# 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 would not be expected in cosmetic use. The granulomatous lesions in the 90-d oral study also appear to be species-specific and not relevant to human exposure. 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*** | **5857** | **2-10** | **108** | **1.5** | **10,274** | **0.092-34.5** |
| **summarized by likely duration and exposure**** | | | | | | |
| ***Duration of Use*** | | | | | | |
| *Leave-On* | *6119* | *2-10* | *105* | *NR* | *10,898* | *0.092-30* |
| *Rinse-Off* | *129* | *NR* | *35* | *1.5* | *375* | *0.75-34.5* |
| *Diluted for (Bath) Use* | *3* | *NR* | *NR* | *NR* | *5* | *NR* |
| *Unknown* | *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; 204[a]; 256[b] | 8.2[c] | 4; 72[a]; 37[b] | 1.5[a] | 98; 450[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 |
| 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 |
| Eyeliner | 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 |
| Other Fragrance Preparation | 34 | NR | 3 | NR | 66 | 1 |

**Table 1. Frequency and concentration of use according to likely duration and exposure and by product category**

| | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] |
|---|---|---|---|---|---|---|
| ***Hair Preparations (non-coloring)*** | | | | | | |
| 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 |
| ***Hair Coloring Preparations*** | | | | | | |
| 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 |
| ***Makeup Preparations (not eye or children's)*** | | | | | | |
| 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 |
| ***Makeup Preparations for Children (not eye)*** | | | | | | |
| 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 |
| ***Manicuring Preparations*** | | | | | | |
| Basecoats and Undercoats | | | | | 24 | NR |
| Cuticle Softeners | 1 | NR | | | 12 | NR |
| Nail Creams and Lotions | 1 | NR | 2 | NR | 24 | NR |
| Nail Extenders | 9 | NR | | | 231 | NR |

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| | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] |
|---|---|---|---|---|---|---|
| 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 |
| ***Other Preparations (i.e., those that do not fit another category)*** | 33 | NA | | | 153 | NA |

**Table 1. Frequency and concentration of use according to likely duration and exposure and by product category**

| | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] |
|---|---|---|---|---|---|---|
| | Montan Wax | | Ozokerite | | Paraffin | |
| **Totals*** | **34** | **0.54** | **8489** | **0.1-23.3** | **7238** | **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* |
| *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; 309[a]; 321[b] | 23.3[a] ; 2-6.5[b] | 44; 308[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 |
| 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 |
| Other Fragrance Preparation | | | 121 | NR | 28 | 7 |

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|---|---|---|---|---|---|---|
| ***Hair Preparations (non-coloring)*** | | | | | | |
| 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 |
| ***Hair Coloring Preparations*** | | | | | | |
| 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 |
| ***Makeup Preparations (not eye or children's)*** | | | | | | |
| 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 |
| ***Makeup Preparations for Children (not eye)*** | | | | | | |
| 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 |
| ***Manicuring Preparations*** | | | | | | |
| 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 |
| Nail Polish and Enamel Removers | | | | | 3 | NR |

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|---|---|---|---|---|---|---|
| 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 |
| ***Other Preparations (i.e., those that do not fit another category)*** | | | 62 | NA | 153 | NA |

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|---|---|---|---|---|---|---|
| | Synthetic Beeswax | | Synthetic Wax | | | |
| **Totals*** | **5600** | **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* | | |
| *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; 436[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 | | |
| 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 RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] |
|---|---|---|---|---|---|---|
| ***Hair Preparations (non-coloring)*** | | | | | | |
| 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 | | |
| ***Hair Coloring Preparations*** | | | | | | |
| 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 | | |
| ***Makeup Preparations (not eye or children's)*** | | | | | | |
| 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 | | |
| ***Makeup Preparations for Children (not eye)*** | | | | | | |
| 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 | | |
| ***Manicuring Preparations*** | | | | | | |
| 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 RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (2022)[4] | # of Uses RLD (2024)[2] | Max Conc of Use % (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 | | |
| ***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 categ ory, 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<br>Ceresin<br>Montan Wax<br>Paraffin*<br>Microcrystalline Wax*<br>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<br>Paraffin*<br>Microcrystalline Wax*<br>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*<br>Microcrystalline Wax*<br>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):<br>Millimicrons Maximum<br>280 to 289 0.15<br>290 to 299 .12<br>300 to 359 .08<br>360 to 400 .02<br>- may contain antioxidant permitted in food by regulations issued in accordance with section 409 of the act<br>- may contain a total of not more than 1 weight percent of residues of polymers listed in 21 CFR 178.3710(d)<br>- may contain 2-hydroxy-4-n-octoxybenzophenone as a stabilizer at a level not to exceed 0.01 weight percent of the petroleum wax<br>- may contain poly(alkylacrylate) (CAS Reg. No. 27029-57-8) as a processing aid in the manufacture of petroleum wax. | 21 CFR 178.3710 |
| Paraffin*<br>Microcrystalline Wax*<br>Synthetic Wax* | Paraffin and Microcrystalline Wax are petrolatum waxes can be used the following:<br>- in chewing gum base, as a masticatory substance up to an amount not to exceed good manufacturing practice<br>- on cheese and raw fruits and vegetables as a protective coating up to an amount not to exceed good manufacturing practice<br>- as a defoamer in food as based on 21 CFR 173.340.<br>- 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*<br>Microcrystalline Wax*<br>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*<br>Microcrystalline Wax*<br>Synthetic Wax* | Paraffin and Microcrystalline Wax may be included in cellophane used for packaging food. | 21 CFR 177.1200 |
| Paraffin*<br>Microcrystalline Wax*<br>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*<br>Microcrystalline Wax*<br>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*<br>Microcrystalline Wax*<br>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:<br>-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)<br>-oil content should not exceed 2.5% as determined by ASTM method D721-56T.<br>-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 |

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. | LD50 > 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;<br>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<br>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. In vitro genotoxicity studies**

| Test Article | Vehicle | Concentration/Dose | Test System | Protocol | Results | Reference |
|---|---|---|---|---|---|---|
| | | | ***Gene Mutation*** | | | |
| 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 | *Salmonella typhimurium* TA1535, TA1537, TA98 and TA100<br><br>*Escherichia coli* 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<br>Experiment II: 10, 33, 100, 333, 1000, 2500, and 5000 µg/plate. | Experiment I: *S. typhimurium* strains TA1535<br>Experiment II: *coli* 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] |
| | | | ***Chromosomal Damage*** | | | |
| Synthetic Wax | THF | Pre-experiment: 0.8 µg/ml - 100 µg/ml<br>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<br>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; not irritating | [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 %<br><br>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<br>Negative control – no irritation<br>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 rhintis 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 underwent 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 accidently 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 lunges. 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 salvia 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 lipoid 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 lipoid pneumonia. | [14] |

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

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