
Amended Safety Assessment of Dialkyl Dimer Dilinoleates as Used in Cosmetics

Status: Tentative Amended Report for Public Comment
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All interested persons are provided 60 days from the above date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included.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 All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a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 2018 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya A. Cherian, Scientific Analyst/Writer.

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ABSTRACT: The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) reviewed the safety of 8 dialkyl dimer dilinoleates as used in cosmetics. These ingredients are diesters formed from the reaction of straight-chained or branched alkyl alcohols and dilinoleic acid; and they are reported to function in cosmetics as skin-conditioning agents. The Panel reviewed data relevant to the safety of these ingredients and concluded that Diisopropyl Dimer Dilinoleate, Dicetearyl Dimer Dilinoleate, Diisostearyl Dimer Dilinoleate, Diethylhexyl Dimer Dilinoleate, Dioctyldodecyl Dimer Dilinoleate, Ditridecyl Dimer Dilinoleate, Di-C16-18 Alkyl Dimer Dilinoleate, and Di-C20-40 Alkyl Dimer Dilinoleate are safe in cosmetics in the present practices of use and concentration described in the safety assessment.

INTRODUCTION

The safety of 6 of the 8 cosmetic ingredients named in this safety assessment has been previously reviewed by the Panel; in 2003, the Panel issued a final report with a conclusion stating that Diisopropyl Dimer Dilinoleate, Dicetearyl Dimer Dilinoleate, Diisostearyl Dimer Dilinoleate, Diethylhexyl Dimer Dilinoleate (at the time named Dioctyl Dimer Dilinoleate), Dioctyldodecyl Dimer Dilinoleate and Ditridecyl Dimer Dilinoleate were safe as used in cosmetic formulations.¹ In accordance with its Procedures, CIR evaluates the conclusions of previously-issued reports every 15 years, and therefore a re-review was initiated. At the June 2018 meeting, the Panel reaffirmed the safe as used conclusion.

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook (wINCI Dictionary)*, the ingredients named above are reported to function as skin-conditioning agents.² Definitions, idealized structures, and functions of these ingredients can be seen in Table 1. In addition to being reported as a skin-conditioning agent, Di-C20-40 Alkyl Dimer Dilinoleate also is reported to function as a viscosity-increasing agent-nonaqueous.

In addition to the six dialkyl dimer dilinoleates mentioned above, this re-review included 2 related, previously unreviewed ingredients. The complete list of ingredients included in this assessment is:

Diisopropyl Dimer Dilinoleate
Dicetearyl Dimer Dilinoleate
Diisostearyl Dimer Dilinoleate
Diethylhexyl Dimer Dilinoleate

Dioctyldodecyl Dimer Dilinoleate
Ditridecyl Dimer Dilinoleate
Di-C16-18 Alkyl Dimer Dilinoleate
Di-C20-40 Alkyl Dimer Dilinoleate

**Previously reviewed ingredients are indicated in blue.*

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook (wINCI Dictionary)*, the ingredients named above are reported to function as skin-conditioning agents.² Definitions, idealized structures, and functions of these ingredients can be seen in Table 1. In addition to being reported as a skin-conditioning agent, Di-C20-40 Alkyl Dimer Dilinoleate also is reported to function as a viscosity-increasing agent-nonaqueous.

These dialkyl dimer dilinoleates are the diesters of their respective alcohols and dilinoleic acid. Table 2 presents all relevant alcohols previously reviewed by CIR, and a list of relevant alcohols that have not yet been reviewed by CIR can be found in Table 3.

Excerpts from the summary of the 2003 report are included throughout the text of this re-review document, as appropriate, and are *identified by italicized text*. The 2003 report contained information regarding relevant alcohols. The full reports on the alcohols can be accessed on the CIR website (<https://www.cir-safety.org/ingredients>); therefore, information regarding these alcohols will not be included in this report. Additionally, excerpts of the Discussion from the original report are included as appropriate in the Discussion included in this amended report. The Summary of this document only includes new data.

CIR safety assessments include relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, is provided on the CIR website (<http://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites>; <http://www.cir-safety.org/supplementaldoc/cir-report-format-outline>). Unpublished data are provided by the cosmetics industry, as well as by other interested parties. Although an extensive search was conducted of the literature published since the original review, no new data were found.

CHEMISTRY

Definition and Structure

All of the ingredients in this report are dialkyl dimer dilinoleates. Each ingredient is the diester formed from the reaction of straight-chained or branched-chain alkyl alcohols with dilinoleic acid. Dilinoleic acid, in turn, is the result of the catalytic dimerization of linoleic acid. This resultant dimer is a mixture of acyclic, monocyclic, and bicyclic compounds (Figure 1). Even these examples serve only as idealized structures, as the degree of unsaturation in each case is variable.³

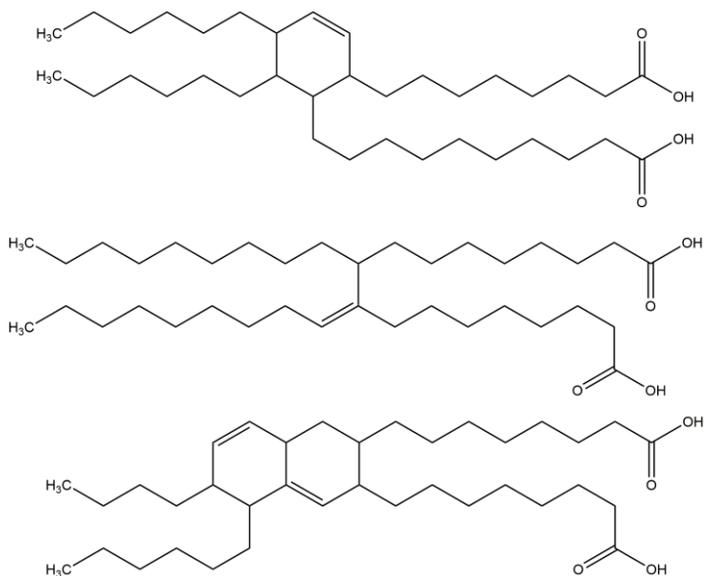


Figure 1. Examples of dinoleic acid structures.

Esterification of this mixture of acids with an alcohol then results in a mixture of esters, the dialkyl dimer dilinoleates (Figure 2.)

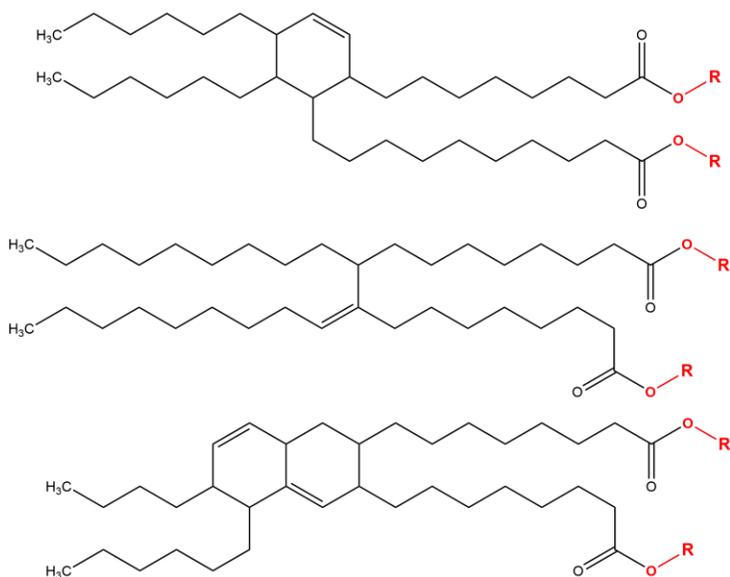


Figure 2. Examples of dialkyl dimer dilinoleates wherein O-R represents the alcohol residue.

For example, Diisopropyl Dimer Dilinoleate is the mixture of esters wherein O-R (Figure 2) is the residue of isopropyl alcohol (Figure 3).

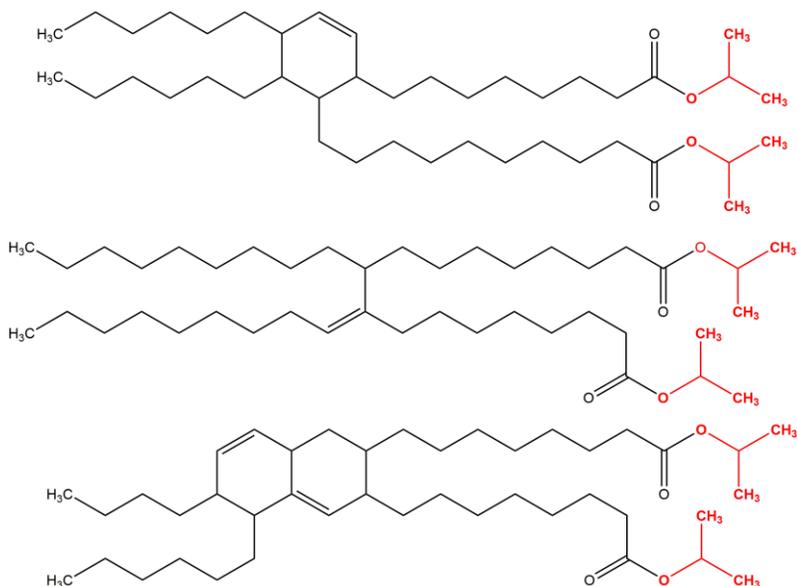


Figure 3. Diisopropyl Dimer Dilinoleate is the esterification product with isopropanol.

Physical and Chemical Properties

These ingredients present as clear to slightly yellow liquids or semi-solids that are isobaric mixtures of molecules with molecular weights ranging from 650 (diisopropyl) to nearly 1700 (di-C40) (Table 4).^{1,11,12} These substances are very lipophilic, and therefore poorly soluble in water, but soluble in suitable oils or organic solvents.

Method of Manufacture

The reviewed dialkyl dimer dilinoleates are manufactured by an esterification process using their respective alcohols and dilinoleic acid.¹

Impurities

Diisopropyl Dimer Dilinoleate

For Diisopropyl Dimer Dilinoleate, impurities were recorded as < 0.1% isopropyl alcohol and < 0.5% dilinoleic acid (test method unavailable).¹

Diisostearyl Dimer Dilinoleate

Impurities of Diisostearyl Dimer Dilinoleate were < 1% isostearyl alcohol and < 0.5% dilinoleic acid.¹

Dicetearyl Dimer Dilinoleate

Impurities of Dicetearyl Dimer Dilinoleate were anticipated to be 0.1%-5.0% dilinoleic acid and cetearyl alcohol.¹

Dioctylododecyl Dimer Dilinoleate

Dioctylododecyl Dimer Dilinoleate impurities were anticipated to be 0.1%-5.0% dilinoleic acid and octylododecanol.¹

Ultraviolet Absorption

Dicetearyl Dimer Dilinoleate

Dicetearyl Dimer Dilinoleate, 1% in 99% hexane, did not absorb in the ultraviolet A (UVA) or UVB range.¹ An absorbance peak of approximately 3.5 was observed at a wavelength of approximately 230 nm. A second peak was observed at approximately 270 nm, with an absorbance of approximately 0.7.

Diocetyldodecyl Dimer Dilinoleate

Diocetyldodecyl Dimer Dilinoleate, 10% in 90% hexane, did not absorb in the UVA or UVB range.¹ An absorbance peak of approximately 4.9 was observed at approximately 230 nm. A second peak was observed at approximately 270 nm, with an absorbance of approximately 4.2.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the U.S. Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

Based on 2018 VCRP data and Council survey data, 2 out of the 8 ingredients included in this safety assessment are currently in use.⁴ The most frequently used ingredient according to 2018 VCRP data, Diisopropyl Dimer Dilinoleate, is reported to be used in 145 formulations, with a maximum concentration of use of 29% in lipsticks (87 uses; Table 5). Diisostearyl Dimer Dilinoleate is reported to be used in 20 formulations, 19 of which are in leave-on products, with a maximum concentration of use of 16% in lipsticks.

Both 1998 and 2018 VCRP data reported Diisopropyl Dimer Dilinoleate as the most frequently used ingredient.^{1,4} According to 1998 VCRP data, Diisopropyl Dimer Dilinoleate had the greatest frequency of use, with 35 total formulations.¹ Of these formulations, 30 were leave-on products, and 5 were rinse-off products. The majority of the uses were lipstick formulations, with concentrations as high as 53%, and in foundations with concentrations as high as 7%. In 1998, Dicetearyl Dimer Dilinoleate and Diethylhexyl Dimer Dilinoleate were reported to be in use, however, these ingredients are not reported to be in use in 2018.

Both historical and current use data are provided in Table 5. The dialkyl dimer dilinoleates not in use, according to 2018 VCRP data and Council survey data, are listed in

Table 6.

All of the ingredients named in this report were found in the EU Cosmetic Ingredients Inventory. None of the ingredients named in this report are restricted from use in any way under the rules governing cosmetic products in the European Union.⁵

Non-Cosmetic

Non-cosmetic uses of dialkyl dimer dilinoleates were not identified in the published literature.

TOXICOKINETIC STUDIES

No toxicokinetics studies of the dialkyl dimer dilinoleates were included in the original report, no new data was found in published literature, and unpublished data were not submitted.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Dilinoleic acid, a component of each relevant ingredient, was studied. A 13-week rat feeding study suggested that dilinoleic acid, or its metabolite(s), is widely distributed through the body when ingested.¹

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Dermal

Diocetyldodecyl Dimer Dilinoleate

Rats were used in an acute dermal toxicity test.¹ Test substance was applied to the dorsal area and trunk at doses of 5 g/kg bw. No gross tissue or organ abnormalities were found. The acute dermal LD₅₀ for Diocetyldodecyl Dimer Dilinoleate was determined to be > 5 g/kg.

Oral

Diisopropyl Dimer Dilinoleate

Groups of five male and five female albino rats were used. The acute oral LD₅₀ of Diisopropyl Dimer Dilinoleate was > 5.0 g/kg.¹ The “limits of acute oral toxicity” of 50% of a lip gloss and a lipstick formulation, both containing 10% Diisopropyl Dimer Dilinoleate, in corn oil was > 15.9 g/kg.

Diisostearyl Dimer Dilinoleate

The LD₅₀ of Diisostearyl Dimer Dilinoleate was > 5.0 g/kg when testing groups of five male and five female albino rats.¹ A similar study suggested an oral LD₅₀ of > 5.0 ml/kg.

Diocetyldodecyl Dimer Dilinoleate

Five male and five female rats were dosed with 5 g/kg Diocetyldodecyl Dimer Dilinoleate.¹ None of the animals died. The oral LD₅₀ for the rats was > 5.0 g/kg.

Subchronic Toxicity

Dilinoleic Acid

In a 13-week feeding study, rats were fed a maximum of 5% (w/w) dilinoleic acid via a basic purified diet, ad libitum.¹ A no-observable-adverse-effect level (NOAEL) was not found because of macrophage aggregation seen in the mesenteric lymph node at the lowest dose level (0.1%).

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

No developmental/reproductive toxicity studies were included in the original report, no new data was found in published literature, and unpublished data were not submitted.

GENOTOXICITY

Genotoxicity studies were not found in the published literature, and unpublished data were not submitted. However, data were included in the original safety assessment on dilinoleic acid.

An Ames test using *Salmonella typhimurium* strains TA 1535, TA 1537, TA 100, and TA 98 to test the genotoxicity of dilinoleic acid yielded negative results.¹ Chromosome aberrations were studied in human lymphocytes with and without metabolic activation at a maximum concentration of 300 µg/ml. No clastogenic effects were reported. Forward mutations were studied in mouse L5178Y lymphoma cells with and without metabolic activation. Dilinoleic acid was considered negative in the mouse lymphoma cell assay.

CARCINOGENICITY STUDIES

No carcinogenicity studies were included in the original report, no new data were found in the published literature, and unpublished data were not submitted.

OTHER RELEVANT STUDIES

Comedogenicity

Diisopropyl Dimer Dilinoleate

Rabbits were treated with 0.5 mL of a test article containing Diisopropyl Dimer Dilinoleate (concentration was not stated).¹ The researchers concluded that Diisopropyl Dimer Dilinoleate only caused very minor irritation and did not produce a comedogenic effect.

Diisostearyl Dimer Dilinoleate

Rabbits were treated with 0.5 mL of a test substance containing Diisostearyl Dimer Dilinoleate (concentration was not stated).¹ The researchers stated that Diisostearyl Dimer Dilinoleate caused only very minor irritation and was not comedogenic.

DERMAL IRRITATION AND SENSITIZATION

Irritation

Animal

Diisopropyl Dimer Dilinoleate

A dose of 0.5 mL Diisopropyl Dimer Dilinoleate was applied to 6 rabbits under an occlusive patch for 72 hours.¹ The primary irritation index (PII) was 0.10.

Dicetearyl Dimer Dilinoleate

The PII was 0.00 for New Zealand albino rabbits dosed with 0.5mL Dicetearyl Dimer Dilinoleate using the same procedure as given above.¹ Dicetearyl Dimer Dilinoleate was considered not to be a skin irritant.

Diisostearyl Dimer Dilinoleate

A 0.5 mL dose of Diisostearyl Dimer Dilinoleate led to a PII of 0.00 using the same procedure as given above.¹ In a separate study, 6 New Zealand White rabbits were exposed to 10% Diisostearyl Dimer Dilinoleate in corn oil. A dose of 0.5 mL was applied and scored at 24 hours and 72 hours after application. The PII was 0.75, and 10% w/w Diisostearyl Dimer Dilinoleate produced minimal irritation.¹

Diocetyldodecyl Dimer Dilinoleate

The PII was 0.00 [in] New Zealand rabbits dosed with 0.5 mL Diocetyldodecyl Dimer Dilinoleate applied dermally, and covered with an occlusive patch.¹ Diocetyldodecyl Dimer Dilinoleate was not a primary skin irritant.

Human

Diisopropyl Dimer Dilinoleate

Multiple studies were performed involving lip products that contained Diisopropyl Dimer Dilinoleate at a maximum concentration of 18%.¹ In one study, three of the twenty-five subjects with sensitive skin reported “a mild burning of the lips” and two reported “mild to moderate tautness of the lips;” the reactions were mild in intensity and transient in nature.

A moisturizer formulation containing 5% Diisopropyl Dimer Dilinoleate was not a dermal irritant.¹ The authors also concluded that makeup formulations containing 2% Diisopropyl Dimer Dilinoleate were not acneogenic, comedogenic, or irritating.

Diisostearyl Dimer Dilinoleate

Twenty subjects underwent a single-insult occlusive patch test (SIOPT) to test a concealer containing 10% Diisostearyl Dimer Dilinoleate.¹ The concealer, which was applied undiluted, had a PII of 0.084/4. In a different study, a 10% Diisostearyl Dimer Dilinoleate concealer was used for 5 days among 22 females, 15 of whom were lactic acid sensitive. Two subjects reported mild clinical changes, and one subject reported slight stinging.

Sensitization

Human

Diisopropyl Dimer Dilinoleate

A human repeat-insult patch test (HRIPT) was conducted using occlusive patches on 154 subjects to determine the sensitization potential of lipstick formulations containing 10%, 18% or 27% Diisopropyl Dimer Dilinoleate.¹ One subject had a single 1+ response upon challenge [at the 10% concentration,], but overall, allergic responses were not observed. No reactions were recorded for the 27% or 18% group upon challenge.

A study [evaluating the sensitization potential of] a liquid makeup formulation was performed using 0.1 mL of test substance containing Diisopropyl Dimer Dilinoleate, according to the same procedures above.¹ Of the 76 subjects completing this study, 16 had scores of 1 (mild reaction—faint/definitely pink) and two had scores of 1 and 2 (moderate reaction—definite redness) during induction. Reactions were not observed upon challenge. In a modified Draize assay of a make-up formulation containing 3.5% Diisopropyl Dimer Dilinoleate, adverse reactions were not reported and the test substance was not a significant skin irritant or sensitizer.

Dicetearyl Dimer Dilinoleate

A test substance (0.1 g or ml) containing Dicetearyl Dimer Dilinoleate was applied to the back under an occlusive patch (3 days/week for 3 weeks) in an HRIPT study involving 60 subjects.¹ After 10-14 days of no treatment, a challenge patch was applied to a previously unexposed area. Adverse reactions were not noted during the induction or challenge phase.

Diisostearyl Dimer Dilinoleate

The sensitization potential of an undereye concealer containing 10% Diisostearyl Dimer Dilinoleate was evaluated in a maximization test.¹ A sensitization reaction was not observed at the 48- or 72-h readings.

Diocetyldodecyl Dimer Dilinoleate

An HRIPT was completed in 60 subjects with occlusive patches of a test material containing Diocetyldodecyl Dimer Dilinoleate (0.2 g or ml).¹ Adverse reactions were not noted during the induction or challenge phases.

Photosensitization/Phototoxicity

Diisopropyl Dimer Dilinoleate

Cosmetic formulations containing 2-27% Diisopropyl Dimer Dilinoleate were not photosensitizers.¹

Diisostearyl Dimer Dilinoleate

In a photosensitization study, it was concluded that a concealer containing 10% Diisostearyl Dimer Dilinoleate had no photocontact-sensitizing potential.¹

OCULAR IRRITATION STUDIES

Diisopropyl Dimer Dilinoleate

Six rabbits had 0.1 mL of a test substance containing Diisopropyl Dimer Dilinoleate placed into the conjunctival sac of one eye.¹ Observations were made for seven days. No signs of irritation occurred.

A lip gloss and lipstick formulation containing 10% Diisopropyl Dimer Dilinoleate were placed into the conjunctival sac of rabbit eyes.¹ The lip gloss caused a maximum 1-h score of 4 for the conjunctivae, and the eyes were normal after one day. The lipstick caused a 1-h score of 2, and the eyes were normal after 3 days.

Dicetearyl Dimer Dilinoleate

In a Draize test conducted using six New Zealand white rabbits, Dicetearyl Dimer Dilinoleate (concentration not specified) had a maximum mean total score (MMTS) of 0.00.¹

Diisostearyl Dimer Dilinoleate

The ocular irritation potential of Diisostearyl Dimer Dilinoleate (concentration not specified) was determined in a Draize test; the test substance did not cause irritation to rabbit eyes.¹ In a similar study, 0.1 mL of 10% w/w Diisostearyl Dimer Dilinoleate in corn oil was applied to the conjunctival sac of 6 New Zealand white rabbits. No irritation was observed.

Diocetyldodecyl Dimer Dilinoleate

One-tenth mL of Diocetyldodecyl Dimer Dilinoleate (concentration not specified) was placed in the conjunctival sac of 6 rabbits.¹ The MMTS was 0.00, and Diocetyldodecyl Dimer Dilinoleate was nonirritating.

SUMMARY

In 2003, the Panel published a safety assessment with the conclusion that Diisopropyl Dimer Dilinoleate, Dicetearyl Dimer Dilinoleate, Diisostearyl Dimer Dilinoleate, Diethylhexyl [Diocetyl] Dimer Dilinoleate, Diocetyldodecyl Dimer Dilinoleate and

Ditridecyl Dimer Dilinoleate were safe as used in the present practices of use. This assessment is a re-review of those original ingredients, as well as 2 additional dialkyl dimer dilinoleates (Di-C16-18 Alkyl Dimer Dilinoleate and Di-C18-20 Alkyl Dimer Dilinoleate). All ingredients reviewed are diesters of their respective alcohols and dilinoleic acid. Each ingredient functions as a skin conditioning agent, however, Di-C20-40 Alkyl Dimer Dilinoleate also functions as a viscosity increasing agent.

Two of the eight ingredients included in this safety assessment are currently in use. Diisopropyl Dimer Dilinoleate has the highest frequency of use, with 145 total uses; the majority of these uses are in leave-on formulations, primarily in lipsticks (87 uses). Diisostearyl Dimer Dilinoleate has 20 reported uses. In the original safety assessment, the maximum concentration of use of Diisopropyl Dimer Dilinoleate was 53% in lipsticks, and the maximum concentration of use for Diisostearyl Dimer Dilinoleate was 12% in lipsticks. According to the Council survey conducted in 2018, concentration of use data also suggests that lipstick formulations contain the highest concentrations among the cosmetics reported to be in use. Diisopropyl Dimer Dilinoleate and Diisostearyl Dimer Dilinoleate had maximum concentrations of use of 29 and 16%, respectively. No new studies regarding toxicity were found in the published literature.

DISCUSSION

In accordance with its procedures, the CIR evaluates the conclusions of previously-issued reports every 15 years. An amended report was published in 2003 for the original 6 dialkyl dimer dilinoleates with the conclusion of safe as used.¹ The Panel reached this conclusion due to negative genotoxicity assays, absence of structural alerts, and lack of dermal penetration evaluated using an estimate of the octanol/water partition coefficient based on the structure of Diisopropyl Dimer Dilinoleate.

At the June 4-5, 2018 meeting, the panel re-evaluated the safety of these ingredients and reaffirmed the original conclusion. Additionally, the Panel determined that it was appropriate to include 2 new ingredients to the dialkyl dimer dilinoleate ingredient family (Di-C16-18 Alkyl Dimer Dilinoleate and Di-C20-40 Alkyl Dimer Dilinoleate). The Panel noted that due to the size and lack of absorption of these dialkyl dimer dilinoleates, the need for systemic endpoints is mitigated.

CONCLUSION

The CIR Expert Panel concluded that the following dialkyl dimer dilinoleates are safe in cosmetics in the present practices of use and concentration described in this safety assessment:

Diisopropyl Dimer Dilinoleate
Dicetearyl Dimer Dilinoleate*
Diisostearyl Dimer Dilinoleate
Diethylhexyl Dimer Dilinoleate*

Dioctyldodecyl Dimer Dilinoleate*
Ditridecyl Dimer Dilinoleate*
Di-C16-18 Alkyl Dimer Dilinoleate*
Di-C20-40 Alkyl Dimer Dilinoleate*

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

TABLES

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment², CIR Staff

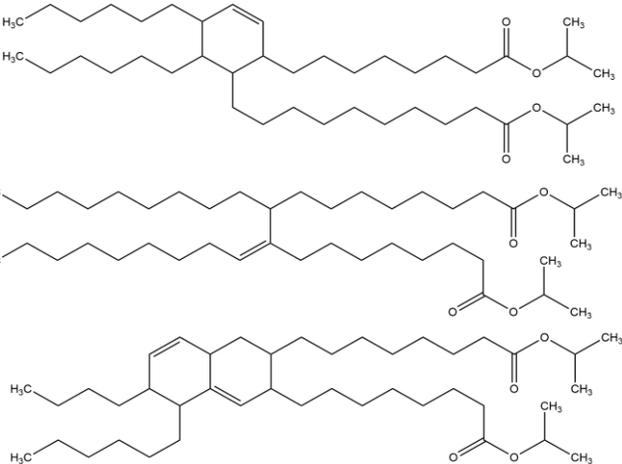
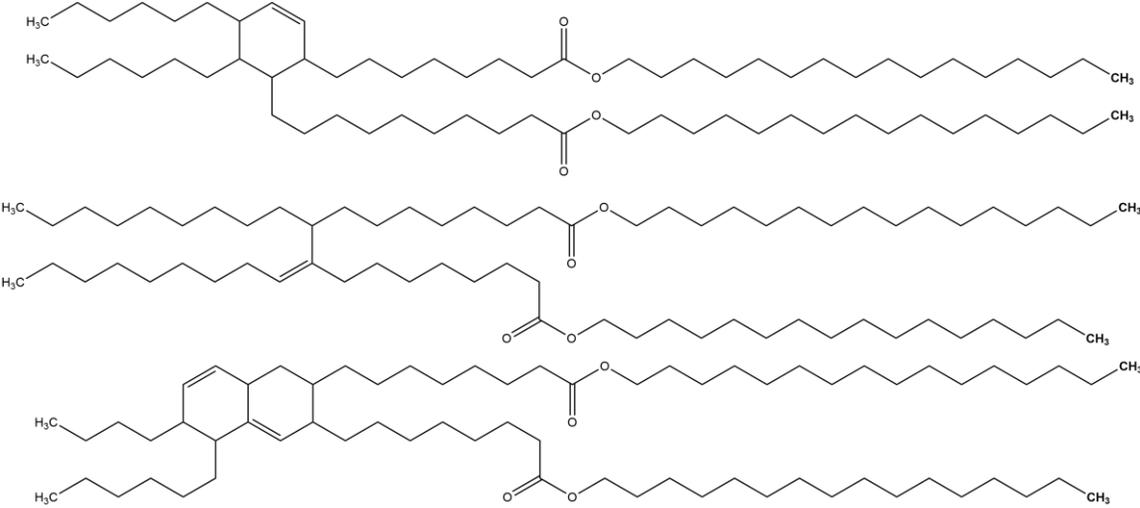
Name & CAS No.	Definition & Structure	Function(s)
Diisopropyl Dimer Dilinoleate 205393-95-9	the diester of isopropyl alcohol and dilinoleic acid	skin-conditioning agent – emollient
		
Dicetearyl Dimer Dilinoleate 135620-20-1	the diester of cetearyl alcohol and dilinoleic acid	skin-conditioning agent— occlusive
		

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment^{2, CIR Staff}

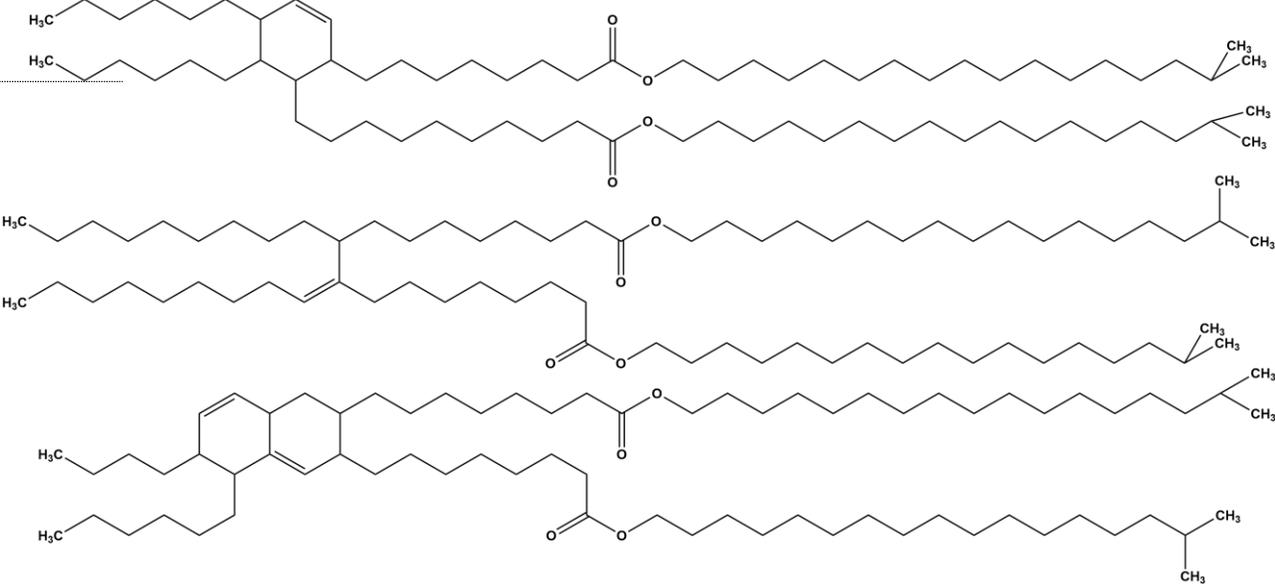
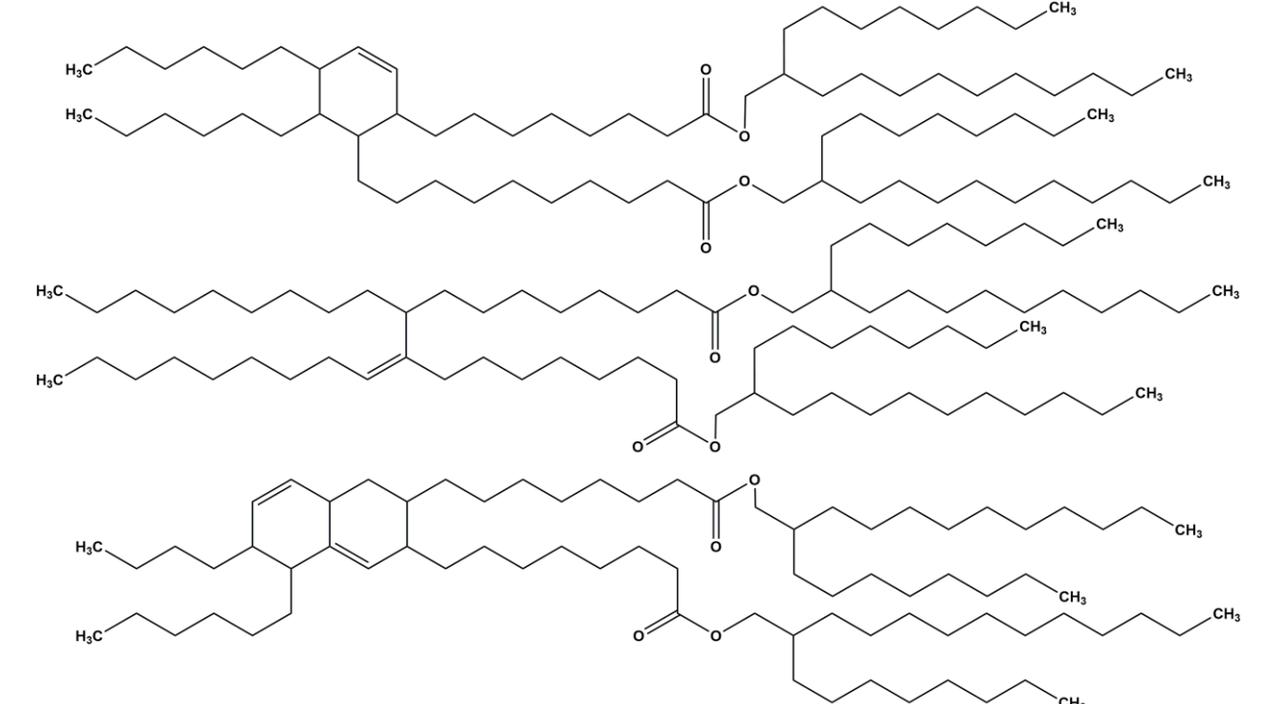
Name & CAS No.	Definition & Structure	Function(s)
Diisostearyl Dimer Dilinoleate 103213-19-0	the diester of isostearyl alcohol and dilinoleic acid	skin-conditioning agent-- occlusive
 <p>The structure shows a central dimer of dilinoleic acid (two linoleic acid units linked at their 1 and 3 positions). This dimer is esterified with two molecules of isostearyl alcohol. The isostearyl alcohol chains are branched, with a methyl group at the end of a side chain. The ester linkages are shown with oxygen atoms and carbonyl groups.</p>		
Dioctylododecyl Dimer Dilinoleate 129423-60-5	the diester of octylododecanol and dilinoleic acid	skin-conditioning agent-- occlusive
 <p>The structure shows a central dimer of dilinoleic acid (two linoleic acid units linked at their 1 and 3 positions). This dimer is esterified with two molecules of octylododecanol. The octylododecanol chains are branched, with an octyl group (8 carbons) attached to a dodecyl chain (12 carbons). The ester linkages are shown with oxygen atoms and carbonyl groups.</p>		

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment^{2, CIR Staff}

Name & CAS No.	Definition & Structure	Function(s)
Ditridecyl Dimer Dilinoleate	the diester of tridecyl alcohol and dilinoleic acid	skin-conditioning agent— occlusive
Diethylhexyl Dimer Dilinoleate	the diester of 2-ethylhexyl alcohol and dilinoleic acid	skin-conditioning agent— occlusive

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment^{2, CIR Staff}

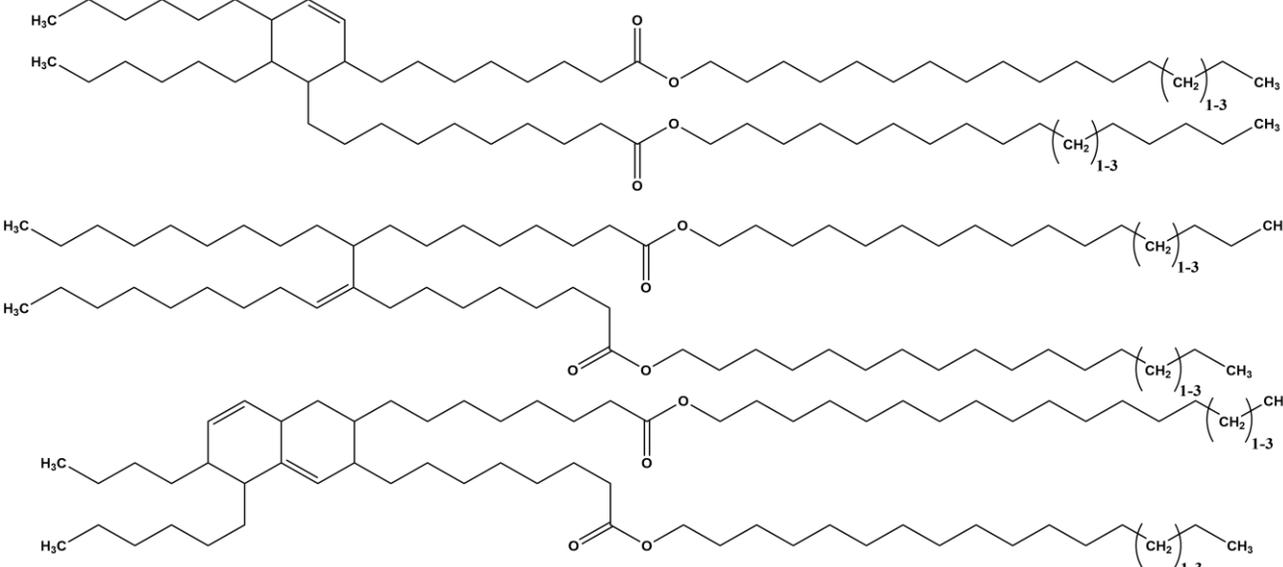
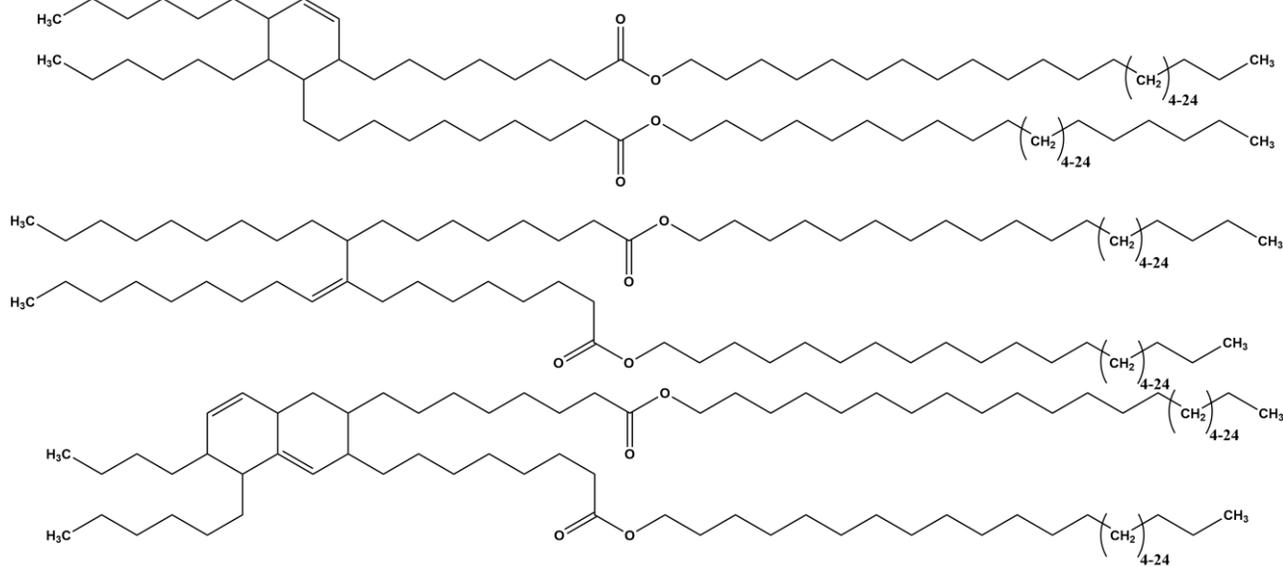
Name & CAS No.	Definition & Structure	Function(s)
Di-C16-18 Alkyl Dimer Dilinoleate 501901-81-1	the diester of C16-18 alcohols and dilinoleic acid	skin-conditioning agent-- occlusive
		
Di-C20-40 Alkyl Dimer Dilinoleate	the diester of C20-40 alcohols and dilinoleic acid	skin-conditioning agent— occlusive/viscosity increasing agent—nonaqueous
		

Table 2. Alcohol components of relevant dialkyl dimer dilinoleates reviewed by CIR

Ingredient	Alcohol	Conclusion	Reference
Diisopropyl Dimer Dilinoleate	Isopropyl Alcohol	Safe as used in present practices of use	2012 ⁶
Dicetearyl Dimer Dilinoleate	Cetearyl Alcohol	Safe as used; this conclusion was reaffirmed in 2008	1988 ⁷ ; 2008 ⁸
Diisostearyl Dimer Dilinoleate	Isostearyl Alcohol	Safe as used; this conclusion was reaffirmed in 2008	1988 ⁷ ; 2008 ⁸
Diocetyl dodecyl Dimer Dilinoleate	Octyldodecanol	Safe as used; this conclusion was reaffirmed in 2006	1985 ⁹ ; 2006 ¹⁰
Di-C16-18 Alkyl Dimer Dilinoleate	Myristyl Alcohol (C14)	Safe as used; this conclusion was reaffirmed in 2008	1988 ⁷ ; 2008 ⁸
Di-C16-18 Alkyl Dimer Dilinoleate	Cetyl Alcohol (C16)	Safe as used; this conclusion was reaffirmed in 2008	1988 ⁷ ; 2008 ⁸
Di-C16-18 Alkyl Dimer Dilinoleate	Oleyl Alcohol (C18)	Safe as used; this conclusion was reaffirmed in 2006	1985 ⁹ ; 2006 ¹⁰
Di-C16-18 Alkyl Dimer Dilinoleate	Stearyl Alcohol (C18)	Safe as used; this conclusion was reaffirmed in 2006	1985 ⁹ ; 2006 ¹⁰
Di-C20-40 Alkyl Dimer Dilinoleate	Behenyl Alcohol (C22)	Safe as used; this conclusion was reaffirmed in 2008	1988 ⁷ ; 2008 ⁸

Table 3. Alcohols components of relevant dialkyl dimer dilinoleates not yet reviewed by CIR

Ingredient	Alcohol(s)
Diethylhexyl Dimer Dilinoleate	2-Ethylhexyl Alcohol
Tridecyl Dimer Dilinoleate	Tridecyl Alcohol
Di-C16-18 Alkyl Dimer Dilinoleate	Linoleyl Alcohol (C18)
Di-C20-40 Alkyl Dimer Dilinoleate	C20-40 Alcohols, Arachidyl Alcohol (C20), tetracosanol (C24), hexacosanol (C26), octacosanol (C28) Myricyl Alcohol (C30), (dotriacontanol (C32), tetratriacontanol (C34), hexatriacontanol (C36), octatriacontanol (C38), tetracontanol (C40)

Table 4. Physical and chemical properties

Property	Description	Reference
Diisopropyl Dimer Dilinoleate		
physical characteristics	<i>non-oily, clear to slightly hazy yellow liquid with a mild, characteristic, fatty odor</i>	1
molecular weight (g/mol)	650	1
solubility	<i>Soluble in most organic solvents; insoluble in water and lower-molecular weight diols and triols</i>	1
boiling point (°C)	> 200	1
freezing point (°C)	-11	1
refractive index (@ 25 °C)	1.4590 - 1.4650 1.4550 - 1.4655	1
specific gravity (@ 25 °C)	0.965 to 0.975	1
log P	17.79	1
Diisostearyl Dimer Dilinoleate		
physical characteristics	<i>clear to slightly hazy yellow liquid with a characteristic odor</i>	1
molecular weight (g/mol)	1078	1
solubility	<i>soluble in most organic solvents; insoluble in water and low-molecular-weight diols and triols</i>	1
freezing point (°C)	5	1
refractive index (@ 25 °C)	1.468 - 1.478	1
specific gravity (@ 25 °C)	0.895± 0.01	1
log P	32.44 (estimated)	11
Dicetearyl Dimer Dilinoleate		
physical characteristics	<i>yellow semi-solid with bland odor practically odorless buttery yellow solid</i>	1
molecular weight (g/mol)	1013.8	12
boiling point (°C)	500	1
solubility	<i>insoluble in water</i>	1
log P	30.62 (estimated)	11
moisture content	0.5%	1
microbial content	500 (opg) max; no pathogens	1
Diocetyl dodecyl Dimer Dilinoleate		
physical characteristics	<i>clear liquid with a bland odor</i>	1
molecular weight (g/mol)	1126.0	12

Table 4. Physical and chemical properties

Property	Description	Reference
boiling point (°C)	450	1
solubility	<i>insoluble in water</i>	1
log P	34.40 (estimated)	11
specific gravity (@ 25°C)	1.15	1
moisture content	0.5%	1
<i>Tridecyl Dimer Dilinoleate</i>		
molecular weight (g/mol)	929.6	12
log P	27.67 (estimated)	11
<i>Diethylhexyl Dimer Dilinoleate</i>		
molecular weight (g/mol)	789.4	12
log P	22.62 (estimated)	11
<i>ADD-ONS</i>		
<i>Di-C16-18 Alkyl Dimer Dilinoleate</i>		
molecular weight (g/mol)	1014 - 1078	12
log P	30.62-32.44 (estimated)	11
<i>Di-C20-40 Alkyl Dimer Dilinoleate</i>		
molecular weight (g/mol)	1126.0 - 1687.1	12
log P	34.55 - 54.19 (estimated)	11

Table 5. Current and historical frequency and concentration of use of Dialkyl Dimer Dilinoleates according to duration and exposure

	Diisopropyl Dimer Dilinoleate				Diisostearyl Dimer Dilinoleate			
	2018 ^d	1998 ¹	2018 ¹³	1999 ¹	2018 ^d	1998 ¹	2018	1999 ¹
Totals*	145	35	1-29	0.1-53	20	20	5-16	1-12
<i>Duration of Use</i>								
<i>Leave-On</i>	142	30	1-29	0.05-53	19	20	5-16	1-12
<i>Rinse-Off</i>	3	5	NR	0.1-5	1	NR	NR	NR
<i>Diluted for (Bath) Use</i>	NR	NR	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>								
Eye Area	12	2	NR	0.1-3	7	11	6	5-11
Incidental Ingestion	87	12	10.8-29	4-53	5	2	16	7-12
Incidental Inhalation-Spray	13 ^a	4 ^a ; 4 ^b	1.5-5.3 ^a	9.25; 2-10 ^a ; 3-5 ^b	4 ^a	NR	NR	NR
Incidental Inhalation-Powder	NR	4 ^b	NR	3-5 ^b ; 30	NR	3	NR	1-7
Dermal Contact	53	22	1-5	0.05-30	15	18	5-6	1-11
Deodorant (underarm)	NR	NR	NR	20 ^a	NR	NR	NR	NR
Hair - Non-Coloring	5	1	1.5-5.3	9.25-10	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	88	12	10.8-29	4-53	6	2	16	7-12
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

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

^a Includes products that can be sprays, but it is not known whether the reported uses are sprays

^b Not specified whether this product is a spray or a powder or neither, but it is possible it may be a spray or a powder, so this information is captured for both categories of incidental inhalation

NR – no reported use

Table 6. Dialkyl Dimer Dilinoleates not reported to be in use, according to the FDA VCRP data and Council survey data.

Ingredient
Dicetearyl Dimer Dilinoleate
Diethylhexyl [Dioctyl] Dimer Dilinoleate
Diocetyldecyl Dimer Dilinoleate
Ditridecyl Dimer Dilinoleate
Di-C16-18 Alkyl Dimer Dilinoleate
Di-C20-40 Alkyl Dimer Dilinoleate

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