Rereview Summaries

Choleth-24

HC Yellow 5

Methyl Alcohol

Peanut Glycerides

Phytantriol

EXPERT PANEL MEETING
March 6-7, 2023

CHOLETH-24

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Choleth-24 as Used in Cosmetics in 1982.[1] The Panel concluded that Choleth-24 is safe for topical applications to humans in the present practices of use and concentration, as stated in that report. The Panel previously considered a re-review of this report and reaffirmed the 1982 conclusion, as published in 2005.[2]

Because it has been at least 15 years since the original re-review was published, in accordance with CIR Procedures, the Panel again considered whether the safety assessment should be reopened. At the December 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.[4] The frequency of use for Choleth-24 has decreased from 191 uses reported in 2002 to 33 uses reported in 2022. In 2002, Choleth-24 was reported to be used at up to 1.3%. In 2022, no uses were reported for Choleth-24 according to the concentration of use survey. The updated and historical frequency and concentration of use for each ingredient is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

An extensive search of the world's literature was performed for studies dated 1998 forward, and no new toxicological data were found. However, it should be noted that Choleth-24 is an inactive ingredient in two FDA-approved drug formulations.[5] In addition, Choleth-24 is not restricted for use in cosmetics according to the European Union CosIng database.[6]

The Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 1982 conclusion that Choleth-24 is safe for topical applications to humans in the present practices of use and concentration.

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses		*Max Conc of Use (%)*	
	Choleth-24			
	2022[3]	**2002[2]**	**2022[4]**	**2002[2]**
Totals	**33**	**191**	**NR**	**0.002 – 1.3**
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	*24*	*140*	*NR*	*0.008 – 1.3*
Rinse-Off	*9*	*49*	*NR*	*0.002 – 1*
Diluted for (Bath) Use	*NR*	*1*	*NR*	*NR*
Exposure Type*				
Eye Area	NR	4	NR	0.2 – 0.3
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	12[a]; 7[b]	17; 44[a]; 33[b]	NR	0.3; 0.008 – 1.3[a]; 0.1 – 0.7[b]
Incidental Inhalation-Powder	7[b]	33[b]	NR	0.2; 0.1 – 0.7[b]
Dermal Contact	20	138	NR	0.002 – 1.3
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	5	15	NR	0.2 – 1
Hair-Coloring	7	38	NR	0.5
Nail	1	NR	NR	0.3
Mucous Membrane	NR	2	NR	0.002 – 0.7
Baby Products	NR	NR	NR	NR
as reported by product category				
Bath Preparations (diluted for use)				
Bubble Baths	NR	2	NR	NR
Eye Makeup Preparations				
Eyeliner	NR	NR	NR	0.3
Eye Shadow	NR	1	NR	NR
Eye Lotion	NR	1	NR	0.3
Mascara	NR	NR	NR	0.2
Other Eye Makeup Preparations	NR	2	NR	0.3
Fragrance Preparations				
Perfumes	NR	9	NR	0.3
Sachets	NR	NR	NR	0.3
Other Fragrance Preparation	NR	8	NR	NR
Hair Preparations (non-coloring)				
Hair Conditioner	2	9	NR	0.3 – 1
Rinses (non-coloring)	NR	NR	NR	0.2
Shampoos (non-coloring)	NR	1	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	2	2	NR	NR

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses		*Max Conc of Use (%)*	
Other Hair Preparations	1	3	NR	NR
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	7	38	NR	0.5
Makeup Preparations				
Face Powders	NR	NR	NR	0.2
Foundations	NR	19	NR	0.2 – 0.3
Makeup Bases	NR	NR	NR	0.5
Other Makeup Preparations	NR	2	NR	0.2 – 0.5
Manicuring Preparations (Nail)				
Cuticle Softeners	1	NR	NR	0.3
Personal Cleanliness Products				
Bath Soaps and Detergents	NR	NR	NR	0.002 – 0.7
Shaving Preparations				
Aftershave Lotion	NR	7	NR	0.3
Skin Care Preparations				
Cleansing	NR	NR	NR	0.3
Face and Neck (exc shave)	4	4	NR	0.4
Body and Hand (exc shave)	3	28	NR	0.1 – 0.7
Foot Powders and Sprays		1	NR	0.3
Moisturizing	4	28	NR	0.008 – 1.3
Night	3	6	NR	0.2 – 0.3
Paste Masks (mud packs)	NR	1	NR	0.3
Skin Fresheners	NR	2	NR	NR
Other Skin Care Preparations	3	11	NR	0.1 – 0.3
Suntan Preparations				
Suntan Gels, Creams, and Liquids	2	3	NR	0.3
Indoor Tanning Preparations	1	2	NR	NR
Other Suntan Preparations	NR	1	NR	NR

NR – not reported
*likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
**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

REFERENCES

1. Andersen FA (ed). Final Report on the Safety Assessment of Choleth-24. *J Am Coll Toxicol*. 1982;1(4):119-126.

2. Andersen FA (ed). Annual review of cosmetic ingredient safety assessments - 2002/2003. *IJT*. 2005;24:1-102.

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).

4. Personal Care Products Council. 2022. Concentration of use by FDA product category: Propylene Carbonate. Unpublished data submitted by Personal Care Products Council on November 22, 2022.

5. U.S. Food and Drug Administration. Inactive ingredient search for approved drug products. https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm. Last Updated 2022. Accessed November 1, 2022.

6. European Commission. CosIng database; following Cosmetic Regulation No. 1223/2009. http://ec.europa.eu/growth/tools-databases/cosing/. Last Updated 2022. Accessed November 1, 2022.

HC YELLOW 5

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of HC Yellow 5 in 2007.[1] The Panel concluded that HC Yellow 5 is safe as a hair dye ingredient in the present practices of use and concentration as described in that safety assessment.

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 December 2022 meeting, the Panel reviewed updated (2022) 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 maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.[3] Since this report was first considered, the frequency of use has decreased from 37 to 5 uses; it should be noted that non-hair dye uses have been reported to the VCRP in 2022, including 2 uses in nail polish and enamel and 1 use in body and hand skin care products.[1,2] In 2003, the maximum concentration of use for hair dye was reported to be 1.6%.[1] A survey performed by the Council in 2022 had no reported concentrations of use.[3] The updated and historical frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

An extensive search of the world's literature was performed for studies dated 2003 forward, and no new toxicological data were found. The Panel did note that the European Union has banned HC Yellow 5 for use in cosmetic products;[4] however, the reasoning behind this ban is not clear and does not appear to be based on any toxicological findings.

The Panel remarked on the reported use in non-coloring cosmetic products (nail polish and enamel; body and hand skin care preparations).[2] 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. HC Yellow 5 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.

The Panel reviewed 2022 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, the Panel reaffirmed the 2007 conclusion that HC Yellow 5 is safe as a hair dye ingredient in the present practices of use and concentration.

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and by product category.

	# of Uses		*Max Conc of Use (%)*	
	2022[2]	**2002[1]**	**2022[3]**	**2003[1]**
Totals	**5**	**37**	**NR**	**0.2-1.6**
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	*3*	*NR*	*NR*	*NR*
Rinse-Off	*2*	*37*	*NR*	*0.2-1.6*
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	1[a]	NR	NR	NR
Incidental Inhalation-Powder	1[a]	NR	NR	NR
Dermal Contact	1	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	2	37	NR	0.2-1.6
Nail	2	NR	NR	NR
Mucous Membrane	NR	NR	NR	NNR
Baby Products	NR	NR	NR	NR
as reported by product category				
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	2	32	NR	1.6
Hair Tints	NR	5	NR	0.2
Manicuring Preparations (Nail)				
Nail Polish and Enamel	2	NR	NR	NR
Skin Care Preparations				
Body and Hand (exc shave)	1	NR	NR	NR

NR – not reported

*likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

**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

REFERENCES

1. Andersen FA (ed.). Final Report on the Safety Assessment of HC Yellow No. 5. *Int J Toxicol.* 2007;26(Suppl. 2):113-124.

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

3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: HC Yellow No. 5. Unpublished data submitted by the Personal Care Products Council on July 6, 2022.

4. European Commission. Cosing database; following Cosmetic Regulation (EC) No. 1223/2009. http://ec.europa.eu/growth/tools-databases/cosing/ Last updated 2022. Accessed 10/07/2022.

METHYL ALCOHOL

The Expert Panel for Cosmetic Ingredient Safety (Panel) published the Final Report on the Safety Assessment of Methyl Alcohol in 2001.[1] The Panel concluded that based on the data presented in the safety assessment, Methyl Alcohol is safe as used to denature alcohol 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 December 2022 meeting, the Panel reviewed updated (2022) 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 maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.[3] In 2022, FDA VCRP data indicated that Methyl Alcohol has 3 reported uses, while 4 uses were reported in 1998. The reported maximum use concentration for this ingredient also decreased. Because concentration of use data were not reported to the FDA at the time of the 2001 report, 1984 data were used, which indicated that the reported concentration of use was 0.1 - 5% (product categories not identified). According to the survey conducted in 2021, the maximum reported concentration of use is 0.15% in hair dyes and colors. The updated and historical frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

An extensive search of the world's literature was performed for studies dated 1996 forward, and a substantial amount of new data was found from two sources, a European Chemicals Agency dossier and a screening assessment dataset initial assessment profile issued by the Organisation for Economic Co-operation and Development.[4,5] A wide breadth of data was found; notably, a short-term and a subchronic oral toxicity study, several short-term and chronic inhalation toxicity studies, 2 Ames tests, carcinogenicity studies in mice and rats, and a guinea pig maximization test for sensitization were found, all of which were not present in the original report. Additionally, chemical properties, dermal, oral, and inhalation data for toxicokinetic and acute toxicity studies, multiple in vitro genotoxicity studies, an in vivo genotoxicity study (administered via the inhalation route), an in vitro developmental toxicity study in mice, a skin irritation study in rabbits, and an ocular irritation study in rabbits were also found. The majority of this data was supplemental to, and did not conflict with, results found in the original report.

It was also noted that Methyl Alcohol is now approved as a food additive [21CFR173.250] as well as a component of adhesives, defoaming agents, paper and paperboard products that come in contact with food [21CFR175.105; 21CFR176.200; 21CFR176.210; 21CFR176.80].

The Panel stated that in addition to the number of reported uses remaining relatively constant over time, the newly available data was mostly additive to the original report, with studies reporting negative results. Thus, the Panel agreed that in spite of the volume of data that was available, the published literature did not reveal toxicity or other data considered significantly different to warrant re-evaluation of the safety of this ingredient in cosmetic products.

The Panel did observe that Methyl Alcohol now has a reported use of 0.006% in aerosol hair sprays. However, negative inhalation toxicity data from the previous report as well as recent 18-month and 24-month inhalation toxicity studies with negative results mitigated any concern. Furthermore, the Panel reasoned that the maximum reported concentration of use for Methyl Alcohol in sprays is far below the permissible exposure limit issued by the Occupational Safety and Health Administration (200 ppm).

The Panel reviewed 2022 frequency of use and 2021 concentration of use data, in addition to any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2001 conclusion that Methyl Alcohol is safe as used to denature alcohol used in cosmetics.

Table 1. Frequency (2022; 1998) and concentration (2021; 1984) of use according to likely duration and exposure and by product category

	# of Uses		*Max Conc of Use (%)*	
	Methyl Alcohol			
	2022[2]	**1998[1]**	**2021[3]**	**1984[1]**
Totals	**3**	**4**	**0.005 – 0.15**	**0.1-5*** **
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	*3*	*NR*	*0.005-0.006*	***
Rinse-Off	*NR*	*NR*	*0.15*	***
Diluted for (Bath) Use	*NR*	*4*	*NR*	***
Exposure Type*				
Eye Area	1	NR	NR	***
Incidental Ingestion	NR	NR	NR	***
Incidental Inhalation-Spray	1[a]	NR	0.006; 0.005[b]	***
Incidental Inhalation-Powder	1[a]	NR	NR	***
Dermal Contact	2	4	NR	***
Deodorant (underarm)	NR	NR	NR	***
Hair - Non-Coloring	1	NR	0.005 – 0.006	***
Hair-Coloring	NR	NR	0.15	***
Nail	NR	NR	NR	***
Mucous Membrane	NR	4	NR	***
Baby Products	NR	NR	NR	***
as reported by product category				
Eye Makeup Preparations				
Eyebrow Pencil	1	4	NR	***
Hair Preparations (non-coloring)				
Hair Spray (aerosol fixatives)	NR	NR	0.006	***
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	0.005	***
Other Hair Preparations	1	NR	NR	***
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	NR	0.15	***
Skin Care Preparations				
Face and Neck (exc shave)	1	NR	NR	***

NR – not reported

*likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

**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 2001 safety assessment, concentration of use data were not reported by the FDA, and an industry survey was not conducted; 1984 FDA data were used, but without specifying use category

[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.

REFERENCES

1. Andersen FA (ed.). Final report on the safety assessment of Methyl Alcohol. *Int J Toxicol.* 2001;20 Suppl 1:57-85.

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

3. Personal Care Products Council. 2021. Concentration of Use by FDA Product Category: Methyl Alcohol. (Unpublished data submitted by Personal Care Products Council on January 12, 2022.)

4. European Chemical Agency (ECHA). REACH registration dossier: Methanol (CAS No. 67-56-1). https://echa.europa.eu/da/registration-dossier/-/registered-dossier/15569/1/1. Last Updated: 2022. Accessed: 10/15/2022.

5. Organisation for Economic Cooperation and Development (OECD) Screening Information Dataset (SIDS). OECD SIDS Initial Assessment Report: Methanol (Methyl Alcohol; CAS No. 67-56-1). 2004. https://hpvchemicals.oecd.org/ui/handler.axd?id=f6aca735-7365-4578-986c-5a3cd5027555. Accessed 10/08/2022.

PEANUT GLYCERIDES

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a safety assessment of Peanut Glycerides (as part of a larger group of ingredients) in 2001.[1] The Panel concluded that Peanut Glycerides is safe for use in cosmetic formulations.

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 of Peanut Glycerides should be reassessed. (Three other ingredients that were included in the 2001 assessment are not considered here because they have been included in the safety assessment of plant-derived fatty acid oils; additionally, one ingredient in the original assessment was found to have insufficient data to conclude safety, and therefore is not considered for rereview.) At the December 2022 meeting, the Panel was informed that, in 2022, no use of Peanut Glycerides was reported to the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database[2] and concentrations of use were not provided in response to the survey conducted by the Personal Care Products Council.[3] Additionally, no reported uses or concentrations of use data were reported for Peanut Glycerides in the original report.

An extensive search of the world's literature was performed for studies dated 1996 forward, and no new data were found.

The Panel noted the lack of frequency and concentration of use data as well as the lack of any new, available, relevant safety data. Considering this, as well as the information provided in the original safety assessment, the Panel found no reason to reopen the review and reaffirmed the 2001 conclusion that Peanut Glycerides is safe for use in cosmetic formulations.

REFERENCES

1. Andersen FA (ed.). Final report on the safety assessment of Peanut (Arachis hypogaea) Oil, Hydrogenated Peanut Oil, Peanut Acid, Peanut Glycerides, and Peanut (Arachis hypogaea) Flour. *Int J Toxicol*. 2001;20 Suppl 2:65-77.

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

3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Peanut Glyceride. Unpublished data submitted by Personal Care Products Council on January 12, 2022.

PHYTANTRIOL

The Expert Panel for Cosmetic Ingredient Safety (Panel) published the Final Report on the Safety Assessment of Phytantriol in 2007. The Panel concluded that Phytantriol is safe as a cosmetic ingredient in the practices of use and concentration as described in the safety assessment.[1]

Because it has been at least 15 years since the final report was published, in accordance with CIR Procedures, the Panel considered whether the safety assessment should be reopened. At the December 2022 meeting, the Panel reviewed updated (2022) 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 maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.[3] Since the final report was issued, the frequency of use has decreased from 94 uses reported in 2002 to 82 uses reported in 2022. In 2022, the maximum concentration of use was reported to be 0.54%. The maximum use concentration reported by industry in 2003 was 0.1%. However, it should be noted that personal communication submitted to CIR in 2004 indicated that the expected use concentration in products under development was 3%; accordingly, the conclusion that was reached in the original report considered use up to 3 %. The updated and historical frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

An extensive search of the world's literature was performed for studies dated 2000 forward. A case study reported that a 44-year-old woman with no past medical history and no exposure to known irritants presented with an acute eczematous skin reaction on the face after utilizing a face cream with Phytantriol.[4] Patch testing revealed the source of the contact allergy was Phytantriol at a concentration 0.02 - 0.5%.

The Panel reviewed 2022 frequency and concentration of use data, in addition to any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2007 conclusion that Phytantriol is safe as a cosmetic ingredient in the practices of use and concentration described herein.

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and product category

	# of Uses		*Max Conc of Use (%)*	
	2022[2]	**2002[1]**	**2022[3]**	**2003[1]**
Totals	**82**	**94**	**0.001-0.54**	**0.0001-1; ≤3.0ǂ**
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	*46*	*42*	*0.001 – 0.54*	*0.0001 - 1; ≤ 3.0ǂ*
Rinse-Off	*36*	*52*	*0.01 – 0.05*	*0.002 – 0.1; ≤ 3.0ǂ*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*0.05; ≤ 3.0ǂ*
Exposure Type*				
Eye Area	10	NR	NR	NR
Incidental Ingestion	1	6	0.25	0.1
Incidental Inhalation-Spray	5; 14[a]; 2[b]	4; 16[a]; 1[b]	0.018 – 0.54; 0.1-0.2[a]	0.0001 – 0.1; 0.0001[a]; 0.1 – 0.2[b]; ≤3.0ǂ[a,b]
Incidental Inhalation-Powder	2[b]	1[b]	0.1[c]	0.1 – 0.2[b]; ≤3.0ǂ[b]
Dermal Contact	13	3	0.01 – 0.2	0.05 – 0.5; ≤3.0ǂ
Deodorant (underarm)	NR	NR	NR	0.5[a]
Hair - Non-Coloring	58	80	0.01 – 0.54	0.0001 – 0.1; ≤3.0ǂ
Hair-Coloring	NR	NR	NR	NR
Nail	1	5	0.001 – 0.25	1; ≤3.0ǂ
Mucous Membrane	2	6	0.25	0.05 – 0.1; ≤ 3.0ǂ
Baby Products	NR	NR	NR	NR
as reported by product category**				
Bath Preparations (diluted for use)				
Other Bath Preparations	NR	NR	NR	0.05, ≤3.0ǂ
Eye Makeup Preparations				
Eye Lotion	1	NR	NR	NR
Mascara	9	NR	NR	NR
Fragrance Preparations				
Other Fragrance Preparation	1	NR	NR	NR
Hair Preparations (non-coloring)				
Hair Conditioner	15	30	0.01-0.5	0.002–0.1, ≤3.0ǂ
Hair Spray (aerosol fixatives)	4	4	0.15-0.54 (aerosol) 0.018 (pump spray)	0.0001–0.1
Rinses (non-coloring)	2	NR	NR	NR
Shampoos (non-coloring)	18	22	0.01-0.05	0.002–0.1, ≤3.0ǂ
Tonics, Dressings, and Other Hair Grooming Aids	12	15	0.1	0.0001, ≤3.0ǂ
Other Hair Preparations	7	9	0.025-0.05	NR
Makeup Preparations				
Foundations	5	NR	NR	NR
Lipstick	1	6	0.25	0.1

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and product category

	# of Uses		*Max Conc of Use (%)*	
	2022[2]	**2002[1]**	**2022[3]**	**2003[1]**
Rouges	NR	NR	NR	0.1
Other Makeup Preparations	NR	1	NR	NR
Manicuring Preparations (Nail)				
Basecoats and Undercoats	NR	2	NR	≤3.0ǂ
Nail Creams and Lotions	NR	NR	0.25	NR
Nail Polish and Enamel	NR	2	0.001	≤3.0ǂ
Other Manicuring Preparations	1	1	NR	1, ≤3.0ǂ
Personal Cleanliness Products				
Deodorants (underarm)	NR	NR	NR	0.5
Other Personal Cleanliness Products	1	NR	NR	0.05
Shaving Preparations				
Aftershave Lotion	NR	NR	0.01	0.05, ≤3.0ǂ
Shaving Cream	NR	NR	0.01	NR
Skin Care Preparations				
Face and Neck (exc shave)	2	1	0.1 (not spray)	0.1–0.2, ≤3.0ǂ
Moisturizing	2	1	0.2 (not spray)	≤3.0ǂ
Other Skin Care Preparations	1	NR	NR	NR
Suntan Preparations				
Other Suntan Preparations	NR	NR	0.2	NR

NR – not reported
*likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
**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.
ǂ Presented as anticipated use concentration; the conclusion that was reached considered use as up to 3%.
[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.

REFERENCES

1. Andersen F.A. (ed). Final report on the safety assessment of Phytantriol. *Int J Toxicol*. 2007;26 (Suppl 1):107-114.

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

3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Phytantriol. Unpublished data submitted by the Personal Care Products Council on July 7, 2022.

4. Brasch J, Lipowsky F, and Kreiselmaier I. Allergic contact dermatitis to phytantriol. *Contact Derm*. 2008;59:251-252.