3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Cottonseed Glyceride and Hydrogenated Cottonseed Glyceride. (Unpublished data submitted by Personal Care Products Council on January 12, 2022.)

GLYCOL STEARATE AND GLYCOL STEARATE SE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Glycol Stearate and Glycol Stearate SE in 1982; The Panel concluded that these ingredients are safe in the present practices of use and concentration, as described in that assessment.[1] Upon review, the Panel reaffirmed the original conclusion, as published in 2003.[2] A third ingredient originally included in these two previous reviews, Glycol Distearate, has subsequently been included in the Safety Assessment of Monoalkylglycol Dialkyl Acid Esters.

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel again considered whether the safety assessment should be reopened. At the June 2022 meeting, the Panel 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,[3] and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council (Council).[4] The maximum concentration of use for Glycol Stearate has decreased slightly, from 6% in 2001 to 5% in 2022. In 2001, Glycol Stearate SE was reported to be used at up to 12%; however, concentration of use data were not reported in 2022.[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 1997 forward. No new toxicity or safety data were found.

After reviewing data on ingredient use frequencies and concentrations, and considering the lack of new toxicological and safety data, the Panel determined to not reopen this safety assessment on Glycol Stearate and Glycol Stearate SE, and again reaffirmed the original conclusion.

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

	Glycol Stearate				Glycol Stearate SE			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2022[3]	2001[2]	2022[4]	2001[2]	2022[3]	2001[2]	2022[4]	2001[2]
Totals*	**602**	**424**	**0.0002-5**	**0.0001-6**	**24**	**14**	**NR**	**0.2-12**
Duration of Use								
Leave-On	*311*	*111*	*0.04-5*	*0.02-6*	*23*	*13*	*NR*	*0.9-5*
Rinse-Off	*270*	*277*	*0.0002-4.3*	*0.0001-6*	*1*	*1*	*NR*	*0.2-12*
Diluted for (Bath) Use	*21*	*36*	*1.4*	*0.2-5*	*NR*	*NR*	*NR*	*0.2*
Exposure Type								
Eye Area	1	NR	NR	3-6	NR	2	NR	NR
Incidental Ingestion	NR	1	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2; 246[a]; 53[b]	1; 40[a]; 36[b]	0.04 -3.1[a]	2-4; 1-5[a]; 0.7-5[b]	11[a]; 8[b]	7[a];3[b]	NR	2-5[a]
Incidental Inhalation-Powder	53[b]; 3[c]	36[b]	1.5-5[c]	4; 0.7-5[b];5[c]	8[b]	3[b]	NR	NR
Dermal Contact	473	217	0.017-5	0.2-6	24	14	NR	0.2-12
Deodorant (underarm)	NR	2[a]	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	119	169	0.034-4	0.0001-4	NR	NR	NR	NR
Hair-Coloring	10	33	0.37	2-6	NR	NR	NR	NR
Nail	NR	3	0.0002	0.02	NR	NR	NR	NR
Mucous Membrane	121	86	0.017-1.4	0.2-6	NR	NR	NR	0.2
Baby Products	3	1	0.034-1.2	5	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 – not reported

REFERENCES

1. Elder RL, (ed). Final report of the safety assessment of Glycol Stearate, Glycol Stearate SE, and Glycol Distearate. *J AM Coll Toxixol.* 1982;1:1-11.

2. Anderson FA (ed). Annual Review of Cosmetic Ingredient Safety Assessments--2001/2002. *Int J Toxicol.* 2003;22 Suppl 1:12-15.

3. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022) College Park, MD

4. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Glycol Stearate and Glycol Stearate SE. (Unpublished data submitted to Personal Care Products Council on January 25, 2021.)

N,*N*-BIS(2-HYDROXYETHYL)-*P*-PHENYLENEDIAMINE SULFATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate in 1992.[1] The Panel concluded that this ingredient is safe as a cosmetic ingredient in present practices of use and concentration, as described in the safety assessment.

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 June 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). When the report was published, the number of reported uses in hair dye formulations was 183.[1] The FDA reported that 119 uses were reported at concentrations of ≤ 0.1%, 55 uses were reported at concentrations of 0.1% to 1%, and 9 uses were reported at concentrations of 1% to 5%. The FDA VCRP database in 2022 has reported an increase in uses to a total of 193.[2] A survey performed by the Council in 2022 reported the maximum use concentration range to be 0.006% to 1.3% in hair dye formulations.[3] 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 1992 forward, and new data were found.[4-6] 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. The Panel did note that *N,N*-Bis(2-Hydroxyethyl)-p-Phenylenediamine Sulfate is a tertiary amine; the Panel cautions that this ingredient should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

After reviewing updated frequency and concentration of use data and toxicity and safety data, the Panel determined to not reopen this safety assessment on *N,N*-Bis(2-Hydroxyethyl)-p-Phenylenediamine Sulfate, and reaffirmed the original conclusion.

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

	***N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate**			
	# of Uses		**Max Conc of Use (%)**	
	2022[2]	**1984[1]**	**2022[3]**	**1984[1]**
Totals*	**193**	**183**	**0.006-1.3**	**≤ 5‡**
Leave-On	*NR*	*NR*	*NR*	*NR*
Rinse-Off	*193*	*183*	*0.006-1.3*	*< 5‡*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*
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	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	193	183	0.006-1.3	< 5‡
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.
‡ The concentration of use data were presented in range groups at the time this report was written. For *N*,*N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate, 119 uses were reported at concentrations < 0.1%, 55 uses were reported between 0.1%-1%, and 9 uses were reported between 1%-5%.
NR – not reported

REFERENCES

1. Elder RL (ed.). Final report on the safety assessment of *N*,*N*-Bis(Hydroxyethyl)-*p*-Phenylenediamine Sulfate. *J Am Coll Toxicol*. 1992;11(1):129-143.

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PEG Soy Sterols

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report on the Safety Assessment of PEG-5, -10, -16, -25, -30, and -40 Soy Sterol in 2000, with the conclusion that the data were insufficient to support the safety of this ingredient group.[1] Subsequently, additional data were received, and in 2004, the Panel published a Final Report of the Amended Safety Assessment of PEG-5, -10, -16, -25, -30, and -40 Soy Sterol, with the conclusion that the 6 PEG Soy Sterol ingredients are safe as used in cosmetics, as described in the safety assessment.[2]

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 June 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] The frequency of use has decreased for all ingredients that were reported to be in use, with the exception that PEG-30 Soy Sterol, which was not previously reported to be used, is now used in 11 formulations.[2,3] In 2000, the maximum concentration of use for this ingredient group was reported to be 2% in leave-on products for PEG-5 Soy Sterol, PEG-10 Soy Sterol, and PEG-25 Soy Sterol. Recent (2020) concentration of use data indicate that PEG-10 Soy Sterol is used at up to 2.6% in rinse-off products, and up to 2.1% in leave-on products.[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 1998 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 or safety data, the Panel determined to not reopen this safety assessment on the PEG Soy Sterol ingredients, and reaffirmed the conclusion published in 2004.

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 (%)*	
	PEG-5 Soy Sterol				**PEG-10 Soy Sterol**			
	1996[1]	**2022[3]**	**2000[2]**	**2020[4]**	**1996[2]**	**2022[3]**	**2000[2]**	**2020[4]**
Totals*	**41**	**7**	**0.2 – 2**	**0.5**	**35**	**9**	**0.05 – 2**	**0.1 – 2.6**
Duration of Use								
Leave-On	*36*	*7*	*0.2 – 2*	*NR*	*17*	*6*	*0.05 – 2*	*0.1 – 2.1*
Rinse-Off	*5*	*NR*	*NR*	*0.5*	*18*	*3*	*2*	*0.1 – 2.6*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	6	1	2	NR	1	NR	0.1 – 2	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	0.5
Incidental Inhalation-Spray	10[a]; 9[c]	3[a]; 2[c]	0.2 – 2[c]	NR	9[a]; 3[c]	4[a]; 1[c]	0.4 – 2[a]; 2[c]	2.1[a]
Incidental Inhalation-Powder	9[c]	2[c]	0.2 – 2[c]	NR	3[c]	1[c]	2[c]	0.1 – 1[b]
Dermal Contact	33	7	0.2 – 2[c]	NR	33	8	0.05 – 2	0.1 – 2.6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	3	NR	NR	0.5	2	2	0.4 – 2	2.1
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	0.5
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	PEG-16 Soy Sterol				**PEG-25 Soy Sterol**			
	1996[2]	**2022[3]**	**2000[2]**	**2020[4]**	**1996[2]**	**2022[3]**	**2000[2]**	**2020[4]**
Totals*	**8**	**3**	**0.2 – 0.5**	**0.01 – 1**	**5**	**2**	**0.5 – 2**	**NR**
Duration of Use								
Leave-On	*5*	*NR*	*0.2 – 0.5*	*0.01 – 0.25*	*2*	*1*	*0.5 – 2*	*NR*
Rinse-Off	*3*	*3*	*0.5*	*1*	*3*	*1*	*0.5*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	3	NR	0.2	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1[a]	NR	0.2 – 0.5[a]	NR	NR	NR	0.5[c]	NR
Incidental Inhalation-Powder	NR	NR	NR	0.25[b]	NR	1[b]	0.5[c]	NR
Dermal Contact	8	3	0.2	0.01 – 1	5	2	0.5 – 2	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	0.5	NR	NR	NR	0.5	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	1	NR	NR
Baby Products	NR	NR	NR	NR	NR	1	NR	NR

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 (%)*	
	PEG-30 Soy Sterol				**PEG-40 Soy Sterol**			
	1996[2]	**2022[3]**	**2000[2]**	**2020[4]**	**1996[2]**	**2022[3]**	**2000[2]**	**2020[4]**
Totals*	NR	11	NR	0.35	1	NR	NR	NR
Duration of Use								
Leave-On	*NR*	*11*	*NR*	*0.35*	*NR*	*NR*	*NR*	*NR*
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	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	5[a]; 6[c]	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	6[c]	NR	NR	NR	NR	NR	NR
Dermal Contact	NR	11	NR	0.35	1	NR	NR	NR
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	NR	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	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.
[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

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POLYACRYLAMIDE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a Final Report of the Safety Assessment of Polyacrylamide in 1991, with the conclusion that Polyacrylamide, with less than 0.01% acrylamide monomer content, is safe as a cosmetic ingredient as currently used.[1] Subsequently, because a large number of studies of acrylamide became available, in 2005 the Panel published an Amended Final Report on the Safety Assessment of Polyacrylamide and Acrylamide Residues in Cosmetics.[2] The Panel concluded that Polyacrylamide is safe as a cosmetic ingredient in the present practices of use and concentration described in the safety assessment, if the level of acrylamide monomer in formulation is not greater than 5 ppm; it was acknowledged that acrylamide is a demonstrated neurotoxin in humans (at high exposure levels that could not be attained with cosmetic use), and a possible carcinogen in animal tests.

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 June 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,[3] and the maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2020.[4] Generally, there has been an increase in frequency of use since the last review in 2005. In 2022, data indicated that Polyacrylamide has 552 reported uses, compared to 110 uses reported in 2002. However, the maximum reported concentration of use for this ingredient has remained constant; in 2001, the maximum reported concentration of use was 2.8%, and in 2020, it was 3%. Additionally, there was 1 reported use in baby lotions, powder, oil and creams, and 2% concentration of use in other baby products, when no baby product use was reported in the 2005 report. 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 published data were found. The Panel considered the reported use in a baby lotion (concentration of use not reported), and discussed the typical average daily consumption of Polyacrylamide in foods, which mitigated systemic toxicity concerns. The Panel noted that the mean dietary intake of Polyacrylamide has been reported to average 0.5 µg/kg/bw/d in adults, whereas intake is higher among children.[5]

After reviewing updated frequency and concentration of use data, and considering the lack of new toxicological data, the Panel determined to not reopen this safety assessment on Polyacrylamide, and reaffirmed the conclusion published in 2005.

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

	# of Uses		*Max Conc of Use (%)*	
	Polyacrylamide			
	2022[3]	**2002[2]**	**2020[4]**	**2001[2]**
Totals*	**552**	**110**	**0.03-3**	**0.05-2.8**
Duration of Use				
Leave-On	*511*	*97*	*0.05-3*	*0.05-2.8*
Rinse-Off	*41*	*13*	*0.03-2.8*	*0.3-1.4*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*
Exposure Type				
Eye Area	58	2	0.05-1	0.05-2.5
Incidental Ingestion	2	NR	NR	NR
Incidental Inhalation-Spray	1; 195[a]; 167[b]	2; 43[a]; 33[b]	0.32-2.1[a]	0.5-1; 0.3-2[a]; 0.2-2.8[b]
Incidental Inhalation-Powder	2; 167[b]; 1[c]	33[b]	0.49; 0.44-3[c]	0.2-2.8[b]
Dermal Contact	503	105	0.03-3	0.05-2.8
Deodorant (underarm)	2[a]	1[a]	NR	NR
Hair - Non-Coloring	45	5	0.2-2.1	0.7-2
Hair-Coloring	NR	NR	0.12	0.9-1.4
Nail	2	NR	0.4-1.5	0.6
Mucous Membrane	5	2	1.6	NR
Baby Products	1	NR	2	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

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PPG-11 and PPG-15 STEARYL ETHER

The Expert Panel first published a Final Report on the Safety Assessment of PPG-11 and PPG-15 Stearyl Ether in 2001.[1] The Panel concluded that these ingredients are safe as used in cosmetics, as described in the safety assessment.

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 June 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).[3] The frequency of use and concentration of use has decreased for PPG-11 Stearyl Ether; however, the frequency and concentration of use has increased for PPG-15 Stearyl Ether (it is currently used in 100 formulations at up to 18%).[1-3] The cumulative frequency and concentration of use data are presented in Table 1.

An exhaustive search of the world's literature was performed for published studies dated 1994 forward, and new data were found.[4] While the Panel agreed that the published literature did not reveal toxicity or other data that warrant re-evaluation of the safety of these ingredients in cosmetic products, they did caution that care should be taken in formulating cosmetic products that may contain this ingredient in combination with any ingredient whose safety was based on their lack of dermal absorption data, or when dermal absorption was a concern.

After reviewing updated frequency and concentration of use data and toxicity and safety data, the Panel determined to not reopen this safety assessment on PPG-11 and PPG-15 Stearyl Ether, and reaffirmed the original conclusion.

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 (%)*	
	PPG-11 Stearyl Ether				**PPG-15 Stearyl Ether**			
	2022[2]	**1998[1]**	**2022[3]**	**1998[1]**	**2022[2]**	**1998[1]**	**2022[3]**	**1998[1]**
Totals*	**1**	**15**	**2 – 5**	**2 - 10**	**100**	**41**	**1 – 18**	**2 - 10**
Duration of Use								
Leave-On	*1*	*NR*	*2.5 – 5*	*NR*	*78*	*29*	*3 – 18*	*NR*
Rinse-Off	*NR*	*14*	*2*	*NR*	*22*	*11*	*1 – 8*	*NR*
Diluted for (Bath) Use	*NR*	*1*	*NR*	*NR*	*NR*	*1*	*NR*	*NR*
Exposure Type								
Eye Area	NR	NR	NR	NR	11	1	4.5	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1	NR	2.5[c]	NR	27[a]; 20[c]	3; 17[a]; 3[c]	NR	NR
Incidental Inhalation-Powder	NR	NR	2.5[c]	NR	20[c]	1[b]; 3[c]	5 – 18[b]	NR
Dermal Contact	1	15	2 – 5	NR	94	38	2 – 18	NR
Deodorant (underarm)	NR	NR	3 – 4.4	NR	6[a]	NR	3 – 4.4	NR
Hair - Non-Coloring	NR	NR	NR	NR	4	3	1	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	13	2.5	NR	2	5	NR	NR
Baby Products	NR	NR	NR	NR	NR	1	NR	NR

*Ingredient concentrations were not presented by specific product category in the original 2001 report; therefore, concentrations of these ingredients are only stated in the "totals" column. In addition, concentrations were provided for multiple years (1984 and 1998). The concentration range presented in the "total" column represents the concentration range for the ingredient reported by ICI Surfactants in 1998.

[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, there fore the information is captured in both categories

NR – no reported use

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