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# Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

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*All interested persons are provided 60 days from the above release date (i.e., by **May 25, 2026**) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.*

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 safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

## ABBREVIATIONS

|                   |  |
|-------------------|--|
| CIR               | Cosmetic Ingredient Review                             |
| Council           | Personal Care Products Council                         |
| <i>Dictionary</i> | <i>International Cosmetic Ingredient Dictionary</i>    |
| EPA               | Environmental Protection Agency                        |
| ET <sub>50</sub>  | time of exposure to reduce viability to 50%            |
| FDA               | Food and Drug Administration                           |
| FOU               | frequency of use                                       |
| HRIPT             | human repeated-insult patch test                       |
| l.o.              | leave-on   |
| MoCRA             | Modernization of Cosmetics Regulation Act of 2022      |
| NA                | not applicable   |
| NR                | not reported   |
| OECD              | Organisation for Economic Co-operation and Development |
| Panel             | Expert Panel for Cosmetic Ingredient Safety            |
| QRA               | quantitative risk assessment                           |
| RLD               | Registration and Listing Data                          |
| r.o.              | rinse-off  |
| TG                | test guideline   |

## **ABSTRACT**

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 7 dimer dilinoleate ingredients, which are reported to function as hair conditioning agents, skin conditioning agents, and viscosity increasing agents in cosmetic products. The Panel reviewed all relevant data related to these ingredients. The Panel concluded that these 7 dimer dilinoleate ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

## **INTRODUCTION**

This assessment reviews the safety of the following 7 dimer dilinoleate ingredients as used in cosmetic formulations:

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate  
Bis-Behenyl/Phytosteryl Dimer Dilinoleate  
Dimer Dilinoleyl Dimer Dilinoleate  
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate  
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate  
Phytosteryl Isostearyl Dimer Dilinoleate  
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate

According to the *International Cosmetic Ingredient Dictionary (Dictionary)*, most of the ingredients named above are reported to function in cosmetics as hair conditioning agents, skin conditioning agents, and viscosity increasing agents; additional functions are listed in Table 1.<sup>1</sup> Each ingredient is a mixture of esters formed from the reaction of alcohols with dilinoleic acid. The precursor core, dilinoleic acid, is produced by catalytic dimerization of linoleic acid.

The Panel concluded in a safety assessment that was finalized in 2019 that Dilinoleic Acid is safe in the present practice 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).<sup>2</sup> The Panel also previously reviewed dialkyl dimer dilinoleate ingredients in a report that was published in 2023 with the conclusion that the 8 ingredients reviewed therein were safe in cosmetics in the present practices of use and concentration described in the safety assessment.<sup>3</sup> Additional reports related to the ingredients in this safety assessment and the respective conclusions are:

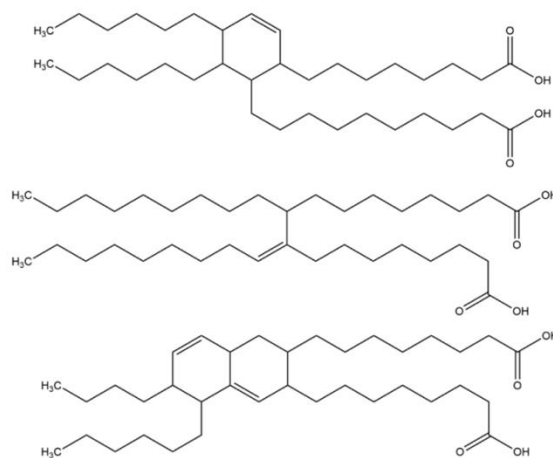
- Diisostearyl Polyglyceryl-3 Dimer Dilinoleate (published in 2023) - safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating<sup>4</sup>
- Phytosterols (final report issued in 2014) - safe in the present practices of use and concentration<sup>5</sup>
- Isostearyl Alcohol, Cetyl Alcohol, and Behenyl Alcohol (published in 1988, re-review published in 2008) - safe in the present practices of use<sup>6,7</sup>
- Stearyl Alcohol (published in 1985, re-review published in 2006) - safe as used<sup>8,9</sup>

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 extensive search of the world's literature; a search was last conducted January 2026. 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 Expert Panel for Cosmetic Ingredient Safety (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.

## **CHEMISTRY**

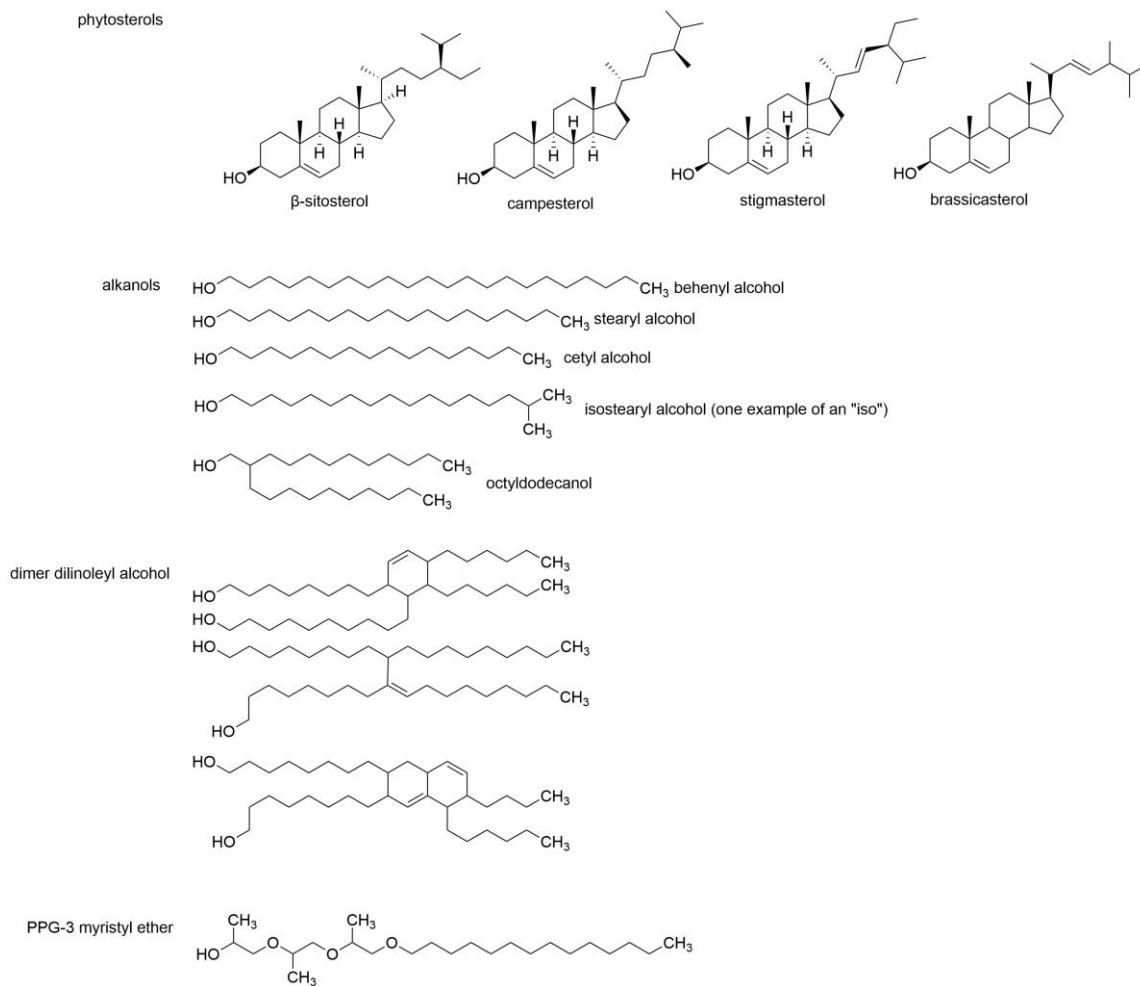
### **Definition and Structure**

The definitions of the ingredients included in this review are provided in Table 1.<sup>1</sup> Each of these ingredients is an ester (or diester) of dilinoleic acid (itself a dimer of linoleic acid) and a mixture of alcohols. For example, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is a mixture of esters wherein one or more of the carboxylic acid groups in Figure 1 are esterified with phytosteryl (a mixture of sterols obtained from higher plants, including  $\beta$ -sitosterol, campesterol, stigmasterol, and brassicasterol), isostearyl, cetyl, stearyl, and/or behenyl alcohols.



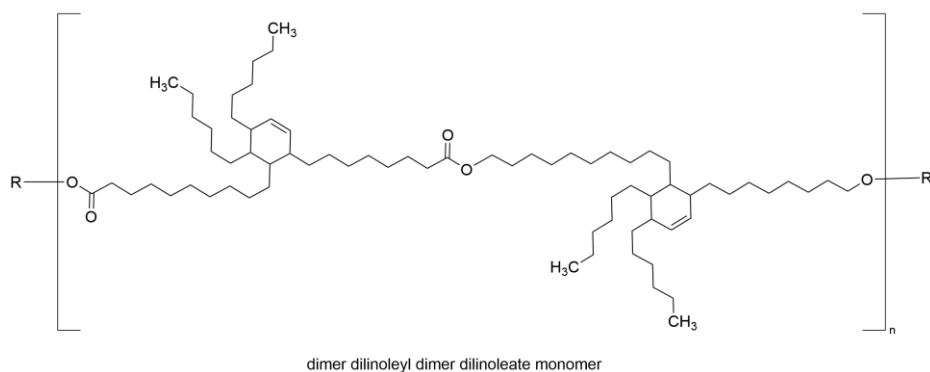
**Figure 1.** Dilinoleic acid (“dimer acid”) (hydrogenated form (i.e., no double bond) is also possible)

Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate is a mixture of esters wherein one or more of the carboxylic acid functional groups in Figure 1 are esterified with stearyl alcohol and PPG-3 myristyl ether (which comprises a secondary alcohol functional group). The various alcohols used to prepare these esters are shown in Figure 2.



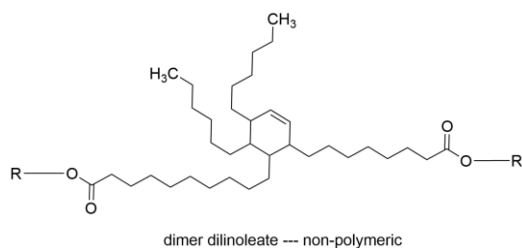
**Figure 2.** Alcohols

Two of these ingredients are polymeric (or at least oligomeric), comprising a repeating “dimer dilinoleyl dimer dilinoleate monomer.”<sup>10-12</sup> These include Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate and Dimer Dilinoleyl Dimer Dilinoleate, as depicted in Figure 3.



**Figure 3.** Examples of idealized structures of Dimer Dilinoleyl Dimer Dilinoleate (wherein R and R' are both hydrogen) and Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (wherein R and R' are independently behenyl, isostearyl, or phytosteryl residue endcaps); n is unknown.

The remaining ingredients are non-polymeric.<sup>10-12</sup> Bis-Behenyl/Phytosteryl Dimer Dilinoleate, Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Phytosteryl Isostearyl Dimer Dilinoleate, and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate are comprise a solitary dilinoleic acid core, as depicted in Figure 4.



**Figure 4.** Examples of idealized structures of Bis-Behenyl/Phytosteryl Dimer Dilinoleate (wherein R and R' are independently behenyl or phytosteryl residue endcaps), Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate (wherein R and R' are independently octyldodecyl or PPG-3 myristyl ether residue endcaps), Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate (wherein R and R' are independently behenyl, isostearyl, cetyl, stearyl, or phytosteryl residue endcaps), Phytosteryl Isostearyl Dimer Dilinoleate (wherein R and R' are independently isostearyl or phytosteryl residue endcaps), and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate (wherein R and R' are independently stearyl or PPG-3 myristyl ether residue endcaps).

### Chemical Properties

Chemical properties of Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate are described in Table 2. Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate is a white to pale yellow hydrophobic paste with a molecular weight > 1000 g/mol.<sup>13</sup> Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is also a white to pale yellow paste, with a melting point of 38°C.<sup>14</sup> Log  $K_{ow}$  estimated for Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate were 32.55 and 30.66, respectively.<sup>15</sup>

### Method of Manufacture

A generic method of manufacturing scheme for Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/Phytosteryl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate was reported by a supplier.<sup>10</sup> For these ingredients, the raw materials are reacted and undergo purification and filtration prior to packaging. No further details were provided.

General method of manufacturing information of dimer dilinoleate reported by the same supplier states that the ester of dimer acid and alcohol can be synthesized by directly esterifying dimer acid and alcohol at high temperatures (180 - 240°C) while removing the water produced in the reaction.<sup>11</sup> The reaction temperature can be lowered by using acid or alkaline catalysts. The catalysts are removed after the reaction by neutralizing with an acid or alkali wash. Antioxidants may be added to the resulting ester to improve its stability.

### Impurities

According to a supplier, heavy metal content and arsenic content are at maximum 20 ppm and 2 ppm, respectively, for the following ingredients: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/ Phytosteryl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate.<sup>10</sup> General composition information of dimer dilinoleate reported by the same

supplier states that trace amounts of free alcohol, free fatty acids, and salts of free fatty acids derived from raw materials may be present.<sup>11</sup>

### **UV Absorption**

Based on the UV spectra provided by a supplier, no UV absorption was observed for the following ingredients (measured from 280 or 290 to 700 nm): Bis-Behenyl/Isostearyl/ Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/Phytosteryl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate.<sup>16</sup> No UV absorption data were provided for the remaining dimer dilinoleate ingredients.

### **USE**

#### **Cosmetic**

The safety of the cosmetic ingredients 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 dimer dilinoleates in cosmetics. Registration and Listing Data (RLD) obtained from the FDA report frequency of use, and responses to a survey conducted by the Personal Care Products Council (Council) indicate maximum reported concentrations of use; it is these values that define the present practices of use and concentration that are assessed by the Panel. Since 2024, as a result of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), manufacturers and processors are required to register facilities and list their products (and ingredients therein) with the FDA (i.e., RLD). An exception is made for small businesses (average gross annual sales in the US of cosmetic products for the previous 3-yr period is less than \$1,000,000, adjusted for inflation), which are exempt from MoCRA reporting for most cosmetic product categories. Eye area products, injected products, internal use products, or products that alter appearance for more than 24 h, and the facilities that manufacture these products, are not included in this exemption.<sup>17</sup> Another change resulting from MoCRA is the addition of tattoo preparations (permanent tattoo inks, temporary tattoo inks, and other tattoo products) to the product categories for which companies need to list their products with FDA. However, evaluating the safety of ingredients as used in tattoo preparations is not within the purview of the Panel; accordingly, such use is not included as part of the present practices of use that are assessed by the Panel.

According to RLD obtained from the FDA in 2025, the ingredient in this group with the most reported uses is Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; it is reported to be used in 2474 formulations (Table 3).<sup>18,19</sup> Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate has the second most reported uses in the RLD; it is reported to be used in 1998 formulations. The results of the concentration of use survey conducted by the Council in 2025 (using MoCRA product categories) indicate Dimer Dilinoleyl Dimer Dilinoleate has the highest reported maximum concentration of use, at up to 48.7% in lipsticks and lip glosses.<sup>20</sup> The highest maximum concentration of use reported for leave-on dermal exposure is 13% Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, in foundations.

Some of the ingredients named in this report may be used in products that can be incidentally ingested or be used near the eye or mucous membranes. For example, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate has been reported to be used in lipsticks and lip glosses at up to 30.1% and in eyeliners at up to 11.7%, and Dimer Dilinoleyl Dimer Dilinoleate has been reported to be used in lipsticks and lip glosses at up to 48.7% and in eyebrow pencils at up to 10%.<sup>20</sup> Additionally, some of the dimer dilinoleates may be used in cosmetic powders, and could possibly be inhaled; for example, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate is reported to be used at up to 2.9% in face powders. 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.

It is possible that some products containing dimer dilinoleates may be marketed for use with airbrush delivery systems. With the advent of MoCRA and the current product categories outlined therein, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such for some, but not all, product categories in the RLD. In other words, a reliable source of frequency of use data regarding the use of cosmetic ingredients in conjunction with airbrush delivery systems is now available, in some instances. None of the reported product categories for these ingredients as listed in the RLD include a designation indicating airbrush application, so it is possible that these ingredients are used with airbrush delivery systems, but not reported as such. Additionally, the concentration of use surveys are conducted based on product categories as stated in the RLD; airbrush use was not reported in response to the survey. No consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with airbrush technology, thereby preempting the ability to evaluate risk or safety. Without information regarding the consumer habits and practices data or product particle size data (or other relevant particle data, e.g., diameter) related to this use technology, the data profile is incomplete, and the Panel is not able to determine safety for use in airbrush formulations. If these ingredients were to be used in airbrush formulations, the data are insufficient to evaluate the exposure resulting from cosmetics applied in such a

manner. None of the dimer dilinoleate ingredients named in the report are restricted from use in any way under the rules governing cosmetic products in the European Union.<sup>21</sup>

### **TOXICOKINETIC STUDIES**

Toxicokinetics studies were not found in the published literature, and unpublished data were not submitted.

### **TOXICOLOGICAL STUDIES**

#### **Acute Toxicity Studies**

Acute toxicity studies are summarized in Table 4. In studies performed in accordance with Organisation for Economic Co-operation and Development (OECD) test guideline (TG) 423 with the following ingredients, the LD<sub>50</sub> was greater than 2000 mg/kg in rats: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate.<sup>10,13,22-25</sup>

#### **Repeated-Dose Toxicity Studies**

Repeated-dose toxicity studies were not found in the published literature, and unpublished data were not submitted.

### **DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES**

Developmental and reproductive toxicity studies were not found in the published literature, and unpublished data were not submitted.

### **GENOTOXICITY STUDIES**

In vitro genotoxicity studies are summarized in Table 5. The following ingredients did not cause gene mutations in the Ames test when tested at 100%: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Bis-Behenyl/Phytosteryl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate.<sup>10,13</sup> Additionally, chromosomal aberrations did not occur with Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, or Phytosteryl Isostearyl Dimer Dilinoleate when tested at 100% in the chromosome aberration assay in mammalian cell cultures<sup>10</sup> or with Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (test concentration not specified) in an in vitro micronucleus assay.<sup>10,13</sup>

### **CARCINOGENICITY STUDIES**

Carcinogenicity studies were not found in the published literature, and unpublished data were not submitted.

### **DERMAL IRRITATION AND SENSITIZATION STUDIES**

Dermal irritation and sensitization studies are summarized in Table 6. Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate at 100% concentration were non-irritating in primary skin irritation studies in animals, while Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl Isostearyl Dimer Dilinoleate were mild irritants.<sup>10,13</sup> Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate and Phytosteryl Isostearyl Dimer Dilinoleate, each at 100% concentration, were non-irritating and practically non-irritating, respectively, in cumulative skin irritation studies in guinea pigs (no further details provided).<sup>10</sup> In 24-h closed patch tests in 42 - 45 subjects, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate at 100% concentration were not irritating.<sup>10,14</sup>

No sensitization was observed in animal studies performed in accordance with OECD TG 406 with the following ingredients: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (up to 25%); Dimer Dilinoleyl Dimer Dilinoleate (at 100%); Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate (at 100%); and Phytosteryl Isostearyl Dimer Dilinoleate (at 100%) (no further details provided on these studies).<sup>10,13</sup> No sensitization was observed in human repeated-insult patch tests (HRIPTs) with the following ingredients: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (at 100% in 42 subjects and at 3% in a lip balm formulation in 106 subjects); Dimer Dilinoleyl Dimer Dilinoleate (at 19% in a lip treatment formulation in 53 subjects); and Phytosteryl/Isostearyl/Cetyl/ Stearyl/Behenyl Dimer Dilinoleate (at 15% in a lip gloss formulation in 100 subjects).<sup>26-28</sup>

### **OCULAR IRRITATION STUDIES**

Ocular irritation studies are summarized in Table 7. Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate at 100% concentration was determined to be non-irritating in an EpiOcular corneal assay.<sup>10,29</sup> Dimer Dilinoleyl Dimer Dilinoleate at 100% concentration was also determined to be non-irritating in an EpiOcular corneal assay, and it was not categorized as an eye irritant in an in vitro short-time exposure test performed in accordance with OECD TG 491 at

concentrations of 0.05 or 5%.<sup>10,30,31</sup> In rabbit studies performed in accordance with OECD TG 405, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate at 100% was practically non-irritating in one study and slightly irritating in another study).<sup>10,13,32</sup> Minimal irritation was observed in rabbit studies with Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate when tested undiluted.<sup>10,14,33-35</sup>

## **SUMMARY**

This assessment reviews the safety of the following 7 dimer dilinoleate ingredients as used in cosmetic formulations: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/Phytosteryl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; Phytosteryl Isostearyl Dimer Dilinoleate; and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate. According to the *Dictionary*, most of the ingredients named above are reported to function as hair conditioning agents, skin conditioning agents, and viscosity increasing agents. These dimer dilinoleates have carboxylic acid functional groups that are esterified with octyldodecanol, PPG-3 myristyl ether, dimer dilinoleyl, phytosteryl, isostearyl, cetyl, stearyl, and/or behenyl chains.

According to RLD obtained from the FDA in 2025, the ingredient in this group with the most reported uses is Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; it is reported to be used in 2474 formulations. Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate has the second most reported uses in the RLD; it is reported to be used in 1998 formulations. The results of the concentration of use survey conducted by the Council in 2025 (using MoCRA product categories) indicate Dimer Dilinoleyl Dimer Dilinoleate has the highest reported maximum concentration of use, at up to 48.7% in lipsticks and lip glosses. The highest maximum concentration of use reported for leave-on dermal exposure is 13% Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate in foundations.

None of the dimer dilinoleate ingredients named in the report are restricted from use in any way under the rules governing cosmetic products in the European Union.

In studies performed in accordance with OECD TG 423 with the following ingredients, the LD<sub>50</sub> was greater than 2000 in rats: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate.

The following ingredients did not cause gene mutations in the Ames test when tested at 100%: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Bis-Behenyl/Phytosteryl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate. Additionally, chromosomal aberrations did not occur with Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate when tested at 100% in the chromosome aberration assay in mammalian cell cultures or with Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (test concentration not specified) in an in vitro micronucleus assay.

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate at 100% concentration were non-irritating in primary skin irritation studies in animals, while Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl Isostearyl Dimer Dilinoleate were mild irritants. Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate and Phytosteryl Isostearyl Dimer Dilinoleate, each at 100% concentration, were non-irritating and practically non-irritating, respectively, in cumulative skin irritation studies in guinea pigs (no further details provided). In 24-h closed patch tests in 42-45 subjects, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate, all tested at 100% concentration, were not irritating. No sensitization was observed in animal studies performed in accordance with OECD TG 406 with the following ingredients: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (up to 25%); Dimer Dilinoleyl Dimer Dilinoleate (at 100%); Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate (at 100%); and Phytosteryl Isostearyl Dimer Dilinoleate (at 100%) (no further details provided on these studies). No sensitization was observed in HRIPTs with the following ingredients: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (at 100% in 42 subjects and at 3% in a lip balm formulation in 106 subjects); Dimer Dilinoleyl Dimer Dilinoleate (at 19% in a lip treatment formulation in 53 subjects); and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate (at 15% in a lip gloss formulation in 100 subjects).

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate at 100% concentration was determined to be non-irritating in an EpiOcular corneal assay. Dimer Dilinoleyl Dimer Dilinoleate at 100% concentration was also determined to be non-irritating in an EpiOcular corneal assay, and it was not categorized as an eye irritant in an in vitro short-time exposure test performed in accordance with OECD TG 491 at concentrations of 0.05 or 5%. In rabbit studies performed in accordance with OECD TG 405, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate at 100% was practically non-irritating in one study and slightly irritating in another study. Minimal irritation was observed in rabbit studies with Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate at 100% concentration.

Toxicokinetics studies, repeated-dose toxicity studies, developmental and reproductive toxicity studies, and carcinogenicity studies on the dimer dilinoleate ingredients were not found in a literature search, and unpublished data were not submitted.

## **DISCUSSION**

This assessment reviews the safety of 7 dimer dilinoleate ingredients as used in cosmetic formulations, in accordance with the product categories and concentrations of use identified in the Use section and Use table. The Panel concluded that the dimer dilinoleates named in this report are safe in cosmetics in the present practices of use and concentrations described in this safety assessment.

The Panel noted that it had previously concluded that dilinoleic acid is safe in the present practice of use and concentration described in the safety assessment when formulated to be non-irritating and non-sensitizing, and other components of the ingredients found in this report have also been found to be safe as cosmetic ingredients.

Although toxicokinetics data are lacking, significant dermal absorption for these dimer dilinoleate ingredients is not expected. The Panel observed that the results of genotoxicity studies were negative. Additionally, the components of these dimer dilinoleate mixtures are not pharmacologically active, thus alleviating any concern by the Panel for the lack of repeated dose and reproductive and developmental data for these ingredients.

The Panel also noted heavy metals may be present in these ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to minimize impurities in cosmetic formulations according to limits set by the US FDA and Environmental Protection Agency (EPA).

The Panel discussed the issue of incidental inhalation exposure resulting from these ingredients. 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 these ingredients. Coupled with the small actual exposure in the breathing zone and the low concentrations at which these ingredients are 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>.

The Panel's respiratory exposure resource document notes that airbrush technology presents a potential safety concern. Although frequency and 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 that if these ingredients are used in airbrush formulations, the data are insufficient to support safe use when applied with such delivery system.

## **CONCLUSION**

The Expert Panel for Cosmetic Ingredient Safety concluded that the following 7 dimer dilinoleate ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment.

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate  
Bis-Behenyl/Phytosteryl Dimer Dilinoleate  
Dimer Dilinoleyl Dimer Dilinoleate  
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate  
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate  
Phytosteryl Isostearyl Dimer Dilinoleate  
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate

## TABLES

**Table 1. Definitions and reported functions<sup>1</sup>**

| <b>Ingredient/CAS No.</b>  | <b>Definition</b>   | <b>Function(s)</b>  |
|--|---|---|
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate<br>CAS No. 654651-30-6 | Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate is Dimer Dilinoleyl Dimer Dilinoleate end-capped with a mixture of phytosterols, behenyl alcohol, and isostearyl alcohol.         | hair condition agent; skin-conditioning agent – emollient; skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous             |
| Bis-Behenyl/Phytosteryl Dimer Dilinoleate  | Bis-Behenyl/Phytosteryl Dimer Dilinoleate is the ester of a mixture of behenyl alcohol and phytosterols with dimer dilinoleic acid.   | hair condition agent; skin-conditioning agent – emollient; skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous             |
| Dimer Dilinoleyl Dimer Dilinoleate<br>CAS No. 378789-58-3                                    | Dimer Dilinoleyl Dimer Dilinoleate is the diester of dilinoleic acid with dimer dilinoleyl alcohol.   | binders; skin-conditioning agent – emollient; skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous                          |
| Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate  | Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate is the diester formed by the reaction of octyldodecanol and PPG-3 myristyl ether with dilinoleic acid.  | dispersing agent – nonsurfactant; skin-conditioning agent – emollient; skin-conditioning agent - occlusive  |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate                               | Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is the ester of dilinoleic acid with a mixture of phytosterols, isostearyl alcohol, cetyl alcohol, stearyl alcohol, and behenyl alcohol. | hair conditioning agent; skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous   |
| Phytosteryl Isostearyl Dimer Dilinoleate   | Phytosteryl Isostearyl Dimer Dilinoleate is the diester of dilinoleic acid with phytosterol and isostearyl alcohol.   | binders; hair conditioning agent; skin-conditioning agent – emollient; skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous |
| Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate<br>CAS No. 522632-67-3                        | Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate is the diester formed by the reaction of stearyl alcohol and PPG-3 myristyl ether with dilinoleic acid.  | dispersing agent – nonsurfactant; skin-conditioning agent – emollient; skin-conditioning agent - occlusive  |

**Table 2. Chemical properties**

| Property   | Value  | Reference |
|--|--|-----------|
| <b>Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate</b> |  |           |
| Physical Form  | White to pale yellow hydrophobic paste         | 13        |
| Molecular Weight (g/mol)   | > 1000   | 13        |
| Density (g/ml @ 50 °C)   | 0.89   | 13        |
| Melting Point (°C)   | ~40  | 13        |
| Water Solubility   | Insoluble                                      | 13        |
| <b>Bis-Behenyl/Phytosteryl Dimer Dilinoleate</b>                             |  |           |
| Molecular Weight (g/mol)   | 1180 - 1356                                    | 15        |
| Vapor Pressure (mmHg @ 25°C)   | $9.14 \times 10^{-29}$ (MPBPVP v1.43 estimate) | 15        |
| Melting Point (°C)   | 349.8 (MPBPVP v1.43 estimate)                  | 15        |
| Boiling Point (°C)   | 1114.5 (MPBPVP v1.43 estimate)                 | 15        |
| Water Solubility @ 25°C (mg/l)   | $6.99 \times 10^{-34}$ (WSKOW v1.42 estimate)  | 15        |
| log K <sub>ow</sub>  | 36.09 (WSKOW v1.42 estimate)                   | 15        |
| <b>Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate</b>                   |  |           |
| Molecular Weight (g/mol)   | 1179 - 1305                                    | 15        |
| Vapor Pressure (mmHg @ 25°C)   | $7.52 \times 10^{-28}$ (MPBPVP v1.43 estimate) | 15        |
| Melting Point (°C)   | 349.8 (MPBPVP v1.43 estimate)                  | 15        |
| Boiling Point (°C)   | 1082.6 (MPBPVP v1.43 estimate)                 | 15        |
| Water Solubility @ 25°C (mg/l)   | $1.12 \times 10^{-30}$ (WSKOW v1.42 estimate)  | 15        |
| log K <sub>ow</sub>  | 32.6 (KOWWIN v1.68 estimate)                   | 15        |
| <b>Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate</b>        |  |           |
| Physical Form  | White to pale yellow paste                     | 14        |
| Molecular Weight (g/mol)   | 1011 - 1356                                    | 15        |
| Viscosity (kg/(s x m)@ 60 °C)  | 0.18   | 14        |
| Melting Point (°C)   | 38   | 14        |
| Water Solubility @ 25°C (mg/l)   | $8.79 \times 10^{-31}$ (WSKOW v1.42 estimate)  | 15        |
| log K <sub>ow</sub>  | 33.14 (WSKOW v1.42 estimate)                   | 15        |
| <b>Phytosteryl Isostearyl Dimer Dilinoleate</b>                              |  |           |
| Molecular Weight (g/mol)   | 1069 - 1356                                    | 15        |
| Vapor Pressure (mmHg @ 25°C)   | $3.11 \times 10^{-27}$ (MPBPVP v1.43 estimate) | 15        |
| Melting Point (°C)   | 349.8 (MPBPVP v1.43 estimate)                  | 15        |
| Boiling Point (°C)   | 1061.1 (MPBPVP v1.43 estimate)                 | 15        |
| Water Solubility @ 25°C (mg/l)   | $9.41 \times 10^{-32}$ (WSKOW v1.42 estimate)  | 15        |
| log K <sub>ow</sub>  | 34.05 (WSKOW v1.42 estimate)                   | 15        |
| <b>Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate</b>                        |  |           |
| Molecular Weight (g/mol)   | 1069 - 1305                                    | 15        |
| Vapor Pressure (mmHg @ 25°C)   | $1.01 \times 10^{-26}$ (MPBPVP v1.43 estimate) | 15        |
| Melting Point (°C)   | 349.8 (MPBPVP v1.43 estimate)                  | 15        |
| Boiling Point (°C)   | 1043.2 (MPBPVP v1.43 estimate)                 | 15        |
| Water Solubility @ 25°C (mg/l)   | $1.13 \times 10^{-28}$ (WSKOW v1.42 estimate)  | 15        |
| log K <sub>ow</sub>  | 30.7 (KOWWIN v1.68 estimate)                   | 15        |

**Table 3. 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        |  |
|--|---|--|---|--|------------------------------------|--|------------------------|--|
|  | RLD (2025) <sup>18,19</sup>   |  | % (2025) <sup>20</sup>                    |  | RLD (2025) <sup>18,19</sup>        |  | % (2025) <sup>20</sup> |  |
|  | Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate |  | Bis-Behenyl/Phytosteryl Dimer Dilinoleate |  | Dimer Dilinoleyl Dimer Dilinoleate |  |                        |  |
| <b>Totals*</b>   | <b>2474</b>   |  | <b>0.15-30.1</b>                          |  | <b>45</b>                          |  | <b>NR</b>              |  |
| <b>summarized by likely duration and exposure**</b>                          |   |  |   |  |                                    |  |                        |  |
| <b>Duration of Use</b>   |   |  |   |  |                                    |  |                        |  |
| Leave-On   | 2506  |  | 0.15-30.1                                 |  | 45                                 |  | NR                     |  |
| Rinse-Off  | 12  |  | 0.2-3.6                                   |  | NR                                 |  | NR                     |  |
| Diluted for (Bath) Use   | NR  |  | NR  |  | NR                                 |  | NR                     |  |
| Unknown  | 7   |  | NR  |  | NR                                 |  | NR                     |  |
| <b>Exposure Type</b>   |   |  |   |  |                                    |  |                        |  |
| Baby Products  | NR  |  | NR  |  | NR                                 |  | NR                     |  |
| Children's Makeup  | 1   |  | NR  |  | NR                                 |  | NR                     |  |
| Eye Area   | 348   |  | 0.15-11.7                                 |  | 4                                  |  | NR                     |  |
| Incidental Ingestion   | 1802  |  | 3-30.1                                    |  | 39                                 |  | NR                     |  |
| Mucous Membrane  | 1802  |  | 3-30.1                                    |  | 39                                 |  | NR                     |  |
| Incidental Inhalation-Spray  | 36 <sup>a</sup> ; 73 <sup>b</sup>                                     |  | 1.6 <sup>b</sup>                          |  | 1 <sup>a</sup> ; 1 <sup>b</sup>    |  | NR                     |  |
| Incidental Inhalation-Airbrush   | NR  |  | NR  |  | NR                                 |  | NR                     |  |
| Incidental Inhalation-Powder   | 43; 73 <sup>b</sup>   |  | 0.4-2.9; 0.4-3 <sup>c</sup>               |  | 1 <sup>b</sup>                     |  | NR                     |  |
| Dermal Contact   | 700   |  | 0.15-11.7                                 |  | 6                                  |  | NR                     |  |
| Deodorant (underarm)   | NR  |  | NR  |  | NR                                 |  | NR                     |  |
| Hair - Non-Coloring  | 14  |  | 1.6                                       |  | NR                                 |  | NR                     |  |
| Hair-Coloring  | NR  |  | NR  |  | NR                                 |  | NR                     |  |
| Nail   | 2   |  | NR  |  | NR                                 |  | NR                     |  |
| Other Preparations (Unknown Exposure Type)                                   | 7   |  | NR  |  | NR                                 |  | NR                     |  |
| <b>as reported by product category</b>                                       |   |  |   |  |                                    |  |                        |  |
| <b>Baby Products</b>   |   |  |   |  |                                    |  |                        |  |
| Baby Shampoos  |   |  |   |  |                                    |  |                        |  |
| Baby Lotions/Oils/Powders/Creams   |   |  |   |  |                                    |  |                        |  |
| Other Baby Products  |   |  |   |  |                                    |  |                        |  |
| <b>Eye Makeup Preparations (not children's)</b>                              |   |  |   |  |                                    |  |                        |  |
| Eyebrow Pencil   | 36  |  | 0.15-2.5                                  |  | 4                                  |  | NR                     |  |
| Eyeliners  | 23  |  | 0.98-11.7                                 |  |                                    |  | 2                      |  |
| Eye Shadow   | 270   |  | 1.4-7                                     |  |                                    |  | 85                     |  |
| Eye Lotion   | 2   |  | NR  |  |                                    |  | 1                      |  |
| False Eyelashes  |   |  |   |  |                                    |  |                        |  |
| Mascara  |   |  |   |  |                                    |  | 44                     |  |
| Eyelash and Eyebrow Adhesives/Glues/Sealants                                 |   |  |   |  |                                    |  | 1                      |  |
| Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers) | 1   |  | 4   |  |                                    |  | 8                      |  |
| Other Eye Makeup Preparations  | 16  |  | 2.1                                       |  |                                    |  | 25                     |  |
| <b>Fragrance Preparations</b>  |   |  |   |  |                                    |  |                        |  |
| Powders (dusting/talcum, excl aftershave talc)                               |   |  |   |  |                                    |  |                        |  |
| Other Fragrance Preparation  |   |  |   |  |                                    |  | 3                      |  |
| <b>Hair Preparations (non-coloring)</b>                                      |   |  |   |  |                                    |  |                        |  |
| Hair Conditioners  | 1 (l.o.); 9 (r.o.)  |  | 1.6 (r.o.)                                |  |                                    |  | 10 (l.o.); 43 (r.o.)   |  |
| Hair Straighteners   |   |  |   |  |                                    |  | 3                      |  |
| Permanent Waves  |   |  |   |  |                                    |  | 1                      |  |
| Rinses (non-coloring)  |   |  |   |  |                                    |  | 9                      |  |

**Table 3. 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 (2025) <sup>18,19</sup> | % (2025) <sup>20</sup>   | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> |
| Shampoos (non-coloring)  |                             |                          |                             |                        | 20 (r.o.)                   | NR                     |
| Tonics, Dressings, Other Hair Grooming Aids                              | 1                           | 1.6                      |                             |                        | 7                           | NR                     |
| Other Hair Preparations  | 3 (l.o.)                    | NR                       |                             |                        | 4 (l.o.); 5 (r.o.)          | NR                     |
| <b>Hair Coloring Preparations</b>  |                             |                          |                             |                        |                             |                        |
| Other Hair Coloring Preparation  |                             |                          |                             |                        | 2                           | NR                     |
| <b>Makeup Preparations (not eye or children's)</b>                       |                             |                          |                             |                        |                             |                        |
| Blushers and Rouges (all types)  | 77                          | 2.9                      |                             |                        | 39                          | 7-8                    |
| Face Powders   | 43                          | 0.4-2.9                  |                             |                        | 38                          | NR                     |
| Foundations  | 69                          | 0.5                      |                             |                        | 98                          | 0.1-4.3                |
| Leg and Body Paints  | 1                           | NR                       |                             |                        |                             |                        |
| Lipsticks and Lip Glosses  | 1801                        | 3-30.1                   | 39                          | NR                     | 632                         | 11.3-48.7              |
| Makeup Bases   | 3                           | NR                       |                             |                        | 1                           | NR                     |
| Makeup Fixatives   | 2                           | NR                       |                             |                        | 4                           | NR                     |
| Other Makeup Preparations  | 50                          | NR                       |                             |                        | 42                          | NR                     |
| <b>Makeup Preparations for Children (not eye)</b>                        |                             |                          |                             |                        |                             |                        |
| Children's Lipsticks and Lip Glosses                                     | 1                           | NR                       |                             |                        | 2                           | NR                     |
| <b>Manicuring Preparations</b>   |                             |                          |                             |                        |                             |                        |
| Cuticle Softeners  |                             |                          |                             |                        | 1                           | NR                     |
| Nail Creams and Lotions  |                             |                          |                             |                        | 3                           | NR                     |
| Nail Polish and Enamel   | 2                           | NR                       |                             |                        |                             |                        |
| Other Manicuring Preparations  |                             |                          |                             |                        | 3                           | NR                     |
| <b>Personal Cleanliness</b>  |                             |                          |                             |                        |                             |                        |
| Bath Soaps and Body Washes   |                             |                          |                             |                        |                             |                        |
| <b>Shaving Preparations</b>  |                             |                          |                             |                        |                             |                        |
| Beard Softeners  |                             |                          |                             |                        | 1                           | NR                     |
| Pre-shave Lotions (all types)  |                             |                          |                             |                        | 1                           | NR                     |
| Shaving Cream (aerosol, brushless, lather)                               | NR                          | 0.6                      |                             |                        |                             |                        |
| <b>Skin Care Preparations</b>  |                             |                          |                             |                        |                             |                        |
| Cleansing  | 2                           | NR                       |                             |                        | 2                           | NR                     |
| Face and Neck (excluding shaving preps)                                  | 49 (l.o.)                   | 0.4-3 (l.o.); 0.2 (r.o.) | 1 (l.o.)                    | NR                     | 28 (l.o.)                   | 3.2 (l.o.)             |
| Body and Hand (excluding shaving preps)                                  | 1 (l.o.)                    | NR                       |                             |                        | 3 (l.o.)                    | NR                     |
| Foot Powders and Sprays  | 1                           | NR                       |                             |                        |                             |                        |
| Moisturizing   | 33                          | 1-3                      |                             |                        | 27                          | NR                     |
| Night  | 2                           | NR                       | 1                           | NR                     | 5                           | 3.2                    |
| Paste Masks (mud packs)  | NR                          | 3.6                      |                             |                        |                             |                        |
| Skin Fresheners  |                             |                          |                             |                        | 7                           | NR                     |
| Other Skin Care Preparations   | 18 (l.o.); 1 (r.o.)         | NR                       |                             |                        | 15 (l.o.); 1 (r.o.)         | 6 (l.o.)               |
| <b>Suntan Preparations</b>   |                             |                          |                             |                        |                             |                        |
| Suntan Gels, Creams, and Liquids   |                             |                          |                             |                        |                             |                        |
| Indoor Tanning Preparations  |                             |                          |                             |                        |                             |                        |
| <b>Other Preparations (i.e., those that do not fit another category)</b> | 7                           | NR                       |                             |                        | 12                          |                        |

**Table 3. 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 (2025) <sup>18,19</sup>                         | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup>                                    | % (2025) <sup>20</sup>      | RLD (2025) <sup>18,19</sup>              | % (2025) <sup>20</sup> |
|  | Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate |                        | Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate |                             | Phytosteryl Isostearyl Dimer Dilinoleate |                        |
| <b>Totals*</b>   | <b>32</b>   | <b>10</b>              | <b>1998</b>  | <b>0.6-30</b>               | <b>202</b>                               | <b>0.099</b>           |
| <b>summarized by likely duration and exposure**</b>                          |   |                        |  |                             |  |                        |
| <b>Duration of Use</b>   |   |                        |  |                             |  |                        |
| Leave-On   | 32  | 10                     | 2197   | 0.6-30                      | 230                                      | 0.099                  |
| Rinse-Off  | NR  | NR                     | 30   | NR                          | 8  | NR                     |
| Diluted for (Bath) Use   | NR  | NR                     | NR   | NR                          | NR                                       | NR                     |
| Unknown  | NR  | NR                     | 2  | NR                          | 1  | NR                     |
| <b>Exposure Type</b>   |   |                        |  |                             |  |                        |
| Baby Products  | NR  | NR                     | 3  | NR                          | 2  | NR                     |
| Children's Makeup  | NR  | NR                     | NR   | NR                          | 3  | NR                     |
| Eye Area   | NR  | NR                     | 110  | 0.88-12.6                   | 5  | NR                     |
| Incidental Ingestion   | 31  | 10                     | 1393   | 15.1-30                     | 145                                      | NR                     |
| Mucous Membrane  | 31  | 10                     | 1393   | 15.1-30                     | 146                                      | NR                     |
| Incidental Inhalation-Spray  | NR  | NR                     | 1; 165 <sup>a</sup> ; 264 <sup>b</sup>                         | NR                          | 12 <sup>a</sup> ; 19 <sup>b</sup>        | NR                     |
| Incidental Inhalation-Airbrush   | NR  | NR                     | NR   | NR                          | NR                                       | NR                     |
| Incidental Inhalation-Powder   | NR  | NR                     | 37; 264 <sup>b</sup> ; 1 <sup>c</sup>                          | 1.4-1.6; 0.6-3 <sup>c</sup> | 2; 19 <sup>b</sup> ; 1 <sup>c</sup>      | 0.099                  |
| Dermal Contact   | 1   | NR                     | 820  | 0.6-13                      | 83                                       | 0.099                  |
| Deodorant (underarm)   | NR  | NR                     | NR   | NR                          | NR                                       | NR                     |
| Hair - Non-Coloring  | NR  | NR                     | 10   | NR                          | 4  | NR                     |
| Hair-Coloring  | NR  | NR                     | NR   | NR                          | NR                                       | NR                     |
| Nail   | NR  | NR                     | 4  | NR                          | 6  | NR                     |
| Other Preparations (Unknown Exposure Type)                                   | NR  | NR                     | 2  | NR                          | 1  | NR                     |
| <b>as reported by product category</b>                                       |   |                        |  |                             |  |                        |
| <b>Baby Products</b>   |   |                        |  |                             |  |                        |
| Baby Shampoos  |   |                        |  |                             | 1  | NR                     |
| Baby Lotions/Oils/Powders/Creams   |   |                        | 1  | NR                          | 1  | NR                     |
| Other Baby Products  |   |                        | 2 (l.o.)   | NR                          |  |                        |
| <b>Eye Makeup Preparations (not children's)</b>                              |   |                        |  |                             |  |                        |
| Eyebrow Pencil   |   |                        | 28   | 0.88-4.8                    | 2  | NR                     |
| Eyeliners  |   |                        | 2  | NR                          | 1  | NR                     |
| Eye Shadow   |   |                        | 65   | 3.6-12.6                    |  |                        |
| Eye Lotion   |   |                        | 2  | NR                          | 1  | NR                     |
| False Eyelashes  |   |                        | 1  | NR                          |  |                        |
| Mascara  |   |                        |  |                             |  |                        |
| Eyelash and Eyebrow Adhesives/Glues/Sealants                                 |   |                        |  |                             |  |                        |
| Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers) |   |                        |  |                             |  |                        |
| Other Eye Makeup Preparations  |   |                        | 12   | NR                          | 1  | NR                     |
| <b>Fragrance Preparations</b>  |   |                        |  |                             |  |                        |
| Powders (dusting/talcum, excl aftershave talc)                               |   |                        |  |                             | 1  | NR                     |
| Other Fragrance Preparation  |   |                        | 1  | NR                          |  |                        |
| <b>Hair Preparations (non-coloring)</b>                                      |   |                        |  |                             |  |                        |
| Hair Conditioners  |   |                        | 2 (r.o.)   | NR                          | 1 (r.o.)                                 | NR                     |
| Hair Straighteners   |   |                        |  |                             |  |                        |
| Permanent Waves  |   |                        |  |                             |  |                        |
| Rinses (non-coloring)  |   |                        | 1  | NR                          | 1  | NR                     |
| Shampoos (non-coloring)  |   |                        |  |                             | 1 (r.o.)                                 | NR                     |

**Table 3. 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 (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> |
| Tonics, Dressings, Other Hair Grooming Aids                                     |                             |                        | 5                           | NR                     |                             |                        |
| Other Hair Preparations   |                             |                        | 2 (r.o.)                    | NR                     |                             |                        |
| <b><i>Hair Coloring Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Other Hair Coloring Preparation   |                             |                        |                             |                        |                             |                        |
| <b><i>Makeup Preparations (not eye or children's)</i></b>                       |                             |                        |                             |                        |                             |                        |
| Blushers and Rouges (all types)   |                             |                        | 106                         | 12                     | 29                          | NR                     |
| Face Powders  |                             |                        | 37                          | 1.4-1.6                | 1                           | 0.099                  |
| Foundations   |                             |                        | 57                          | 13                     | 5                           | NR                     |
| Leg and Body Paints   |                             |                        |                             |                        | 1                           | NR                     |
| Lipsticks and Lip Glosses   | 31                          | 10                     | 1393                        | 15.1-30                | 142                         | NR                     |
| Makeup Bases  |                             |                        | 10                          | NR                     | 1                           | NR                     |
| Makeup Fixatives  |                             |                        | 23                          | NR                     |                             |                        |
| Other Makeup Preparations   | 1                           | NR                     | 33                          | NR                     | 3                           | NR                     |
| <b><i>Makeup Preparations for Children (not eye)</i></b>                        |                             |                        |                             |                        |                             |                        |
| Children's Lipsticks and Lip Glosses  |                             |                        |                             |                        | 3                           | NR                     |
| <b><i>Manicuring Preparations</i></b>   |                             |                        |                             |                        |                             |                        |
| Cuticle Softeners   |                             |                        | 1                           | NR                     |                             |                        |
| Nail Creams and Lotions   |                             |                        | 1                           | NR                     | 3                           | NR                     |
| Nail Polish and Enamel  |                             |                        | 2                           | NR                     |                             |                        |
| Other Manicuring Preparations   |                             |                        |                             |                        | 3                           | NR                     |
| <b><i>Personal Cleanliness</i></b>  |                             |                        |                             |                        |                             |                        |
| Bath Soaps and Body Washes  |                             |                        |                             |                        | 1                           | NR                     |
| <b><i>Shaving Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Beard Softeners   |                             |                        |                             |                        |                             |                        |
| Pre-shave Lotions (all types)   |                             |                        |                             |                        |                             |                        |
| Shaving Cream (aerosol, brushless, lather)                                      |                             |                        |                             |                        |                             |                        |
| <b><i>Skin Care Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Cleansing   |                             |                        | 14                          | NR                     | 2                           | NR                     |
| Face and Neck (excluding shaving preps)   |                             |                        | 200 (l.o.); 3 (r.o.)        | 0.6-3 (l.o.)           | 14 (l.o.)                   | NR                     |
| Body and Hand (excluding shaving preps)   |                             |                        | 10 (l.o.)                   | 3                      | 1 (l.o.)                    | NR                     |
| Foot Powders and Sprays   |                             |                        |                             |                        |                             |                        |
| Moisturizing  |                             |                        | 141                         | 3.4                    | 10                          | NR                     |
| Night   |                             |                        | 14                          | NR                     | 1                           | NR                     |
| Paste Masks (mud packs)   |                             |                        | 4                           | NR                     | 1                           | NR                     |
| Skin Fresheners   |                             |                        | 2                           | NR                     |                             |                        |
| Other Skin Care Preparations  |                             |                        | 49 (l.o.); 3 (r.o.)         | NR                     | 4 (l.o.)                    | NR                     |
| <b><i>Suntan Preparations</i></b>   |                             |                        |                             |                        |                             |                        |
| Suntan Gels, Creams, and Liquids  |                             |                        |                             |                        | 1                           | NR                     |
| Indoor Tanning Preparations   |                             |                        |                             |                        | 1                           | NR                     |
| <b><i>Other Preparations (i.e., those that do not fit another category)</i></b> |                             |                        |                             |                        | 1                           | NR                     |

**Table 3. 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 (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> |
| <b>Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate</b>                        |                             |                        |                             |                        |                             |                        |
| <b>Totals*</b>   | <b>44</b>                   | <b>4.7-8.9</b>         |                             |                        |                             |                        |
| <b>summarized by likely duration and exposure**</b>                          |                             |                        |                             |                        |                             |                        |
| <b>Duration of Use</b>   |                             |                        |                             |                        |                             |                        |
| <i>Leave-On</i>  | 44                          | 4.7-8.9                |                             |                        |                             |                        |
| <i>Rinse-Off</i>   | NR                          | NR                     |                             |                        |                             |                        |
| <i>Diluted for (Bath) Use</i>  | NR                          | NR                     |                             |                        |                             |                        |
| <i>Unknown</i>   | NR                          | NR                     |                             |                        |                             |                        |
| <b>Exposure Type</b>   |                             |                        |                             |                        |                             |                        |
| Baby Products  | NR                          | NR                     |                             |                        |                             |                        |
| Children's Makeup  | NR                          | NR                     |                             |                        |                             |                        |
| Eye Area   | NR                          | NR                     |                             |                        |                             |                        |
| Incidental Ingestion   | 43                          | 4.7-8.9                |                             |                        |                             |                        |
| Mucous Membrane  | 43                          | 4.7-8.9                |                             |                        |                             |                        |
| Incidental Inhalation-Spray  | NR                          | NR                     |                             |                        |                             |                        |
| Incidental Inhalation-Airbrush   | NR                          | NR                     |                             |                        |                             |                        |
| Incidental Inhalation-Powder   | NR                          | NR                     |                             |                        |                             |                        |
| Dermal Contact   | 1                           | 6.7                    |                             |                        |                             |                        |
| Deodorant (underarm)   | NR                          | NR                     |                             |                        |                             |                        |
| Hair - Non-Coloring  | NR                          | NR                     |                             |                        |                             |                        |
| Hair-Coloring  | NR                          | NR                     |                             |                        |                             |                        |
| Nail   | NR                          | NR                     |                             |                        |                             |                        |
| Other Preparations (Unknown Exposure Type)                                   | NR                          | NR                     |                             |                        |                             |                        |
| <b>as reported by product category</b>                                       |                             |                        |                             |                        |                             |                        |
| <b>Baby Products</b>   |                             |                        |                             |                        |                             |                        |
| Baby Shampoos  |                             |                        |                             |                        |                             |                        |
| Baby Lotions/Oils/Powders/Creams   |                             |                        |                             |                        |                             |                        |
| Other Baby Products  |                             |                        |                             |                        |                             |                        |
| <b>Eye Makeup Preparations (not children's)</b>                              |                             |                        |                             |                        |                             |                        |
| Eyebrow Pencil   |                             |                        |                             |                        |                             |                        |
| Eyeliner   |                             |                        |                             |                        |                             |                        |
| Eye Shadow   |                             |                        |                             |                        |                             |                        |
| Eye Lotion   |                             |                        |                             |                        |                             |                        |
| False Eyelashes  |                             |                        |                             |                        |                             |                        |
| Mascara  |                             |                        |                             |                        |                             |                        |
| Eyelash and Eyebrow Adhesives/Glues/Sealants                                 |                             |                        |                             |                        |                             |                        |
| Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers) |                             |                        |                             |                        |                             |                        |
| Other Eye Makeup Preparations  |                             |                        |                             |                        |                             |                        |
| <b>Fragrance Preparations</b>  |                             |                        |                             |                        |                             |                        |
| Powders (dusting/talcum, excl aftershave talc)                               |                             |                        |                             |                        |                             |                        |
| Other Fragrance Preparation  |                             |                        |                             |                        |                             |                        |
| <b>Hair Preparations (non-coloring)</b>                                      |                             |                        |                             |                        |                             |                        |
| Hair Conditioners  |                             |                        |                             |                        |                             |                        |
| Hair Straighteners   |                             |                        |                             |                        |                             |                        |
| Permanent Waves  |                             |                        |                             |                        |                             |                        |
| Rinses (non-coloring)  |                             |                        |                             |                        |                             |                        |
| Shampoos (non-coloring)  |                             |                        |                             |                        |                             |                        |
| Tonics, Dressings, Other Hair Grooming Aids                                  |                             |                        |                             |                        |                             |                        |

**Table 3. 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 (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> | RLD (2025) <sup>18,19</sup> | % (2025) <sup>20</sup> |
| Other Hair Preparations   |                             |                        |                             |                        |                             |                        |
| <b><i>Hair Coloring Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Other Hair Coloring Preparation   |                             |                        |                             |                        |                             |                        |
| <b><i>Makeup Preparations (not eye or children's)</i></b>                       |                             |                        |                             |                        |                             |                        |
| Blushers and Rouges (all types)   | 1                           | 6.7                    |                             |                        |                             |                        |
| Face Powders  |                             |                        |                             |                        |                             |                        |
| Foundations   |                             |                        |                             |                        |                             |                        |
| Leg and Body Paints   |                             |                        |                             |                        |                             |                        |
| Lipsticks and Lip Glosses   | 43                          | 4.7-8.9                |                             |                        |                             |                        |
| Makeup Bases  |                             |                        |                             |                        |                             |                        |
| Makeup Fixatives  |                             |                        |                             |                        |                             |                        |
| Other Makeup Preparations   |                             |                        |                             |                        |                             |                        |
| <b><i>Makeup Preparations for Children (not eye)</i></b>                        |                             |                        |                             |                        |                             |                        |
| Children's Lipsticks and Lip Glosses  |                             |                        |                             |                        |                             |                        |
| <b><i>Manicuring Preparations</i></b>   |                             |                        |                             |                        |                             |                        |
| Cuticle Softeners   |                             |                        |                             |                        |                             |                        |
| Nail Creams and Lotions   |                             |                        |                             |                        |                             |                        |
| Nail Polish and Enamel  |                             |                        |                             |                        |                             |                        |
| Other Manicuring Preparations   |                             |                        |                             |                        |                             |                        |
| <b><i>Personal Cleanliness</i></b>  |                             |                        |                             |                        |                             |                        |
| Bath Soaps and Body Washes  |                             |                        |                             |                        |                             |                        |
| <b><i>Shaving Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Beard Softeners   |                             |                        |                             |                        |                             |                        |
| Pre-shave Lotions (all types)   |                             |                        |                             |                        |                             |                        |
| Shaving Cream (aerosol, brushless, lather)                                      |                             |                        |                             |                        |                             |                        |
| <b><i>Skin Care Preparations</i></b>  |                             |                        |                             |                        |                             |                        |
| Cleansing   |                             |                        |                             |                        |                             |                        |
| Face and Neck (excluding shaving preps)   |                             |                        |                             |                        |                             |                        |
| Body and Hand (excluding shaving preps)   |                             |                        |                             |                        |                             |                        |
| Foot Powders and Sprays   |                             |                        |                             |                        |                             |                        |
| Moisturizing  |                             |                        |                             |                        |                             |                        |
| Night   |                             |                        |                             |                        |                             |                        |
| Paste Masks (mud packs)   |                             |                        |                             |                        |                             |                        |
| Skin Fresheners   |                             |                        |                             |                        |                             |                        |
| Other Skin Care Preparations  |                             |                        |                             |                        |                             |                        |
| <b><i>Suntan Preparations</i></b>   |                             |                        |                             |                        |                             |                        |
| Suntan Gels, Creams, and Liquids  |                             |                        |                             |                        |                             |                        |
| Indoor Tanning Preparations   |                             |                        |                             |                        |                             |                        |
| <b><i>Other Preparations (i.e., those that do not fit another category)</i></b> |                             |                        |                             |                        |                             |                        |

NR – not reported

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>)

<sup>a</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

<sup>b</sup> 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

<sup>c</sup> It is possible these products are powders, but it is not specified whether the reported uses are powders.

**Table 4. Acute toxicity studies**

| Test Article  | Vehicle      | Animals/Group  | Concentration/Dose | Protocol   | LD <sub>50</sub> /LC <sub>50</sub> /Results  | Reference |
|---|--------------|--|--------------------|--|--|-----------|
| <b>ORAL</b>   |              |  |                    |  |  |           |
| Bis-Behenyl/Isostearyl/<br>Phytosteryl Dimer<br>Dilinoleyl Dimer<br>Dilinoleate | DMSO         | 6 female Sprague-Dawley CD<br>(CrI: CD (SD) IGS BR rats                | 2000 mg/kg bw      | Acute toxicity test performed in accordance with OECD TG 423; rats received 10 ml/kg test material in a single gavage treatment. Clinical signs and body weight development were monitored during the study for up to 14 d after dosing. All animals subjected to gross necropsy | LD <sub>50</sub> > 2000 mg/kg; no deaths or clinical signs of toxicity were observed. All animals had expected body weight gains and no abnormalities were noted at necropsy.  | 10,25     |
| Bis-Behenyl/Isostearyl/<br>Phytosteryl Dimer<br>Dilinoleyl Dimer<br>Dilinoleate | not reported | rats; no further details<br>provided                                   | at most 2000 mg/kg | Acute toxicity test performed in accordance with OECD TG 423; no further details provided  | LD <sub>50</sub> > 2000 mg/kg  | 13        |
| Dimer Dilinoleyl<br>Dimer Dilinoleate   | arachis oil  | 3 male and 3 female Sprague-<br>Dawley CD (CrI: CD (SD)<br>IGS BR rats | 2000 mg/kg bw      | Acute toxicity test performed in accordance with OECD TG 423; rats received 10 ml/kg test material in a single gavage treatment. Clinical signs and body weight development were monitored during the study for up to 14 d after dosing. All animals subjected to gross necropsy | LD <sub>50</sub> > 2000 mg/kg; no deaths occurred during study. Hunched posture was noted in all female rats 1 d after dosing. No signs of systemic toxicity noted in males. All animals had expected body weight gains and no abnormalities were noted at necropsy. | 10,24     |
| Phytosteryl/Isostearyl/<br>Cetyl/Stearyl/Behenyl<br>Dimer Dilinoleate           | arachis oil  | 6 female Sprague-Dawley CD<br>(CrI: CD (SD) IGS BR rats                | 2000 mg/kg bw      | Acute toxicity test performed in accordance with OECD TG 423; rats received 10 ml/kg test material in a single gavage treatment. Clinical signs and body weight development were monitored during the study for up to 14 d after dosing. All animals subjected to gross necropsy | LD <sub>50</sub> > 2000 mg/kg; no deaths or clinical signs of toxicity were observed. All animals had expected body weight gains and no abnormalities were noted at necropsy.  | 10,23     |
| Phytosteryl/Isostearyl/<br>Cetyl/Stearyl/Behenyl<br>Dimer Dilinoleate           | undiluted    | not reported   | at most 2500 mg/kg | Acute toxicity test performed in accordance with OECD TG 423; no further details provided  | LD <sub>50</sub> > 2500 mg/kg  | 10,14     |
| Phytosteryl Isostearyl<br>Dimer Dilinoleate                                     | arachis oil  | 3 male and 3 female Sprague-<br>Dawley CD (CrI: CD (SD)<br>IGS BR rats | 2000 mg/kg bw      | Acute toxicity test performed in accordance with OECD TG 423; rats received 10 ml/kg test material in a single gavage treatment. Clinical signs and body weight development were monitored during the study for up to 14 d after dosing. All animals subjected to gross necropsy | LD <sub>50</sub> > 2000 mg/kg; no deaths or clinical signs of toxicity were observed. All animals had expected body weight gains and no abnormalities were noted at necropsy.  | 10,22     |

**Table 5. Genotoxicity studies**

| Test Article  | Vehicle      | Concentration/Dose | Test System  | Protocol  | Results       | Reference |
|---|--------------|--------------------|--------------|---|---------------|-----------|
| <b>IN VITRO</b>   |              |                    |              |   |               |           |
| <i>Gene Mutation</i>  |              |                    |              |   |               |           |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | not reported | not reported       | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 13        |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted    | 100%               | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 10        |
| Bis-Behenyl/Phytosteryl Dimer Dilinoleate                             | undiluted    | 100%               | not reported | Ames test; no further details provided  | Not mutagenic | 10        |
| Dimer Dilinoleyl Dimer Dilinoleate                                    | undiluted    | 100%               | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 10        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted    | 100%               | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 10        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted    | 100%               | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 10        |
| Phytosteryl Isostearyl Dimer Dilinoleate                              | undiluted    | 100%               | not reported | Ames test in accordance with OECD TG 471; no further details provided                   | Not mutagenic | 10        |
| <i>Chromosomal Damage</i>   |              |                    |              |   |               |           |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted    | 100%               | not reported | Chromosome aberration test using mammalian cell cultures; no further details provided   | Not genotoxic | 10        |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | not reported | not reported       | not reported | In vitro micronucleus assay in accordance with OECD TG 487; no further details provided | Not genotoxic | 13        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted    | 100%               | not reported | Chromosome aberration test using mammalian cell cultures; no further details provided   | Not genotoxic | 10        |
| Phytosteryl Isostearyl Dimer Dilinoleate                              | undiluted    | 100%               | not reported | Chromosome aberration test using mammalian cell cultures; no further details provided   | Not genotoxic | 10        |

**Table 6. Dermal irritation and sensitization studies**

| Test Article  | Vehicle   | Concentration | Test Population                          | Protocol  | Results                    | Reference |
|---|-----------|---------------|--|---|----------------------------|-----------|
| <b>IRRITATION</b>   |           |               |  |   |                            |           |
| <b>ANIMAL</b>   |           |               |  |   |                            |           |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted | 100%          | not reported                             | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Non-irritating             | 10        |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted | 100%          | rabbit; no further details provided      | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Non-irritating             | 13        |
| Dimer Dilinoleyl Dimer Dilinoleate                                    | undiluted | 100%          | not reported                             | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Mild irritant              | 10        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted | 100%          | not reported                             | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Non-irritating             | 10        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted | 100%          | not reported                             | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Non-irritating             | 10        |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted | 100%          | guinea pigs; no further details provided | Cumulative skin irritation study; no further details provided                             | Non-irritating             | 10        |
| Phytosteryl Isostearyl Dimer Dilinoleate                              | undiluted | 100%          | not reported                             | Primary skin irritation study in accordance with OECD TG 404; no further details provided | Mild irritant              | 10        |
| Phytosteryl Isostearyl Dimer Dilinoleate                              | undiluted | 100%          | guinea pigs; no further details provided | Cumulative skin irritation study; no further details provided                             | Practically non-irritating | 10        |

**Table 6. Dermal irritation and sensitization studies**

| Test Article  | Vehicle      | Concentration | Test Population | Protocol   | Results                       | Reference        |
|---|--------------|---------------|-----------------|--|-------------------------------|------------------|
| <b>HUMAN</b>  |              |               |                 |  |                               |                  |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate                           | undiluted    | 100%          | 42 subjects     | 24-h closed patch test; no further details provided  | Not irritating                | <sup>10</sup>    |
| Dimer Dilinoleyl Dimer Dilinoleate  | undiluted    | 100%          | 42 subjects     | 24-h closed patch test; no further details provided  | Not irritating                | <sup>10</sup>    |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate                                  | undiluted    | 100%          | 45 subjects     | 24-h closed patch test; no further details provided  | Not irritating                | <sup>10</sup>    |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate                                  | undiluted    | 100%          | 45 subjects     | 24-h closed patch test; no further details provided  | Not irritating                | <sup>10,14</sup> |
| Phytosteryl Isostearyl Dimer Dilinoleate  | undiluted    | 100%          | 45 subjects     | 24-h closed patch test; no further details provided  | Not irritating                | <sup>10</sup>    |
| <b>SENSITIZATION</b>  |              |               |                 |  |                               |                  |
| <b>ANIMAL</b>   |              |               |                 |  |                               |                  |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate                           | not reported | not reported  | not reported    | Skin sensitization adjuvant test (maximization test) in accordance with OECD TG 406; no further details provided | Not sensitizing               | <sup>13</sup>    |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate                           | not reported | 25%           | not reported    | Skin sensitization study in accordance with OECD TG 406; no further details provided                             | Not sensitizing               | <sup>10</sup>    |
| Dimer Dilinoleyl Dimer Dilinoleate  | undiluted    | 100%          | not reported    | Skin sensitization study in accordance with OECD TG 406; no further details provided                             | Not sensitizing               | <sup>10</sup>    |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate                                  | undiluted    | 100%          | not reported    | Skin sensitization study in accordance with OECD TG 406; no further details provided                             | Not sensitizing               | <sup>10</sup>    |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate                                  | undiluted    | 100%          | not reported    | Skin sensitization study in accordance with OECD TG 406; no further details provided                             | Not sensitizing               | <sup>10</sup>    |
| Phytosteryl Isostearyl Dimer Dilinoleate  | undiluted    | 100%          | not reported    | Skin sensitization study in accordance with OECD TG 406; no further details provided                             | Not sensitizing               | <sup>10</sup>    |
| <b>HUMAN</b>  |              |               |                 |  |                               |                  |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate                           | undiluted    | 100%          | 42 subjects     | HRIPT; no further details provided   | Not sensitizing               | <sup>10</sup>    |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate in a lip balm formulation | tested neat  | 3%            | 106 subjects    | HRIPT; lip balm formulation containing test article was tested undiluted; no further details provided            | Not sensitizing               | <sup>28</sup>    |
| Dimer Dilinoleyl Dimer Dilinoleate in a lip treatment formulation                               | tested neat  | 19%           | 53 subjects     | HRIPT; lip treatment formulation containing test article was tested undiluted; no further details provided       | Not irritating or sensitizing | <sup>27</sup>    |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate in a lip gloss formulation       | tested neat  | 15%           | 100 subjects    | HRIPT; lip gloss formulation containing test article was tested undiluted; no further details provided           | Not sensitizing               | <sup>26</sup>    |

**Table 7. Ocular irritation studies**

| Test Article  | Vehicle     | Concentration | Test System                                   | Protocol   | Results   | Reference |
|---|-------------|---------------|---|--|---|-----------|
| <b>IN VITRO</b>   |             |               |   |  |   |           |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted   | 100%          | human-derived epidermal keratinocytes         | MatTek EpiOcular™ corneal model; 100 µl of test material added to Millicells. Exposure was up to 4 h   | Non-irritating; test material elicited in vitro results that indicate the time of exposure to reduce viability to 50% (ET <sub>50</sub> ) is > 256 min. The estimated Draize ocular irritation score is 0.  | 10,29     |
| Dimer Dilinoleyl Dimer Dilinoleate                                    | undiluted   | 100%          | human-derived epidermal keratinocytes         | MatTek EpiOcular™ corneal model; 100 µl of test material added to Millicells. Exposure was up to 4 h   | Non-irritating; the ET <sub>50</sub> is > 256 min. The estimated Draize ocular irritation score is 0.   | 10,30     |
| Dimer Dilinoleyl Dimer Dilinoleate                                    | mineral oil | 0.05 or 5%    | epithelial cell line from rabbit cornea       | Eye irritation study using the short time exposure method in accordance with OECD TG 491; 200 µl of test material added to cells for 5 min. Tested in triplicate   | Not categorized as eye irritant; mean cell viability was 89.5% at 0.05% concentration and 93.1% at 5% concentration   | 10,31     |
| <b>ANIMAL</b>   |             |               |   |  |   |           |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted   | 100%          | 3 female New Zealand albino rabbits           | Ocular irritation study in accordance with OECD TG 405; 0.1 ml of the test material was instilled in the conjunctival sac of the left eye of each rabbit. Untreated right eye served as a control. Eyes were not rinsed and evaluated at 1, 24, 48, and 72 h post-instillation | Practically non-irritating; slight redness (score 1) was observed in all animals at 1 h   | 10,32     |
| Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate | undiluted   | 100%          | rabbits; no further details provided          | Ocular irritation study in accordance with OECD TG 405; no further details provided  | Slightly irritating   | 13        |
| Dimer Dilinoleyl Dimer Dilinoleate                                    | undiluted   | 100%          | 3 New Zealand White rabbits; sex not reported | Ocular irritation study in accordance with OECD TG 405; 0.1 ml of the test material was instilled in the conjunctival sac of the right eye of each rabbit. Untreated left eye served as a control. Eyes were not rinsed and evaluated at 1, 24, 48, and 72 h post-instillation | Minimal irritation; no corneal or iridial effects were observed, but moderate conjunctival irritation was noted in all treated eyes 1 h after treatment with minimal conjunctival irritation at 24 h  | 10,34     |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted   | 100%          | 3 New Zealand White rabbits; sex not reported | Ocular irritation study in accordance with OECD TG 405; 0.1 ml of the test material was instilled in the conjunctival sac of the right eye of each rabbit. Untreated left eye served as a control. Eyes were not rinsed and evaluated at 1, 24, 48, and 72 h post-instillation | Minimal irritation; no corneal or iridial effects were observed, but moderate conjunctival irritation was noted in all treated eyes 1 h after treatment with minimal conjunctival irritation at 24 h  | 10,33     |
| Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate        | undiluted   | 100%          | not reported                                  | Ocular irritation study in accordance with OECD TG 405; no further details provided  | Minimal irritation  | 10,14     |
| Phytosteryl Isostearyl Dimer Dilinoleate                              | undiluted   | 100%          | 3 New Zealand White rabbits; sex not reported | Ocular irritation study in accordance with OECD TG 405; 0.1 ml of the test material was instilled in the conjunctival sac of the right eye of each rabbit. Untreated left eye served as a control. Eyes were not rinsed and evaluated at 1, 24, 48, and 72 h post-instillation | Minimal irritation; no corneal or iridial effects were observed, but moderate conjunctival irritation was noted in 1 rabbit with minimal conjunctival irritation in the other 2 rabbits 1 h after treatment. Minimal conjunctival irritation was observed in the 1 rabbit at 24 h | 10,35     |

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