
Final Amended Safety Assessment of Octyldodecyl Stearoyl Stearate as Used in Cosmetics

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPSC	Consumer Product Safety Commission
Da	daltons
DART	developmental and reproductive toxicity
FDA	Food and Drug Administration
HPLC	high performance liquid chromatography
HRIPT	human repeated-insult patch test
IARC	International Agency for Research on Cancer
MPCE	micronucleated polychromatic erythrocyte
NR	none reported
Panel	Expert Panel for Cosmetic Ingredient Safety
QRA	quantitative risk assessment
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products
US	United States
UV	ultraviolet
VCRP	Voluntary Cosmetic Registration Program
wINCI; <i>Dictionary</i>	web-based <i>International Cosmetic Ingredient Dictionary and Handbook</i>

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Octyldodecyl Stearoyl Stearate. Octyldodecyl Stearoyl Stearate is reported to function in cosmetics as a skin conditioning and viscosity increasing agent. The Panel reviewed the relevant new data concerning the safety of this ingredient in cosmetic formulations, as well as data from previously published safety assessments, and concluded that Octyldodecyl Stearoyl Stearate is safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating.

INTRODUCTION

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), Octyldodecyl Stearoyl Stearate is reported to function in cosmetics as a skin conditioning agent-occlusive and viscosity increasing agent-nonaqueous.¹ This ingredient was first reviewed by the Expert Panel for Cosmetic Ingredient Safety (Panel) in a safety assessment that was published in 2001.² At that time, the Panel issued a Final Report with an insufficient data conclusion; in that report, the Panel considered assessments on related ingredients (i.e., octyldodecanol, stearic acid, and octyl stearate), but those data also did not provide a sufficient basis to make a determination of safety. Subsequently, the data needs were met, and in 2005, the Panel published a Final Amended Report with a conclusion of safe for use in cosmetic products in the practices of use and concentration described in that safety assessment.³

In accordance with its Procedures, the Panel evaluates the conclusions of previously issued reports approximately every 15 years, and it has been at least 15 years since this assessment has been issued. In September 2022, the Panel determined that this safety assessment should be re-opened for re-evaluation due to significant increases in concentration of use.

Stearic acid, octyldodecanol, and octyldodecyl hydroxystearate are part of the composition of Octyldodecyl Stearoyl Stearate.³ The safety of stearic acid was last reviewed in 2019 in the report on fatty acid and fatty acid salts; the Panel concluded that the fatty acid and fatty acid salts, including stearic acid, are safe in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating and non-sensitizing, which may be based on a quantitative risk assessment (QRA).⁴ The Panel originally published a safety assessment of octyldodecanol in 1985, with the conclusion that octyldodecanol is safe as used in cosmetics. This decision was reaffirmed, as published in 2006.⁵ The safety of octyldodecyl hydroxystearate was reviewed as part of the safety assessment of alkyl esters; in 2015, the Panel published the report with the conclusion safe in the present practices of use and concentration described in this safety assessment when formulated to be nonirritating.⁶

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (<https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites>; <https://www.cir-safety.org/supplementaldoc/cir-report-format-outline>). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Excerpts from the summaries of the previous report on Octyldodecyl Stearoyl Stearate are disseminated throughout the text of this re-review document, as appropriate, and are identified by *italicized text*. (This information is not included in the tables or the summary section.) It should be noted that only information on Octyldodecyl Stearoyl Stearate, and not the component ingredients, is included herein.

CHEMISTRY

Definition and Structure

According to the *Dictionary*, Octyldodecyl Stearoyl Stearate (CAS No. 90052-75-8) is the ester that conforms generally to the formula in Figure 1.¹ This ingredient comprises a branched fatty carboxyl diester.

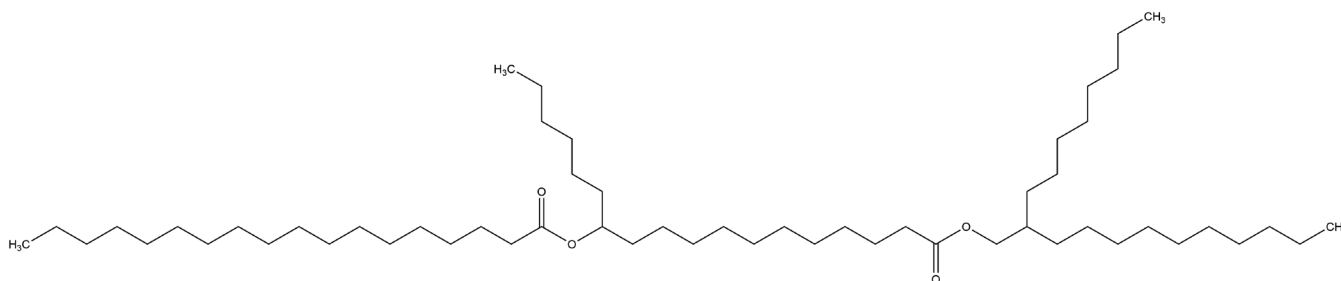


Figure 1. Octyldodecyl Stearoyl Stearate

Chemical Properties

Octyldodecyl Stearoyl Stearate occurs as an amber, yellow liquid with a mild, characteristic odor.³ It has a molecular weight of 846.87 daltons (Da). Octyldodecyl Stearoyl Stearate is partly soluble in 95% ethanol, propylene glycol, glycerin, 70% sorbitol and PEG 400. It is insoluble in water.

Method of Manufacture

Octyldodecyl Stearoyl Stearate is manufactured by an inorganic acid-catalyzed, high-temperature (150°C to 160°C) esterification reaction of guerbet alcohol.³ (Guerbet alcohol is comprised of a mixture of alcohols (primarily C-20) and a mixture of fatty acids (primarily C-18) with no impurities.) The product is neutralized to a water-soluble soap, washed to purity, dried, and filtered.

Composition/Impurities

Octyldodecyl Stearoyl Stearate is composed of stearic acid (2.5% max), octyldodecanol (5.0% max), octyldodecyl hydroxystearate (5.0% max), and Octyldodecyl Stearoyl Stearate (88.0% max).³

USE

Cosmetic

The safety of the cosmetic ingredient addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of this ingredient in cosmetics and does not cover its use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories, based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety.

According to 2023 VCRP survey data, Octyldodecyl Stearoyl Stearate is reported to be used in 584 total formulations, (580 leave-on and 4 rinse off; Table 1).⁷ This is a significant increase since the last review; in 2001, VCRP survey data reported 106 uses (102 leave-on and 4 rinse-off).³ The results of the concentration of use survey conducted by the Council in 2020 indicate Octyldodecyl Stearoyl Stearate is used at up to 28% in leave-on products; in 2001, the maximum reported concentration of use was 15%. The product category with the highest use concentration in 2020 is lipsticks, 28%; in 2001, the maximum concentration of use reported for lipstick was 10%.

Cosmetic products containing Octyldodecyl Stearoyl Stearate may be applied near the eyes, (e.g., at up to 18.5% in eye shadows; this is compared to 10% reported for products applied near the eye in 2001). Octyldodecyl Stearoyl Stearate is also used in cosmetic products that could possibly be inhaled (e.g., it is reported to be used in in face powders at concentrations up to 7.5%). In practice, as stated in the Panel's respiratory exposure resource document (<https://www.cir-safety.org/cir-findings>), most droplets/particles incidentally inhaled from cosmetics would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

Although products containing this ingredient may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of this ingredient (and without consumer habits and practices data or particle size data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

Octyldodecyl Stearoyl Stearate is not restricted from use in any way under the rules governing cosmetic products in the European Union.⁸

TOXICOKINETIC STUDIES

Dermal Penetration

In Vitro

An in vitro study of skin penetration and permeation of Octyldodecyl Stearoyl Stearate was conducted.³ Permeation at 48 h was $0.023 \pm 0.005 \mu\text{g}/\text{cm}^2$, representing $0.005\% \pm 0.001\%$ of the applied dose. Permeation at 24 h was higher, but the researchers cautioned that the actual scintillation counts measured in the receptor fluid were very close to background levels. A total of 4% to 5% of the label was found in the tape strips and remaining epidermis combined.

Additional toxicokinetic studies were not found in the updated literature search, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Octyldodecyl Stearoyl Stearate, tested as a trade compound, had an oral LD₅₀ of >20 g/kg in albino rats.³

Additional acute toxicity studies were not found in the updated literature search, and unpublished data were not submitted.

Short-Term Toxicity Studies

Octyldodecyl Stearoyl Stearate, tested as a trade compound at an oral dose of 5.0 g/kg in 10 rats (5 of each sex) for 14 d, produced no deaths.³ (No additional details were provided.)

Additional repeated-dose toxicity studies were not found in the updated literature search, and unpublished data were not submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Developmental and reproductive toxicity (DART) studies of Octyldodecyl Stearoyl Stearate were not included in the original reports and were not found in the updated literature search, and unpublished data were not submitted.

GENOTOXICITY STUDIES

In a Salmonella typhimurium gene mutation assay with up to 100 µl/plate Octyldodecyl Stearoyl Stearate, there was no positive increase in the number of revertant colonies for any of the tester strains (TA98, TA100, TA1535, TA1537, and TA1538) with or without S-9 activation.³ In vivo, a micronucleus assay was used to determine the genotoxicity of Octyldodecyl Stearoyl Stearate. A single dose of 2.0, 5.0 or 10.0 ml/kg Octyldodecyl Stearoyl Stearate was given to CD-1 mice. No significant increases occurred in the proportion of micronucleated polychromatic erythrocytes (MPCEs) in the test groups compared to the concurrent negative control groups.

Additional genotoxicity studies were not found in the updated literature search, and unpublished data were not submitted.

CARCINOGENICITY STUDIES

Carcinogenicity studies of Octyldodecyl Stearoyl Stearate were not included in the original reports and were not found in the updated literature search, and unpublished data were not submitted.

DERMAL IRRITATION AND SENSITIZATION

Irritation

An eyeshadow containing 7.5% Octyldodecyl Stearoyl Stearate was tested on 9 rabbits, in a single insult occlusive patch test and was moderately irritating to the skin.³ A concealer containing 7.8% Octyldodecyl Stearoyl Stearate was similarly tested on 9 rabbits; no signs of irritancy were observed at 24 h, but erythema was observed at 2 h. A lipstick containing 7.8% Octyldodecyl Stearoyl Stearate was tested similarly to the previous studies in a 4-d cumulative study on 9 rabbits; the lipstick was “essentially non-irritating.” Octyldodecyl Stearoyl Stearate, tested as a trade compound, was applied (0.5 ml) under a 24-h occlusive patch to abraded and intact skin on the backs of 6 rabbits. It was considered to have a “potential for slight irritation—rarely irritating to people.” A single dermal application of 0.5 ml of Octyldodecyl Stearoyl Stearate, at a 10% w/w dilution in corn oil, was applied to one abraded and one intact site on 6 New Zealand white rabbits. Each test site was observed for erythema and edema 24 and 72 h after application, and the test compound was found to be non-irritating to the skin. A cumulative irritation study of an eyeshadow having 10.4% Octyldodecyl Stearoyl Stearate was completed in 10 subjects. The test material was applied with occlusive patches to the skin 21 times for 23-h intervals. Scoring and reapplication occurred every 24 h. The eyeshadow was classified as a mild irritant. The human irritancy potential of an eyeshadow pencil containing 10.4% Octyldodecyl Stearoyl Stearate was evaluated in a single insult patch test using 19 subjects. No differences in irritancy were observed between subjects of the test and control groups. A concealer containing 5.0% Octyldodecyl Stearoyl Stearate was tested for primary irritation using 20 subjects. No significant differences in irritancy were observed between test subjects and controls. A lipstick having 15.0% Octyldodecyl Stearoyl Stearate was similarly tested using 18 subjects. No differences in irritancy were observed between test subjects and control groups. A clinical use study was performed using a lipstick containing 7.8% Octyldodecyl Stearoyl Stearate with 62 female subjects. The women applied the lipstick at least twice daily for 3 wk. No clinical changes were observed after use of the lipstick.

Sensitization

An eyeshadow containing 10.4% Octyldodecyl Stearoyl Stearate was evaluated in a human repeated insult patch test (HRIPT) using 107 subjects.³ Applications were made under a closed patch three times weekly during the 22-d induction

period, and scored 48 or 72 h after application. Challenge applications were made using 24-h occlusive patches. No evidence of contact sensitization was observed in any of the test subjects. The contact sensitization potential of a concealer containing 5.0% Octyldodecyl Stearoyl Stearate was determined using a maximization test. The test material was evaluated with an occlusive patch. During the induction phase, sodium lauryl sulfate (SLS, 1%) was applied to a different site and examined after 48 or 72 h. The procedure was repeated for 5 induction exposures. None of the 27 subjects had adverse reactions, and no contact sensitization was observed. A lipstick containing 7.8% Octyldodecyl Stearoyl Stearate was tested in an HRIPT using 85 subjects. Occlusive patches with the test material were applied to the upper back for 24 h, three times weekly, for 3 wk. Challenge applications were made 3 wk after the last induction treatment and scored 24 and 48 h after patch removal. None of the subjects had erythematous responses during induction or challenge, and the investigators concluded that the lipstick did not have allergic sensitization potential.

Human

An HRIPT with a makeup base containing 21.01% Octyldodecyl Stearoyl Stearate was performed in 107 subjects.⁹ Two-tenths (0.2) g of the test material, or an amount sufficient to cover the contact surface, was applied to the treatment site using occlusive patches. During the induction phase, 24-h patches were applied 3 times per week, for a total of 9 applications. Approximately 2 wk after the final induction application, a challenge patch was applied for 24 h to a previously untreated site, and the site was scored on day 1 and day 3 post-application. No visible skin reactions were observed throughout the test interval. Under the conditions of the study, the test material indicated no potential for dermal irritation or allergic contact sensitization.

OCULAR IRRITATION STUDIES

An EYETEX *in vitro* irritation assay was performed on a nail cuticle pencil containing 20.6% Octyldodecyl Stearoyl Stearate; the test material produced minimal to mild irritation.³ In animal studies, an eyeliner containing 7.5% Octyldodecyl Stearoyl Stearate was applied 3 times to the eyes of 6 rabbits; the eyes were not rinsed. The investigators concluded that the eye liner was moderately irritating under the conditions of this study. A concealer containing 12.7% Octyldodecyl Stearoyl Stearate was applied once to the eyes of 6 rabbits, and the eyes were not rinsed; the formulation was classified as mildly irritating. In another study, none of the 6 rabbits tested had signs of ocular irritation from a lipstick containing 7.8% Octyldodecyl Stearoyl Stearate. Octyldodecyl Stearoyl Stearate, tested as a trade compound, instilled (0.1 ml) into the right conjunctival sac of six rabbit, was scored on days 1 to 4, and 7, and no reactions were observed. A single application of 0.1 ml of Octyldodecyl Stearoyl Stearate, at a 10% w/w dilution in corn oil, was instilled into one eye each of 6 rabbits. No reactions were observed.

Additional ocular irritation studies were not found in the updated literature search, and unpublished data were not submitted.

SUMMARY

Octyldodecyl Stearoyl Stearate is reported to function in cosmetics as a skin conditioning agent-occlusive and viscosity increasing agent-nonaqueous. Octyldodecyl Stearoyl Stearate was previously reviewed by the Panel, and in 2005 the Panel published a final amended report with a conclusion of safe for use in cosmetic products in the practices of use and concentration described in that safety assessment. (The 2005 report should be consulted for additional studies that support the safety of Octyldodecyl Stearoyl Stearate.) In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years, and it has been at least 15 years since the previous assessment has been issued. In September 2022, the Panel determined that this safety assessment should be re-opened for re-evaluation due to a significant increase in concentrations of use.

According to 2023 VCRP survey data, Octyldodecyl Stearoyl Stearate is reported to be used in 584 total formulations, (580 leave-on and 4 rinse off). The results of the concentration of use survey provided by the Council in 2020, indicate Octyldodecyl Stearoyl Stearate is used at up to 28% in leave-on products, with the highest maximum concentration of use reported for lipstick. When the final amended safety assessment was published in 2005, Octyldodecyl Stearoyl Stearate reported use was in 106 formulations (2001 VCRP data). The highest maximum concentration of use at that time were at up to 15% in body and hand creams, lotions, etc. (excluding shaving).

An HRIPT using 24-h occlusive patches of a makeup base containing 21.01% Octyldodecyl Stearoyl Stearate was completed in 107 subjects. No visible skin reactions were observed throughout the test interval. Under the conditions of the study, the test material indicated no potential for dermal irritation or allergic contact sensitization.

No DART or carcinogenicity studies on Octyldodecyl Stearoyl Stearate were found in an updated search of the published literature, and data were not submitted.

DISCUSSION

In 2005, the Panel published a final amended report with the conclusion that Octyldodecyl Stearoyl Stearate is safe for use in cosmetic products in the practices of use and concentration described in that safety assessment. In accordance with its Procedures, the Panel re-evaluates the conclusion of previously issued reports approximately every 15 years. At the

September 2022 meeting the Panel re-opened the safety assessment of Octyldodecyl Stearoyl Stearate due to significant increases in concentration of use. (In 2020 the reported concentration of use in lipstick was 28%, compared to 10% in 2001.) Accordingly, the Panel reviewed all the new and existing data and concluded that Octyldodecyl Stearoyl Stearate is safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating.

As noted, this ingredient is now used at up to 28%. Concerns regarding dermal sensitization at this higher concentration of use were obviated by a negative HRIPT study of a formulation containing 21% Octyldodecyl Stearoyl Stearate. Accordingly, the Panel considered the lack of irritation and sensitization at this concentration sufficient to determine safety. However, the Panel was concerned that the potential exists for ocular irritation with the use of products formulated with Octyldodecyl Stearoyl Stearate. Accordingly, the Panel specified that products containing Octyldodecyl Stearoyl Stearate must be formulated to be non-irritating.

The Panel noted that DART and carcinogenicity data are absent. Nevertheless, because in vitro skin permeation and penetration data indicated absorption would be minimal and a 14-d oral toxicity study did not suggest this ingredient was systemically toxic, the need for DART studies was mitigated. Furthermore, the need for carcinogenicity data was mitigated by negative genotoxicity studies.

The Panel discussed the issue of incidental inhalation exposure resulting from this ingredient (for example, Octyldodecyl Stearoyl Stearate is reported to be used in face powders at concentrations up to 7.5%). Inhalation toxicity data were not available. However, the Panel noted that the majority of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or tracheobronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of this ingredient. Coupled with the small actual exposure in the breathing zone and the low concentrations at which this ingredient is used (or expected to be used) in potentially inhaled products, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. 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>.

Finally, the Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that Octyldodecyl Stearoyl Stearate is safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating.

TABLES

Table 1. Updated and historical frequency (2023; 2001) and concentration (2020; 2001) of use according to duration and exposure

	# of Uses		Max Conc of Use (%)	
	Octyldodecyl Stearoyl Stearate			
	2023 ⁷	2001 ³	2020 ¹⁰	2001 ³
Totals	584	106	0.5-28	2-15
summarized by likely duration and exposure*				
<i>Duration of Use</i>				
<i>Leave-On</i>	580	102	0.5-28	2-15
<i>Rinse-Off</i>	4	4	3.3-3.5	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR
<i>Exposure Type**</i>				
Eye Area	325	35	0.5-18.5	4-10
Incidental Ingestion	29	1	3.4-28	5-10
Incidental Inhalation-Spray	7 ^a ; 8 ^b	1; 5 ^a ; 2 ^b	NR	8 ^a ; 4-15 ^c
Incidental Inhalation-Powder	88; 8 ^b	34; 2 ^b	1.9-7.5; 1 ^c	2-7; 4-15 ^c
Dermal Contact	555	103	0.5-25.4	2-15
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	3.3-3.5	NR
Nail	NR	2	NR	NR
Mucous Membrane	30	1	3.4-28	5-10
Baby Products	NR	NR	NR	NR
as reported by product category				
<i>Eye Makeup Preparations</i>				
Eyebrow Pencil	2	2	0.75	NR
Eyeliners	3	1	NR	4
Eye Shadow	311	30	1.4-18.5	4-10
Other Eye Makeup Preparations	10	2	0.5-3.2	NR
<i>Fragrance Preparations</i>				
Powders (dusting/talcum, excl aftershave talc)	NR	2	NR	4
Other Fragrance Preparation	NR	1	NR	NR
<i>Hair Coloring Preparations</i>				
Hair Tints	NR	NR	3.3	NR
Other Hair Coloring Preparation	NR	NR	3.5	NR
<i>Makeup Preparations</i>				
Blushers (all types)	55	8	1.8-24	2-7
Face Powders	88	32	1.9-7.5	2-7
Foundations	41	5	0.5-6.7	4-9
Lipstick	29	1	3.4-28	5-10
Makeup Bases	2	5	6.1-24	10
Rouges	6	1	25.4	NR
Other Makeup Preparations	16	1	1.9-3	5
<i>Manicuring Preparations (Nail)</i>				
Cuticle Softeners	NR	1	NR	NR
Nail Creams and Lotions	NR	1	NR	NR
<i>Personal Cleanliness</i>				
<i>Other Personal Cleanliness Products</i>				
	1	NR	NR	NR
<i>Skin Care Preparations</i>				
Cleansing	2	3	NR	NR
Face and Neck (exc shave)	1	1	1 (not spray)	4
Body and Hand (exc shave)	7	1	NR	15
Moisturizing	7	4	2-9 (not spray)	NR
Night	NR	1	2.5 (not spray)	NR
Paste Masks (mud packs)	1	1	NR	NR
Other Skin Care Preparations	3	2	NR	NR
<i>Suntan Preparations</i>				
Suntan Gels, Creams, and Liquids	NR	NR	NR	8

NR – not reported

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

**Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

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

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

^c 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

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