

Wave 2 Data Supplement

Basic Yellow 87

Clays

Mallow

Octyldodecyl Stearoyl Stearate

Polyhydroxystearic Acid

Rosa Centifolia

Trisodium Ethylenediamine Disuccinate

EXPERT PANEL MEETING

MARCH 6-7, 2023

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Christina L. Burnett, MSES, Senior Scientific Writer/Analyst, CIR
 Date: February 24, 2023
 Subject: Wave 2 - Safety Assessment of Basic Yellow 87 as Used in Cosmetics

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on Basic Yellow 87 is in the Draft Final Report stage, we are submitting an updated Use Table. Total reported uses for this ingredient have decreased since 2022. Basic Yellow 87 was used in 40 formulations last year; it is reported to be used in 33 formulations this year. Of these uses, 5 are reported in non-coloring hair products, while the remaining 28 are used in hair-coloring products.

Table 2. Frequency (2023) and concentration of use (2022) according to likely duration and exposure and by product category.

	# of Uses	Max Conc of Use (%)
Totals	33	0.0007-1
summarized by likely duration and exposure*		
Duration of Use		
Leave-On	4	NR
Rinse-Off	29	0.0007-1
Diluted for (Bath) Use	NR	NR
Exposure Type**		
Eye Area	NR	NR
Incidental Ingestion	NR	NR
Incidental Inhalation-Spray	1	NR
Incidental Inhalation-Powder	NR	NR
Dermal Contact	NR	NR
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	5	NR
Hair-Coloring	28	0.0007-1
Nail	NR	NR
Mucous Membrane	NR	NR
Baby Products	NR	NR
as reported by product category		
Hair Preparations (non-coloring)		
Hair Conditioner	1	NR
Shampoos (non-coloring)	1	NR
Other Hair Preparations	3	NR
Hair Coloring Preparations		
Hair Dyes/Colors (all types requiring caution statements and patch tests)	12	0.0007-1
Hair Rinses (coloring)	4	NR
Hair Shampoos (coloring)	5	0.02
Hair Color Sprays (aerosol)	1	NR
Other Hair Coloring Preparation	6	NR

*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.

NR – not reported



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Christina L. Burnett, MSES, Senior Scientific Writer/Analyst, CIR
 Date: February 24, 2023
 Subject: Wave 2 – Amended Safety Assessment of Naturally-Sourced Clays as Used in Cosmetics

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on Naturally-Sourced Clays is in the Draft Final Amended Report stage, we are submitting an updated Use Table. Total reported uses decreased for all but 1 ingredient since 2022: Fuller's Earth increased from 8 to 9 uses. Kaolin still has the most reported uses with a total of 787 (down from 1046 in 2022); the majority of uses are in leave-on formulations. Bentonite also still has the second most reported uses in cosmetic products with a total of 221 (down from 262); a little more than half are reported in leave-on formulations. There were no significant changes in types of product categories in which these ingredients are used.

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023	1998	2022	1999	2023	1998	2022	1999
	Attapulgite				Bentonite			
Totals	1	10	NR	8	221	94	0.00025-17.3	0.5-80
summarized by likely duration and exposure*								
Duration of Use								
Leave-On	1	5	NR	8	110	37	0.00025-8	0.8-8
Rinse-Off	NR	5	NR	8	98	57	0.22-17.3	0.5-80
Diluted for (Bath) Use	NR	NR	NR	NR	13	NR	NR	5
Exposure Type**								
Eye Area	1	NR	NR	NR	20	8	0.00025-4.5	0.8-5
Incidental Ingestion	NR	NR	NR	NR	8	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	NR	8 ^b	14 ^a ; 40 ^b	5 ^a ; 7 ^b	0.9	1-3 ^a ; 2-5 ^b
Incidental Inhalation-Powder	NR	5	NR	8 ^b	2; 1 ^c ; 40 ^b	7 ^b	8 ^c	2-5 ^b
Dermal Contact	1	10	NR	8	185	88	0.00025-10	0.5-80
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	6	4	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	17.3	NR
Nail	NR	NR	NR	NR	12	1	2.8	1
Mucous Membrane	NR	NR	NR	NR	29	3	0.22-4.7	0.5-5
Baby Products	NR	NR	NR	NR	3	NR	NR	NR
as reported by product category								
Baby Products								
Baby Lotions/Oils/Powders/Creams					1	NR	NR	NR
Other Baby Products					2	NR	NR	NR
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts					11	NR	NR	5
Bath Capsules								
Other Bath Preparations					2	NR	NR	NR
Eye Makeup Preparations								
Eyebrow Pencil								
Eyeliner					4	6	0.00025	5
Eye Shadow					2	NR	4.5	NR
Eye Lotion					2	NR	NR	NR
Eye Makeup Remover					1	NR	NR	NR
Mascara					10	1	1.5	0.8
Other Eye Makeup Preparations	1	NR	NR	NR	1	1	NR	NR

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023	1998	2022	1999	2023	1998	2022	1999
<i>Fragrance Preparations</i>								
Powders (dusting/talcum, excl aftershave talc)	NR	5	NR	NR				
<i>Hair Preparations (non-coloring)</i>								
Hair Conditioner					NR	1	NR	NR
Hair Sprays (aerosol fixatives)								
Hair Straighteners					NR	3	NR	NR
Rinses (non-coloring)								
Shampoos (non-coloring)								
Tonics, Dressings, and Other Hair Grooming Aids					4	NR	NR	NR
Wave Sets								
Other Hair Preparations					2	NR	NR	NR
<i>Hair Coloring Preparations</i>								
Hair Tints								
Hair Shampoos (coloring)								
Hair Lighteners with Color								
Hair Bleaches					NR	NR	17.3	NR
<i>Makeup Preparations</i>								
Blushers (all types)					2	NR	4	NR
Face Powders					2	NR	NR	NR
Foundations						5	NR	2 - 8
Leg and Body Paints								
Lipstick					1			
Makeup Bases					1	3	NR	1
Rouges								
Makeup Fixatives								
Other Makeup Preparations					1	NR	0.6	NR
<i>Manicuring Preparations (Nail)</i>								
Basecoats and Undercoats								
Cuticle Softeners					NR	1	NR	1
Nail Polish and Enamel					11	NR	NR	NR
Nail Polish and Enamel Removers								
Other Manicuring Preparations					1	NR	2.8	NR
<i>Oral Hygiene Products</i>								
Dentifrices					4	NR	NR	NR
Other Oral Hygiene Products					3	NR	NR	NR
<i>Personal Cleanliness Products</i>								
Bath Soaps and Detergents					6	1	0.22 - 4.7	0.5
Deodorants (underarm)								
Other Personal Cleanliness Products					2	2	NR	NR
<i>Shaving Preparations</i>								
Beard Softeners								
Mens Talcum								
Preshave Lotions (all types)					1	NR	NR	NR
Shaving Cream								
Shaving Soap								
Other Shaving Preparations								
<i>Skin Care Preparations</i>								
Cleansing					15	6	1.3 - 7	NR
Depilatories								
Face and Neck (exc shave)					38	1	8	2 - 5
Body and Hand (exc shave)	NR	NR	NR	8	2	6	NR	2 - 5
Moisturizing					9	2	NR	3
Night					NR	1	NR	NR
Paste Masks (mud packs)	NR	5	NR	8	66	44	1.5 - 10	12 - 80
Skin Fresheners					1	1	NR	NR
Other Skin Care Preparations					13	8	NR	NR
<i>Suntan Preparations</i>								
Suntan Gels, Creams, and Liquids					NR	1	2.5 (not spray) 0.9 (spray)	NR
Other Suntan Preparations					NR	NR	NR	1

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023	1998	2022	1999	2023	1998	2022	1999
Totals	53	NA	4.5	NA	8	3	NR	NR
summarized by likely duration and exposure*								
Duration of Use								
Leave-On	37	NA	NR	NA	3	1	NR	NR
Rinse-Off	14	NA	4.5	NA	5	2	NR	NR
Diluted for (Bath) Use	2	NA	NR	NA	NR	NR	NR	NR
Exposure Type**								
Eye Area	12	NA	NR	NA	NR	NR	NR	NR
Incidental Ingestion	8	NA	NR	NA	NR	NR	NR	NR
Incidental Inhalation-Spray	1 ^a ; 11 ^b	NA	NR	NA	1 ^a ; 1 ^b	NR	NR	NR
Incidental Inhalation-Powder	1; 11 ^b	NA	NR	NA	1 ^b	NR	NR	NR
Dermal Contact	38	NA	4.5	NA	7	3	NR	NR
Deodorant (underarm)	NR	NA	NR	NA	NR	NR	NR	NR
Hair - Non-Coloring	4	NA	NR	NA	1	NR	NR	NR
Hair-Coloring	NR	NA	NR	NA	NR	NR	NR	NR
Nail	NR	NA	NR	NA	NR	NR	NR	NR
Mucous Membrane	14	NA	NR	NA	1	NR	NR	NR
Baby Products	NR	NA	NR	NA	NR	NR	NR	NR
as reported by product category								
Baby Products								
Baby Lotions/Oils/Powders/Creams								
Other Baby Products								
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts	2	NA	NR	NA				
Bath Capsules								
Other Bath Preparations								
Eye Makeup Preparations								
Eyebrow Pencil	1	NA	NR	NA				
Eyeliner								
Eye Shadow	8	NA	NR	NA				
Eye Lotion								
Eye Makeup Remover								
Mascara	3	NA	NR	NA				
Other Eye Makeup Preparations								
Fragrance Preparations								
Powders (dusting/talcum, excl aftershave talc)								
Hair Preparations (non-coloring)								
Hair Conditioner	1	NA	NR	NA				
Hair Sprays (aerosol fixatives)								
Hair Straighteners								
Rinses (non-coloring)								
Shampoos (non-coloring)	2	NA	NR	NA				
Tonics, Dressings, and Other Hair Grooming Aids					1	NR	NR	NR
Wave Sets								
Other Hair Preparations	1	NA	NR	NA				
Hair Coloring Preparations								
Hair Tints								
Hair Shampoos (coloring)								
Hair Lighteners with Color								
Hair Bleaches								
Makeup Preparations								
Blushers (all types)	3	NA	NR	NA				
Face Powders	1	NA	NR	NA				
Foundations	1	NA	NR	NA				
Leg and Body Paints								
Lipstick	6	NA	NR	NA				
Makeup Bases	1	NA	NR	NA				
Rouges								
Makeup Fixatives								
Other Makeup Preparations								
Manicuring Preparations (Nail)								
Basecoats and Undercoats								
Cuticle Softeners								

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023	1998	2022	1999	2023	1998	2022	1999
<i>Fragrance Preparations</i>								
Powders (dusting/talcum, excl aftershave talc)								
<i>Hair Preparations (non-coloring)</i>								
Hair Conditioner	3	NR	0.13	NR				
Hair Sprays (aerosol fixatives)								
Hair Straighteners								
Rinses (non-coloring)	1	NR	NR	NR				
Shampoos (non-coloring)	1	NR	0.1	1	1	NA	NR	NA
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	0.13 (not spray)	NR	2	NA	0.025	NA
Wave Sets								
Other Hair Preparations	1	NR	NR	NR				
<i>Hair Coloring Preparations</i>								
Hair Tints								
Hair Shampoos (coloring)	1	NR	0.1	NR				
Hair Lighteners with Color								
Hair Bleaches	NR	5	NR	NR				
<i>Makeup Preparations</i>								
Blushers (all types)								
Face Powders	1	NR	NR	NR	2	NA	NR	NA
Foundations	NR	NR	1.5	15	1	NA	NR	NA
Leg and Body Paints								
Lipstick								
Makeup Bases	2	NR	NR	NR				
Rouges								
Makeup Fixatives								
Other Makeup Preparations	NR	1	NR	NR				
<i>Manicuring Preparations (Nail)</i>								
Basecoats and Undercoats	NR	1	NR	NR				
Cuticle Softeners								
Nail Polish and Enamel	NR	1	NR	NR				
Nail Polish and Enamel Removers								
Other Manicuring Preparations	1	NR	NR	NR				
<i>Oral Hygiene Products</i>								
Dentifrices	NR	NR	NR	NR	1	NA	NR	NA
Other Oral Hygiene Products								
<i>Personal Cleanliness Products</i>								
Bath Soaps and Detergents					1	NA	0.34	NA
Deodorants (underarm)	NR	1	NR	0.7				
Other Personal Cleanliness Products	NR	1	NR	NR				
<i>Shaving Preparations</i>								
Beard Softeners								
Mens Talcum								
Preshave Lotions (all types)								
Shaving Cream								
Shaving Soap								
Other Shaving Preparations								
<i>Skin Care Preparations</i>								
Cleansing	5	NR	NR	100	6	NA	3.8	NA
Depilatories								
Face and Neck (exc shave)	8	NR	0.1 (not spray)	NR	18	NA	NR	NA
Body and Hand (exc shave)	NR	NR	NR	8				
Moisturizing					2	NA	NR	NA
Night	1	NR	NR	NR				
Paste Masks (mud packs)	3	2	NR	0.4 - 8	17	NA	1 - 2	NA
Skin Fresheners								
Other Skin Care Preparations	1	1	NR	NR	6	NA	NR	NA
<i>Suntan Preparations</i>								
Other Suntan Preparations	NR	1	NR	NR				
Other Suntan Preparations								

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2023	1998	2022	1999	2023	1998	2022	1999
Totals	787[†]	509	0.0005-53.2	0.01-100	54	NR	0.1-3	NR
summarized by likely duration and exposure*								
Duration of Use								
Leave-On	502	501	0.0015-53.2	2-100	20	NR	1.2-2	NR
Rinse-Off	262	7	0.0005-33	0.01-84	32	NR	0.1-3	NR
Diluted for (Bath) Use	23	1	NR	NR	2	NR	NR	NR
Exposure Type**								
Eye Area	89	231	0.001-8.5	3-48	2	NR	NR	NR
Incidental Ingestion	135	6	0.0053-14.5	12-30	1	NR	NR	NR
Incidental Inhalation-Spray	1; 35 ^a ; 90 ^b	NR	0.0015-25 ^a	2-25 ^a ; 3 ^b	2 ^a ; 10 ^b	NR	NR	NR
Incidental Inhalation-Powder	38; 90 ^b ; 1 ^c	98	0.01-15; 0.11-16 ^c	5-30; 3 ^b	1 ^c ; 10 ^b	NR	1.2-2 ^c	NR
Dermal Contact	562	466	0.001-33	0.01-100	48	NR	0.1-3	NR
Deodorant (underarm)	6 ^a	NR	2.6	NR	NR	NR	NR	NR
Hair - Non-Coloring	46	5	0.0005-26	4-15	5	NR	NR	NR
Hair-Coloring	8	1	5-19.5	NR	NR	NR	NR	NR
Nail	11	NR	0.023-53.2	53-54	NR	NR	NR	NR
Mucous Membrane	182	8	0.0053-14.5	3-30	8	NR	NR	NR
Baby Products	1	NR	0.0085	NR	1	NR	NR	NR
as reported by product category								
Baby Products								
Baby Lotions/Oils/Powders/Creams	1	NR	NR	NR	1			
Other Baby Products	NR	NR	0.0085	NR				
Bath Preparations (diluted for use)								
Bath Oils, Tablets, and Salts	15	NR	NR	NR	1	NR	NR	NR
Bath Capsules								
Other Bath Preparations	8	1	NR	NR	1	NR	NR	NR
Eye Makeup Preparations								
Eyebrow Pencil	3	5	4.3	15 - 17	1	NR	NR	NR
Eyeliner	6	9	0.82 - 2	25 - 48				
Eye Shadow	42	171	0.35 - 8.5	3 - 29				
Eye Lotion	1	NR	NR	NR	NR	NR	NR	NR
Eye Makeup Remover	NR	NR	0.001	NR	1	NR	NR	NR
Mascara	25	31	0.5 - 4.7	8 - 18				
Other Eye Makeup Preparations	12	15	NR	20				
Fragrance Preparations								
Powders (dusting/talcum, excl aftershave talc)	NR	40	NR	5				
Hair Preparations (non-coloring)								
Hair Conditioner	6	5	0.0005 - 26	4	1	NR	NR	NR
Hair Spray (aerosol fixatives)	1	NR	NR	NR				
Hair Straighteners								
Rinses (non-coloring)								
Shampoos (non-coloring)	14	NR	0.058 - 0.14	NR	1	NR	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	14	NR	0.0015 - 25	15				
Wave Sets	1	NR	NR	NR				
Other Hair Preparations	10	1	0.1	5	3	NR	NR	NR
Hair Coloring Preparations								
Hair Tints	NR	NR	5	NR				
Hair Shampoos (coloring)								
Hair Lighteners with Color	2	NR	19.3	NR				
Hair Bleaches	6	NR	19.5	NR				
Makeup Preparations								
Blushers (all types)	10	72	0.05 - 15	14 - 20				
Face Powders	38	58	0.01 - 15	30				
Foundations	29 [†]	45	0.5 - 6	6 - 36				
Leg and Body Paints	1	NR	NR	NR				
Lipstick	118	6	0.0053 - 14.5	12 - 30				
Makeup Bases	2	24	1	7 - 25				
Rouges	3	2	NR	NR				
Makeup Fixatives	NR	3	NR	NR				
Other Makeup Preparations	11	20	2 - 4	10 - 24	1	NR	NR	NR
Manicuring Preparations (Nail)								
Basecoats and Undercoats	1	NR	NR	NR				

Table 1. Frequency (2023/1998) and concentration (2022/1999) of use according to likely duration and exposure and by product category.

	<i># of Uses</i>		<i>Max Conc of Use (%)</i>		<i># of Uses</i>		<i>Max Conc of Use (%)</i>	
	2023	1998	2022	1999	2023	1998	2022	1999
Cuticle Softeners								
Nail Polish and Enamel	9	NR	0.023	NR				
Nail Polish and Enamel Removers								
Other Manicuring Preparations	1	NR	35.5 - 53.2	53 - 54				
Oral Hygiene Products								
Dentifrices	16	NR	NR	NR	1	NR	NR	NR
Other Oral Hygiene Products	1							
Personal Cleanliness Products								
Bath Soaps and Detergents	15 [†]	1	1 - 5	3	2	NR	NR	NR
Deodorants (underarm)	6	NR	2.6 (not spray)	NR				
Other Personal Cleanliness Products	9	NR	NR	NR	3	NR	NR	NR
Shaving Preparations								
Beard Softeners	1	NR	NR	NR				
Mens Talcum								
Preshave Lotions (all types)								
Shaving Cream	NR	NR	0.25	NR				
Shaving Soap								
Other Shaving Preparations								
Skin Care Preparations								
Cleansing	72	NR	3.4 - 20	0.01	8	NR	0.3	NR
Depilatories	NR	NR	4	NR				
Face and Neck (exc shave)	76	NR	0.11 - 16 (not spray)	3	7	NR	1.2 - 2 (not spray)	NR
Body and Hand (exc shave)	14	NR	3.3 - 12 (not spray)	NR	3	NR	NR	NR
Moisturizing	18	NR	0.2 - 1 (not spray)	25	2	NR	NR	NR
Night	2	NR	NR	NR				
Paste Masks (mud packs)	120 [†]	NR	5 - 33	12 - 84	15	NR	0.1-3	NR
Skin Fresheners	1	NR	0.25	2				
Other Skin Care Preparations	46 [†]	NR	10 - 20.4	3 - 100	2	NR	NR	NR
Suntan Preparations								
Suntan Gels, Creams, and Liquids	NR	NR	NR	25				
Other Suntan Preparations								

NR – not reported

NA – not applicable

*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^c It is possible these products are powders, but it is not specified whether the reported uses are powders.[†] Includes entries for Kaolinite from the VCRP database.

Commitment & Credibility since 1976
Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Preeti S. Raj, Senior Scientific Analyst/Writer, CIR
 Date: February 24, 2023
 Subject: Wave 2 - Safety Assessment of *Malva sylvestris* (Mallow) – Derived Ingredients as Used in Cosmetics

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on *Malva sylvestris* (Mallow) - derived ingredients is in the Draft Final Report stage, we are submitting an updated Use Table. Total reported use for these ingredients has not changed significantly since 2022. As an exception, Malva Sylvestris (Mallow) Flower Extract had reported usage in 72 formulations last year; it is reported to be used in 25 formulations this year.

Table 4. Frequency (2023) and concentration (2022) of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Malva Sylvestris (Mallow) Extract		Malva Sylvestris (Mallow) Flower		Malva Sylvestris (Mallow) Flower Extract	
Totals	200	0.0002 – 0.003	1	NR	25	0.00012 – 0.1
summarized by likely duration and exposure*						
Duration of Use						
Leave-On	189	0.003	NR	NR	20	0.005 – 0.1
Rinse-Off	10	0.0002	NR	NR	5	0.00012 – 0.1
Diluted for (Bath) Use	1	NR	1	NR	NR	0.002
Exposure Type**						
Eye Area	10	NR	NR	NR	1	NR
Incidental Ingestion	52	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	37 ^a ; 34 ^b	NR	NR	NR	4 ^a ; 7 ^b	NR
Incidental Inhalation-Powder	2; 34 ^b	0.003 ^c	NR	NR	5; 7 ^b ; 1 ^c	0.02 – 0.1 ^c
Dermal Contact	146	0.0002 – 0.003	1	NR	24	0.002 – 0.1
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	2	NR	NR	NR	1	NR
Hair-Coloring	NR	NR	NR	NR	NR	0.00012
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	56	NR	1	NR	1	0.002
Baby Products	NR	NR	NR	NR	1	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams					1	NR
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts	1	NR	1	NR		
Bubble Baths					NR	0.002
Eye Makeup Preparations						
Eyebrow Pencil	4	NR				
Eye Lotion	2	NR				
Other Eye Makeup Preparations	4	NR			1	NR
Hair Preparations (non-coloring)						
Hair Conditioner	1	NR				
Shampoos (non-coloring)	1	NR			1	NR
Tonics, Dressings, and Other Hair Grooming Aids						

Table 4. Frequency (2023) and concentration (2022) of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Hair Coloring Preparations						
Hair Dyes and Colors (all types requiring caution statements and patch tests)					NR	0.00012
Makeup Preparations						
Blushers (all types)						
Face Powders	2	NR			5	NR
Foundations					1	0.02
Lipstick	52	NR				
Makeup Bases	1	NR				
Rouges	15	NR				
Makeup Fixatives	1	NR				
Other Makeup Preparations	6	NR				
Oral Hygiene Products						
Mouthwashes and Breath Fresheners						
Personal Cleanliness Products						
Bath Soaps and Detergents	1	NR			1	NR
Deodorants (underarm)						
Other Personal Cleanliness Products	2	NR				
Skin Care Preparations						
Cleansing	3	0.0002			2	0.02
Depilatories					NR	0.1
Face and Neck (exc shave)	32	0.003 (not spray)			3	0.04 (not spray)
Body and Hand (exc shave)	2	NR			4	0.02-0.1 (not spray)
Moisturizing	31	NR			3	0.03 (not spray)
Night	5	NR			1	0.03 (not spray)
Paste Masks (mud packs)	2	NR			1	NR
Skin Fresheners	1	NR				
Other Skin Care Preparations	31	NR			1	0.005
		Malva Sylvestris (Mallow) Flower/Leaf Extract		Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract		Malva Sylvestris (Mallow) Leaf Extract
Totals	4	NR	6	NR	4	NR
summarized by likely duration and exposure*						
Duration of Use						
Leave-On	4	NR	6	NR	4	NR
Rinse-Off	NR	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type**						
Eye Area	1	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1 ^a , 2 ^b	NR	3 ^a	NR	2 ^b	NR
Incidental Inhalation-Powder	2 ^b	NR	NR	NR	2 ^b	NR
Dermal Contact	3	NR	6	NR	4	NR
Deodorant (underarm)	NR	NR	NR	NR	1 ^a	NR
Hair - Non-Coloring	1	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams						
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts						
Bubble Baths						
Eye Makeup Preparations						
Eyebrow Pencil						
Eye Lotion						
Other Eye Makeup Preparations						
Hair Preparations (non-coloring)						
Hair Conditioner						
Shampoos (non-coloring)						
Tonics, Dressings, and Other Hair Grooming Aids	1	NR				
Hair Coloring Preparations						
Hair Dyes and Colors (all types requiring caution statements and patch tests)						
Makeup Preparations						
Blushers (all types)			1	NR		
Face Powders						

Table 4. Frequency (2023) and concentration (2022) of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Foundations						
Lipstick						
Makeup Bases						
Rouges						
Makeup Fixatives						
Other Makeup Preparations						
Oral Hygiene Products						
Mouthwashes and Breath Fresheners	1	NR				
Personal Cleanliness Products						
Bath Soaps and Detergents						
Deodorants (underarm)					1	NR
Other Personal Cleanliness Products						
Skin Care Preparations						
Cleansing						
Depilatories						
Face and Neck (exc shave)	2	NR			1	NR
Body and Hand (exc shave)					1	NR
Moisturizing			2	NR		
Night						
Paste Masks (mud packs)						
Skin Fresheners			1	NR		
Other Skin Care Preparations			2	NR	1	NR
	Malva Sylvestris (Mallow) Leaf Powder					
Totals	1	NR				
summarized by likely duration and exposure*						
Duration of Use						
Leave-On	NR	NR				
Rinse-Off	1	NR				
Diluted for (Bath) Use	NR	NR				
Exposure Type**						
Eye Area	NR	NR				
Incidental Ingestion	NR	NR				
Incidental Inhalation-Spray	NR	NR				
Incidental Inhalation-Powder	NR	NR				
Dermal Contact	NR	NR				
Deodorant (underarm)	NR	NR				
Hair - Non-Coloring	NR	NR				
Hair-Coloring	1	NR				
Nail	NR	NR				
Mucous Membrane	NR	NR				
Baby Products	NR	NR				
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams						
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts						
Bubble Baths						
Eye Makeup Preparations						
Eyebrow Pencil						
Eye Lotion						
Other Eye Makeup Preparations						
Hair Preparations (non-coloring)						
Hair Conditioner						
Shampoos (non-coloring)	1	NR				
Tonics, Dressings, and Other Hair Grooming Aids						
Hair Coloring Preparations						
Hair Dyes and Colors (all types requiring caution statements and patch tests)						
Makeup Preparations						
Blushers (all types)						
Face Powders						
Foundations						
Lipstick						
Makeup Bases						
Rouges						
Makeup Fixatives						
Other Makeup Preparations						

Table 4. Frequency (2023) and concentration (2022) of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Oral Hygiene Products						
Mouthwashes and Breath Fresheners						
Personal Cleanliness Products						
Bath Soaps and Detergents						
Deodorants (underarm)						
Other Personal Cleanliness Products						
Skin Care Preparations						
Cleansing						
Depilatories						
Face and Neck (exc shave)						
Body and Hand (exc shave)						
Moisturizing						
Night						
Paste Masks (mud packs)						
Skin Fresheners						
Other Skin Care Preparations						

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

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

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Regina Tucker, M.S., Scientific Analyst/Writer, CIR
 Date: February 24, 2023
 Subject: Wave 2 – Amended Safety Assessment of Octyldodecyl Stearoyl Stearate as Used in Cosmetics

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on Octyldodecyl Stearoyl Stearate is in the Draft Final Amended Report stage, we are submitting an updated Use Table. Total reported uses for this ingredient has decreased since 2022. Octyldodecyl Stearoyl Stearate was used in 605 formulations last year; it is reported to be used in 584 formulations this year. There were no significant changes in types of product categories in which these ingredients are used.

Table 1. Frequency (2023; 2001) and concentration (2020; 2001) of use according to likely duration and exposure

	# of Uses		Max Conc of Use (%)	
	2023	2001	2020	2001
Totals	584	106	0.5-28	2-15
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	580	102	0.5-28	2-15
Rinse-Off	4	4	3.3-3.5	NR
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type**				
Eye Area	325	35	0.5-18.5	4-10
Incidental Ingestion	29	1	3.4-28	5-10
Incidental Inhalation-Spray	7 ^a ; 8 ^b	1; 5 ^a ; 2 ^b	NR	8 ^a ; 4-15 ^b
Incidental Inhalation-Powder	88; 8 ^b	34; 2 ^b	1.9-7.5; 1 ^c	2-7; 4-15 ^b
Dermal Contact	555	103	0.5-25.4	2-15
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	3.3-3.5	NR
Nail	NR	2	NR	NR
Mucous Membrane	30	1	3.4-28	5-10
Baby Products	NR	NR	NR	NR
as reported by product category				
Eye Makeup Preparations				
Eyebrow Pencil	2	2	0.75	NR
Eyeliner	2	1	NR	4
Eye Shadow	311	30	1.4-18.5	4-10
Other Eye Makeup Preparations	10	2	0.5-3.2	NR
Fragrance Preparations				
Powders (dusting/talcum, excl aftershave talc)	NR	2	NR	4
Other Fragrance Preparation	NR	1	NR	NR
Hair Coloring Preparations				
Hair Tints	NR	NR	3.3	NR
Other Hair Coloring Preparation	NR	NR	3.5	NR
Makeup Preparations				
Blushers (all types)	55	8	1.8-24	2-7
Face Powders	88	32	1.9-7.5	2-7
Foundations	41	5	0.5-6.7	4-9
Lipstick	29	1	3.4-28	5-10
Makeup Bases	2	5	6.1-24	10
Rouges	6	1	25.4	NR
Other Makeup Preparations	16	1	1.9-3	5

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Table 1. Frequency (2023; 2001) and concentration (2020; 2001) of use according to likely duration and exposure

	# of Uses		Max Conc of Use (%)	
	2023	2001	2020	2001
Manicuring Preparations (Nail)				
Cuticle Softeners	NR	1	NR	NR
Nail Creams and Lotions	NR	1	NR	NR
Personal Cleanliness				
Other Personal Cleanliness Products	1	NR	NR	NR
Skin Care Preparations				
Cleansing	2	3	NR	NR
Face and Neck (exc shave)	1	1	1 (not spray)	4
Body and Hand (exc shave)	7	1	NR	15
Moisturizing	7	4	2-9 (not spray)	NR
Night	NR	1	2.5 (not spray)	NR
Paste Masks (mud packs)	1	1	NR	NR
Other Skin Care Preparations	3	2	NR	NR
Suntan Preparations				
Suntan Gels, Creams, and Liquids	NR	NR	NR	8

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

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

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Preeti S. Raj, Senior Scientific Analyst/Writer, CIR
 Date: February 24, 2023
 Subject: Wave 2 - Safety Assessment of Polyhydroxystearic Acid, Poly(3-Hydroxyoctanoic Acid), and Polylactic Acid as Used in Cosmetics

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on Polyhydroxystearic Acid, Poly(3-Hydroxyoctanoic Acid), and Polylactic Acid is in the Draft Final Report stage, we are submitting an updated Use Table. Total reported uses for these ingredients have remained relatively constant since 2022, with slight increases in previously reported categories. In 2022, Polyhydroxystearic Acid and Polylactic Acid were reported to be used in 265 formulations and 18 formulations, respectively. This year, Polyhydroxystearic Acid and Polylactic Acid are reported to be used in 276 formulations and in 22 formulations, respectively. As in 2022, Poly(3-Hydroxyoctanoic Acid) has no uses reported.

Table 3. Frequency (2023) and concentration (2022) of use according to likely duration and exposure by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Polyhydroxystearic Acid		Polylactic Acid	
Totals	276	0.014 – 14.2	22	0.084 - 5
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	272	0.014 – 14.2	16	0.084
Rinse-Off	4	NR	6	3.5 - 5
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type**				
Eye Area	56	0.12 - 8	3	NR
Incidental Ingestion	136	0.4 – 14.2	1	0.084
Incidental Inhalation-Spray	10 ^a ; 10 ^b	0.5; 0.2 -8 ^a	8 ^a ; 1 ^b	NR
Incidental Inhalation-Powder	4; 10 ^b	0.014 -0.88 ^c	1 ^b	NR
Dermal Contact	136	0.014 - 10	20	3.5 - 5
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	3	0.5 - 8	1	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	136	0.4 – 14.2	2	0.084
Baby Products	2	0.9	NR	NR
as reported by product category				
Baby Products				
Other Baby Products	2	0.9		
Eye Makeup Preparations				
Eyebrow Pencil	9	0.4-0.72		
Eyeliner	25	0.4		
Eye Shadow	15	NR	3	NR
Eye Lotion	1	0.12		
Mascara	1	8		
Other Eye Makeup Preparations	5	0.18		
Hair Preparations (non-coloring)				
Hair Conditioner			1	NR
Hair Spray (aerosol fixatives)	NR	0.5		
Tonics, Dressings, and Other Hair Grooming Aids	2	8		
Other Hair Preparations	1	NR		

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Table 3. Frequency (2023) and concentration (2022) of use according to likely duration and exposure by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
Makeup Preparations				
Blushers (all types)	7	0.11-0.3		
Face Powders	4	NR		
Foundations	5	0.1-0.22		
Leg and Body Paints	2	NR		
Lipstick	136	0.4-14.2	1	0.084
Makeup Bases	6	NR		
Makeup Fixatives	1	NR		
Other Makeup Preparations	21	0.25		
Personal Cleanliness Products				
Bath Soaps and Detergents			1	NR
Skin Care Preparations				
Cleansing	2	NR	4	5
Face and Neck (exc shave)	10	0.014-0.88 (not spray)	1	NR
Body and Hand (exc shave)	NR	0.1 (not spray)		
Moisturizing	8	0.15-10 (not spray)	8	NR
Paste Masks (mud packs)	2	NR	NR	3.5
Other Skin Care Preparations	11	0.49-1.5	3	NR
Suntan Preparations				
Other Suntan Preparations	NR	0.2-0.3		

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

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



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Regina Tucker, M.S., Scientific Analyst/Writer, CIR
Date: February 24, 2023
Subject: Wave 2 - Safety Assessment of *Rosa centifolia*-Derived Ingredients as Used in Cosmetics

CIR has received correspondence from Dr. Belsito that the test article in the studies submitted by RIFM were evaluated at 2%, not undiluted as currently stated in the report. We have contacted RIFM requesting updated versions of the studies that were previously provided, to include this information. An updated table with this information (Table 7; identified in this pdf as *table7_RosaCentifolia_Wave2_032023*) is included in this report package with the affected studies highlighted in yellow for your review. Please note that the unpublished study provided by RIFM to the CIR on Rosa Centifolia Flower Oil (Urbach, 1973) found this ingredient is non-irritating, non-phototoxic, and absorbs (peak shoulder) UV at 320 nm (no further test parameters were provided). The absorbance information is currently included in the report.

CIR has also received 2023 FDA VCRP data. Because the Safety Assessment on *Rosa centifolia*-derived ingredients is in the Draft Final Report stage, we are submitting an updated Use Table (*usetable_RosaCentifolia_Wave2_032023*) in this package. No significant changes in frequency of use or product categories were reported. Rosa Centifolia Flower Extract still has the greatest frequency of use; it was used in 174 formulations last year and is reported to be used in 179 formulations this year, 152 of which are leave-on. Rosa Centifolia Flower Juice, however, which had one reported use according to 2022 VCRP data, but no reported concentrations of use, is no longer reported in the VCRP.

Table 1. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category.

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Rosa Centifolia Flower		Rosa Centifolia Flower Extract		Rosa Centifolia Flower Oil	
Totals	16	NR	179	0.0001-0.025	30	0.001-0.002
summarized by likely duration and exposure*						
Duration of Use						
Leave-On	7	NR	152	0.0001-0.025	22	0.001-0.002
Rinse-Off	2	NR	26	0.0001-0.002	6	NR
Diluted for (Bath) Use	7	NR	1	0.0001-0.002	2	NR
Exposure Type**						
Eye Area	NR	NR	5	0.0005-0.02	NR	NR
Incidental Ingestion	NR	NR	7	0.002	1	0.001
Incidental Inhalation-Spray	3 ^a ; 4 ^b	NR	2; 57 ^a ; 63 ^b	0.0005-0.025; 0.01 ^b	9 ^a ; 8 ^b	NR
Incidental Inhalation-Powder	3 ^a	NR	57 ^a ; 1 ^c	0.0001; 0.00013-0.002 ^c	9 ^a	0.001-0.002 ^c
Dermal Contact	15	NR	160	0.0001-0.025	26	0.001-0.002
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	12	0.001-0.002	3	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	8	NR	10	0.0001-0.002	4	0.001
Baby Products	NR	NR	1	NR	NR	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams			1	NR		
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts	5	NR			2	NR
Bubble Baths			1	0.0001		
Other Bath Preparations	2	NR	NR	0.002		
Eye Makeup Preparations						
Eye Lotion			2	0.0005		
Eye Makeup Remover			1	NR		
Mascara			NR	0.02		
Other Eye Makeup Preparations			2	NR		
Fragrance Preparations						
Cologne and Toilet Water			NR	0.0005-0.025		
Perfumes			1	NR		
Other Fragrance Preparation			1	0.025		
Hair Preparations (non-coloring)						
Hair Conditioner			4	0.001	1	NR
Hair Spray (aerosol fixatives)						
Rinses (non-coloring)					1	NR
Shampoos (non-coloring)			5	0.001-0.002	1	NR
Tonics, Dressings, and Other Hair Grooming Aids			2	NR		
Other Hair Preparations			1	NR		
Hair Coloring Preparations						
Hair Dyes/Colors (all types requiring caution statements and patch tests)						
Makeup Preparations						
Blushers			2	NR		
Face Powders			NR	0.0001		
Foundations			NR	0.0001		
Lipstick			7	0.002	1	0.001
Makeup Bases			2	NR		
Other Makeup Preparations			1	NR		
Personal Cleanliness Products						
Bath Soaps and Detergents			1	0.0001-0.001	1	NR
Douches	1	NR				
Other Personal Cleanliness Products			1	0.0001		
Skin Care Preparations						
Cleansing			9	0.002	1	NR
Face and Neck (exc shave)	4	NR	39	0.00013-0.002	7	0.002
Body and Hand (exc shave)			24	0.001-0.002	1	0.001
Moisturizing	3	NR	52	0.001	8	0.002
Night					1	NR
Paste Masks (mud packs)	1	NR	5	NR	1	NR
Skin Fresheners			3	0.01		
Other Skin Care Preparations			12	0.001	4	0.001

Table 1. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category.

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Rosa Centifolia Flower Powder		Rosa Centifolia Flower Water		Rosa Centifolia Flower Wax	
Totals	10	NR	72	0.0000096-0.096	10	NR
summarized by likely duration and exposure*						
Duration of Use						
Leave-On	8	NR	62	0.000096-0.096	9	NR
Rinse-Off	1	NR	10	0.0000096-0.023	1	NR
Diluted for (Bath) Use	1	NR	NR	0.0048	NR	NR
Eye Area	NR	NR	8	NR	1	NR
Incidental Ingestion	NR	NR	3	NR	2	NR
Incidental Inhalation-Spray	1 ^a ;6 ^b	NR	1; 24 ^a ; 24 ^b	0.00096; 0.00096 ^b	1 ^a ; 3 ^b	NR
Incidental Inhalation-Powder	1;1 ^a	NR	24 ^a	0.096 ^c	1 ^a	NR
Dermal Contact	10	NR	67	0.0000096-0.096	7	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	2	0.00096-0.023	NR	NR
Hair-Coloring	NR	NR	NR	0.0096	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	6	0.0048	3	NR
Baby Products	1	NR	NR	NR	NR	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams	1					
Bath Preparations (diluted for use)						
Bath Oil, Tablets, and Salts	1	NR	NR	0.0048		
Bubble Baths						
Other Bath Preparations						
Eye Makeup Preparations						
Eye Lotion			1	NR		
Eye Makeup Remover			3	NR		
Mascara					1	NR
Other Eye Makeup Preparations						
Fragrance Preparations						
Cologne and Toilet Water						
Perfumes						
Other Fragrance Preparation			1	NR		
Hair Preparations (non-coloring)						
Hair Conditioner			1	0.023		
Hair Spray (aerosol fixatives)			NR	0.00096		
Rinses (non-coloring)						
Shampoos (non-coloring)			1	0.0096		
Tonics, Dressings, and Other Hair Grooming Aids			NR	0.00096		
Other Hair Preparations						
Hair Coloring Preparations						
Hair Dyes/Colors (all types requiring caution statements and patch tests)			NR	0.0096		
Makeup Preparations						
Face Powders						
Foundations						
Lipstick			3	NR	2	NR
Makeup Bases						
Other Makeup Preparations						
Personal Cleanliness Products						
Bath Soaps and Detergents			2	NR	1	NR
Douches						
Other Personal Cleanliness Products						
Skin Care Preparations						
Cleansing			2	0.0000096		
Face and Neck (exc shave)	5	NR	21	0.096	1	NR
Body and Hand (exc shave)	1	NR	3	0.096	2	NR
Moisturizing	1	NR	21	0.096	1	NR
Night			2	0.000096		
Paste Masks (mud packs)	1	NR		NR		
Skin Fresheners						
Other Skin Care Preparations			5	0.02	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.

^aNot 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.^bIt is possible these products are sprays, but it is not specified whether the reported uses are sprays.^cIt is possible these products are powders, but it is not specified whether the reported uses are powders.

Table 1. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
IRRITATION					
ANIMAL					
Rosa Centifolia Flower Oil	Undiluted	Hairless mice (number and strain not stated)	Applied to the back for an unspecified duration. Additional study details not included	No evidence of skin irritation	4
Rosa Centifolia Flower Oil	Undiluted	Rabbits (number and strain not stated)	Applied for 24 h to intact or abraded skin using occlusive patches. Additional study details not included	Test substance classified as moderately irritating to the skin	4
HUMAN					
Face mask containing 0.8% Rosa Centifolia Flower	Undiluted	20 subjects	Single-insult occlusive patch test; 24 h patch. Irritation scores determined at time of patch removal	No evidence of skin irritation	49
Rosa Centifolia Flower Oil	2% in petrolatum	number of subjects not stated	48-h closed patch test	No evidence of skin irritation	4
SENSITIZATION					
HUMAN					
Face mask containing 0.8% Rosa Centifolia Flower	tested neat (0.05 ml)	25 subjects (20 females, 5 males)	Maximization test. Test article (0.05 ml) applied under 15 mm occlusive patch to SLS (0.25%) pretreated site on upper outer arm or back. Procedure involved five 48-h induction patches (72 h on weekends). After a 10 - 14 d non-treatment period, a -h occlusive patch with 5% aq. SLS was applied to a previously untreated site, and an occlusive patch with the test substance was applied for 48 h. Challenge site evaluated for reactions at time of patch removal and 24 h later.	No adverse or unexpected reactions during induction phase. No evidence of contact allergy at time of challenge patch removal or 24 later. Concluded that the test article does not possess a detectable contact-sensitizing potential and, hence, is not likely to cause contact sensitivity reactions under normal use conditions.	50
Eye serum containing 0.1% Rosa Centifolia Flower Extract	tested neat (0.1 – 0.15 g) approximately 25 – 38 mg/cm ² test material	49 subjects	HRIPT. Occlusive patches were applied 3x/wk for 3 wk, for a total of 9 induction applications. (The test material was volatilized for 30 – 90 min on the patch prior to application.) After a 2-wk non-treatment period, a challenge patch was applied to a new site, and 24 to 72 h after, the site was scored.	No reactions were observed during induction or challenge and the researchers concluded that the test article was not associated with skin irritation or allergic contact dermatitis.	51
Rosa Centifolia Flower Extract trade name mixture	20%	55 subjects (45 females, 10 males)	HRIPT (modified Shelanski method). Total of 9 induction patches (occlusive patches) applied over 3-wk period. Induction phase followed by 10- to 21-d non-treatment period. Occlusive challenge patch applied to new site on lower back.	No dermal reactions observed during induction or challenge phase. Test substance did not induce delayed contact sensitization.	24,52
Rosa Centifolia Flower Extract (concrete rose)	2%	28 subjects	Maximization test. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate-day 48-h periods. Test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-d non-treatment period, challenge phase. Single challenge application preceded by 30-min application of SLS (under occlusion). Another challenge application (different site, no pretreatment) also made	Moderate degree of irritation observed at SLS-treated site. No other significant or allergic reactions observed.	8

Table 1. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
Rosa Centifolia Flower Extract (concrete rose)	2%	25 subjects	Modified maximization test procedure. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial patch test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-d non-treatment period, test substance (under occlusive challenge patch) applied for 48 h to new test site. Challenge applications preceded by 30 min application of 5% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	Approximately 1/3 of subjects tested developed irritation at SLS-treated site. No other significant irritation or allergic reactions observed. Test substance produced no reactions that were considered significantly irritating or allergic in nature	10
Rosa Centifolia Flower Extract (concrete rose)	2%	22 subjects	Modified maximization test procedure, as described above	Test substance produced no reactions that were considered significantly irritating or allergic in nature	11
Rosa Centifolia Flower Extract (rose centifolia concrete)	2%	33 subjects	Modified maximization test procedure, as described above.	Sweat retention response observed in 1 subject. Test substance produced no reactions that were considered significantly irritating or allergic in nature	12
Rosa Centifolia Flower Extract (rose absolute)	2%	24 subjects	Modified maximization test procedure, as described above, except, challenge applications preceded by 30 min application of 2% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	A 3+ reaction observed in 1 subject after initial patch application. Retesting of subject did not yield positive reaction. Test substance did not induce skin sensitization	13
Rosa Centifolia Flower Extract (rose absolute)	2%	25 subjects	Maximization test. Test substance applied, under occlusion, to volar forearm for 5 alternate-day 48-h periods. Patch test sites pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10-d non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 1 h application of 10% aqueous SLS (under occlusion). Challenge sites evaluated at time of patch removal and 24 h later.	Test substance induced contact sensitization (mild reaction) in 1 subject; therefore, the researcher concluded the test material is a mild sensitizer	7
Rosa Centifolia Flower Oil	2% in petrolatum	24 subjects	Maximization test. Protocol details not included	No evidence of skin sensitization	4



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Priya Cheria, M.S., Senior Scientific Writer/Analyst, CIR
 Date: February 24, 2023
 Subject: Wave 2 - Safety Assessment of Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate

CIR has received 2023 FDA VCRP data. Because the Safety Assessment on Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate is in the Draft Final Report stage, we are submitting an updated Use Table. Total reported uses for Tetrasodium Ethylenediamine Disuccinate have decreased since 2022, while total reported uses for Tetrasodium Iminodisuccinate have increased since 2022. Last year, Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate were used in 228 and 9 formulations respectively. This year, Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate were reported to be used in 199 and 41 formulations, respectively.

Table 1. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Trisodium Ethylenediamine Disuccinate		Tetrasodium Iminodisuccinate	
Totals	199	0.0039 – 0.64	41	NR
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	102	0.01 – 0.64	40	NR
Rinse-Off	97	0.0039 – 0.51	1	NR
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type**				
Eye Area	5	NR	1	NR
Incidental Ingestion	21	0.01	NR	NR
Incidental Inhalation-Spray	1; 13 ^a ; 24 ^b	0.039; 0.12 – 0.64 ^b	32 ^a ; 1 ^b	NR
Incidental Inhalation-Powder	13 ^a	0.06 – 0.19 ^c	32 ^a	NR
Dermal Contact	96	0.06 – 0.56	36	NR
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	68	0.0039 – 0.64	5	NR
Hair-Coloring	9	0.3 – 0.36	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	41	0.01 – 0.19	NR	NR
Baby Products	5	0.19	NR	NR
as reported by product category				
Baby Products				
Baby Shampoos	1	0.19		
Other Baby Products	4	NR		
Eye Makeup Preparations				
Eye Lotion	2	NR		
Mascara	1	NR		
Other Eye Makeup Preparations	2	NR	1	NR
Fragrance Preparations				
Cologne and Toilet Water	1	NR		
Hair Preparations (non-coloring)				
Hair Conditioner	4	0.0039	1	NR
Hair Spray (aerosol fixatives)	NR	0.039		
Shampoos (non-coloring)	54	0.12 – 0.51		
Tonics, Dressings, and Other Hair Grooming Aids	7	0.34 – 0.64	1	NR
Other Hair Preparations	2	NR	3	NR

Table 1. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use (%)	
	Trisodium Ethylenediamine Disuccinate		Tetrasodium Iminodisuccinate	
<i>Hair Coloring Preparations</i>				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	8		NR	
Hair Rinses (coloring)	NR		0.3	
Hair Shampoos (coloring)	1		0.36	
<i>Makeup Preparations</i>				
Blushers (all types)	3		NR	
Foundations	16		NR	
Lipstick	21		0.01	
Makeup Bases	3		NR	
Other Makeup Preparations	7		NR	
<i>Personal Cleanliness Products</i>				
Bath Soaps and Detergents	9		0.12 – 0.19	
Douches	4		NR	
Other Personal Cleanliness Products	7		NR	
<i>Shaving Preparations</i>				
Aftershave Lotion				1 NR
Other Shaving Preparations	1		NR	
<i>Skin Care Preparations</i>				
Cleansing	5		0.093 – 0.14	
Face and Neck (exc shave)	12		0.06 – 0.8 (not spray)	32 NR
Body and Hand (exc shave)	1		0.078 – 0.19 (not spray)	
Moisturizing	14		0.12 – 0.56 (not spray)	
Night	3		0.074 (not spray)	
Paste Masks (mud packs)	3		0.063	
Skin Fresheners	NR		0.12	
Other Skin Care Preparations	3		0.074	2 NR
<i>Suntan Preparations</i>				
Other Suntan Preparations	NR		0.2 (not spray)	

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.

^aNot 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^bIt is possible these products are sprays, but it is not specified whether the reported uses are sprays.^cIt is possible these products are powders, but it is not specified whether the reported uses are powders.