

ADMIN

Use Table Format Reconsideration

EXPERT PANEL MEETING
September 26-27, 2022



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice M. Fiume *MMF*
Senior Director, CIR
Date: September 1, 2022
Subject: Use Table format

As discussed at the June 2022 Panel meeting, for the past 10+ years, CIR reports have included Use Tables that comprise a format in which the frequency and concentration of use for each ingredient is summarized by duration (e.g., leave-on, rinse-off) and type of exposure (e.g., eye area, incidental inhalation, etc.). The product use categories reported in the FDA Voluntary Cosmetic Registration Program (VCRP) and the Personal Care Products Council (Council) concentration of use surveys are used to determine the durations and exposures that are identified in the Use Table for each ingredient (<https://www.cir-safety.org/cir-findings>). Although Use Tables are included in every report, an example is included with this memo for ease of reference (*currentformat_UseTable_092022*).

As discussed in June, it is becoming readily apparent that duration and type of exposure can no longer be accurately determined based on the product category. For example, shampoos, which are currently classified in current Use Tables as liquid rinse-off formulations, can actually be spray leave-on formulations (e.g., dry shampoo). Although the intended area of exposure can be surmised with some confidence, how the product is applied (e.g., spray) and the expected duration of exposure (i.e., leave-on or rinse-off) can be presumed, but not truly known.

A proposed format for the Use Table is once again being presented to the Panel (*proposedformat_UseTable_092022*), in which all reported product categories (for both frequency and concentration of use) as received from the VCRP and Council survey are included for each ingredient. At the last meeting, the Panel voiced concern that duration and exposure were not included in the proposed format. As stated earlier, attempting to include duration of exposure, or how the product is applied (e.g., spray), could be misleading and incorrect. However, it does seem valid to indicate the likely exposure site (e.g., skin, eye area, etc.). Accordingly, a column identifying the likely exposure site has been added to the proposed table (as identified here; *IntendedExposures_UseTable_092022*).

Also, to aid the Panel in its review, if it is known that an ingredient is used in formulations that are applied to the eye area, that may result in incidental ingestion, or may be incidentally inhaled (e.g., hairsprays, face powders), the writers will continue to note that in the Use section. The Panel can then use their judgement as to other possible routes or methods of exposure by examining the product categories identified in the table.

Finally, attached herein please find comments that were submitted by the CIR Science and Support Committee (SSC; *CIRSSCcomments_UseTables_092022*). It is the recommendation of the CIR SSC that use information from the VCRP and the Council concentration of use surveys be presented in the safety assessment by FDA product category, as it is received.

Please be prepared to discuss the proposed Use Table format, as well as any other suggestions that you may have.



TO: Bart Heldreth Ph.D.
Executive Director – Cosmetic Ingredient Review

FROM: CIR Science and Support Committee of the Personal Care Products Council

DATE: August 2, 2022

SUBJECT: Cosmetic Product Use Tables in CIR Reports

The CIR Science and Support Committee (CIR SSC) appreciates the opportunity to comment on the format of the cosmetic product use tables included in CIR reports.

We recommend use information from the FDA Voluntary Cosmetic Registration Program (VCRP) and Personal Care Products Council (PCPC) concentration of use surveys be presented in CIR reports by FDA product category, as it is received. Easy access to the product category is helpful, as knowing the product category is necessary to complete an exposure assessment.

We understand that in CIR reports that include multiple ingredients, the Journal may want to reduce the size of the use table, and the presentation of the table by duration and exposure may be necessary. If the use information is presented in CIR reports by duration and exposure, it would be helpful if the Journal could include the use information by FDA product category as supplementary data.

Table N. Frequency (2022) and concentration (2021) of use according to duration and exposure

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate		Phytosteryl/Behenyl/Octyldodecyl/ Isostearyl Lauroyl Glutamate		Phytosteryl/Octyldodecyl Lauroyl Glutamate	
Totals*	25	NR	1	0.00028-25.6	325	0.005-25
<i>Duration of Use</i>						
<i>Leave-On</i>	25	NR	1	0.03-25.6	311	0.01-25
<i>Rinse-Off</i>	NR	NR	NR	0.00028-1	14	0.005-2
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>						
Eye Area	4	NR	NR	1-8.6	26	0.1-12
Incidental Ingestion	1	NR	1	0.1-7	133	1-25
Incidental Inhalation-Spray	4 ^a ; 4 ^b	NR	NR	0.2 ^a	1; 94 ^a ; 40 ^b	0.1-2 ^a
Incidental Inhalation-Powder	4 ^b	NR	NR	1; 0.03-5 ^c	40 ^b	5; 0.01-8 ^c
Dermal Contact	24	NR	NR	0.00028-25.6	178	0.005-25
Deodorant (underarm)	NR	NR	NR	NR	NR	not spray: 0.1 spray: 0.1
Hair - Non-Coloring	NR	NR	NR	0.2	13	0.1-2
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	1	NR
Mucous Membrane	1	NR	1	0.1-7	133	0.005-25
Baby Products	NR	NR	NR	NR	NR	0.3

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.

^a It is possible that these products may be sprays, but it is not specified whether the reported uses are sprays^b Not specified these products are sprays or powders, but it is possible the use can be as a spray or powder, therefore the information is captured in both categories^c It is possible that these products may be powders, but it is not specified whether the reported uses are powders

Table N. Frequency (2022) and concentration (2021) of use by product category

Product Category	# of uses	Max conc of use (%)	Likely Exposure Site
Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate			
Eye Lotion	4	-	eye area
Lipstick	1	-	skin; mucous membrane
Rouges	12	-	skin
Face and Neck Preparations (including shave)	4	-	skin
Moisturizing Preparations	2	-	skin
Night Preparations	2	-	skin
Totals	25	NR	
Phytosteryl/Behenyl/Octyldodecyl/Isostearyl Lauroyl Glutamate			
Eye Shadow	-	8.6	eye area
Eye Lotion	-	1	eye area
Tonics, Dressings, and Other Hair Grooming Aids	-	0.2	hair
Blushers	-	7.3	skin
Face Powders	-	1	skin
Foundations	-	1	skin
Lipstick	1	0.1-7	skin; mucous membrane
Rouges	-	25.6	skin
Other Makeup Preparations	-	0.42	skin
Skin Cleansing (cold creams, cleansing lotions, liquids, and pads)	-	0.00028-1	skin
Face and Neck Preparations (excluding shave)	-	0.03-5 (not spray)	skin
Moisturizing Preparations	-	0.5 (not spray)	skin
Other Skin Care Preparations	-	0.5	skin
Totals	1	0.00028-25.6	
Phytosteryl/Octyldodecyl Lauroyl Glutamate			
Baby Lotions, Oils, Powders, and Creams	-	0.3 (not powder)	infant skin
Eyeliners	-	7.5	eye area
Eye Shadow	14	12	eye area
Eye Lotion	5	2.5	eye area
Eye Makeup Remover	1	-	eye area
Other Eye Makeup Preparations	6	0.1-4.2	eye area
Hair Conditioner	3	0.1-0.7	hair
Hair Spray (aerosol fixative)	1	-	hair
Rinses (non-coloring)	1	-	hair
Shampoos (non-coloring)	2	-	hair
Tonics, Dressings, and Other Hair Grooming Aids	5	0.7-2	hair
Other Hair Preparations	1	-	hair
Blushers (all types)	-	5.4	skin
Face Powders	-	5	skin
Foundations	12	2.2-3.1	skin
Lipstick	133	1-25	skin; mucous membrane
Makeup Bases	-	1	skin
Rouges	1	25	skin
Other Makeup Preparations	3	1	skin
Other Manicuring Preparations	1	-	nail
Bath Soaps and Detergents	-	0.005	skin; mucous membrane
Deodorants (underarm)	-	0.1 (not spray) 0.1 (aerosol)	skin
Skin Cleansing Preparations	5	1-2	skin
Face and Neck Preparations (excluding shave)	30	0.3-8 (not spray)	skin
Body and Hand Preparations (excluding shave)	10	0.01-1 (not spray)	skin
Moisturizing Preparations	80	0.1-0.5 (not spray)	skin
Night Preparations	3	1 (not spray)	skin
Paste Masks (mud packs)	2	0.1	skin
Skin Fresheners	-	0.1-0.5	skin
Other Skin Care Preparations	6	0.1-2	skin
Totals	325	0.005-25	

Intended Exposures

Product Category	Intended Exposure
Baby Shampoos	hair; infant skin
Baby Lotions, Oils, Powders, and Creams	infant skin
Other Baby Products	infant skin
Bath Oils, Tablets, and Salts	skin; mucous membrane
Bubble Baths	skin; mucous membrane
Bath Capsules	skin; mucous membrane
Other Bath Preparations	skin; mucous membrane
Eyebrow Pencil	eye area
Eyeliners	eye area
Eye Shadow	eye area
Eye Lotion	eye area
Eye Makeup Remover	eye area
Mascara	eye area
Other Eye Makeup Preparations	eye area
Cologne and Toilet waters	skin
Perfumes	skin
Powders (dusting and talcum, excluding aftershave talc)	skin
Other Fragrance Preparation	skin
Hair Conditioner	hair
Hair Spray (aerosol fixatives)	hair
Hair Straighteners	hair
Permanent Waves	hair
Rinses (non-coloring)	hair
Shampoos (non-coloring)	hair
Tonics, Dressings, and Other Hair Grooming Aids	hair
Wave Sets	hair
Other Hair Preparations	hair
Hair Dyes and Colors (all types requiring caution statements and patch tests)	hair
Hair Tints	hair
Hair Rinses (coloring)	hair
Hair Shampoos (coloring)	hair
Hair Color Sprays (aerosol)	hair
Hair Lighteners with Color	hair
Hair Bleaches	hair
Other Hair Coloring Preparation	hair
Blushers (all types)	skin
Face Powders	skin
Foundations	skin
Leg and Body Paints	skin
Lipstick	skin; mucous membrane
Makeup Bases	skin
Rouges	skin
Makeup Fixatives	skin
Other Makeup Preparations	skin
Basecoats and Undercoats	nail
Cuticle Softeners	nail
Nail Creams and Lotions	nail
Nail Extenders	nail
Nail Polish and Enamel	nail
Nail Polish and Enamel Removers	nail
Other Manicuring Preparations	nail
Dentifrices	mucous membrane
Mouthwashes and Breath Fresheners	mucous membrane
Other Oral Hygiene Products	mucous membrane

Product Category	Intended Exposure
Bath Soaps and Detergents	skin; mucous membrane
Deodorants (underarm)	skin
Douches	mucous membrane
Feminine Deodorants	mucous membrane
Other Personal Cleanliness Products	mucous membrane
Aftershave Lotion	skin
Beard Softeners	skin
Mens Talcum	skin
Preshave Lotions (all types)	skin
Shaving Cream	skin
Shaving Soap	skin
Other Shaving Preparation Products	skin
Cleansing	skin
Depilatories	skin
Face and Neck (exc shave)	skin
Body and Hand (exc shave)	skin
Foot Powders and Sprays	skin
Moisturizing	skin
Night	skin
Paste Masks (mud packs)	skin
Skin Fresheners	skin
Other Skin Care Preps	skin
Suntan Gels, Creams, and Liquids	skin
Indoor Tanning Preparations	skin
Other Suntan Preparations	skin