
Safety Assessment of Fossil and Synthetic Waxes as Used in Cosmetics

Status: Extended Re-Review Summary for Panel Approval
Release Date: February 17, 2026
Panel Meeting Date: March 12-13, 2026

History

Original Safety Assessment – published 1984

Original Re-Review – published 2005

Most Recent Action – new data considered at the September 2025 Panel meeting; not re-opened

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This summary was prepared by Temima Nguyen, M.S., Scientific Analyst/Writer, CIR.

FOSSIL AND SYNTHETIC WAXES

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Fossil and Synthetic Waxes in 1984.¹ The Panel concluded that these 8 ingredients (i.e., Ceresin, Emulsifying Wax NF, Microcrystalline Wax, Montan Wax, Ozokerite, Paraffin, Synthetic Beeswax, and Synthetic Wax) are safe in cosmetics in the present practices of concentration and use, as stated in that assessment.

Because it has been at least 15 years since the previous re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At the September 2025 meeting, the Panel reviewed updated information regarding product types and ingredient use frequencies according to US Food and Drug Administration (FDA) Registration and Listing Data (RLD; 2024)² and the Voluntary Cosmetic Registration Program (VCRP; 2023) database,³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2022.⁴

A comparison of VCRP data from 2002 with that of 2023 indicate a decrease in the frequency of use of 5 ingredients (i.e., Ceresin, Emulsifying Wax NF, Montan Wax, Ozokerite, and Synthetic Wax) and increase in use of 3 ingredients (i.e., Microcrystalline Wax, Paraffin, and Synthetic Wax). The following provides a 2002 and 2023 comparison of the VCRP data as (2002/2023): Ceresin (404/170); Emulsifying Wax NF (102/5); Microcrystalline Wax (548/1130); Montan Wax (13/3); Ozokerite (680/371); Paraffin (481/737); Synthetic Beeswax (179/164); and Synthetic Wax (215/1050). In 2024, RLD reported that Synthetic Wax had the highest frequency of use at 15,166 uses (Table 1). In 2003, Paraffin was used at 99% in other skin care preparations, making it the ingredient with the highest concentration of use. In 2022, concentration of use for Paraffin decreased to 21% in bath soaps and body washes and the highest leave-on concentration was 18.6% in eyeliners. Synthetic Wax had the highest reported concentration of use in this ingredient family according to the 2022 survey at 36% in eyebrow pencils. Overall, there were no prominent changes in the exposure type for the family of ingredients reviewed.

In July 2025, an extensive search of the world's literature was performed for studies dated 2000 forward, and new data were found. Paraffin induced microgranulomas in both Fischer-344 and Sprague Dawley rats in a 60-d study, while it produced granulomas in the liver of only the latter rat strains in a 90-d study. The Panel discussed that there was no concern regarding the granuloma formation as this would be caused upon injection into the skin, which is not prevalent in cosmetic use. The granulomatous lesions in the 90--d oral study also appear to be exaggerated and would be considered inconsequential and incidental in humans. Although the Panel was of the opinion that these new data served to reaffirm the existing conclusion of safety, they acknowledged it was important that this information was captured robustly. Accordingly, these studies are summarized in Tables 2-10.

Furthermore, the Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>. This resource document also notes that airbrush technology presents a potential safety concern. Although frequency and/or concentration of use data are now available (and in some cases mandated) for ingredients marketed for use with airbrush delivery systems in certain product categories, no data are available for consumer habits and practices thereof, product particle size, or other relevant particle data (e.g., diameter). As a result of deficiencies in these critical data needs, the data profile is incomplete, and the safety of cosmetic ingredients applied by airbrush delivery systems cannot be determined by the Panel. Accordingly, the Panel has concluded the data are insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

In summary, the Panel reviewed updated frequency and concentration of use data, in addition to any new, available, relevant safety data. After considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 1984 conclusion that Ceresin, Emulsifying Wax NF, Microcrystalline Wax, Montan Wax, Ozokerite, Paraffin, Synthetic Beeswax, and Synthetic Wax are safe in cosmetics in the present practices of concentration and use.

Table 1. Frequency and concentration 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
	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
	Ceresin		Emulsifying Wax NF		Microcrystalline Wax	
Totals*	5859	2-10	108	1.5	10,285	0.092-34.5
summarized by likely duration and exposure**						
Duration of Use						
<i>Leave-On</i>	6119	2-10	105	NR	10,898	0.092-30
<i>Rinse-Off</i>	129	NR	35	1.5	375	0.75-34.5
<i>Diluted for (Bath) Use</i>	3	NR	NR	NR	5	NR
<i>Permanent Tattoo Ink</i>	1	NR	NR	NR	1	NR
<i>Unknown</i>	33	NR	NR	NR	153	NR
Exposure Type						
Baby Products	1	NR	2	NR	5	NR
Children's Makeup	771	NR	NR	NR	240	NR
Eye Area	1254	NR	NR	NR	2483	2.8-24.3
Incidental Ingestion	3118	6.6	NR	NR	4610	5.9-34.5
Mucous Membrane	3128	6.6	3	NR	4649	5.9-34.5
Incidental Inhalation-Spray	50; 207 ^a ; 256 ^b	8.2 ^c	4; 72 ^a ; 37 ^b	1.5 ^a	98; 453 ^a ; 494 ^b	0.2-1; 0.32-30 ^b
Incidental Inhalation-Airbrush	1	NR	NR	NR	11	NR
Incidental Inhalation-Powder	54; 256 ^b ; 1 ^c	8.2 ^c	37 ^b ; 1 ^c	NR	248; 494 ^b ; 3 ^c	5.4; 0.32-30 ^b ; 0.2-2.2 ^c
Dermal Contact	2796	2-10	121	1.5	5482	0.1-24.3
Deodorant (underarm)	28 (not spray)	NR	NR	NR	2 (not spray)	7.7
Hair - Non-Coloring	88	8.2	8	NR	153	0.32-30
Hair-Coloring	38	NR	8	NR	73	1-2
Nail	84	NR	3	NR	688	0.092
Tattoo Preparations	2	NR	NR	NR	11	NR
Other Preparations (Unknown Exposure Type)	33	NR	NR	NR	153	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams	1	NR	1	NR	3	NR
Other Baby Products			1 (r.o.)	NR	1 (l.o.); 1 (r.o.)	NR
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts	1	NR				
Other Bath Preparations	2	NR			5	NR
Eye Makeup Preparations (not children's)						
Eyebrow Pencil	257	10			403	3-24.3
Eyeliners	455	7			675	2.8-19.1
Eye Shadow	303	10			812	3.2-14.7
Eye Lotion	2	NR			27	NR
Eye Makeup Remover	1	NR			1	NR
False Eyelashes	1	NR			1	NR
Mascara	128	NR			284	4.6-11
Eyelash and Eyebrow Adhesives/Glues/Sealants	9	NR			24	NR
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)	22	NR			44	NR
Eyelash Cleansers					3	NR
Other Eye Makeup Preparations	55	10			181	NR
Children's Eye Makeup Preparations						
Children's Eyeshadows	19	NR			26	NR
Other Children's Eye Makeup	1	NR			1	NR
Fragrance Preparations						
Perfumes	10	NR	1	NR	19	0.2

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Other Fragrance Preparation	34	NR	3	NR	66	1
<i>Hair Preparations (non-coloring)</i>						
Hair Conditioners	6 (l.o.); 2 (r.o.)	NR	2 (r.o.)	NR	4 (l.o.); 3 (r.o.)	2
Hair Sprays (aerosol fixatives)	6	NR			13	NR
Hair Straighteners	3	NR	1	NR	4	NR
Permanent Waves					4	NR
Rinses (non-coloring)	2	NR			1	NR
Shampoos (non-coloring)	1	NR			2 (r.o.)	NR
Tonics, Dressings, Other Hair Grooming Aids	12	8.2	5	NR	33	0.32-30
Wave Sets						
Other Hair Preparations	54 (l.o.); 2 (r.o.)	NR			82 (l.o.); 7 (r.o.)	NR
<i>Hair Coloring Preparations</i>						
Hair Dyes and Colors (all types requiring caution statements and patch tests)	6	NR	7	NR	27	1
Hair Tints	16	NR			29	NR
Hair Rinses (coloring)	1 (r.o.)	NR			1 (r.o.)	2
Hair Color Sprays (aerosol)						
Hair Lighteners with Color	3	NR			2	NR
Hair Bleaches	1	NR				
Eyelash and Eyebrow Dyes	1	NR			1	NR
Other Hair Coloring Preparation	5 (l.o.); 5 (r.o.)	NR	1 (r.o.)	NR	11 (l.o.); 2 (r.o.)	NR
<i>Makeup Preparations (not eye or children's)</i>						
Blushers and Rouges (all types)	271	5			721	2.2-13
Face Powders	52	NR			246	5.4
Foundations	208 (traditional application)	NR			314 (traditional application); 7 (airbrush application)	5.6-15
Leg and Body Paints	113 (traditional application)	NR			123 (traditional application)	NR
Lipsticks and Lip Glosses	2398	6.6			4440	5.9-17.6
Makeup Bases	176 (traditional application)	NR			137 (traditional application); 1 (airbrush application)	0.1
Makeup Fixatives	49	NR			52	NR
Other Makeup Preparations	249 (traditional application); 1 (airbrush application)	NR			525 (traditional application); 3 (airbrush application)	16.8
<i>Makeup Preparations for Children (not eye)</i>						
Children's Blushers and Rouges (All Types)	15	NR			10	NR
Children's Face Paints	6	NR			7	NR
Children's Face Powders	2	NR			2	NR
Children's Foundations					1	NR
Children's Lipsticks and Lip Glosses	718	NR			167	NR
Other Children's Makeup	10	NR			26	NR
<i>Manicuring Preparations</i>						
Basecoats and Undercoats					24	NR
Cuticle Softeners	1	NR			12	NR
Nail Creams and Lotions	1	NR	2	NR	24	NR

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	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
Nail Extenders	9	NR			231	NR
Nail Polish and Enamel	20	NR			329	0.092
Nail Polish and Enamel Removers					26	NR
Other Manicuring Preparations	53	NR	1	NR	42	NR
Oral Hygiene Products						
Dentifrices						
Other Oral Products	2	NR			3	34.5
Personal Cleanliness						
Bath Soaps and Body Washes	5	NR	1	NR	23	NR
Deodorants (underarm)	28	NR			2	7.7 (not spray)
Douches						
Feminine Deodorants						
Other Personal Cleanliness Products	1 (l.o.); 1 (r.o.)	NR	2 (r.o.)	NR	2 (l.o.); 9 (r.o.)	NR
Shaving Preparations						
Aftershave Lotions	1	NR				
Beard Softeners					2	NR
Shaving Cream (aerosol, brushless, lather)	3	NR	NR	1.5	3	NR
Shaving Soap (cakes, sticks, etc.)					NR	10
Other Shaving Preparations					8	NR
Skin Care Preparations						
Cleansing	29	NR	7	NR	69	0.75-10
Depilatories	16	NR			50	8
Face and Neck (excluding shaving preps)	119 (l.o.); 16 (r.o.)	NR	5 (l.o.); 3 (r.o.)	NR	186 (l.o.); 30 (r.o.)	0.85-2.2 (not spray)
Body and Hand (excluding shaving preps)	24 (l.o.); 2 (r.o.)	NR	23 (l.o.); 3 (r.o.)	NR	84 (l.o.); 2 (r.o.)	0.2-0.5 (not spray)
Foot Powders and Sprays					3	NR
Moisturizing	158	2 (not spray)	55	NR	335	0.37 (not spray)
Night	2	NR	3	NR	4	1
Paste Masks (mud packs)	2	NR	2	NR	22	1
Skin Fresheners	10	NR	2	NR	30	NR
Other Skin Care Preparations	42 (l.o.); 8 (r.o.)	NR	4 (l.o.); 5 (r.o.)	NR	87 (l.o.); 30 (r.o.)	NR
Suntan Preparations						
Suntan Gels, Creams, and Liquids	1	NR			5	NR
Indoor Tanning Preparations	1	NR			1 (traditional application)	NR
Other Suntan Preparations					5	NR
Tattoo Preparations						
Permanent Tattoo Inks	1	NR				
Temporary Tattoo Inks	1	NR			1	NR
Other Tattoo Preparations					10	NR
Other Preparations (i.e., those that do not fit another category)	33	NA			153	NA

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	Montan Wax		Ozokerite		Paraffin	
Totals*	34	0.54	8498	0.1-23.3	7243	0.01-21
summarized by likely duration and exposure**						
Duration of Use						
Leave-On	34	0.54	8889	0.2-23.3	6280	0.01-18.6
Rinse-Off	1	NR	131	0.1	1417	0.45-21
Diluted for (Bath) Use	NR	NR	3	NR	4	NR
Permanent Tattoo Ink	NR	NR	NR	NR	NR	NR
Unknown	NR	NR	62	NR	153	NR
Exposure Type						
Baby Products	NR	NR	NR	NR	5	NR
Children's Makeup	1	NR	158	NR	73	NR
Eye Area	9	NR	2243	0.98-15.2	1890	0.19-18.6
Incidental Ingestion	3	0.54	3919	5.8-12	2375	9-18.2
Mucous Membrane	3	0.54	3941	5.8-12	2400	9-21
Incidental Inhalation-Spray	1 ^a ; 1 ^b	NR	181; 311 ^a ; 321 ^b	23.3 ^a ; 2-6.5 ^b	44; 310 ^a ; 447 ^b	7; 0.8-5 ^a ; 0.5-15 ^b
Incidental Inhalation-Airbrush	NR	NR	4	NR	NR	NR
Incidental Inhalation-Powder	1 ^b	NR	168; 321 ^b	2; 2-6.5 ^b ; 6 ^c	75; 447 ^b ; 1 ^c	0.091; 0.5-15 ^b ; 1-8 ^c
Dermal Contact	26	NR	4511	0.1-23.3	3316	0.091-21
Deodorant (underarm)	NR	NR	147 (not spray)	2.8	3 (not spray)	11-11.1
Hair - Non-Coloring	2	NR	174	2-6.5	226	1.5-13.5
Hair-Coloring	NR	NR	62	NR	1032	0.45-5
Nail	1	NR	10	NR	50	0.01-3.2
Tattoo Preparations	NR	NR	9	NR	5	NR
Other Preparations (Unknown Exposure Type)	NR	NR	62	NR	153	NR
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams					1	NR
Other Baby Products					3 (l.o.); 1 (r.o.)	NR
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts					2	NR
Other Bath Preparations			3	NR	2	NR
Eye Makeup Preparations (not children's)						
Eyebrow Pencil	4	NR	336	8	171	17.9
Eyeliner	2	NR	827	0.98-15.2	446	18.6
Eye Shadow			554	7.1	393	0.19-15.3
Eye Lotion			12	4	9	NR
Eye Makeup Remover			1	NR	1	NR
False Eyelashes					3	NR
Mascara	3	NR	337	NR	700	9-17
Eyelash and Eyebrow Adhesives/Glues/Sealants			17	NR	12	NR
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)			30	NR	39	NR
Eyelash Cleansers						
Other Eye Makeup Preparations			127	NR	111	6
Children's Eye Makeup Preparations						
Children's Eyeshadows					1	NR
Other Children's Eye Makeup			1	NR	4	NR
Fragrance Preparations						
Perfumes			50	NR	5	NR

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	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
Other Fragrance Preparation			121	NR	28	7
<i>Hair Preparations (non-coloring)</i>						
Hair Conditioners			14	NR	16 (l.o.); 15 (r.o.)	1.5-2
Hair Sprays (aerosol fixatives)			8	NR	11	NR
Hair Straighteners			2	NR	12	NR
Permanent Waves			1	NR	7	NR
Rinses (non-coloring)					25	NR
Shampoos (non-coloring)					6 (r.o.)	NR
Tonics, Dressings, Other Hair Grooming Aids			61	2-6.5	48	2.2-13.5
Wave Sets			2	NR		
Other Hair Preparations	1 (l.o.); 1 (r.o.)	NR	81 (l.o.); 5 (r.o.)	NR	72 (l.o.); 14 (r.o.)	NR
<i>Hair Coloring Preparations</i>						
Hair Dyes and Colors (all types requiring caution statements and patch tests)			33	NR	787	5
Hair Tints			17	NR	209	NR
Hair Rinses (coloring)			1	NR	1 (l.o.); 3 (r.o.)	NR
Hair Color Sprays (aerosol)			2	NR	NR	NR
Hair Lighteners with Color						
Hair Bleaches			1	NR	4	0.45
Eyelash and Eyebrow Dyes			1	NR		
Other Hair Coloring Preparation			5 (l.o.); 2 (r.o.)	NR	17 (l.o.); 11 (r.o.)	NR
<i>Makeup Preparations (not eye or children's)</i>						
Blushers and Rouges (all types)			307	NR	212	6
Face Powders			168	2	75	0.091
Foundations			655 (traditional application); 3 (airbrush application)	NR	404 (traditional application)	0.5-6
Leg and Body Paints			68 (traditional application)	NR	103 (traditional application)	NR
Lipsticks and Lip Glosses	3	0.54	3765	5.8-12	2330	9-18.2
Makeup Bases			116 (traditional application); 1 (airbrush application)	NR	162	NR
Makeup Fixatives			52	NR	7	NR
Other Makeup Preparations	19 (traditional application)	NR	398 (traditional application)	6.5	223 (traditional application)	0.5
<i>Makeup Preparations for Children (not eye)</i>						
Children's Blushers and Rouges (All Types)			3	NR	1	NR
Children's Face Paints	1	NR	1	NR	5	NR
Children's Face Powders						
Children's Foundations						
Children's Lipsticks and Lip Glosses			152	NR	45	NR
Other Children's Makeup			1	NR	17	NR
<i>Manicuring Preparations</i>						
Basecoats and Undercoats			1	NR	NR	0.01
Cuticle Softeners			3	NR	1	NR
Nail Creams and Lotions					1	NR
Nail Extenders					1	NR
Nail Polish and Enamel	1	NR	1	NR	30	NR

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	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
Nail Polish and Enamel Removers					3	NR
Other Manicuring Preparations			5	NR	14	3.2
Oral Hygiene Products						
Dentifrices			1	NR		
Other Oral Products			1	NR	NR	11.2
Personal Cleanliness						
Bath Soaps and Body Washes			1	NR	7	21
Deodorants (underarm)			147	2.8 (not spray)	3	11-11.1 (not spray)
Douches			NR	NR	5 (l.o.); 9 (r.o.)	NR
Feminine Deodorants			13 (l.o.)	NR		
Other Personal Cleanliness Products			1 (l.o.); 4 (r.o.)	NR		
Shaving Preparations						
Aftershave Lotions			1	NR	1	NR
Beard Softeners					1	NR
Shaving Cream (aerosol, brushless, lather)			2	NR	2	NR
Shaving Soap (cakes, sticks, etc.)						
Other Shaving Preparations			1	NR	9	NR
Skin Care Preparations						
Cleansing			18	0.1	51	NR
Depilatories			6	NR	194	NR
Face and Neck (excluding shaving preps)			62 (l.o.); 15 (r.o.)	6 (not spray)	99 (l.o.); 14 (r.o.)	1-8 (not spray)
Body and Hand (excluding shaving preps)			34 (l.o.)	NR	121 (l.o.); 7 (r.o.)	0.5-15 (not spray)
Foot Powders and Sprays			13	NR	1	NR
Moisturizing			256	0.2-3 (not spray)	208	0.8-5 (not spray)
Night			3	NR	5	NR
Paste Masks (mud packs)			5	NR	6	NR
Skin Fresheners			5	NR	18	NR
Other Skin Care Preparations			50 (l.o.); 8 (r.o.)	NR	80 (l.o.); 19 (r.o.)	15
Suntan Preparations						
Suntan Gels, Creams, and Liquids			12	23.3	10	NR
Indoor Tanning Preparations						
Other Suntan Preparations			3	NR	2	NR
Tattoo Preparations						
Permanent Tattoo Inks						
Temporary Tattoo Inks			2	NR	1	NR
Other Tattoo Preparations			7	NR	4	NR
Other Preparations (i.e., those that do not fit another category)			62	NA	153	NA

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	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
	Synthetic Beeswax		Synthetic Wax			
Totals*	5602	0.0012-24.9	15,166	0.05-36		
summarized by likely duration and exposure**						
Duration of Use						
Leave-On	5324	0.0012-24.9	16,155	0.05-36		
Rinse-Off	659	5	353	0.3-11.2		
Diluted for (Bath) Use	1	NR	4	NR		
Permanent Tattoo Ink	NR	NR	NR	NR		
Unknown	62	NR	51	NR		
Exposure Type						
Baby Products	5	NR	4	NR		
Children's Makeup	58	NR	275	NR		
Eye Area	1820	1-24.9	4828	0.75-36		
Incidental Ingestion	1818	2-23.3	7466	2.6-16.8		
Mucous Membrane	1828	2-23.3	7522	2.6-16.8		
Incidental Inhalation-Spray	28; 438 ^a ; 584 ^b	20; 5.3 ^b	60; 268 ^a ; 330 ^b	0.3; 5-5.9 ^a ; 0.05-10 ^b		
Incidental Inhalation-Airbrush	2	NR	8	NR		
Incidental Inhalation-Powder	31; 584 ^b ; 4 ^c	5.3 ^b ; 0.0012-1.5 ^c	280; 330 ^b ; 2 ^c	1.2-5; 0.05-10 ^b ; 0.1-0.3 ^c		
Dermal Contact	2880	0.0012-24.9	8663	0.1-36		
Deodorant (underarm)	8 (not spray)	NR	6 (not spray)	3.4-12		
Hair - Non-Coloring	69	5.3	49	0.05-5		
Hair-Coloring	684	NR	96	NR		
Nail	15	NR	9	NR		
Tattoo Preparations	2	NR	NR	NR		
Other Preparations (Unknown Exposure Type)	62	NR	51	NR		
as reported by product category						
Baby Products						
Baby Lotions/Oils/Powders/Creams	4	NR	2	NR		
Other Baby Products	1 (l.o.)	NR	1 (l.o.); 1 (r.o.)	NR		
Bath Preparations (diluted for use)						
Bath Oils, Tablets, and Salts	1	NR				
Other Bath Preparations			4	NR		
Eye Makeup Preparations (not children's)						
Eyebrow Pencil	144	NR	682	5-36		
Eyeliner	470	2-24.9	1731	0.75-14.1		
Eye Shadow	475	1-13.6	1835	4.1-9.6		
Eye Lotion	16	NR	11	NR		
Eye Makeup Remover	1	NR	1	NR		
False Eyelashes	1	NR	5	NR		
Mascara	519	8-9.3	226	1.5-8.7		
Eyelash and Eyebrow Adhesives/Glues/Sealants	20	NR	19	NR		
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)	77	NR	60	NR		
Eyelash Cleansers						
Other Eye Makeup Preparations	86	14.7	256	13		
Children's Eye Makeup Preparations						
Children's Eyeshadows	3	NR	1	NR		
Other Children's Eye Makeup	1	NR	1	NR		
Fragrance Preparations						
Perfumes	12	20	13	0.3		
Other Fragrance Preparation	16	NR	46	NR		

Table 1. Frequency and concentration 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
	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
<i>Hair Preparations (non-coloring)</i>						
Hair Conditioners	7 (l.o.); 2 (r.o.)	NR	3 (l.o.)	0.3		
Hair Sprays (aerosol fixatives)			1	NR		
Hair Straighteners	1	NR	2	NR		
Permanent Waves	1	NR	1	NR		
Rinses (non-coloring)			3	NR		
Shampoos (non-coloring)						
Tonics, Dressings, Other Hair Grooming Aids	22	5.3	15	0.05-5		
Wave Sets	3	NR	1	NR		
Other Hair Preparations	26 (l.o.); 7 (r.o.)	NR	17 (l.o.); 6 (r.o.)	NR		
<i>Hair Coloring Preparations</i>						
Hair Dyes and Colors (all types requiring caution statements and patch tests)	404	NR	45	NR		
Hair Tints	9	NR	20	NR		
Hair Rinses (coloring)	1 (r.o.)	NR	1 (l.o.)	NR		
Hair Color Sprays (aerosol)						
Hair Lighteners with Color	1	NR	1	NR		
Hair Bleaches	1	NR	2	NR		
Eyelash and Eyebrow Dyes	7	NR				
Other Hair Coloring Preparation	144 (l.o.); 117 (r.o.)	NR	26 (l.o.); 1 (r.o.)	NR		
<i>Makeup Preparations (not eye or children's)</i>						
Blushers and Rouges (all types)	308	9	1031	1.8-9.3		
Face Powders	31	NR	278	5		
Foundations	175 (traditional application; 2 (airbrush application)	NR	758 (traditional application); 2 (airbrush application)	0.1-8.4		
Leg and Body Paints	22 (traditional application)	NR	30 (traditional application)	NR		
Lipsticks and Lip Glosses	1772	2-23.3	7227	2.6-16.8		
Makeup Bases	42	NR	177 (traditional application)	NR		
Makeup Fixatives	13	NR	140	NR		
Other Makeup Preparations	168 (traditional application)	NR	811 (traditional application); 6 (airbrush application)	NR		
<i>Makeup Preparations for Children (not eye)</i>						
Children's Blushers and Rouges (All Types)	8	NR	2	NR		
Children's Face Paints			11	NR		
Children's Face Powders			2	NR		
Children's Foundations			1	NR		
Children's Lipsticks and Lip Glosses	44	NR	238	NR		
Other Children's Makeup	2	NR	19	NR		
<i>Manicuring Preparations</i>						
Basecoats and Undercoats						
Cuticle Softeners	2	NR	2	NR		
Nail Creams and Lotions	2	NR	1	NR		
Nail Extenders						
Nail Polish and Enamel	1	NR	5	NR		

Table 1. Frequency and concentration 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
	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴	RLD (2024) ²	% (2022) ⁴
Other Manicuring Preparations	10	NR	1	NR		
Oral Hygiene Products						
Other Oral Products	2	NR	1	11.2		
Personal Cleanliness						
Bath Soaps and Body Washes			21	7.9		
Deodorants (underarm)	8	NR	6	3.4-12 (not spray)		
Douches						
Feminine Deodorants						
Other Personal Cleanliness Products	3 (l.o.); 6 (r.o.)	NR	31 (r.o.)	NR		
Shaving Preparations						
Aftershave Lotions						
Beard Softeners	1	NR				
Shaving Cream (aerosol, brushless, lather)	2	NR				
Shaving Soap (cakes, sticks, etc.)						
Other Shaving Preparations	4	NR	6	NR		
Skin Care Preparations						
Cleansing	35	5	118	4-7.6		
Depilatories	13	NR	15	NR		
Face and Neck (excluding shaving preps)	163 (l.o.); 21 (r.o.)	0.0012-0.5 (not spray)	153 (l.o.); 36 (r.o.)	1.2 (not spray)		
Body and Hand (excluding shaving preps)	132 (l.o.); 6 (r.o.)	1.5 (not spray)	13 (l.o.); 5 (r.o.)	0.1-0.3 (not spray)		
Foot Powders and Sprays	1	NR	2	NR		
Moisturizing	227	NR	165	5-5.9 (not spray)		
Night	36	NR	7	NR		
Paste Masks (mud packs)	6	NR	4	NR		
Skin Fresheners	7	NR	4	NR		
Other Skin Care Preparations	92 (l.o.); 7 (r.o.)	NR	98 (l.o.); 30 (r.o.)	2-10		
Suntan Preparations						
Suntan Gels, Creams, and Liquids	6	NR	10	1 (not spray)		
Indoor Tanning Preparations			1 (traditional application)	NR		
Other Suntan Preparations	2	NR	4	NR		
Tattoo Preparations						
Permanent Tattoo Inks						
Temporary Tattoo Inks						
Other Tattoo Preparations	2	NR				
Other Preparations (i.e., those that do not fit another category)	62	NA	51	NA		

NR – not reported; NA – not applicable

l.o. – leave-on; r.o. – rinse-off

*The sum of the counts given for duration of use and by exposure type, and the sum of the frequency reported by product category, may not equal the sum of total uses because each ingredient may be used in cosmetic formulations that are reported under more than one product category.

**Likely duration and exposure are derived from survey data based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)^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.

Table 2. Non-Cosmetic Use

Ingredient	Data	Reference										
Ozokerite Ceresin Montan Wax Paraffin* Microcrystalline Wax* Synthetic Wax*	Ozokerite, Ceresin, Montan Wax, Paraffin, Microcrystalline Wax, and Synthetic Wax are permitted for use in adhesives intended for use in packaging, transporting, or holding food.	21 CFR 175.105										
Montan Wax	Montan Wax is permitted for use as a defoaming agent in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food.	21 CFR 176.210										
Montan Wax Paraffin* Microcrystalline Wax* Synthetic Wax*	Montan Wax, Paraffin, Microcrystalline Wax, and Synthetic Wax are permitted for use in rubber articles intended for repeated use. It may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.	21 CFR 177.2600										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin, Microcrystalline Wax, and Synthetic Wax must meet the following ultraviolet absorbance limits when subjected to the analytical procedure described in 21 CFR 172.886(b): <table border="1"> <thead> <tr> <th>Millimicrons</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>280 to 289</td> <td>0.15</td> </tr> <tr> <td>290 to 299</td> <td>.12</td> </tr> <tr> <td>300 to 359</td> <td>.08</td> </tr> <tr> <td>360 to 400</td> <td>.02</td> </tr> </tbody> </table> <ul style="list-style-type: none"> - may contain antioxidant permitted in food by regulations issued in accordance with section 409 of the act - may contain a total of not more than 1 weight percent of residues of polymers listed in 21 CFR 178.3710(d) - may contain 2-hydroxy-4-n-octoxybenzophenone as a stabilizer at a level not to exceed 0.01 weight percent of the petroleum wax -may contain poly(alkylacrylate) (CAS Reg. No. 27029-57-8) as a processing aid in the manufacture of petroleum wax. 	Millimicrons	Maximum	280 to 289	0.15	290 to 299	.12	300 to 359	.08	360 to 400	.02	21 CFR 178.3710
Millimicrons	Maximum											
280 to 289	0.15											
290 to 299	.12											
300 to 359	.08											
360 to 400	.02											
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax are petrolatum waxes can be used the following: <ul style="list-style-type: none"> - in chewing gum base, as a masticatory substance up to an amount not to exceed good manufacturing practice - on cheese and raw fruits and vegetables as a protective coating up to an amount not to exceed good manufacturing practice -as a defoamer in food as based on 21 CFR 173.340. - as a component of microcapsules for spice-flavoring substances to exceed 50 percent by combined weight of the microcapsule and spice-flavoring substance mentioned in 21 CFR 172.230. 	21 CFR 172.886										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax may be included the production of defoaming agents in articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.	21 CFR 176.200										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax may be included in cellophane used for packaging food.	21 CFR 177.1200										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax may be included in surface lubricants employed in the manufacture of metallic articles that contact food.	21 CFR 178.3910										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax may be included not to exceed 1 pct by weight of the polymer in films prepared from basic polymers and with or without adjuvants for use during the irradiation of prepackaged foods.	21 CFR 179.45										
Paraffin* Microcrystalline Wax* Synthetic Wax*	Paraffin and Microcrystalline Wax may be used in used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods.	21 CFR 176.170										
Paraffin	Paraffin can be used as used in an antimicrobial pesticide formulation that can be used in the following: food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.	40 CFR 180.940										

Table 2. Non-Cosmetic Use

Paraffin	Paraffin may be used as substance in the preparation of an acrylate ester copolymer coating for a food-contact surface of an article intended for packaging and holding food, including heating of prepared food.	21 CFR 175.210
Paraffin	Paraffin may be used as a substance in the preparation of a resinous and polymeric coating for a food-contact surface of article intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.	21 CFR 175.300
Microcrystalline Wax*	Microcrystalline Wax may be used in used as substances in resinous and polymeric coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food	21 CFR 175.320
Synthetic Wax	Synthetic Wax may be used in applications and under the same conditions where petroleum wax is permitted provided that the synthetic petroleum wax meets the definition and specifications prescribed in § 172.888 of this chapter.	21 CFR 172.888
Synthetic Wax	Synthetic Wax should conform to the following specifications: -there is not specification for congealing point except those components that have a congealing point below 50°C as mentioned in 21 CFR 175.250(b)(1) -oil content should not exceed 2.5% as determined by ASTM method D721-56T. -the absorptivity at 290 millimicrons in decahydronaphthalene at 88°C should not exceed 0.01 as determined by ASTM method E131-81a.	21 CFR 175.250

Prescription/OTC/Therapeutic Use Studies

Paraffin	Paraffin can be used up to 5 percent in combination with one or more other emollient agents included in the monograph as an ophthalmic emollient.	21 CFR 349.14
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CFR - Code of Federal Regulations; OTC - over-the-counter

*In the regulations, "petroleum wax" is mentioned but as Paraffin and Microcrystalline Wax are petroleum waxes, this applies to these ingredients as well. Synthetic Wax may also be used in the same applications that petroleum wax is mentioned.

Table 3. Acute toxicity studies

Test Article	Vehicle	Animals/Group	Dose/Concentration	Protocol	LD ₅₀ /LC ₅₀ /Results	Reference
ORAL						
Montan Wax	oil	rats (10/sex/dose)	12,000 mg/kg (6000 mg/kg applied in 2 doses within 2 h)	OECD TG 401 (acute oral toxicity); administered via gavage; applied 2x within 2 h & observed after 7 d.	LD ₅₀ > 12000 mg/kg bw; 1 female rat died directly after application while other rats had no symptoms.	5
Paraffin	arachis oil	rats (5/sex/dose)	1000 and 5000 mg/kg	OECD TG 401 (acute oral toxicity); administered via gavage; weighed and observed after dosing at 20 min, 1, 24, 48, and 72 h, and 7 d.	LD ₅₀ > 5000 mg/kg bw; lack of systemic toxicity effects and mortality	6
Synthetic Wax	none	Sprague-Dawley rats (5/sex/dose)	5000 mg/kg	OECD TG 420 (acute oral toxicity - fixed dose method); administered via gavage; clinical observations made at 0.5, 1, 2, and 4 h and 1x per day for 14 d; body weights recorded at 0, 7, and 14 d; organ weights and histopathology also examined	LD ₅₀ > 5000 mg/kg; no deaths or signs of systemic toxicity; body weight gain was normal; no abnormalities at necropsy. Histopathology information was not provided.	7
DERMAL						
Paraffin	olive oil	Sprague-Dawley rats (5/sex/dose)	2000 mg/kg bw	OECD TG 402 (acute dermal toxicity); dermally exposed for 24 h; observed for 14 d.	LD ₅₀ > 2000 mg/kg bw; scab formations on 4/5 male & 2/5 female rats (lesions remained throughout whole study but were not severe); lack of systemic toxicity effects and mortality, minimal clinical observations, standard body weight and weight gain, and necropsy results	6

Table 4. Oral repeated-dose toxicity studies

Test Article	Vehicle	Animals/Group	Study Duration	Dose/Concentration	Protocol	Results	Reference
Paraffin	NR	Fischer-344 and Sprague Dawley rats (9-10 animals/group)	60 d	2%	Animals were monitored for food uptake, clinical condition, and weight gain during the study. At 60 d, rats were killed to undergo hematology evaluation, serum liver enzyme analysis, MHC analysis, histopathological evaluation, and KC were examined for granuloma formation.	LOEL is 2% of dietary concentration of Paraffin but no NOAEL established; Fischer-344: microgranulomas, lymphoid cell aggregates in all, greater ALT, AST, & GGT activities in serum, elevated total white blood cell & neutrophil counts, changes in KC cells Sprague Dawley: microgranulomas in 1	⁶
Paraffin	none	Fischer 344 rats (20/sex/dose for waxes, 60/sex for control)	90 d	0.002, 0.02, 0.2, or 2.0% in diet (~1.5, 15, 150, 1500 mg/kg/d)	OECD TG 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents); rats given test substance via diet; rats observed for mortality, food consumption, ophthalmoscopic examination, body weight changes, hematology, organ weights, histopathology, and clinical chemistry.	The NOAEL was determined to be 1.5 mg/kg/d; the rats had histiocytosis in the mesenteric lymph nodes, granuloma in the liver, and inflammation of cardiac mitral valve.	⁶

ALT – alanine aminotransferase, AST – aspartate aminotransferase, GGT – gamma-glutamyl transferase; KC – Kupffer cells; LOEL – lowest observed effect level; MHC – major histocompatibility complex; NOAEL – no observed adverse effect level

Table 5. Cytotoxicity studies

Test Article	Vehicle	Animals/Group	Dose/Concentration	Procedure	Results	Reference
Paraffin	Dressings, creams, and ointments	HaCaTs and primary human keratinocytes	0.2 g	Cytotoxicity was measured using toluidine blue staining (photo visualization) and cell count of trypan blue excluded cells after 24 h incubation period. Melolite (a brand of wound dressing) was used as negative control.	White soft Paraffin (50% white soft & 50% liquid Paraffin) were found to be noncytotoxic.	⁸

Table 6. Genotoxicity studies

Test Article	Vehicle	Concentration/Dose	Test System	Protocol	Results	Reference
IN VITRO						
Paraffin	DMSO	0.018, 0.037, 0.074, 0.15, 0.29, 0.59, 1.2, 1.7, 2.4, 3.4, 4.9, 7, 10 mmol/l.	mouse lymphoma L5178Y cells	OECD TG 476 (in vitro mammalian cell gene mutation test); positive controls MMS & MCA; negative control DMSO; 24 h @ 37°C under 5% carbon dioxide.	No evidence of Paraffin inducing mutant colonies over background.	6
Synthetic Wax	THF	0, 15, 50, 150, 500, 1500, and 5000 µg/plate	<i>Salmonella typhimurium</i> TA1535, TA1537, TA98 and TA100 <i>Escherichia coli</i> WP2 uvr A	OECD Guideline 471 (bacterial reverse mutation assay); positive controls (4-nitroquinoline-N-oxide, N-ethyl-N-nitro-N-nitrosoguanidine, 9-aminoacridine, 2-Aminoanthracene, benzo(a)pyrene); incubated for 48 h & exposure duration was 48-72 h	Non-mutagenic.	7
Synthetic Wax	THF	Experiment I: 3, 10, 33, 100, 333, 1000, 2500; and 5000 µg/plate Experiment II: 10, 33, 100, 333, 1000, 2500, and 5000 µg/plate.	Experiment I: <i>S. typhimurium</i> strains TA1535 Experiment II: <i>coli</i> strain WP2 uvrA	OECD TG 471 (bacterial reverse mutation assay); negative controls untreated; positive controls (sodium azide, MMS, 4-nitro-o-phenylenediamine, 2-aminoanthracene); preincubation – 30 min; exposure – 72 h.	Non-mutagenic.	7
Synthetic Wax	THF	Pre-experiment: 0.8 µg/ml - 100 µg/ml Main experiment: 0.09; 0.27; 0.8; 1.6; 3.1; and 6.3 µg/ml	Chinese hamster lung fibroblasts (V79)	OECD TG 487 (in vitro mammalian cell micronucleus test); positive controls (ethylmethanesulfonate, 7,12-dimethylbenzanthracene); 4-h exposure before expression time at 7 d and selection time at 10 d.	Did not induce gene mutations at HRPT locus in V79 cells so non-mutagenic.	7
Synthetic Wax	THF	100 µg/ml	Human lymphocytes	OECD TG 487 (in vitro mammalian cell micronucleus test); positive controls (cyclophosphamide, mitomycin C, vinblastine); exposed for 3 h with and without test article and 28 h with Cytochalasin B.	Did not induce micronuclei; non-mutagenic.	7
Synthetic Wax	acetone	preliminary toxicity text: 9.77 to 2500 µg/ml Main experiment: 2500 µg/ml	Human lymphocytes	OECD Guidelines for Testing of Chemicals (2006) No. 487, Draft Proposal for a New Guideline 487: in vitro micronucleus test; observed 4 and 20 h.	Did not induce statistically significant increases in cell frequency with micronuclei. Synthetic Wax considered non-clastogenic & non-aneugenic to human lymphocytes in vitro.	7

DMSO – dimethyl sulfoxide; MCA - 3-methylcholanthrene; MMS - methyl methanesulfonate; THF - tetrahydrofuran

Table 7. Carcinogenicity studies

Test Article	Vehicle	Dose/Concentration	Test Population/System	Protocol	Results	Reference
Paraffin	NR	~5700 mg/kg	Sprague Dawley rats (~5/wax/sex); control group (140 male / 157 female)	OECD TG 451 (carcinogenicity studies); 5 Paraffin waxes were included into a feed at 10% for 2 yr. Rats were weighted & inspected every week until all the rats passed away; histological examination was completed after death.	Survival rates and growth rates – unaffected; tumors were found but incidence was similar across all groups and no other toxic effects were found. No carcinogenic potential.	6

Table 8. Dermal irritation and sensitization studies

Test Article	Vehicle	Dose/Concentration	Test Population/System	Protocol	Results	Reference
IRRITATION						
IN VITRO						
Montan Wax	none	25.6 to 25.9 mg per tissue	EpiDerm™ skin model	OECD TG 431; in vitro skin irritation: reconstituted human epidermis (Rhe) test method for 60 min; incubation time was 42 h	Montan Wax was not considered irritating and it did not reduce cell viability.	5
ANIMAL						
Paraffin	none	0.5 ml	New Zealand white rabbits (n=3)	OECD TG 404 (acute dermal irritation/ corrosion); exposed to dose for 4 h under semi-occlusive conditions and observed for 96 h before irritation score was measured.	Mean erythema score – 0.86; Mean edema score - 0.67;	6
Paraffin	none	0.5 mg	New Zealand male albino Rabbits (n=3)	OECD TG 404 (acute dermal irritation/ corrosion); exposed to dose for 4 h under semi-occlusive conditions and observed for at 1, 24, 48, and 72 h before evaluation.	Slight erythema at 1 h mark; considered not irritating.	6
Synthetic Wax	none	0.5 ml	New Zealand white rabbits (n=3)	OECD TG 404 (Acute Dermal Irritation / Corrosion); test material was placed via cotton gauze patch and observations were made 1, 24, 48, & 72 h afterwards for primary irritation & scoring.	Primary irritation index was 0 & Synthetic Wax was classified as a non irritant to rabbit skin; no corrosive effects.	7
SENSITIZATION						
ANIMAL						
Montan Wax	methyl ethyl ketone	0, 2.5, 5.0, 10.0 %	female mice (4/sex/dose)	OECD TG 429 (local lymph node assay); applied to dorsum of each ear lobe for 3 consecutive days; positive control was hexyl cinnamic aldehyde	All treated animals survived during scheduled study period with no signs of toxicity. Montan Wax was not considered skin sensitizing.	5
Synthetic Wax	olive oil and liquid paraffin	Intradermal -100% was used for challenge testing after sighting test of 100 %, 50 %, 25 %, 12.5 %, 6.25 % and 3.125 % Topical – 50% was used for challenge testing after sighting testing of 50 %, 25 % and 12.5 %	Dunkin Hartley female guinea pigs (n=16; 11 test animals and 5 control animals)	OECD TG 406 (Skin Sensitization); positive control was α -Hexylcinnamaldehyde; sighting tests done first intradermally and topically before challenge tests were performed	Synthetic Wax produced a 0% sensitization rate & was classified as a nonsensitizer to guinea pig skin.	7

Table 9. Ocular irritation studies

Test Article	Vehicle	Dose/Concentration	Test Population	Protocol	Results	Reference
IN VITRO						
Montan Wax	NR	300 ml (~167.6 mg)	In vitro HET-CAM (6 eggs for test substance, 3 eggs per control)	OECD TG 405 (acute eye irritation/corrosion); negative control: physiological sodium chloride solution; positive controls: sodium dodecyl sulphate (1% solution) and sodium hydroxide (0.1-N solution); observation time was 5 min at room temperature	Positive control – severe irritation in blood vessels Negative control – no irritation Montan Wax had mean irritation score of 0.0 and was classified as not an irritant.	5
ANIMAL						
Paraffin Wax	NR	0.1 ml	New Zealand female white Rabbits (n=3)	OECD TG 405 (acute eye irritation/corrosion); eyes remained unwashed and animals were observed for 72 h; redness was observed 1 h after treatment but no other effects were reported.	Not irritating to rabbits.	6
Synthetic Wax	NR	0.1 ml	New Zealand male white Rabbits (n=3)	OECD TG 405 (acute eye irritation/corrosion); single rabbit treated then 2 additional rabbits were treated after considered response; assessment of damage/irritation made 1, 24, 48, & 72 h after treatment.	Synthetic Wax scored a maximum group mean score of 5.3. It was classified as a minimal irritant to rabbit eyes.	7

Table 10. Case reports

Ingredient	Subjects	Protocol/Study Description	Results/Case Report Summary	Reference
Ceresin	37-yr-old female	Case report on subject that had recurring cheilitis on upper and lower lip due to the usage of lipstick containing Ceresin.	A 37-yr-old woman with a history of cheilitis and personal/family history of atopy including allergic rhinitis and eczema was patch tested in 2 separate sessions. The first test consisted of the North American Contact Dermatitis Group Baseline including 47 supplementary allergens and 4 of the patient's own products. The patient only had 1 positive reaction to her own product (Clinique 'Long last shine berry freeze' lipstick) and was negative to the other 125 allergens tested. In the second test, the woman had patch testing with the individual ingredients of the lipstick formulation and only tested positive to Ceresin. The controls on day 2 and day 4 were negative.	⁹
Paraffin	35-yr-old female	Case report on subject that was diagnosed with Paraffin-induced ELP that developed into interstitial pulmonary disease with a 25 yr follow up.	In 1979, a 35-yr-old woman with a history of working in a factory where the workers were exposed to aerosolized Paraffin. Pulmonary function tests showed a restrictive pattern, BAL showed increased cell count and a high percentage of lymphocytes. She was diagnosed with Paraffin-induced ELP and was treated with steroid therapy and discontinued Paraffin exposure. Eventually in a 25 yr follow up, her CT scan indicated extensive lung fibrosis with diffuse ground-glass, interlobular septal thickening, intralobular opacities, traction bronchiectasis, and a subpleural honeycomb pattern.	¹⁰
Paraffin	29-yr-old. male	Case report on subject that developed foreign body granulomas due to the subcutaneous infiltration of liquid Paraffin.	A 29-yr-old male came into a sexually-transmitted diseased unit with a painless papule on his penis that had been growing for several months. However, upon examination there a 4 cm large painful tumor with irregular wound margins and covered with pus. The edges also contained pus-filled fistulae. The patient mentioned he received a penicillin injection for syphilis a month ago. Eventually, the patient disclosed that he had undergone penile enlargement using liquid paraffin at age 15. The subject had a two-stage scrotum-skin graft as the primary wound closure to cover the penis after surgical excision was recommended.	¹¹
Paraffin	25-yr-old male	Case report on subject that experienced acute aspiration pneumonia due to accidentally ingesting liquid Paraffin during the act of 'fire-breathing' or 'fire eating'.	A 25-yr-old male was admitted to the emergency unit experiencing dizziness, strong headaches, and a persistent dry cough with hemoptysis. He had a fever, shortness of breath, and trouble breathing. His initial treatment included oxygen therapy via mask, IV fluids, antibiotics, corticosteroids, bronchodilators, vitamins, anticoagulant, and Ranitidine. Eventually, after 17 d of treatment, the patient showed improvement where he was transferred to a regular stationary ward. He continued the oral antibiotics, IV fluids, and vitamin therapy until he was able to leave after 4 wk. The patient was monitored for 3 mo and an x-ray was done after 5 mo which showed a regression of the pulmonary changes.	¹²
Paraffin	83-yr-old female	Case report on subject that developed ELP due to the usage of paraffin oil as a mouthwash for an extended period of time.	An 83-yr-old female with dyspnea, hypertension, obesity, and a productive cough was admitted. In an initial evaluation, it was suspected that she had a non-specific interstitial fibrosis. A chest CT scan revealed ground-glass opacities and consolidations in the lower lobes of the lungs. When the patient confirmed that she had been using liquid Paraffin oil to manage her xerostomia, she was diagnosed with ELP. Her treatment included discontinuing the usage of liquid paraffin oil, using artificial saliva products to help with her xerostomia, avoid irritants such as caffeine and tobacco. Eventually, there was a reduction in cough and no new symptoms reported.	¹³
Paraffin	7-yr-old. female	Case report on subject that was given liquid paraffin to treat her constipation but developed lipid pneumonia.	A 7-yr-old female with a history of chromosomal unstable translocation and developmental delay had recurrent lower respiratory tract infections and a persistent cough for 3 yr before being admitted to the pediatric pulmonology division. A chest CT revealed that she had consolidations in the right middle lobe, right lower lobe, and left lower lobe of her lungs. Her mother revealed that she had been giving her child liquid paraffin for chronic constipation. With this information, and bronchoscopy evaluation (resulted in 70% lipid-laden macrophage), she was diagnosed with lipid pneumonia.	¹⁴

BAL- bronchoalveolar lavage; CT - computed tomography; ELP - exogenous liquid pneumonia; IV – intravenous

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