Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Status:	Draft Final Report for Panel Review
Release Date:	May 22, 2026
Panel Meeting Date:	June 15-16, 2026

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Bruce A. Brod, M.D., M.H.C.I., F.A.A.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. Previous Panel member involved in this assessment: David E. Cohen, M.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.

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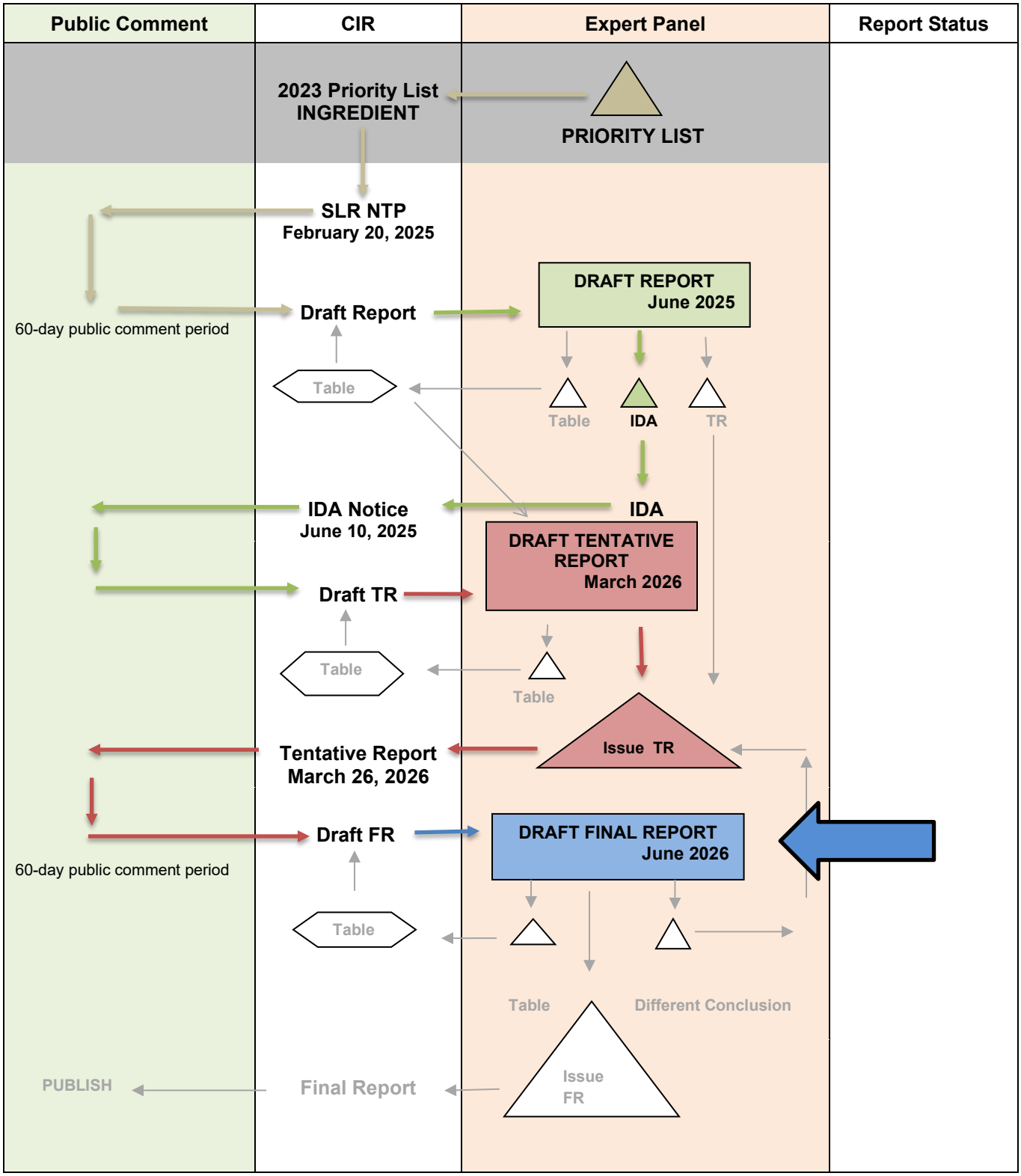
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Dimer Dilinoleates

MEETING June 2026



Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR
Date: May 22, 2026
Subject: Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Enclosed is the Draft Final Report on the Safety of Dimer Dilinoleates as Used in Cosmetics. (It is identified as *report_DimerDilinoleates_062026* in the pdf document). At the March 2026 meeting, the Panel issued a Tentative Report with the conclusion that these 7 dimer dilinoleate ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

No additional data have been received since the March meeting. Comments received from the Council on the Tentative Report have been addressed (*PCPCcomments_DimerDilnoleates_062026* and *response-PCPCcomments_DimerDilinoleates_062026*).

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," the product names thereof were useful in determining the product type. The majority of entries for the dimer dilinoleates in category 17 were for lip care products. Other entries include uses in skin care products, a tanning product, and a makeup product.

Additional supporting documents for this report package include a flow chart (*flow_DimerDilinoleates_062026*), report history (*history_DimerDilinoleates_062026*), a search strategy (*search_DimerDilinoleates_062026*), a data profile (*dataprofile_DimerDilinoleates_062026*), and meeting transcripts (*transcripts_DimerDilinoleates_062026*).

The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Report.

Dimer Dilinoleates History

February 2025 – A Scientific Literature Review (SLR) Notice to Proceed (NTP) was issued by CIR

March/April 2025 – CIR received unpublished data on some of the dimer dilinoleate ingredients.

June 2025 - The Panel issued an IDA for the following 7 dimer dilinoleate ingredients:

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

The additional data needed to determine safety for these ingredients are:

- Structures for all ingredients
- Method of manufacturing for all ingredients
- Impurities/composition data for all ingredients
- Repeated oral-dose toxicity data for Dimer Dilinoleyl Dimer Dilinoleate at maximum concentrations of use
- Developmental and reproductive toxicity (DART) data
- Ocular irritation data
- Dermal irritation and sensitization data at maximum concentration of use for Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate

July 2025 – Additional unpublished data received from the Council.

March 2026 - The Panel issued a Tentative Report for public comment with the conclusion that these 7 dimer dilinoleate ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment.

Dimer Dilinoleates Data Profile* – June 2026 – Christina Burnett																														
				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	X	X	X					X							X					X	X		X	X		X	X		
Bis-Behenyl/Phytosteryl Dimer Dilinoleate	X	X	X	X											X														
Dimer Dilinoleyl Dimer Dilinoleate	X	X	X					X							X					X	X		X	X		X	X		
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate	X			X																									
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	X	X	X	X				X							X					X	X		X	X			X		
Phytosteryl Isostearyl Dimer Dilinoleate	X	X	X	X				X							X					X	X		X				X		
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	X			X																									
dimer dilinoleates - generic		X	X																										

* "X" indicates that new data were available in a category for the ingredient.

Dimer Dilinoleates

Ingredient	CAS #	PubMed	FDA	CompTox	ChemPort	NIOSH	NTIS	NTP	FEMA	EU	ECHA	SIDS	SCCS	AICIS	FAO	WHO	Web
Bis-Behenyl/Isostearyl/ Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	654651-30-6	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Bis-Behenyl/ Phytosteryl Dimer Dilinoleate	None in dictionary	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Dimer Dilinoleyl Dimer Dilinoleate	378789-58-3	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate	None in dictionary	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Phytosteryl/Isostearyl/ Cetyl/Stearyl/Behenyl Dimer Dilinoleate	None in dictionary	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Phytosteryl Isostearyl Dimer Dilinoleate	None in dictionary	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	None in dictionary	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Search Strategy

PubMed

(Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate) OR (654651-30-6[EC/RN Number]) – 1 hit, 1 useful
Bis-Behenyl/Phytosteryl Dimer Dilinoleate – 1 hit, 1 useful (same as above)
(Dimer Dilinoleyl Dimer Dilinoleate) OR (378789-58-3[EC/RN Number]) - 1 hit, 1 useful (same as above)
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate – 0 hits
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate – 0 hits
Phytosteryl Isostearyl Dimer Dilinoleate – 1 hit, 1 useful (same as above)
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate – 0 hits
Dimer Dilinoleate – 8 hits, 1 useful (same as above) and 2 related CIR reports

LINKS

Search Engines

- Pubmed - http://www.ncbi.nlm.nih.gov/pubmed
  - appropriate qualifiers are used as necessary
  - search results are reviewed to identify relevant documents
- CompTox: https://comptox.epa.gov/dashboard/chemical/pubmed-abstract-sifter/DTXSID3039242; https://www.epa.gov/comptox-tools/downloadable-computational-toxicology-data#LM
- eChemPortal: https://www.echemportal.org/echemportal/
- DeepDyve: https://www.deepdyve.com/
- Connected Papers - https://www.connectedpapers.com/

Pertinent Websites

- wINCI - https://incipedia.personalcarecouncil.org/winci/ingredient-custom-search/
- FDA Cosmetics page - https://www.fda.gov/cosmetics
- eCFR (Code of Federal Regulations) - https://www.ecfr.gov/
- FDA search databases: https://www.fda.gov/industry/fda-basics-industry/search-databases
- Substances Added to Food (formerly, EAFUS): https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus
- GRAS listing: https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras
- SCOGS database: https://www.fda.gov/food/generally-recognized-safe-gras/gras-substances-scogs-database
- Inventory of Food Contact Substances Listed in 21 CFR: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives
- Drug Approvals and Database: https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases
- FDA Orange Book: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book
- OTC Monographs - https://dps.fda.gov/omuf
- Inactive Ingredients Approved For Drugs: https://www.accessdata.fda.gov/scripts/cder/iig/
- FEMA (Flavor & Extract Manufacturers Association) GRAS: https://www.femaflavor.org/fema-gras
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
  - technical reports search page: https://ntrl.ntis.gov/NTRL/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- EUR-Lex - https://eur-lex.europa.eu/homepage.html
- Scientific Committees (SCCS, etc) opinions: https://health.ec.europa.eu/scientific-committees_en https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs_en
- ECHA (European Chemicals Agency – REACH dossiers) – https://echa.europa.eu/
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- EFSA (European Food Safety Authority) - https://www.efsa.europa.eu/en
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- AICIS (Australian Industrial Chemicals Introduction Scheme)- https://www.industrialchemicals.gov.au/
- International Programme on Chemical Safety http://www.inchem.org/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) IRIS library - https://apps.who.int/iris/
- a general Google and Google Scholar search should be performed for additional background information, to identify references that are available, and for other general information - www.google.com https://scholar.google.com/

Personal Care Products Council

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: April 7, 2026

SUBJECT: Tentative Report: Safety Assessment of Dimer Dilinoleates as Used in Cosmetics (release date: March 26, 2026)

The Personal Care Products Council respectfully submits the following comment on the tentative report, Safety Assessment of Dimer Dilinoleates as Used in Cosmetics.

Definition and Structure – Please review the structure of isostearyl alcohol provided by the supplier of five of the ingredients in the CIR report, compared to the example structure of isostearyl alcohol included in the CIR report. The structure of isostearyl alcohol from the supplier (shown on the last page of the March 2026 meeting panel book) has “n” carbons on one side of the iso group and “m” carbons on the other side of the iso group and they indicate that “n”+”m”=14. The example isostearyl alcohol structure in the tentative report does not appear to be consistent with this and should be replaced with the structure provided by the supplier.

Dimer Dilinoleates – June 2026 – Christina Burnett	
Comment Submitter: Jaap Venema, Ph.D, Personal Care Products Council **Subject:** Tentative Report: Safety Assessment of Dimer Dilinoleates as Used in Cosmetics (release date: March 26, 2026) **Date of Submission:** April 7, 2026	
Comment	**Response/Action**
Definition and Structure – Please review the structure of isostearyl alcohol provided by the supplier of five of the ingredients in the CIR report, compared to the example structure of isostearyl alcohol included in the CIR report. The structure of isostearyl alcohol from the supplier (shown on the last page of the March 2026 meeting panel book) has “n” carbons on one side of the iso group and “m” carbons on the other side of the iso group and they indicate that “n”+”m”=14. The example isostearyl alcohol structure in the tentative report does not appear to be consistent with this and should be replaced with the structure provided by the supplier.	Dr. Heldreth provided additional verbiage to the Definition and Structure section to address this comment.

JUNE 2025 MEETING – FIRST REVIEW/DRAFT REPORT

Belsito Team – June 9, 2025

DR. SNYDER: Okay, now the Dimer Dilinoleates. Let me bring that up. This is a Draft Report. There are seven ingredients, they're listed on Page 3. Most uses are in lipsticks, up to 48.7 percent. In February of 2025, we issued an SLR. We received some data that's listed, again, on Page 3 of 52.

There are 801 formulations for the Dimer Dilinoleyl Dimer Dilinoleate. There are 78 formulations with Phytosteryl Isostearyl Dimer Dilinoleate. We have two choices, again, with this Draft Report. If no further data are needed, then we can issue a Discussion and a Tentative Report. Or if we need additional data needs, we need to issue an Insufficient Data Announcement and delineate what data needs we need. So, what was your choice there?

DR. BELSITO: Well, we have lipstick use at 58.7 percent. And we have no in vivo genotox, and we have no DART data. And we have no repeated dose data. I mean, granted, the high level in lipstick, how much are you going to absorb? But I don't know that.

DR. SNYDER: Well, it's a Draft Report, so I think we should go out insufficient for in vivo genotox, DART, and repeat dose tox studies.

DR. RETTIE: I thought those were fine, but a bigger issue -- or a big issue for me -- was the heterogeneity.

DR. BELSITO: Allan, turn on your mic.

DR. RETTIE: Oh, sorry. Yeah, a big issue for me was the heterogeneity composition. I wasn't sure what we were looking at. I thought we needed to have some clarification on what these Dilinoleates are.

Bart took on the, I thought, fairly heroic job of drawing them out for us. And for even a single ingredient, it was possible to come up with a lot of structures. And so, I think we need to have that clarified as to the extent of the heterogeneity.

And in the report, once we get that clarified, I'd like to see the structures, all of them in there. Because we have ethers and we have esters, and we can't read across, in my opinion, from the ethers to the esters for a lot of the missing data. So, there will be read across questions, so we feel like we really need to know what we're dealing with, and I just don't know at the moment.

DR. SNYDER: Okay. Well, we can ask for it. It's, again, a draft report. So, now we have an Insufficient Data Announcement, and we're going to go for in vitro genotox, DART, repeat dose tox data, and then more information on the heterogeneity of the composition, clarification of what they are. And would like to see all of the structures in the next draft of the report.

DR. BELSITO: And also the UV absorption I wasn't happy with it. They said they have almost no UV absorption. What does that mean? They didn't provide any molar extinction coefficients. In the data that the company sent, in the blurb, it says the data was attached but it wasn't attached. And I would like to see the data. You know, could they please attach the data?

DR. SNYDER: Any particular one you want to see?

DR. BELSITO: Well, they said they had UV absorption, almost no UV absorption, on the Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate.

DR. EISENMANN: They sent a spectrum, and I provided it.

DR. BELSITO: I can't hear you, Carol.

DR. EISENMANN: They did send some spectrum that I provided; I don't know where they are, though.

MS. BURNETT: It's PDF Page 44, it starts.

DR. RETTIE: I'm looking at them right now. They don't have any bumps.

DR. EISENMANN: Right.

DR. BELSITO: Yeah, there's nothing in there. There's a box, but there's no graph.

DR. EISENMANN: They didn't find anything, I don't think.

MS. BURNETT: I think they're showing a straight line.

DR. BELSITO: So they're showing zero? You think that the line is the zero line from 290 to 700?

DR. RETTIE: Yep. They're running all these at 100 parts per million. It doesn't seem like a lot. But there's no evidence of a UV peak in the region we'd care about, even a tiny one.

DR. SNYDER: So, okay, we'll take that one off.

DR. BELSITO: Okay.

DR. SNYDER: All right.

DR. BELSITO: I thought it was missing.

DR. EISENMANN: My question, in the original Dimer Dilinoleates report, you included some data on dilinoleic acid, and I wonder if that should be brought over. I don't know, Christina, if you did an updated literature search on dilinoleic acid, but that might be worthwhile doing.

DR. KOWCZ: Just to make it more complete.

DR. SNYDER: Yeah. So we could ask to bring some of that data in as part of the Insufficient Data Announcement?

DR. KOWCZ: Just to make it more complete.

DR. SNYDER: Yep. Yep.

DR. RETTIE: I mean, the chemical names just didn't mean an awful lot to me. This was terminology that I was not familiar with, so the structures will be helpful.

DR. SNYDER: Okay. Do you have that, Christina?

MS. BURNETT: Yep.

DR. HELDRETH: And then Dr. Rettie had mentioned something about the structures. When I discussed it with him, I provided just a handful of the estimated properties using EPISuite. Do you want them just for a representative from each one, or would you like to see estimated properties for all the structures?

DR. RETTIE: I don't think I need to see all that data. The two that I looked at, I think you drew an ether and an ester, a representative one. You know, the logPs were 30 for both of them. I wondered if they'd be different, but they weren't.

So, you know, I'd be good with a limited amount. Don't know what we can take from any of that data, really. Structures we can take something from.

DR. SNYDER: Okay, we're good?

DR. BELSITO: Yeah, I mean, do we -- when we're asking -- I mean, I think we need in vivo genotox. Did you ask for that, Paul?

DR. SNYDER: Yes.

DR. BELSITO: Okay. Do we want to say, like, dermal absorption, and if absorbed then we need DART data, rather than saying we need DART data?

DR. SNYDER: Well, I have skin absorption as in formulation. And then I should say if absorbed then we want additional data?

DR. BELSITO: Yeah, because if there's not significant absorption -- well, I guess the biggest issue with that is the largest use is mucosa, right? It's lipstick?

DR. SNYDER: Yeah.

DR. EISENMANN: I think the company would say you don't need absorption data based on the --

DR. BELSITO: I can't hear you, Carol.

DR. EISENMANN: I said, you may not need absorption data because the LogKOW is so large.

DR. RETTIE: It'll just sit in the skin, or -- yeah.

DR. SNYDER: Well, we don't have the data.

DR. BELSITO: I mean, we're going insufficient, so we could ask for it. If we don't get it, that could be an argument in the Discussion, where we don't think it's absorbed because of the LogKow, right?

DR. SNYDER: Yeah, right.

DR. KLAASSEN: So what are we saying about the Log-ow?

DR. SNYDER: K-O-W.

DR. RETTIE: LogP is 30, so it's probably going to get into a skin layer and just stay there, rather than be available for systemic absorption.

DR. KLAASSEN: Is there -- I'm asking this for my own edification. Is there good data for that concept? Or is there any data for that concept?

DR. RETTIE: That's a good scientific question that I can't answer, so it's still open. I don't know.

DR. KLAASSEN: yeah, I wonder. I mean, I've often wondered about that. You know, in general, we say if something is very lipid soluble it's well absorbed. But I know there's an exception to that. But I've never been able to find any data to support my hypothesis. I've never looked that diligently. Does anybody in the audience know?

DR. BJERKE: Can you repeat the question, please?

DR. KLAASSEN: Do you know of any data that shows that if a compound is extremely lipid soluble, super lipid soluble, like a ratio of 30 to 1, that it wouldn't be absorbed?

DR. BJERKE: Yeah. There is the guidelines in the old Crowe's manuscript that talks about kind of the optimal absorption, I think, between minus one and four.

DR. KLAASSEN: Okay.

DR. BJERKE: So, if you get to the extreme, I think it's less bioavailable across the spectrum.

DR. RETTIE: Okay. But has anybody done an experiment, I wonder?

DR. KLAASSEN: Well, you always wonder, just because you read something, if it's based on science. But I'll assume it is. Could you send me the name of that so I could find that? I would like to at least read through it.

DR. BJERKE: Yeah.

DR. KLAASSEN: I think the concept is correct. I've just never been able to find any data to support the concept. In fact, I haven't even found anybody previously that had written it down. But apparently you have found it written down.

DR. BJERKE: Yeah, I think there are three. There's the Crow's Report, there's Potts and Guy, and then there's, like, Bremer.

DR. KLAASSEN: Okay.

DR. BJERKE: I'll get you those.

DR. KLAASSEN: I appreciate that.

DR. RETTIE: That's a super hard concept for students to put across, that we have a parabolic kind of relationship. It's good only within a certain amount. I don't know, I've never been very good at putting that across.

While we're talking about insufficiencies, I was wondering whether we needed to go all in -- pretty much all in -- on at least one of the ethers, because we will be reading across -- or we'll want to read across -- from the non-ethers to the ethers for just about every endpoint that we have. Because there's just no data in the data tables, unlike the Dimer Dilinoleates. So, for there and there, we have no data.

DR. SNYDER: So, what do you want to ask for then?

DR. RETTIE: That data for the ethers.

DR. SNYDER: What data?

DR. RETTIE: Okay. repeat dose, acute tox?

DR. BELSITO: Which ethers are we talking about?

DR. RETTIE: The fourth and the seventh entry in the data table. Those are different beasts, although their logP's are the same.

DR. HELDRETH: So, the PPG?

DR. RETTIE: PPG ethers, yes.

DR. BELSITO: Oh, yeah. Okay, I see what you're talking about now. So should they be in the same group?

DR. RETTIE: The fact that the ethers don't change the logP that much, or at least the estimated logP, makes me think that they probably belong in the same group. Splitting them out, hmm, I could go that way, too.

DR. SNYDER: So, what are we specifically asking for?

DR. RETTIE: We're asking whether the ethers, the two ethers, belong in the same group as the Dilinoleates. And I'm kind of on the fence.

DR. SNYDER: What table is that table?

DR. BELSITO: I missed that, too. They're part of the group we're looking at, so it's PDF Page 11, in the Introduction. And then we never see any more data on either one of the ethers.

DR. RETTIE: Yeah.

DR. SNYDER: Okay.

DR. RETTIE: Maybe it'll be a productive conversation with the Cohen group tomorrow.

DR. SNYDER: Yep, perfect.

DR. RETTIE: Since I can't really say.

DR. SNYDER: All right. So, that's a complicated insufficient data; do you have it all?

MS. BURNETT: I think so.

DR. SNYDER: You want me to repeat it?

MS. BURNETT: Or I can repeat it to you to make sure I got it straight.

DR. SNYDER: You do that, please.

MS. BURNETT: Dermal absorption data and then, if absorbed, DART and any other supportive data. In vivo genotox, repeated dose genotox, clarification on the heterogeneity composition. And for the future draft, add the dilinoleic acid information.

DR. SNYDER: Yep.

MS. BURNETT: Estimated property values on some of these. The ones that I know about. And then structures drawn for each.

DR. SNYDER: Okay. And then the question of -- we'll have a discussion about whether the two ethers belong with this group.

MS. BURNETT: Right.

DR. SNYDER: Okay. I think you've got it.

MS. BURNETT: Okay.

DR. BELSITO: And then eventually, in the Discussion, the heavy-metal boilerplate.

DR. SNYDER: Okay. Thank you.

DR. RETTIE: It seems to me they've done a report in the past on PPG ethers in general, and for some reason these were not included. Do you have any recollection of those discussions?

DR. SNYDER: No. I don't.

DR. HELDRETH: Those ones only differed -- they didn't have the Dimer Dilinoleate other piece of the puzzle there. We did lots of PPGs all by themselves, just like, you know, PPG 40 or something like that.

DR. RETTIE: Yeah, those are different for sure.

DR. HELDRETH: We also did alkyl-substituted PPG ethers and so forth.

DR. RETTIE: I mean, the fact that the physical-chemical parameters that got spat out for the ones you looked at, the representative "ether" and "ester" looked like they were the same, it's an argument for clustering them together.

DR. HELDRETH: Right. I mean, they're all esters as well.

DR. RETTIE: They're all esters as well.

DR. HELDRETH: The ether is just their ether-ester chain.

DR. RETTIE: Yes.

DR. BELSITO: The ether is just a component of the ester.

DR. SNYDER: Right, exactly.

DR. BELSITO: Say that three times fast.

Cohen Team – June 9, 2025

DR. DAVID COHEN: We have a Draft Report for Dimer Dilinoleates. And there's seven ingredients reported to function as hair conditioning agents, skin conditioning agents, and viscosity-increasing agents in cosmetics.

For brevity, the seven ingredients are listed in the report. According to the RLD in 2024, the ingredients in this group with the most reported uses is Dimer Dilinoleyl Dimer Dilinoleate. And it has 801 formulations. Phytosteryl Isostearyl Dimer Dilinoleate has the second most reported uses at 78 formulations. The results of a concentration of use survey by the Council, in 2025, indicated that Dimer Dilinoleyl Dimer Dilinoleate is used up to 48.7 percent in lipsticks and lip glosses.

So we come to our data needs. It looks like there's several.

DR. BERGFELD: Can I ask you a question first? Is there any read-across?

DR. DAVID COHEN: That was my first question. It is can we read-across?

DR. ROSS: Susan, you want to go or do you want me to go?

DR. TILTON: Go ahead.

DR. ROSS: So, we did look at this the first problem here is there's a -- well, many of them are esters, but you've also got a couple of them that are ethers, okay? So that raised a little bit of the flag.

But then Bart helped us out and drew some structures from a program he has. And it turns out that a couple of the ethers have up to 12 possible different structures. So we need some information on compound heterogeneity on each of these before I think we can make resolutions. And, you know, at this point, it's difficult --

DR. DAVID COHEN: So it's not a read across?

DR. ROSS: It's not a read across at this point.

DR. BERGFELD: Are the esters read across and ethers aren't, or what?

DR. ROSS: I only have different structures, as you can see here, on the ethers. I haven't got those on the esters. But I would imagine there's a similar heterogeneity with at least some of the esters.

DR. DAVID COHEN: So we want structural heterogeneity on all of them?

DR. ROSS: Yeah.

DR. DAVID COHEN: So we're issuing an IDA.

DR. SAM COHEN: Do you think they'll be able to actually do that?

DR. ROSS: I think so. We have no repeat dose toxs, we've got no DART or carcinogenicity studies.

DR. DAVID COHEN: Wait, let's start the list, because I have a few things here, too.

DR. ROSS: Okay. Well, first of all, the molecular weights are over 1000, so I don't think you've got to worry too much about dermal absorption.

DR. DAVID COHEN: And we have good irritation and sensitization.

DR. ROSS: Yeah.

DR. SAM COHEN: And the genotox is totally negative.

DR. ROSS: We don't have a maximum concentration of use, again, of Compound 2. I'm numbering these as they were in the list. We don't have dermal irritation and sensitization on the ethers.

DR. DAVID COHEN: What's their molecular weight?

DR. ROSS: They're over 1000.

DR. DAVID COHEN: Unlikely could it be --

DR. ROSS: If you just go down the list, they're compounds 4 and 7.

DR. DAVID COHEN: 4, and 7 we have.

MS. BURNETT: The one with PPG in the title.

DR. DAVID COHEN: Yeah.

DR. ROSS: So they're the ones with PPG-3 in their title.

DR. DAVID COHEN: So since we can't read across, you think we need sensitization on those. What about the Bis-Behenyl?

DR. ROSS: I thought that was okay.

DR. DAVID COHEN: I don't know if we have sensitization on that, do we?

DR. ROSS: First compound can be cleared based on HRIPT at neat. The others we have dermal sensitization at neat in animals. The HRIPT with compounds 3, 5, and 6, for example, is not at the max, which is 48.7 percent. The max HRIPT is it 19 percent, but we have the animal data. You know? So I think that's probably okay. Ocular irritation for the ethers we don't have.

DR. DAVID COHEN: Okay. So we're going back to the list building.

DR. ROSS: Okay.

DR. DAVID COHEN: Can you start enumerating?

DR. ROSS: Sure. The heterogeneity.

DR. DAVID COHEN: Yup.

DR. ROSS: We need dermal irritation and sensitization on the compounds 4 and 7, which are the two ethers. All of the others, I feel, can be cleared on dermal irritation using data from animals and/or humans. With respect to dermal sensitization that's also needed on the two ethers. I didn't see that. That's compounds 4 and 7 in my nomenclature. And we need ocular irritation there also.

DR. DAVID COHEN: For both of those?

DR. ROSS: Yeah.

DR. BERGFELD: So you are concentrating on the ethers?

DR. ROSS: Pretty much. Yeah.

DR. DAVID COHEN: Yeah.

DR. TILTON: And you mentioned one of the others doesn't have a concentration of use, but other than that, I mean, due to the large molecular weight and the negative genotox, general irritation and sensitization data, I would be okay clearing the others.

DR. ROSS: Yeah. I think it would still be nice to have some information on heterogeneity, but that could be editorial to some degree.

DR. DAVID COHEN: What do you think of the impurities and method of manufacturing?

DR. TILTON: We also don't have that for the ethers.

DR. ROSS: That's probably true.

DR. DAVID COHEN: I don't know how you make these, but I couldn't figure out how you made them from the method of manufacturing. And consequently, if we don't have method of manufacturing and we don't have impurities, then aren't we missing something, if we had one or the other?

DR. ROSS: You do have some in the method of manufacturing and impurities, though.

DR. DAVID COHEN: Hmm?

DR. BERGFELD: We have some there.

DR. ROSS: Yeah, there is some there. Generic method of manufacturing.

DR. DAVID COHEN: Is what? What does it say?

DR. ROSS: Very little.

DR. DAVID COHEN: It doesn't say anything.

DR. ROSS: No. Impurities you've got --

DR. DAVID COHEN: Just heavy metals.

DR. ROSS: Heavy metals and arsenic.

DR. DAVID COHEN: But how are those in there?

DR. ROSS: Yeah, you can ask for that.

DR. DAVID COHEN: Both?

DR. ROSS: Um-hmm. Certainly method of manufacture, which I think it's a little lacking.

DR. TILTON: That one or the composition.

DR. ROSS: I think it's the heterogeneity more than anything. You don't know what you're dealing with exactly.

DR. DAVID COHEN: What was that comment, Susan? I wanted to add that.

DR. TILTON: Method of manufacturing in addition to the heterogeneity.

DR. DAVID COHEN: Okay. There's a comment: "According to a supplier, the following ingredients have almost no UV absorption." I'm not sure I know what that meant.

DR. EISENMANN: They provided UV spectra that were straight lines.

DR. DAVID COHEN: Straight lines, okay.

MS. BURNETT: On PDF, I think, 44. Yeah, starting there.

MS. FIUME: Dr. Ross, so you're asking for ocular irritation for 4 and 7, but do they have ocular uses?

DR. ROSS: That's a good point, actually. I didn't know that, I think.

DR. DAVID COHEN: It's 4 and 7; I got to keep the compounds straight.

DR. ROSS: Yeah.

MS. FIUME: Ones with the PPG. That's how I do it. It makes it easier.

DR. DAVID COHEN: It does.

DR. TILTON: It appears not.

DR. ROSS: Well, if it don't then we don't need it. Good point, Monice. Yeah, if they don't have ocular we don't need it.

DR. DAVID COHEN: I think it's in lipsticks, but okay. Any other needs? So are we -- we're not clearing anything in the group right now. Is that right, Susan?

DR. ROSS: I think a summary was mainly on the ethos being used, David. With respect to -- before we started discussing heterogeneity we probably would have cleared, I think, the majority of the esters. But we just need some clarity with respect to heterogeneity on all of these compounds.

DR. DAVID COHEN: What data comes back that doesn't clear it?

DR. ROSS: Well, maybe one is primarily an Isostearyl ester, and another is a phytosterol ester. So maybe they're just different esters. So, for example, reading across would be different.

DR. DAVID COHEN: So you're saying -- okay. So the read across leaves compound 4 and 7, needing irritation and sensitization because you can't read across?

DR. ROSS: At this point, I think that's correct. Any other comments, Susan, from our discussion?

DR. TILTON: That could potentially be used.

DR. DAVID COHEN: What's that?

DR. TILTON: To support read across.

DR. DAVID COHEN: Say that again.

DR. TILTON: I said it could potentially be used to support read across. We just don't have any information.

DR. BERGFELD: Are we talking the non-ether, the esters?

DR. TILTON: Yes.

DR. ROSS: I think the esters are fine. You could probably go ahead and clear the esters with respect to a lot of this. But again, we just don't know a lot of information about what's in there.

MS. FIUME: Method of manufacture is needed for all ingredients, correct? The method of manufacture is needed for all ingredients?

DR. DAVID COHEN: And impurities.

DR. ROSS: I suspect it's going to be similar in the esters, i.e., just depending on the reagents used. I think it's going to be kind of generic, but you need some detail, I think, as David pointed out. There's no detail on that part of it. At least the way I read it.

DR. DAVID COHEN: Okay.

DR. ROSS: Do you have this one? Yeah, you have this one.

DR. DAVID COHEN: I do have this one.

DR. ROSS: So conclusion is heterogeneity and all of them. We felt we could just about clear the esters, but we need some information on heterogeneity. And the ethers we need more data.

DR. DAVID COHEN: Yeah, so what's the last comment again?

DR. ROSS: And the ethers, we need more data. And they may go tomorrow clearing.

DR. DAVID COHEN: I know.

DR. ROSS: That's quite a possibility I would think.

DR. BERGFELD: All of them? Clearing all of them?

DR. ROSS: It's possible.

DR. BERGFELD: Or just the esters?

DR. ROSS: Either or.

DR. DAVID COHEN: Yes. My gut is there. My gut is there. Yeah, we may not get a second.

DR. ROSS: Yeah. We're expecting that.

DR. DAVID COHEN: It's okay. We've been there before.

Full Panel – June 10, 2025

DR. DAVID COHEN: Okay so this is a Draft Report on Dimer Dilinoleates. There are seven ingredients reported to function as hair conditioning agents, skin conditioning agents and viscosity increasing agents. The seven ingredients are listed in the report. According to the RLD submitted to CIR in 2024, the ingredients in this group with the most reported use is Dimer Dilinoleyl Dimer Dilinoleate, and it is reported in 801 formulations. Phytosteryl Isostearyl Dimer Dilinoleate has the second most reported uses at 78 formulations. According to the 2023 VCRP dataset, lipsticks are common uses.

Concentration of use survey by the Council in 2025 indicate that Dimer Dilinoleyl Dimer Dilinoleate is used in up to 48.7 percent in lipsticks and lip glosses. Our group had a discussion about reading across with these seven ingredients and had difficulty coming to a full conclusion. Many are esters, some are ethers. The ethers can have up to 12 different structures and we had some difficulty with the read across there.

Our motion, therefore, is an Insufficient Data Announcement. Our needs are as follows: Structural heterogeneity on all of them to facilitate read across, dermal irritation and sensitization for compounds number 4 and 7, those are both with the PPG-3 in them, and we need a method of manufacturing and impurities for all of them. That's our motion. We can capture the discussion.

DR. SNYDER: I'll second the Insufficient Data Announcement where we had some additional needs.

DR. BERGFELD: Okay. Can we hear these?

DR. ROSS: And I had some additional needs also. I thought we had additional needs to that.

DR. SNYDER: We have in vivo genotox, we have no DART. We have no repeat dose tox data. We also agreed about the heterogeneity and Allan in particular said he would like -- Allan and Curt -- would like to see the structures. That heterogeneity and regards to the read across, we agree with that. We wanted the dilinoleic acid data added to the report. And then a minor thing with the Discussion to have the heavy metals boilerplate.

DR. DAVID COHEN: So you're adding an ingredient?

DR. SNYDER: Well, just the data from the dilinoleic acid.

DR. HELDRETH: Do you just want to have a reference back to that report? I mean, it's going to be significantly different from all of these esters. I mean you maybe -- if the enzyme could handle it, you could consider it a metabolite, but.

DR. SNYDER: What do you think about that, Don?

DR. BELSITO: Yeah, I mean it is going to be different from the esters, but wouldn't you expect some esterification in the skin? I think we can just summarize the data. Doesn't hurt.

DR. ROSS: Desterification.

DR. RETTIE: Desterification, yeah.

DR. BERGFELD: Allan, are you saying something?

DR. RETTIE: Oh, I may have misheard Don. I thought he said --

DR. BELSITO: Allan, your mic please.

DR. RETTIE: I may have misheard, Don. I thought you said esterification in the skin and I'm sure you must have said desterification, yeah?

DR. BELSITO: That's what I meant, yes.

DR. RETTIE: Okay. Then that's good.

DR. BERGFELD: David?

DR. ROSS: Yeah, I thought with these -- I agree with Paul. I thought, David, we had talked about for the ethers -- which I think we referred to as compounds 4 and 7 just the nomenclature taking by numbers there -- we needed acute toxicity data as well as dermal irritation and sensitization. I think we also talked about ocular.

Because if you look at the toxicity data on the table, you know if you look at those ethers, there's nothing all the way across there. Which I think was getting at Paul's point that he needed more data.

DR. BERGFELD: Did you include ocular?

DR. ROSS: I did, there was nothing listed and I think they have ocular uses.

DR. SNYDER: I'll amended the data request to also include ocular.

DR. SAM COHEN: For the esters, do we really need more tox data because the LD50 is greater than 2 grams per kilogram, and so I doubt if there's going to be any toxicity issues.

DR. SNYDER: We have no data, so, I mean.

DR. BELSITO: But we also discussed that it's not likely to be absorbed.

DR. ROSS: Yeah, we discussed that. Yeah.

DR. BERGFELD: All right, have we commented enough about what we need for the IDA?

DR. BELSITO: Allan, do you want to comment?

DR. RETTIE: Well, just following up on the last comment about absorption. We have molecular weights in excess of 1000, so I don't think there's an issue there.

The structures can be drawn in so many different ways, as Bart has shown us. But if we could get clarification on the structure of one of the Dimer Dilinoleates, we could extrapolate to the others. And if we could get clarification of the structure of one of the PPG-3 ethers, then we could extrapolate to the others, I think.

I didn't think we needed all that information in the report, but we do need clarification on a representative ether and a representative Dimer Dilinoleate.

DR. ROSS: I think that's a fair point. And getting back to that toxicity data and the molecular weight, we did actually discuss that. I'll retract that comment about needing that.

DR. SNYDER: Well, our concern on that was that these are lipsticks so we were assuming their potential for ingestion is high, so we wanted some data on systemic exposure.

DR. ROSS: You wanted oral toxicity data?

DR. SNYDER: Yeah.

DR. ROSS: And I would agree with that, but you don't necessarily need dermal, yeah.

DR. SNYDER: Correct.

DR. ROSS: Yeah, I agree, Paul.

DR. SNYDER: Okay.

DR. DAVID COHEN: I think before Wilma asks us to clarify this again, because I think it will be a fair comment, we've gone back and forth a lot.

DR. BELSITO: David, are you saying something?

DR. DAVID COHEN: Sounds like home. I'm sorry. I said, I think before Wilma asks me to clarify our IDA, I'm going to try to clarify the IDA more. Paul, could you run your list? I'll compare it to ours and then we could restate it.

DR. SNYDER: Well because it's an Insufficient Data Announcement and we have no in vivo genotox, we wanted some genotox data. We have no DART, again that supports that. We wanted repeat dose tox data on oral because of the potential for ingestion. We added ocular based upon the discussion. We wanted information on the heterogeneity of the composition of the different ingredients. And I think that was it.

DR. DAVID COHEN: And we wanted irritation and sensitization on the two PPG products, and we needed method of manufacturing and impurities for all of them.

DR. SNYDER: That's correct.

DR. SAM COHEN: Why do you need in vivo genotox data because all the in vitro is negative?

DR. SNYDER: But we're just going out insufficient so we -- I mean, because we're -- Don, Allan, Curt?

DR. SAM COHEN: Especially since you can't get --

DR. BELSITO: All right. My question was we have multiple negative in vitros, do we need in vivo is what I had in my report.

DR. SNYDER: It was kind of a question. I guess if Sam's comfortable with the data then we can remove that.

DR. SAM COHEN: Yeah, I don't think you need in vivo.

DR. SNYDER: Okay. We can take that off then.

DR. DAVID COHEN: Don, were you saying something that -- to keep it on?

DR. BELSITO: No, I was deferring to Sam as the expert. Because typically we do ask for in vivo, but you know we haven't really had a genotox expert on the Panel for a while. So, you know, we do have multiple negative in vitros and if Sam is happy with that then I'm more than happy with it.

DR. SAM COHEN: I'm happy.

DR. SNYDER: Okay. So, I'll amend that proposed Insufficient Data Announcement and take that one out.

DR. BERGFELD: All right, David, give your list please.

DR. DAVID COHEN: Okay. We need a structural -- we need data on structure, dermal sensitization and irritation on compounds 4 and 7, method of manufacturing and impurity of all of them, ocular tox, oral tox.

DR. BELSITO: And structures.

DR. DAVID COHEN: And structures. Yeah, the structural heterogeneity.

DR. SNYDER: We're in alignment.

DR. DAVID COHEN: Yeah. Okay.

DR. BERGFELD: You're in alignment. I can call in the question.

DR. SNYDER: Okay. Wait, Christina has a question.

DR. BERGFELD: You have a question, Christina?

MS. BURNETT: Yeah. I just wanted clarification, did you want --

DR. BELSITO: Is you mic on, Christina?

MS. BURNETT: Yes. Did you want the data from the dilinoleic acid report pulled in, or did you just want it to be referred back to?

DR. SNYDER: Just summarize. Right? Is that what you said, Don, just a summary of that data?

MS. BURNETT: Like italics for each --

DR. BELSITO: Well, then, that's the question is do we pull in the report or how do you summarize it? I mean I guess maybe just a referral back to that report without summarizing. We could say in the Introduction that we previously looked at dilinoleic acid and found it to be safe as used, da, da, da, da, da.

DR. DAVID COHEN: Can't we just reference that report?

DR. SNYDER: That's fine. That's fine.

DR. HELDRETH: It's historically what we have done.

DR. DAVID COHEN: We'll just reference the report.

DR. SNYDER: That's fine.

DR. BELSITO: Right.

DR. RETTIE: Just one last thing on the structural stuff. Can we be clear that -- it would be helpful if it was also clarified the extent of diesters versus monoesters. This came up in another report. The heterogeneity is profound, but if we list that within the insufficient data for composition, maybe we'll get it.

DR. BERGFELD: I think that can be just added. Can we just add that? Okay. I'm going to call the question then.

We've listed our Insufficient Data Announcement and the items within it. We've had an adequate discussion and especially with the structure. I'll call the question. All those in favor of this movement, please indicate by raising your hands. Okay. Unanimous. All right. Thank you so much.

MS. FIUME: Can I clarify for the IDA?

DR. BERGFELD: Sure.

MS. FIUME: So for the ocular irritation, I think they were on 4 and 7. The oral data, did it need to be on esters versus ethers, both? What is needed for that for the IDA?

DR. BELSITO: Well, it's the Dimer Dilinoleyl Dimer Dilinoleate that is used in a lipstick, right, 48.7 percent?

DR. DAVID COHEN: At very high concentration, yeah.

DR. BELSITO: So wouldn't we want it on that product?

DR. DAVID COHEN: I think that's right, Don.

DR. BERGFELD: Any other questions, Monice?

MS. FIUME: No. Thank you.

DR. DAVID COHEN: No, that's the clarification.

DR. BERGFELD: Okay, great. We're going to move on then to our next ingredient in this group of reports advancing. Dr. Snyder.

DR. SNYDER: Did you call the question?

DR. BERGFELD: I thought we all voted. We voted yes and then Monice had some questions.

DR. SNYDER: My apology. Okay. I'm sorry.

MARCH 2026 MEETING – DRAFT TENTATIVE AMENDED REPORT

Belsito Team – March 12, 2026

DR. BELSITO: So, next is Dimer Dilinoleates. At the June 2025 meeting, we issued an Insufficient Data Announcement for all seven ingredients, structures of all ingredients, method of manufacture, all ingredients, impurities, composition, all ingredients, a repeat oral-dose tox for Dimer Dilinoleyl Dimer Dilinoleate at maximum concentration of use, developmental and reproductive tox data, ocular irritation, dermal irritation and sensitization data, max concentration of use for Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate

Since that, we've received some of the requested data and more details on some of the data that we already had in the report. We got acute and ocular toxicity data. We got additional generic methods of manufacture, summary of data on clarification of the structures, and we got updated 2025 RLD.

To review our insufficiencies, the oral-dose tox we didn't get, the dermal irritation we didn't get, and the developmental and repro-tox we didn't get. And so, the question is, really, do we need some of these if it's not absorbed? I mean, these materials are not absorbed, so I'm not sure why we're so concerned about developmental issues.

And again, I think some of these insufficiencies come from the Cohen group, and I disagree with how they look at data. But we have irritation data to 100 percent. We have guinea pig maximization tests. We need to clarify the dosage in some, because they're usually three different -- an ID induction with our friend Freud's complete argument, that a topical induction, which is usually the highest concentration, and then a topical challenge, which is the highest non-irritant. The guinea pig studies were negative, but I'm not sure what the doses were with them. But we've also got some negative human studies.

So, I'm not sure that we need the dermal irritation and sensitization. I'm not sure we need the oral tox data because it's not absorbed when applied dermally; it's not relevant to its use in cosmetics. And, therefore, we also don't need the developmental and repro tox.

So I thought we could go sufficient for this, and discuss how we resolve the prior insufficiencies. And obviously in the Discussion, heavy metals. And that's where I came out on this.

DR. SNYDER: I would support that.

DR. KLAASSEN: Yeah, Don, I agree with you. I concluded that there's very, very little data; but, if it's not absorbed, we don't need much data.

DR. BELSITO: Yeah, I mean, it's used in lip, but the amount -- you know, I mean, it's a high concentration, but the amount applied to the lip is very small.

DR. RETTIE: Yeah, I agree with all of this. I mean, they're essentially toxicologically and biologically -- I don't want to say inert, but it's kind of what I feel. So, I'm happy going sufficient.

DR. BELSITO: Okay. Then in terms of the report, I just had a couple of questions. This is PDF Page 28, Christina. It says that Phytosteryl/Isostearyl -- dadadada -- Dimer has the highest maximum concentration of use reported on leave-on dermal exposure at 13 percent. And when I first read that it seemed to be contradictory to when you said the highest exposure in lipsticks and lip glosses was 48.7. But then I realized you're probably differentiating mucosal exposure from dermal exposure.

I just thought that this is the second paragraph in Use. It says, the results of the concentration of use survey conducted by the Council indicate that Dimer Dilinoleyl has the highest reported maximum concentration of use on mucosa, up to 48 percent lipsticks, and then dermal exposure. Because otherwise it just, you know, lipstick is --

MS. BURNETT: I think possibly I'm missing a word in that last sentence, which should have been the next highest maximum concentration of use. But I could point out mucosal versus dermal exposure. I'll fix that somehow.

DR. BELSITO: Okay. And then in the Discussion the fourth paragraph, this is PDF Page 31. It says, "The Panel expressed concern regarding heavy metals." I thought that was a little too alarming. I would suggest maybe, "The Panel noted that heavy metals may be present in these ingredients." I mean, I don't think we're alarmed by it.

MS. BURNETT: Okay.

DR. BELSITO: Maybe Curt was, I don't know.

DR. KLAASSEN: No. In fact, I was thinking when I was reading through these documents, you know, we often have that metal statement. I don't know of an example where it's ever been a problem. And also the metals don't go across the skin very well. So, I agree wholeheartedly that we can say may, but we're definitely not alarmed.

MS. BURNETT: I know what happened there. I think three of the paragraphs started with, "the Panel noted, the panel noted," and I think I was trying to change wording; but I will fix that so we're not alarmed.

DR. BELSITO: Anything else on these?

DR. SNYDER: Nothing for me.

MS. BURNETT: So, safe is used?

DR. BELSITO: Yeah.

MS. BURNETT: Okay, thank you.

Cohen Team – March 12, 2026

DR. DAVID COHEN: So, this is a Draft Tentative Report on the Dimer Dilinoleates, a group of seven ingredients used as primarily skin conditioning, hair conditioning and viscosity-increasing agents in cosmetics. At a previous review, the Panel issued an Insufficient Data Announcement primarily to address questions regarding structural heterogeneity, methods of manufacturing and impurities, and to obtain additional toxicologic and irritation sensitization data for certain members of the group. Some additional data has been received, including structures, manufacturing information and impurities, although several of the previously identified data gaps remained unresolved.

So for us, what can we clear and what should remain insufficient? It looks like the esters we're okay with. Is that possible?

DR. ROSS: Well --

DR. DAVID COHEN: Okay. All right. Let's hear it. Let's open it up, okay?

DR. ROSS: All right. Well, I think there's some changes on this, or at least potential changes. This was the one where we had zero uses jumping up to 2,400 uses. I thought that was kind of interesting. But, anyway, that is in the dossier. The structures, I think Bart put them in here, were great, showing the heterogeneity. We got MOM, we got impurities, we got ocular, that's great.

Previously, we discussed these things as two different groups, I think. There was a couple of compounds that had the PPG3 in them, you remember? We discussed those as ethers, and we discussed the rest of them as esters, and that's how David opened up this discussion.

It turns out, if you read this carefully, the compounds, as they say, previously known as ethers, are actually esters. And so, if you look at the chemistry of that -- and I didn't realize that until the very end here. So, they are esters. And so, actually, fundamentally, they're not very different structurally. They're all in the same ester pot and all have very high logP values. I can't even imagine how you formulate this, but logP values of over 30. I think Bart did some calculations and they were 29 to 37 or so.

Anyway, they're just incredibly lipophilic, and so they're very, very unlikely to be absorbed. They're not genotoxic at all. They're essentially non-toxic orally. They're not irritating to skin or eye when tested neat. They're not sensitizing to skin. They're basically negative in essentially all of our tests. I mean, these are emollients and moisturizers and the like, so they're not potent agents in any way. Does anyone have any real concerns about in vivo toxicities of these agents?

DR. TILTON: I have no concerns about toxicity. And I think, yeah, our primary discussion before was about whether or not we could read-across between the esters and the ethers. And if that is no longer part of the discussion, then, as a group, I really don't have a lot of concerns about these ingredients.

DR. ROSS: Yeah, that's kind of where I came down, Susan. I mean, if you look at the potential of read-across, the one problem with them is that all of these compounds are, you know, they're mixtures of different esters and that sort of thing. And I think we're on record as saying that read-across with mixtures is difficult. But, I think this case is an exception because all components of these mixtures are basically toxicologically inert. There's nothing in the mixture that's going to -- you know, they're all reading -- but we're seeing no readouts for tox endpoints.

So, I think previously we had a requirement for dermal irritation and sensitization for the PPG3-containing compounds, and if you were reading across that would go away. We don't have any dermal tox at all; we have no repeat dose oral tox, and we don't have any DART on any of the compounds.

So, I'm not too worried about the repeat-dose tox, given the single-dose tox data. The dermal tox data, while that would be preferred but, again, these compounds are toxicologically inert, the DART data, yeah, it'd be great if we had it. I think we asked for it, we didn't get it, but these compounds will not get across membranes. I mean, logP of 30?

I think in that case, and also key to this, I just want to say this, they're not known to have pharmacological actions via receptors on the reproductive system. And so, these agents are not in that class, so I didn't have any trouble with that. I don't know, that's a long logic argument, but that's how I got to safe as used for these things.

DR. DAVID COHEN: Yeah, I didn't think you were holding me back. I thought you were stopping me for more data; I didn't think you were stopping me for a full safe as used. Okay.

DR. ROSS: That's not my style, but there you go.

DR. DAVID COHEN: It was a surprise, yeah. That was a surprise. Sam?

DR. SAM COHEN: Yeah, I don't see any problem with these, especially now that they're all esters.

DR. DAVID COHEN: Okay.

DR. ROSS: Now, Dr. Rettie, tomorrow, may have other opinions, but we'll have that discussion tomorrow.

DR. DAVID COHEN: Okay.

DR. BERGFELD: Well, I think that discussion is going to be very important to include many of the things you just stated, David, as to how -- sort of the arithmetic of thinking there?

DR. ROSS: Yeah.

DR. DAVID COHEN: Yeah, yeah, the sequence of getting to not having DART -- explaining all of those issues about not getting through membranes, and not having the stigmata of a DART-concerning chemical, right?

DR. ROSS: Yeah.

DR. SAM COHEN: Well, as we heard this morning, is that you can have DART consequences without impacting the receptor if it impacts the synthesis. But these aren't going to impact synthesis of the steroids either, so it's not an issue.

DR. ROSS: Yeah, it's not a known endpoint of concern for these agents, so.

DR. SAM COHEN: No.

DR. DAVID COHEN: Okay. Any other comments on the Dilinoleates? Okay.

Full Panel – March 13, 2026

DR. BELSITO: At the June 2025 meeting, we issued an Insufficient Data Announcement for the seven ingredients in the Dimer Dilinoleates packet. We wanted structure for all ingredients, method of manufacture for all ingredients, impurities and composition data for all ingredients, repeated oral dose tox for Dimer Dilinoleyl, Dimer Dilinoleate at maximum concentration of use, developmental and repro tox, ocular irritation, dermal irritation and sensitization data at maximum concentration for Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate and Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate.

Since the IDA, we received some of the requested data, more details on some of the data that was already in the report. We got acute and ocular toxicity, we got generic methods of manufacturing and impurities, we got summary of data upon data, we got updated frequency of use with 2025 RLD concentrations.

And in looking at our data needs, basically, these are huge molecules, they're not going to be absorbed. And given the information we've received, we thought we could go safe as used.

DR. DAVID COHEN: Second. Don, we came to the same conclusions. And they're all different esters. And everything you enumerated came up in our meeting, and we came to the same conclusion. Didn't come quick, but we did come to that same conclusion.

DR. BERGFELD: Anything that needs to go into the Discussion?

DR. BELSITO: Yeah. One, that they're huge molecules and wouldn't be absorbed. Heavy metal boilerplate in the Discussion. A few clarifications in the report that I went over with Christina.

And in the Discussion, the next-to-last paragraph, it says, "The Panel expressed concern regarding heavy metals." I think that's a little too alarming. You know, we weren't concerned, we noted that there were heavy metals that might be present in these ingredients. And so, a little change in that. But otherwise, we were fine. Remove the prior insufficiencies in the Discussion and go with safe as used.

DR. BERGFELD: Any other comments by the Panel members? Okay, David.

DR. DAVID COHEN: David, Sam and Susan, we all had this conversation about that these molecules don't seem to have stigmata for DART issues, right?

DR. ROSS: Well, I mean, we felt that there were no issues with respect to a need for DART issues, simply because they are not pharmacologically active agents working through receptors with known reproductive endpoints. Again, these things are toxicologically inert, essentially, as Don just said. So, we weren't too worried about all those requirements.

DR. KLAASSEN: And also that they're not absorbed.

DR. SAM COHEN: And plus as Don have said, they're not absorbed.

DR. ROSS: Yeah, they're not absorbed. And sure they're mixtures, but it's a bit of an exception with these mixtures because they're all toxicologically inert, each component of the mixture is. I think we're fine with all of this.

DR. DAVID COHEN: Okay.

DR. BERGFELD: All right. I'm going to call the question then. All those opposed? Abstaining? It's approved and moving forward then to the next ingredient.

Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Status:	Draft Final Report for Panel Review
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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Bruce A. Brod, M.D., M.H.C.I., F.A.A.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. Previous Panel member involved in this assessment: David E. Cohen, M.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.

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
Dictionary	*International Cosmetic Ingredient Dictionary*
EPA	Environmental Protection Agency
ET_{50}	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.[1] 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).[2] 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.[3] Additional reports related to the ingredients in this safety assessment and the respective conclusions are:

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

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 April 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.[1] 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 β-sitosterol, campesterol, stigmasterol, and brassicasterol), isostearyl, cetyl, stearyl, and/or behenyl alcohols.

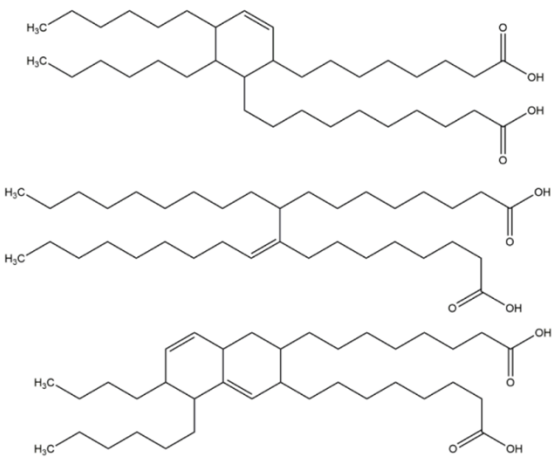


Figure 1. Dilinoleic acid ("dimer acid") (hydrogenated form (i.e., no double bond) is also possible)

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. According to one supplier, in addition the customary methyl substitution pattern of alkanes with an "iso" prefix (as drawn in Figure 2), methyl-substitution may instead occur at any of C2-C15 in isostearyl alcohol.

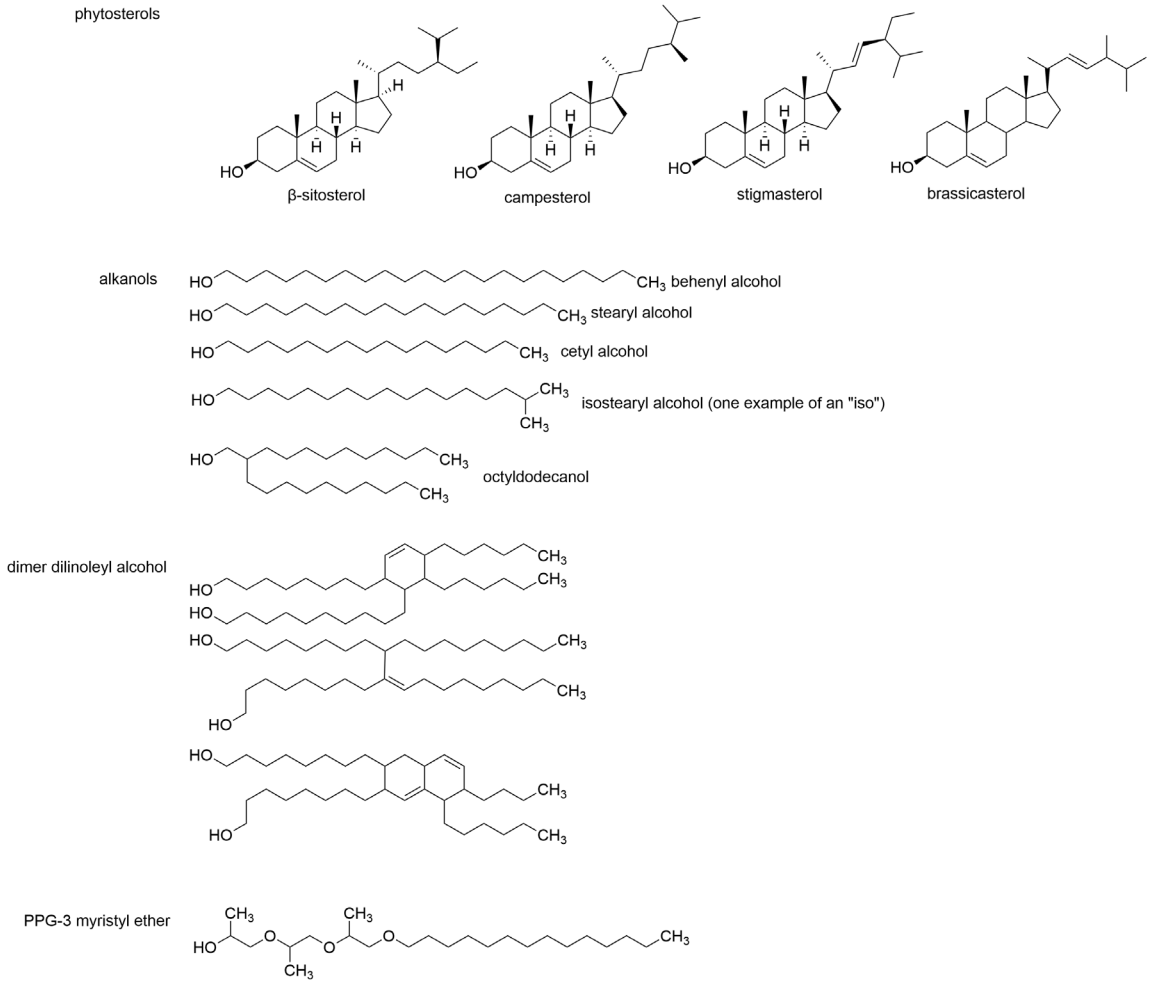
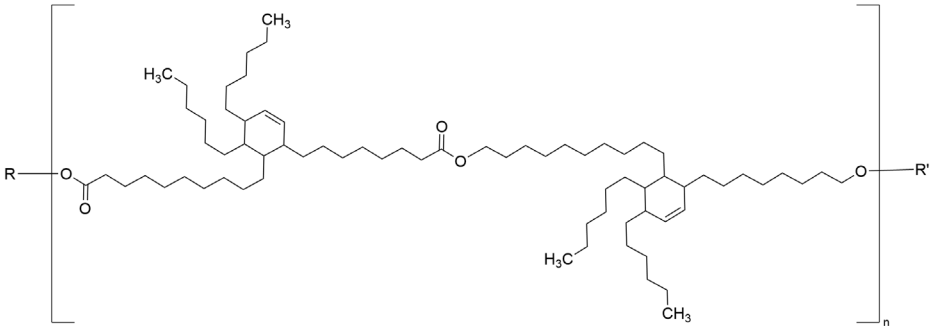


Figure 2. Alcohols

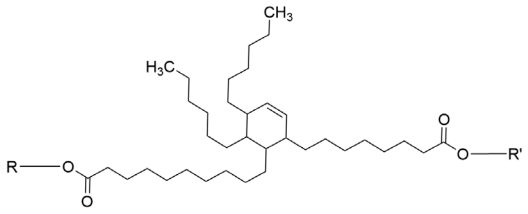
Two of these ingredients are polymeric (or at least oligomeric), comprising a repeating "dimer dilinoleyl dimer dilinoleate monomer."[10-12] These include Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate and Dimer Dilinoleyl Dimer Dilinoleate, as depicted in Figure 3.



dimer dilinoleyl dimer dilinoleate monomer

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 phytostearyl residue endcaps); n is unknown.

The remaining ingredients are non-polymeric.[10-12] 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.



dimer dilinoleate --- non-polymeric

Figure 4. Examples of idealized structures of Bis-Behenyl/Phytosteryl Dimer Dilinoleate (wherein R and R' are independently behenyl or phytostearyl 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 phytostearyl residue endcaps), Phytosteryl Isostearyl Dimer Dilinoleate (wherein R and R' are independently isostearyl or phytostearyl 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.[13] Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is also a white to pale yellow paste, with a melting point of 38ºC.[14] 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.[15]

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.[10] 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 - 240ºC) while removing the water produced in the reaction.[11] 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.[10] 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.[11]

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.[16] 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.[17] 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).[18,19] 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.[20] 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%.[20] Uses in baby products were also reported; for example, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate and Phytosteryl Isostearyl Dimer Dilinoleate are used in baby lotions, oils, powders, and creams (concentration not reported).

Additionally, some of the dimer dilinoleates are used in cosmetic sprays and powders and could possibly be inhaled; for example, Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate are reported to be used in other fragrance preparations (concentration not reported) and 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 cosmetic sprays 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.[21]

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_{50} 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.[10,13,22-25]

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.[10,13] 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[10] or with Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (test concentration not specified) in an in vitro micronucleus assay.[10,13]

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.[10,13] 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).[10] 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.[10,14]

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).[10,13] 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).[26-28]

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.[10,29] 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%.[10,30,31] 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).[10,13,32] 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.[10,14,33-35]

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_{50} 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[1]

Ingredient/CAS No.	Definition	Function(s)
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate 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 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 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
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate		
Physical Form	White to pale yellow hydrophobic paste	13
Molecular Weight (g/mol)	> 1000	13
Density (g/ml @ 50 ºC)	0.89	13
Melting Point (ºC)	~40	13
Water Solubility	Insoluble	13
Bis-Behenyl/Phytosteryl Dimer Dilinoleate		
Molecular Weight (g/mol)	1180 - 1356	15
Vapor Pressure (mmHg @ 25ºC)	9.14×10^{-29} (MPBPVP v1.43 estimate)	15
Melting Point (ºC)	349.8 (MPBPVP v1.43 estimate)	15
Boiling Point (ºC)	1114.5 (MPBPVP v1.43 estimate)	15
Water Solubility @ 25ºC (mg/l)	6.99×10^{-34} (WSKOW v1.42 estimate)	15
log K_{ow}	36.09 (WSKOW v1.42 estimate)	15
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate		
Molecular Weight (g/mol)	1179 - 1305	15
Vapor Pressure (mmHg @ 25ºC)	7.52×10^{-28} (MPBPVP v1.43 estimate)	15
Melting Point (ºC)	349.8 (MPBPVP v1.43 estimate)	15
Boiling Point (ºC)	1082.6 (MPBPVP v1.43 estimate)	15
Water Solubility @ 25ºC (mg/l)	1.12×10^{-30} (WSKOW v1.42 estimate)	15
log K_{ow}	32.6 (KOWWIN v1.68 estimate)	15
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate		
Physical Form	White to pale yellow paste	14
Molecular Weight (g/mol)	1011 - 1356	15
Viscosity (kg/(s x m)@ 60 ºC)	0.18	14
Melting Point (ºC)	38	14
Water Solubility @ 25ºC (mg/l)	8.79×10^{-31} (WSKOW v1.42 estimate)	15
log K_{ow}	33.14 (WSKOW v1.42 estimate)	15
Phytosteryl Isostearyl Dimer Dilinoleate		
Molecular Weight (g/mol)	1069 - 1356	15
Vapor Pressure (mmHg @ 25ºC)	3.11×10^{-27} (MPBPVP v1.43 estimate)	15
Melting Point (ºC)	349.8 (MPBPVP v1.43 estimate)	15
Boiling Point (ºC)	1061.1 (MPBPVP v1.43 estimate)	15
Water Solubility @ 25ºC (mg/l)	9.41×10^{-32} (WSKOW v1.42 estimate)	15
log K_{ow}	34.05 (WSKOW v1.42 estimate)	15
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate		
Molecular Weight (g/mol)	1069 - 1305	15
Vapor Pressure (mmHg @ 25ºC)	1.01×10^{-26} (MPBPVP v1.43 estimate)	15
Melting Point (ºC)	349.8 (MPBPVP v1.43 estimate)	15
Boiling Point (ºC)	1043.2 (MPBPVP v1.43 estimate)	15
Water Solubility @ 25ºC (mg/l)	1.13×10^{-28} (WSKOW v1.42 estimate)	15
log K_{ow}	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	# of Uses	Max Conc of Use
	RLD (2025)[18,19]	% (2025)[20]	RLD (2025)[18,19]	% (2025)[20]	RLD (2025)[18,19]	% (2025)[20]
	Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate		Bis-Behenyl/Phytosteryl Dimer Dilinoleate		Dimer Dilinoleyl Dimer Dilinoleate	
Totals*	**2474**	**0.15-30.1**	**45**	**NR**	**1189**	**0.1-48.7**
summarized by likely duration and exposure**						
Duration of Use						
Leave-On	*2506*	*0.15-30.1*	*45*	*NR*	*1163*	*0.1-48.7*
Rinse-Off	*12*	*0.2-3.6*	*NR*	*NR*	*88*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Unknown	*7*	*NR*	*NR*	*NR*	*12*	*NR*
Exposure Type						
Baby Products	NR	NR	NR	NR	NR	NR
Children's Makeup	1	NR	NR	NR	2	NR
Eye Area	348	0.15-11.7	4	NR	191	0.8-10
Incidental Ingestion	1802	3-30.1	39	NR	634	11.3-48.7
Mucous Membrane	1802	3-30.1	39	NR	634	11.3-48.7
Incidental Inhalation-Spray	36[a];73[b]	1.6[b]	1[a]; 1[b]	NR	3; 47[a]; 57[b]	6[b]
Incidental Inhalation-Airbrush	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	43; 73[b]	0.4-2.9; 0.4-3[c]	1[b]	NR	38; 57[b]	6[b]; 3.2[c]
Dermal Contact	700	0.15-11.7	6	NR	463	0.1-10
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	14	1.6	NR	NR	102	NR
Hair-Coloring	NR	NR	NR	NR	2	NR
Nail	2	NR	NR	NR	7	NR
Other Preparations (Unknown Exposure Type)	7	NR	NR	NR	12	NR
as reported by product category						
Baby Products						
Baby Shampoos						
Baby Lotions/Oils/Powders/Creams						
Other Baby Products						
Eye Makeup Preparations (not children's)						
Eyebrow Pencil	36	0.15-2.5	4	NR	25	10
Eyeliner	23	0.98-11.7			2	NR
Eye Shadow	270	1.4-7			85	1.5-2
Eye Lotion	2	NR			1	
False Eyelashes						
Mascara					44	0.8-3
Eyelash and Eyebrow Adhesives/Glues/Sealants					1	NR
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)	1	4			8	2
Other Eye Makeup Preparations	16	2.1			25	NR
Fragrance Preparations						
Powders (dusting/talcum, excl aftershave talc)						
Other Fragrance Preparation					3	NR
Hair Preparations (non-coloring)						
Hair Conditioners	1 (l.o.); 9 (r.o.)	1.6 (r.o.)			10 (l.o.); 43 (r.o.)	NR
Hair Straighteners					3	NR
Permanent Waves					1	NR
Rinses (non-coloring)					9	NR

Table 3. Frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]
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
Hair Coloring Preparations						
Other Hair Coloring Preparation					2	NR
Makeup Preparations (not eye or children's)						
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
Makeup Preparations for Children (not eye)						
Children's Lipsticks and Lip Glosses	1	NR			2	NR
Manicuring Preparations						
Cuticle Softeners					1	NR
Nail Creams and Lotions					3	NR
Nail Polish and Enamel	2	NR				
Other Manicuring Preparations					3	NR
Personal Cleanliness						
Bath Soaps and Body Washes						
Shaving Preparations						
Beard Softeners					1	NR
Pre-shave Lotions (all types)					1	NR
Shaving Cream (aerosol, brushless, lather)	NR	0.6				
Skin Care Preparations						
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.)
Suntan Preparations						
Suntan Gels, Creams, and Liquids						
Indoor Tanning Preparations						
Other Preparations (i.e., those that do not fit another category)	7	NR			12	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)[18,19]	% (2025)[20]	RLD (2025)[18,19]	% (2025)[20]	RLD (2025)[18,19]	% (2025)[20]
	Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate		Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate		Phytosteryl Isostearyl Dimer Dilinoleate	
Totals*	**32**	**10**	**1998**	**0.6-30**	**202**	**0.099**
summarized by likely duration and exposure**						
Duration of Use						
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*
Exposure Type						
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[a]. 264[b]	NR	12[a]; 19[b]	NR
Incidental Inhalation-Airbrush	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	37; 264[b]; 1[c]	1.4-1.6; 0.6-3[c]	2; 19[b]; 1[c]	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
as reported by product category						
Baby Products						
Baby Shampoos					1	NR
Baby Lotions/Oils/Powders/Creams			1	NR	1	NR
Other Baby Products			2 (l.o.)	NR		
Eye Makeup Preparations (not children's)						
Eyebrow Pencil			28	0.88-4.8	2	NR
Eyeliner			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
Fragrance Preparations						
Powders (dusting/talcum, excl aftershave talc)					1	NR
Other Fragrance Preparation			1	NR		
Hair Preparations (non-coloring)						
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 RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]
Tonics, Dressings, Other Hair Grooming Aids			5	NR		
Other Hair Preparations			2 (r.o.)	NR		
Hair Coloring Preparations						
Other Hair Coloring Preparation						
Makeup Preparations (not eye or children's)						
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
Makeup Preparations for Children (not eye)						
Children's Lipsticks and Lip Glosses					3	NR
Manicuring Preparations						
Cuticle Softeners			1	NR		
Nail Creams and Lotions			1	NR	3	NR
Nail Polish and Enamel			2	NR		
Other Manicuring Preparations					3	NR
Personal Cleanliness						
Bath Soaps and Body Washes					1	NR
Shaving Preparations						
Beard Softeners						
Pre-shave Lotions (all types)						
Shaving Cream (aerosol, brushless, lather)						
Skin Care Preparations						
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
Suntan Preparations						
Suntan Gels, Creams, and Liquids					1	NR
Indoor Tanning Preparations					1	NR
Other Preparations (i.e., those that do not fit another category)					1	NR

Table 3. Frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]
	Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate					
Totals*	**44**	**4.7-8.9**				
summarized by likely duration and exposure**						
Duration of Use						
Leave-On	*44*	*4.7-8.9*				
Rinse-Off	*NR*	*NR*				
Diluted for (Bath) Use	*NR*	*NR*				
Unknown	*NR*	*NR*				
Exposure Type						
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				
as reported by product category						
Baby Products						
Baby Shampoos						
Baby Lotions/Oils/Powders/Creams						
Other Baby Products						
Eye Makeup Preparations (not children's)						
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						
Fragrance Preparations						
Powders (dusting/talcum, excl aftershave talc)						
Other Fragrance Preparation						
Hair Preparations (non-coloring)						
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 RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]	# of Uses RLD (2025)[18,19]	Max Conc of Use % (2025)[20]
Other Hair Preparations						
Hair Coloring Preparations						
Other Hair Coloring Preparation						
Makeup Preparations (not eye or children's)						
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						
Makeup Preparations for Children (not eye)						
Children's Lipsticks and Lip Glosses						
Manicuring Preparations						
Cuticle Softeners						
Nail Creams and Lotions						
Nail Polish and Enamel						
Other Manicuring Preparations						
Personal Cleanliness						
Bath Soaps and Body Washes						
Shaving Preparations						
Beard Softeners						
Pre-shave Lotions (all types)						
Shaving Cream (aerosol, brushless, lather)						
Skin Care Preparations						
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						
Suntan Preparations						
Suntan Gels, Creams, and Liquids						
Indoor Tanning Preparations						
Other Preparations (i.e., those that do not fit another category)						

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)

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

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

Table 4. Acute toxicity studies

Test Article	Vehicle	Animals/Group	Concentration/Dose	Protocol	LD_{50}/LC_{50}/Results	Reference
			ORAL			
Bis-Behenyl/Isostearyl/ Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	DMSO	6 female Sprague-Dawley CD (Crl: 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_{50} > 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/ Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	not reported	rats; no further details provided	at most 2000 mg/kg	Acute toxicity test performed in accordance with OECD TG 423; no further details provided	LD_{50} > 2000 mg/kg	13
Dimer Dilinoleyl Dimer Dilinoleate	arachis oil	3 male and 3 female Sprague-Dawley CD (Crl: 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_{50} > 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/ Cetyl/Stearyl/Behenyl Dimer Dilinoleate	arachis oil	6 female Sprague-Dawley CD (Crl: 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_{50} > 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/ Cetyl/Stearyl/Behenyl 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_{50} > 2500 mg/kg	10,14
Phytosteryl Isostearyl Dimer Dilinoleate	arachis oil	3 male and 3 female Sprague-Dawley CD (Crl: 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_{50} > 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
IN VITRO						
Gene Mutation						
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
Chromosomal Damage						
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
IRRITATION						
ANIMAL						
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
HUMAN						
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	42 subjects	24-h closed patch test; no further details provided	Not irritating	[10]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	42 subjects	24-h closed patch test; no further details provided	Not irritating	[10]
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[10]
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[10,14]
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[10]
SENSITIZATION						
ANIMAL						
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	[13]
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	[10]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Skin sensitization study in accordance with OECD TG 406; no further details provided	Not sensitizing	[10]
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	[10]
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	[10]
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Skin sensitization study in accordance with OECD TG 406; no further details provided	Not sensitizing	[10]
HUMAN						
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	42 subjects	HRIPT; no further details provided	Not sensitizing	[10]
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	[28]
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	[27]
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	[26]

Table 7. Ocular irritation studies

Test Article	Vehicle	Concentration	Test System	Protocol	Results	Reference
IN VITRO						
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_{50}) 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_{50} 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]
ANIMAL						
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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