Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Status:	Draft Report for Panel Review
Release Date:	May 16, 2025
Panel Meeting Date:	June 9-10, 2025

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

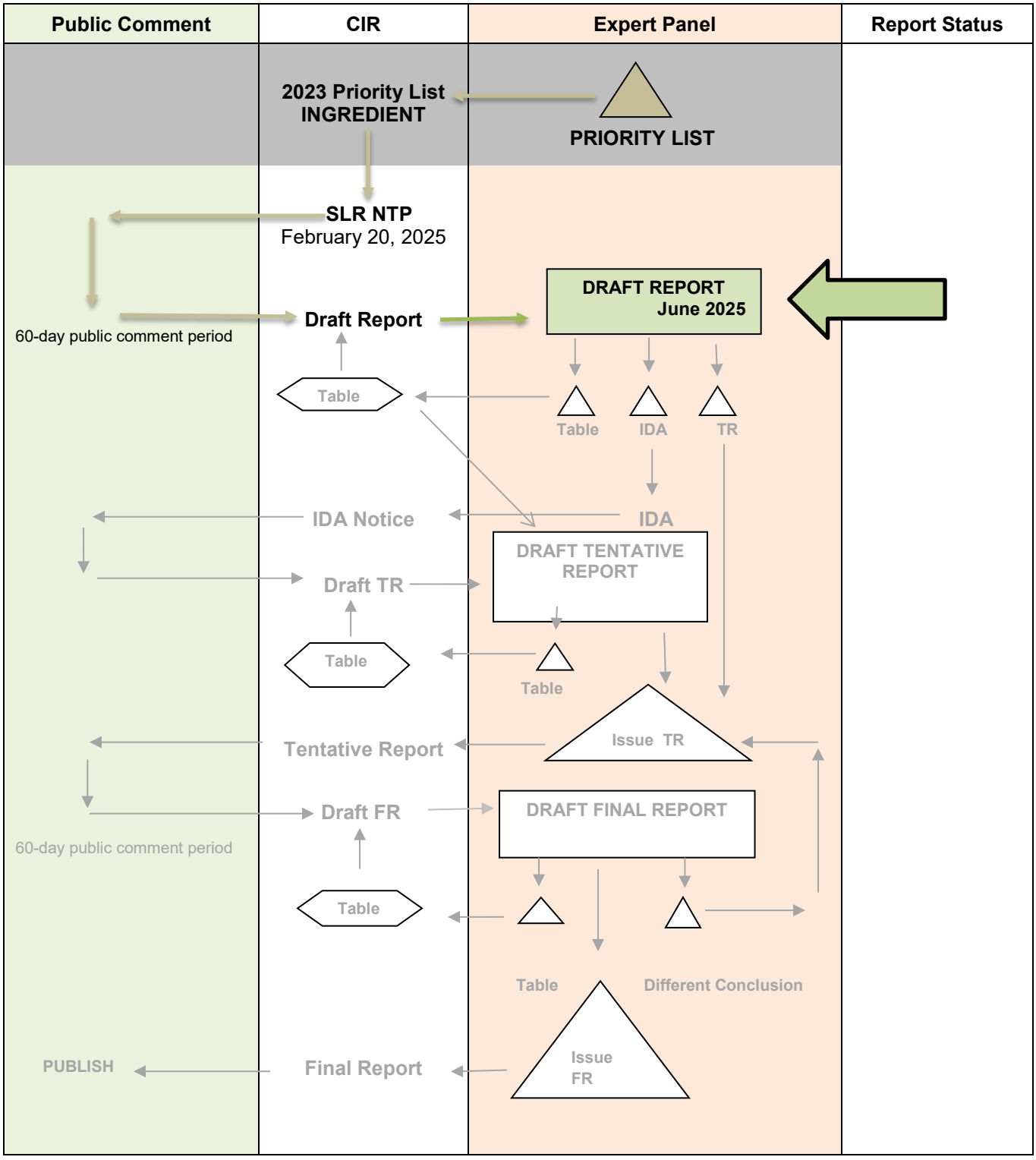
© Cosmetic Ingredient Review
555 13th Street, NW, Suite 300W, Washington, DC 20004
cirinfo@cir-safety.org

Distributed for Comment Only -- Do Not Cite or Quote

SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Dimer Dilinoleates

MEETING June 2025



Cosmetic Ingredient Review

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR
Date: May 16, 2025
Subject: Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Enclosed is the Draft Report on the Safety of Dimer Dilinoleates as Used in Cosmetics. (It is identified as *report_DimerDilinoleates_062025* in the pdf document). In February 2025, CIR issued a Scientific Literature Review (SLR) Notice to Proceed (NTP) for these 7 ingredients that are reported to function as hair conditioning agents, skin conditioning agents, and viscosity increasing agents in cosmetics:

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

An extensive search of information in the published scientific literature, online databases, and other sources on these ingredients provided insufficient information to justify preparation of a formal SLR. CIR issued the SLR NTP to alert interested parties that a safety assessment is being prepared and to request information in multiple areas, including:

- Chemistry information, including structure, UV spectra, method of manufacture, and composition/impurity data;
- Dermal penetration and/or absorption data;
- Toxicokinetics data relevant to routes of exposure expected with cosmetic use;
- General toxicity data;
- Developmental and reproductive toxicity data;
- Genotoxicity data;
- Carcinogenicity data;
- Dermal irritation and sensitization data;
- Inhalation toxicity data; and
- Any other relevant safety information that may be available

Since the SLR NTP was issued, CIR staff have received some of the requested data. These data have been incorporated into the Draft Report:

- *data1_DimerDilinoleates_062025* – HRIPT data on Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate in lip formulations
- *data2_DimerDilinoleates_062025* – UV spectra data on 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
- *data3_DimerDilinoleates_062025* – extremely brief summary data on acute toxicity, genotoxicity, dermal irritation and sensitization, and ocular irritation on 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

According to RLD submitted to CIR in 2024, the ingredient in this group with the most reported uses is Dimer Dilinoleyl Dimer Dilinoleate; it is reported to be used in 801 formulations. Phytosteryl Isostearyl Dimer Dilinoleate has the second most reported uses in the RLD; it is reported to be used in 78 formulations. The 2023 VCRP data reported Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate to have the most reported uses, 244 formulations, most of which were in lipsticks. The results of the concentration of use survey collected by the Council in 2025 indicate Dimer Dilinoleyl Dimer Dilinoleate is used at up to 48.7% in lipsticks and lip glosses (*data4_DimerDilinoleates_062025*).

Additional supporting documents for this report package include a flow chart (*flow_DimerDilinoleates_062025*), report history (*history_DimerDilinoleates_062025*), a search strategy (*search_DimerDilinoleates_062025*), and a data profile (*dataprofile_DimerDilinoleates_062025*).

If no further data are needed, the Panel should formulate a Discussion and issue a Tentative Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an Insufficient Data Announcement.

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.

Dimer Dilinoleates Data Profile* – June 2025 – 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														
Dimer Dilinoleyl Dimer Dilinoleate	X	X	X					X							X					X	X		X	X		X	X		
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate	X																												
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	X	X	X					X							X					X	X		X	X			X		
Phytosteryl Isostearyl Dimer Dilinoleate	X	X	X					X							X					X	X		X				X		
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	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 Dilinoneate – 7 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/

Safety Assessment of Dimer Dilinoleates as Used in Cosmetics

Status: Draft Report for Panel Review
Release Date: May 16, 2025
Panel Meeting Date: June 9-10, 2025

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

© Cosmetic Ingredient Review
555 13th Street, NW, Suite 300W, Washington, DC 20004
cirinfo@cir-safety.org

ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
Dictionary	*International Cosmetic Ingredient Dictionary and Handbook*
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
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
VCRP	Voluntary Cosmetic Registration Program

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 web-based *International Cosmetic Ingredient Dictionary and Handbook* (*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 Expert Panel for Cosmetic Ingredient Safety (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] Additionally, the Panel reviewed Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate in a report that was also published in 2023; the Panel concluded this ingredient is safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating.[4]

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 2025. 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 the carboxylic acid groups in Figure 1 are esterified with phytosteryl, isostearyl, cetyl, stearyl, and/or behenyl alcohols.

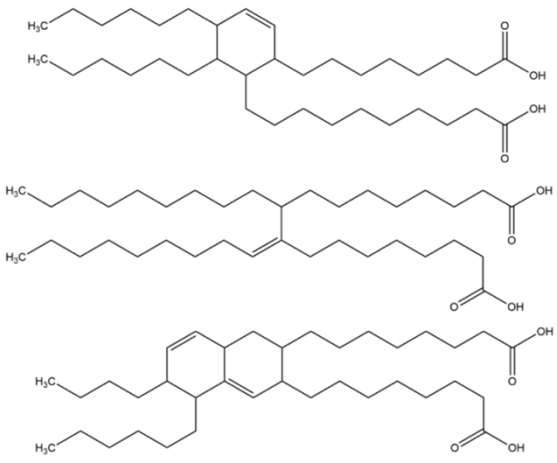


Figure 1. Dilinoleic acid ("dimer acid")

Chemical Properties

Chemical properties of Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate and Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl 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.[5] Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is also a white to pale yellow paste, with a melting point of 38ºC.[6]

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.[8] For these ingredients, the raw materials are reacted and undergo purification and filtration prior to packaging. No further details were provided. No other method of manufacture data for any of the ingredients in this report were found in the published literature, nor were unpublished data not submitted.

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.[8] No further information is available.

UV Absorption

According to a supplier, the following ingredients have almost no UV absorption: 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.[7] 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. Data included herein were obtained from the FDA and in response to a survey of maximum use concentrations conducted by the Personal Care Products Council (Council), and it is these values that define the present practices of use and concentration. Frequencies of use obtained from the FDA include data from the Voluntary Cosmetic Registration Program (VCRP) database as well as Registration and Listing Data (RLD). As a result of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, the VCRP was discontinued in 2023 and, as of 2024, 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-year 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.[9] Please note, at this time, it is not appropriate to contrast data from the VCRP and RLD to determine a trend in frequency of use because there are numerous differences in the ways the data for the VCRP and the RLD were collected and processed, and because reporting frequency of use is now mandatory (as opposed to the past practice of voluntary reporting). Although the VCRP program is now defunct, trends in frequency of use from the RLD alone are not yet possible in that a baseline is currently not available.

According to RLD submitted to CIR in 2024, the ingredient in this group with the most reported uses is Dimer Dilinoleyl Dimer Dilinoleate; it is reported to be used in 801 formulations (Table 3).[10] Phytosteryl Isostearyl Dimer Dilinoleate has the second most reported uses in the RLD; it is reported to be used in 78 formulations. The 2023 VCRP data reported Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate to have the most reported uses, 244 formulations, most of which were in lipsticks.[11] The results of the concentration of use survey conducted by the Council in 2025 indicate Dimer Dilinoleyl Dimer Dilinoleate has the highest reported maximum concentration of use, at up to 48.7% in lipsticks and lip glosses.[12] Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate has the highest maximum concentration of use reported for leave-on dermal exposure, at 13% 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%.[11,12] Additionally, some of the dimer dilinoleates may be used in cosmetic powders, and could possibly be inhaled; for example, Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate is reported to be used at at up to 2.9% in face powders, In practice, as stated in the Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-

findings), most droplets/particles incidentally inhaled from cosmetics would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

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 by the FDA, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such 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 using airbrush application, so it is possible that these ingredients are used with airbrush delivery systems, but not reported as such. Additionally, the Council currently surveys the cosmetic industry for maximum reported use concentrations of ingredients in products which may be used in conjunction with an airbrush delivery system; thus, this type of data may also be available when submitted. Please note that no concentration of use data were provided indicating airbrush application. However, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. 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. Accordingly, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

All of the dimer dilinoleate ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union.[13]

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 or 2500 mg/kg in unknown species of animals (no further details were provided): Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate.[8] In a study in rats, the LD_{50} was greater than 2000 mg/kg for Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate.[5]

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 were not mutagenic in an Ames test when tested at 100% (no further details provided): 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.[5,8] Additionally, Bis-Behenyl/Phytosteryl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate were not genotoxic in chromosome aberration tests when tested at 100% (no further details provided).[8] Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate was not genotoxic in a chromosome aberration test when tested at 100% or in a micronucleus assay (no further details provided for either study).[5,8]

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.[5,8] 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).[8] 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.[6,8]

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).[5,8] 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).[14-16]

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.[8] Dimer Dilinoleyl Dimer Dilinoleate at 100% concentration was also determined to be non-irritating in an EpiOcular corneal assay, but it could not be categorized in an eye irritation study performed in accordance with OECD TG 491 (no further details provided). In animals 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 in rabbits (no further details on either study provided).[5,8] Minimal irritation was observed in studies with Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate at 100% concentration (no further details provided).[6,8]

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 phytosteryl, isostearyl, cetyl, stearyl, and/or behenyl chains.

According to RLD submitted to CIR in 2024, the ingredient in this group with the most reported uses is Dimer Dilinoleyl Dimer Dilinoleate; it is reported to be used in 801 formulations. Phytosteryl Isostearyl Dimer Dilinoleate has the second most reported uses in the RLD; it is reported to be used in 78 formulations. VCRP data (2023) reported Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate to have the greatest number of reported uses, 244 formulations, most of which were in lipsticks. The results of the concentration of use survey conducted by the Council in 2025 indicate Dimer Dilinoleyl Dimer Dilinoleate has the highest reported maximum concentration of use, at up to 48.7% in lipsticks and lip glosses. Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate has the highest maximum concentration of use reported for leave-on dermal exposure, at 13% in foundations.

All of the dimer dilinoleate ingredients named in the report are not 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 or 2500 mg/kg in unknown species of animals (no further details were provided): Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate; Dimer Dilinoleyl Dimer Dilinoleate; Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate; and Phytosteryl Isostearyl Dimer Dilinoleate. In a study in rats, the LD_{50} was greater than 2000 mg/kg for Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate.

The following ingredients were not mutagenic in an Ames test when tested at 100% (no further details provided): 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, Bis-Behenyl/Phytosteryl Dimer Dilinoleate, Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate were not genotoxic in chromosome aberration tests when tested at 100% (no further details provided). Bis-Behenyl/Isostearyl/

Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate was not genotoxic in a chromosome aberration test when tested at 100% or in a micronucleus assay (no further details provided for either study).

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, but it could not be categorized in an eye irritation study performed in accordance with OECD TG 491 (no further details provided). In animal 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 in rabbits (no further details on either study provided). Minimal irritation was observed in studies with Dimer Dilinoleyl Dimer Dilinoleate, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, and Phytosteryl Isostearyl Dimer Dilinoleate at 100% concentration (no further details provided).

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

To be developed.

CONCLUSION

To be determined.

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	5
Molecular Weight (g/mol)	> 1000	5
Density (g/ml @ 50 ºC)	0.89	5
Melting Point (ºC)	~40	5
Water Solubility	Insoluble	5
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate		
Physical Form	White to pale yellow paste	6
Viscosity (kg/(s x m)@ 60 ºC)	0.18	6
Melting Point (ºC)	38	6

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]
	Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate			Bis-Behenyl/Phytosteryl Dimer Dilinoleate			Dimer Dilinoleyl Dimer Dilinoleate		
Totals*	**NR**	**93**	**0.15-30.1**	**NR**	**19**	**NR**	**801**	**28**	**0.8-48.7**
summarized by likely duration and exposure**									
Duration of Use									
Leave-On	***	*93*	*0.15-30.1*	***	*19*	*NR*	***	*27*	*0.8-48.7*
Rinse-Off	***	*NR*	*0.2-3.6*	***	*NR*	*NR*	***	*1*	*NR*
Diluted for (Bath) Use	***	*NR*	*NR*	***	*NR*	*NR*	***	*NR*	*NR*
Exposure Type									
Eye Area	***	5	0.15-11.7	***	3	NR	***	2	0.8-10
Incidental Ingestion	***	61	3-30.1	***	15	NR	***	15	11.3-48.7
Incidental Inhalation-Spray	***	8[a]; 1[c]	1.6[a]	***	NR	NR	***	4[a]; 1[c]	NR
Incidental Inhalation-Powder	***	5	0.4-2.9; 0.2-3[b]	***	NR	NR	***	NR	3.2[b]
Dermal Contact	***	32	0.15-11.7	***	4	NR	***	12	1.5-10
Deodorant (underarm)	***	NR	NR	***	NR	NR	***	NR	NR
Hair - Non-Coloring	***	NR	1.6	***	NR	NR	***	1	NR
Hair-Coloring	***	NR	NR	***	NR	NR	***	NR	NR
Nail	***	NR	NR	***	NR	NR	***	NR	NR
Mucous Membrane	***	61	3-30.1	***	15	NR	***	15	11.3-48.7
Baby Products	***	NR	NR	***	NR	NR	***	NR	NR
as reported by product category									
Eye Makeup Preparations (not children's)							***155***		
Eyebrow Pencil	NR	NR	0.15-2.5	NR	2	NR	19	NR	10
Eyeliner	NR	NR	0.98-11.7	NR	1	NR			
Eye Shadow	NR	3	1.4-7				79	NR	1.5-2
Eye Lotion							1	NR	NR
Mascara							39	NR	0.8-3
Eyelash and Eyebrow Adhesives, Glues, and Sealants							1	NA	NR
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)	NR	NR	4				1	NA	2
Other Eye Makeup Preparations	NR	2	2.1				16	2	NR
Fragrance Preparations							***3***		
Other Fragrance Preparation							3	NR	NR
Hair Preparations (non-coloring)							***64***		
Hair Conditioners	NR	NR	1.6 (r.o.)				8 (l.o.) 31 (r.o.)	1	NR
Hair Straighteners							3	NR	NR
Permanent Waves							1	NR	NR
Rinses (non-coloring)							3	NR	NR
Shampoos (non-coloring)							9 (r.o.)	NR	NR
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	1.6				6	NR	NR
Other Hair Preparations							3 (l.o.) 2 (r.o.)	NR	NR
Hair Coloring Preparations							**2**		
Other Hair Coloring Preparation							2 (r.o.)	NR	NR
Makeup Preparations (not eye; not children's)							***530***		
Blushers and Rouges (all types)	NR	1	2.9	NR	1	NR	29	NR	7-8

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]
Face Powders	NR	5	0.4-2.9				22	NR	NR
Foundations	NR	NR	0.5				75	1	0.1-4.3
Lipsticks and Lip Glosses	NR	61	3-30.1	NR	15	NR	380	15	11.3-48.7
Makeup Bases							1	NR	NR
Makeup Fixatives							4	NR	NR
Other Makeup Preparations	NR	2	NR				29 (l.o.)	3	NR
Makeup Preparations for Children (not eye)									
Children's Lipsticks and Lip Glosses									
Manicuring Preparations							***4***		
Cuticle Softeners							1	NR	NR
Nail Creams and Lotions							3	NR	NR
Other Manicuring Preparations							3	NR	NR
Shaving Preparations							***1***		
Beard Softeners							1	NR	NR
Pre-shave Lotions (all types)							1	NR	NR
Shaving cream	NR	NR	0.6						
Skin Care Preparations							***48***		
Face and Neck (excluding shaving preps)	NR	1	0.4-3 (l.o.) 0.2 (r.o.)				20 (l.o.)	1	3.2 (l.o.)
Body and Hand (excluding shaving preps)							3 (l.o.)	NR	NR
Moisturizing	NR	7	1-3				21	3	NR
Night	NR	1	NR				4	NR	3.2
Paste Masks (mud packs)	NR	NR	3.6						
Skin Fresheners							6	NR	NR
Other Skin Care Preparations	NR	10	NR				10 (l.o.)	1	6
Suntan Preparations									
Suntan Gels, Creams, and Liquids							NR	1	NR
Other Preparations (i.e., those that do not fit another category)							***6***		

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]
	Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate			Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate			Phytosteryl Isostearyl Dimer Dilinoleate		
Totals*	**32**	**1**	**10**	**2**	**244**	**0.6-30**	**78**	**6**	**0.099**
summarized by likely duration and exposure**									
Duration of Use									
Leave-On	***	*1*	*10*	***	*244*	*0.6-30*	***	*2*	*0.099*
Rinse-Off	***	*NR*	*NR*	***	*NR*	*NR*	***	*4*	*0.7*
Diluted for (Bath) Use	***	*NR*	*NR*	***	*NR*	*NR*	***	*NR*	*NR*
Exposure Type									
Eye Area	***	NR	NR	***	2	0.88-12.6	***	NR	NR
Incidental Ingestion	***	1	10	***	198	15.1-30	***	1	NR
Incidental Inhalation-Spray	***	NR	NR	***	18[a]; 1[c]	NR	***	NR	NR
Incidental Inhalation-Powder	***	NR	NR	***	2	1.4-1.6; 0.6-3[b]	***	NR	0.099
Dermal Contact	***	NR	NR	***	46	0.6-13	***	1	0.099
Deodorant (underarm)	***	NR	NR	***	NR	NR	***	NR	NR
Hair - Non-Coloring	***	NR	NR	***	NR	NR	***	4	NR
Hair-Coloring	***	NR	NR	***	NR	NR	***	NR	NR
Nail	***	NR	NR	***	NR	NR	***	NR	NR
Mucous Membrane	***	1	10	***	198	15.1-30	***	1	NR
Baby Products	***	NR	NR	***	NR	NR	***	NR	NR
as reported by product category									
Eye Makeup Preparations				***1***			***3***		
Eyebrow Pencil				NR	1	0.88-4.8	2	NR	NR
Eyeliner									
Eye Shadow				1	NR	3.6-12.6			
Eye Lotion							1	NR	NR
Mascara									
Eyelash and Eyebrow Adhesives, Glues, Sealants									
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)									
Other Eye Makeup Preparations				NR	1	NR			
Fragrance Preparations									
Other Fragrance Preparation									
Hair Preparations (non-coloring)									
Hair Conditioner							NR	1	NR
Hair Straighteners									
Permanent Waves									
Rinses (non-coloring)							NR	3	NR
Shampoos (non-coloring)									
Tonics, Dressings, and Other Hair Grooming Aids									
Other Hair Preparations									
Hair Coloring Preparations									
Other Hair Coloring Preparation									
Makeup Preparations (not eye; not children's)	***32***			***1***			***56***		
Blushers and Rouges (all types)				1	12	12	8	1	NR
Face Powders				NR	2	1.4-1.6	NR	NR	0.099
Foundations				NR	1	13	1	NR	NR
Lipsticks and Lip Glosses	31	1	10	1	198	15.1-30	46	1	NR

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]
Makeup Bases									
Makeup Fixatives				1	NR	NR			
Other Makeup Preparations	1	NR	NR	NR	2	NR	1 (l.o.)	NR	NR
Makeup Preparations for Children (not eye)							*3*		
Children's Lipsticks and Lip Glosses							3	NA	NR
Manicuring Preparations (Nail)							*3*		
Cuticle Softeners									
Nail Creams and Lotions							3	NR	NR
Other Manicuring Preparations							3	NR	NR
Shaving Preparations									
Beard Softeners									
Pre-shave Lotions (all types)									
Skin Care Preparations				***1***			*16*		
Face and Neck (excluding shaving preps)				1	1	0.6-3 (l.o.)	8 (l.o.)	NR	NR
Body and Hand (excluding shaving preps)				NR	NR	3			
Moisturizing				NR	17	3.4	8	NR	NR
Night				NR	1	NR			
Paste Masks (mud packs)									
Skin Fresheners									
Other Skin Care Preparations				NR	8	NR	3 (l.o.)	NR	NR
Suntan Preparations									
Suntan Gels, Creams, and Liquids									
Other Preparations (i.e., those that do not fit another category)									
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate									
Totals*	**50**	**35**	**4.7-8.9**						
summarized by likely duration and exposure**									
Duration of Use									
Leave-On	***	*35*	*4.7-8.9*						
Rinse-Off	***	*NR*	*NR*						
Diluted for (Bath) Use	***	*NR*	*NR*						
Exposure Type									
Eye Area	***	NR	NR						
Incidental Ingestion	***	1	4.7-8.9						
Incidental Inhalation-Spray	***	NR	NR						
Incidental Inhalation-Powder	***	8	NR						
Dermal Contact	***	34	6.7						
Deodorant (underarm)	***	NR	NR						
Hair - Non-Coloring	***	NR	NR						
Hair-Coloring	***	NR	NR						
Nail	***	NR	NR						
Mucous Membrane	***	1	4.7-8.9						
Baby Products	***	NR	NR						
as reported by product category									
Eye Makeup Preparations (not children's)									
Eyebrow Pencil									
Eyeliner									
Eye Shadow									

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use	# of Uses		Max Conc of Use
	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]	RLD (2024)[10]	VCRP (2023)[11]	% (2025)[12]
Eye Lotion									
Mascara									
Eyelash and Eyebrow Adhesives, Glues, and Sealants									
Eyelash and Eyebrow Preparations (primers, conditioners, serums, fortifiers)									
Other Eye Makeup Preparations									
Fragrance Preparations									
Other Fragrance Preparation									
Hair Preparations (non-coloring)									
Hair Conditioners									
Hair Straighteners									
Permanent Waves									
Rinses (non-coloring)									
Shampoos (non-coloring)									
Tonics, Dressings, and Other Hair Grooming Aids									
Other Hair Preparations									
Hair Coloring Preparations									
Other Hair Coloring Preparation									
Makeup Preparations (not eye; not children's)	***50***								
Blushers and Rouges (all types)	12	11	6.7						
Face Powders	NR	8	NR						
Foundations									
Lipsticks and Lip Glosses	38	1	4.7-8.9						
Makeup Bases									
Makeup Fixatives									
Other Makeup Preparations	NR	15	NR						
Makeup Preparations for Children (not eye)									
Children's Lipsticks and Lip Glosses									
Manicuring Preparations									
Cuticle Softeners									
Nail Creams and Lotions									
Other Manicuring Preparations									
Shaving Preparations									
Beard Softeners									
Pre-shave Lotions (all types)									
Skin Care Preparations									
Face and Neck (excluding shaving preps)									
Body and Hand (excluding shaving preps)									
Moisturizing									
Night									
Paste Masks (mud packs)									
Skin Fresheners									
Other Skin Care Preparations									
Suntan Preparations									
Suntan Gels, Creams, and Liquids									
Other Preparations (i.e., those that do not fit another category)									

NR – not reported; NA – not applicable (this category was not part of the VCRP)
l.o. – leave-on; r.o. – rinse-off
*The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple product categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple exposure types.
**Likely duration and exposure are derived from VCRP and survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)
*** In the RLD each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.)
[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.
[b] It is possible these products are powders, but it is not specified whether the reported uses are powders.
[c] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

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	undiluted	not reported	at most 2000 mg/kg	Acute toxicity test performed in accordance with OECD TG 423; no further details provided	LD_{50} > 2000 mg/kg	8
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	5
Dimer Dilinoleyl 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	8
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	8
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	6,8
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	not reported	at most 2000 mg/kg	Acute toxicity test performed in accordance with OECD TG 423; no further details provided	LD_{50} > 2000 mg/kg	8

Table 5. Genotoxicity studies

Test Article	Vehicle	Concentration/Dose	Test System	Protocol	Results	Reference
IN VITRO						
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	5
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	8
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	8
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	5
Bis-Behenyl/Phytosteryl Dimer Dilinoleate	undiluted	100%	not reported	Ames test; no further details provided	Not mutagenic	8
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Ames test in accordance with OECD TG 471; no further details provided	Not mutagenic	8
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	8
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	8
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	undiluted	100%	not reported	Chromosome aberration test using mammalian cell cultures; no further details provided	Not genotoxic	8
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Ames test in accordance with OECD TG 471; no further details provided	Not mutagenic	8
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Chromosome aberration test using mammalian cell cultures; no further details provided	Not genotoxic	8

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	8
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	5
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Primary skin irritation study in accordance with OECD TG 404; no further details provided	Mild irritant	8
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	8
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	8
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	8
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Primary skin irritation study in accordance with OECD TG 404; no further details provided	Mild irritant	8
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	guinea pigs; no further details provided	Cumulative skin irritation study; no further details provided	Practically non-irritating	8

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	[8]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	42 subjects	24-h closed patch test; no further details provided	Not irritating	[8]
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[8]
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[6,8]
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	45 subjects	24-h closed patch test; no further details provided	Not irritating	[8]
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	[5]
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	[8]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Skin sensitization study in accordance with OECD TG 406; no further details provided	Not sensitizing	[8]
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	[8]
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	[8]
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Skin sensitization study in accordance with OECD TG 406; no further details provided	Not sensitizing	[8]
HUMAN						
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	42 subjects	HRIPT; no further details provided	Not sensitizing	[8]
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	[16]
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	[15]
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	[14]

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%	not reported	EpiOcular corneal model; no further details provided	Non-irritating	[8]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	EpiOcular corneal model; no further details provided	Non-irritating	[8]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Eye irritation study in accordance with OECD TG 491; no further details provided	Not categorized	[8]
ANIMAL						
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Ocular irritation study in accordance with OECD TG 405; no further details provided	Practically non-irritating	[8]
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	[5]
Dimer Dilinoleyl Dimer Dilinoleate	undiluted	100%	not reported	Ocular irritation study in accordance with OECD TG 405; no further details provided	Minimal irritation	[8]
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	[8]
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	[6,8]
Phytosteryl Isostearyl Dimer Dilinoleate	undiluted	100%	not reported	Ocular irritation study in accordance with OECD TG 405; no further details provided	Minimal irritation	[8]

REFERENCES

1. Nikitakis J, Kowcz A. 2025. Web-Based International Cosmetic Ingredient Dictionary and Handbook. https://incipedia.personalcarecouncil.org/winci/. Date Accessed: February 13, 2025.
2. Burnett CL, Bergfeld WF, Besito DV, et al. 2019. Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics. https://cir-reports.cir-safety.org/view-attachment?id=3a3ac6dd-8c74-ec11-8943-0022482f06a6.
3. Cherian PA, Bergfeld WF, Belsito DV, et al. Amended Safety Assessment of Dialkyl Dimer Dilinoleates as Used in Cosmetics. *Int J Toxicol*. 2023;42(Suppl 2):114S–125S.
4. Fiume MM, Bergfeld WF, Belsito DV, et al. Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics. *Int J Toxicol*. 2023;42(Suppl 2):5S–101S.
5. National Industrial Chemicals Notification and Assessment Scheme. 2016. Polymer of Low Concern Public Report: Fatty acids, C18-unsatd., dimers, di-Me esters, hydrogenated, polymers with 1-docosanol, hydrogenated C18-unsatd. fatty acid dimers, isooctadecanol and soya hydroxysteroids (INCI Name: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate). File No PLC/1328. https://www.industrialchemicals.gov.au/sites/default/files/PLC1328%20Public%20Report%20PDF.pdf. Date Accessed: April 23, 2025.
6. Ohashi Y, Myojo K. Development of the novel plant-derived lanolin substitute and its cosmetic applications. *J Cosmet Sci*. 2006;57(2):193–194.
7. Nippon Fine Chemical Co. Ltd. 2025. UV spectrum of dimer dilinoleate ingredients. [Unpublished data submitted by the Personal Care Products Council on April 21, 2025].
8. Nippon Fine Chemical Co. Ltd. 2025. The information of dimer dilinoleate ingredients. [Unpublished data submitted by the Personal Care Products Council on April 21, 2025].
9. U.S. Food and Drug Administration. Federal Food, Drug, and Cosmetic Act Section 612 Title 21.
10. U.S. Food and Drug Administration Office of the Chief Scientist. 2024. Registration and Listing Data - Frequency of Use of Cosmetic Products. [Obtained under the Freedom of Information Act from the Division of Freedom of Information; requested as "Frequency of Use Data" July 17, 2024; received July 30, 2024].
11. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition. 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. [Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023].
12. Personal Care Products Council. 2025. Concentration of Use by FDA Product Categories (new MoCRA categories): Dimer Dilinoleates 2025. [Unpublished data submitted by the Personal Care Products Council on March 27, 2025].
13. EUR-Lex. 2009. Regulation (EC) No 1223/2009 of the European Parliment and of the Council of 30 November 2009 on cosmetic products (recast). (Text with EEA relevance). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1223&qid=1682529291932.
14. Anonymous. 2024. Summary Repeated Insult Patch Test (lip gloss containing 15% Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate). [Unpublished data submitted by the Personal Care Products Council on April 3, 2025].
15. Anonymous. 2014. Summary Repeated Insult Patch Test (lip treatment containing 19% Dimer Dilinoleyl Dimer Dilinoleate). [Unpublished data submitted by the Personal Care Products Council on April 3, 2025].
16. Anonymous. 2012. Summary Repeated Insult Patch Test (lip balm containing 3% Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate). [Unpublished data submitted by the Personal Care Products Council on April 3, 2025].

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

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

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: April 3, 2025

SUBJECT: Dimer Dilinoleates 2025

Anonymous. 2024. Summary Repeated Insult Patch Test (lip gloss containing 15% Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate).

Anonymous. 2014. Summary Repeated Insult Patch Test (lip treatment containing 19% Dimer Dilinoleyl Dimer Dilinoleate).

Anonymous. 2012. Summary Repeated Insult Patch Test (lip balm containing 3% Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate).

[redacted]

Lip Gloss
Leave-on, neat, no sensitization
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate 15%

[redacted]

TABLE I: SUMMARY OF REACTIONS

TOTAL NUMBER OF SUBJECTS ENROLLED: 123
TOTAL NUMBER OF SUBJECTS COMPLETED: 100

Reaction	Induction Reading									Challenge Reading			
Grade	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**1**	**1a**	**2**	**2a**
0	115	113	112	110	108	103	101	102	101	100	2	99	1
±	1				1	1	1					1	
1													
1E													
2													
2E													
3E													
4E													
-											98		99
N9R													
Total	116	113	112	110	109	104	102	102	101	100	100	100	100

SCORING SYSTEM:

0	= No visible reaction
±	= Faint, minimal erythema
1	= Erythema
2	= Intense erythema, induration
3	= Intense erythema, induration, vesicles
4	= Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	= Edema
-	= No reading
N9R	= No 9th reading

[redacted]

[redacted]

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	SGS	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
1	53123	[redacted]	F	56	0	0	0	0	0	0	0	0	0	0	-	0	-
2	53750		M	23	0	0	0	0	0	0	0	0	0	0	-	0	-
3	52999		F	66	0	0	0	0	0	0	0	0	0	0	-	0	-
4	45959		F	34	0	0	0	0	0	0	0	0	0	0	-	0	-
5	42590		M	34	0	0	0	0	0	0	0	0	0	0	-	0	-
6	47090		M	60	0	0	0	0	0	0	0	0	0	0	-	0	-
7	48586		F	65	0	0	0	0	0	0	0	0	0	0	-	0	-
8	53556		F	57	0	0	0	0	0	0	0	0	0	0	-	0	-
9	43490		M	56	0	0	0	0	0	0	0	0	0	0	-	0	-
10	52568		F	33	0	0	0	0	0	0	0	0	0	0	-	0	-
11	53998		F	37	0	0	X	X	X	X	X	X	X	X	X	X	X
12	50867		F	33	0	0	0	0	0	0	0	0	0	0	-	0	-
13	54248		M	25	0	0	0	0	0	0	0	0	0	0	-	0	-
14	54120		M	45	0	X	X	X	X	X	X	X	X	X	X	X	X
15	49532		F	50	0	0	0	0	0	0	0	0	0	0	-	0	-
16	47109		M	29	0	0	0	0	0	0	0	0	0	0	0 ♦	0	-
17	53334		M	56	X	X	X	X	X	X	X	X	X	X	X	X	X
18	52210		F	57	0	0	0	0	0	0	0	0	0	0	-	0	-
19	40171		F	62	0	0	0	0	0	0	0	0	0	0	-	0	-
20	24935		M	60	0	0	0	0	0	0S	0	0	0	0	-	0	-
21	49422		M	53	0	0	0	0	0	0	0	0	0	0	-	0	-
22	51957		F	38	0	0	0	0	0	0	0	0	0	0	-	0	-
23	53484		F	67	0	0	0	0	0	0	0	0	0	0	-	0	-
24	37120		F	43	0	0	0	0	0	0	0	0	0	0	-	0	-
25	16807		F	56	0	0	0	0	0	0	0	0	0	0	-	0	-

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	SGS	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
26	51918	[redacted]	F	64	0	0	0	0	0	0	0	0	0	0	-	0	-
27	53985		F	33	0	0	0	0	0	0	0	0	0	0	-	0	-
28	53986		F	39	0	0	0	0	0	0	0	0	0	0	-	0	-
29	51476		F	64	0	0	0	0	0	0	0	0	0	0	-	0	-
30	54290		F	22	0	0	0	0	±	0	0	0	0	0	-	0	-
31	40237		F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
32	50478		F	57	0	0	0	0	0	0	0	0	0	0	-	0	-
33	49339		M	64	0	0	0	0	0	0	0	0	0	0	-	0	-
34	47653		M	42	0	0	0	0	0	0	0	0	0	0	-	0	-
35	53885		F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
36	22546		F	50	0	0	0	0	0	0S	0S	0	0	0	-	0	-
37	36482		M	67	0	0	0	0	0	0	0	0	0	0	-	0	-
38	54232		M	28	0	X	X	X	X	X	X	X	X	X	X	X	X
39	41220		F	64	X	X	X	X	X	X	X	X	X	X	X	X	X
40	52835		M	58	0	0	0	0	0	±	0	0	0	0	-	0	-
41	54105		M	36	0	0	0	0	0	0	0	0	0	0	-	0	-
42	18725		F	63	0	0	0	0	0	0	0	0	0	0	-	0	-
43	47942		F	70	0	0	0	0	0	0	0	0	0	0	-	0	-
44	31209		M	57	0	0	0	0	0	0	0	0	0	0	-	0	-
45	42329		F	63	0	0	0	0	0	0	0	0	0	0	-	0	-
46	53860		F	30	0	0	0	0	0	0	0	0	0	0	-	0	-
47	51403		F	24	0	0	0	0	0	0	0	0	0	0	-	0	-
48	39398		M	45	0	0	0	0	0	0	0	0	0	0	-	0	-
49	37963		F	36	0	0	0	0	0	0	0	0	0	0	-	0	-
50	50303		M	62	0	0	0	0	0	0	0	0	0	0	-	0	-

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	SGS	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
51	39784	[redacted]	M	61	0	0	0S	0	0	0	0	0	0	0	-	±	-
52	53807	[redacted]	F	46	0	0	0	0	0	0	0	0	0	0	-	0	-
53	51840	[redacted]	F	66	0	0	0	0	0	0	0	0	0	0	-	0	-
54	22745	[redacted]	F	58	0	0	0	0	0	0	0	0	0	0	-	0	-
55	30066	[redacted]	F	58	0	0	0	0	0	0	0	0	0	0	-	0	-
56	32521	[redacted]	M	58	0	0	0	0	0	0	0	0	0	0	-	0	-
57	25993	[redacted]	M	38	0	0	0	0	0	0	0	0	0	0	-	0	-
58	54293	[redacted]	M	51	0	0	0	0	0	0	0	0	0	0	-	0	-
59	52389	[redacted]	F	19	0	0	0	0	0	X	X	X	X	X	X	X	X
60	49441	[redacted]	M	47	0	0	0	0	0	X	X	X	X	X	X	X	X
61	51784	[redacted]	F	23	0	0	0	0	0	0	0	0	0	0	-	0	-
62	45903	[redacted]	M	26	0	0	0	0	0	0	0	0	0	0	-	0	-
63	45836	[redacted]	M	28	0	0	0	0	0	0	0	0	0	0	-	0	-
64	52828	[redacted]	F	37	0	0	0	X	X	X	X	X	X	X	X	X	X
65	45065	[redacted]	F	60	0	0	0	0	0	0	0	0	0	0	-	0	-
66	54101	[redacted]	F	61	0S	0S	0	0	0	0	0	0	0	0	-	0	-
67	54268	[redacted]	M	26	0	0	0	0	0	0	0	0	0	X	X	X	X
68	54252	[redacted]	M	41	0	0	0	0	0	0	0	0	0	0	-	0	-
69	36446	[redacted]	F	56	0	0	0	0	0	0	0	0	0	0	-	0	-
70	54294	[redacted]	M	22	0	0	0	0	0	0	X	X	X	X	X	X	X
71	50081	[redacted]	F	59	0	0	0	0	0	0	0	0	X	X	X	X	X
72	50086	[redacted]	F	69	0	0	0	0	0	0	0	0	0	0	-	0	-
73	54266	[redacted]	F	47	0	0	0	0	0	0	0	0	0	0	-	0	-
74	53382	[redacted]	F	37	0	0	0	0	0	0	0	0	0	0	-	0	-
75	53381	[redacted]	F	20	0	0	0	0	0	0	0	0	0	0	-	0	-

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	SGS	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
76	31237	[redacted]	F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
77	30780		M	60	0	0	0	0	0	0	0	0	0	0	-	0	-
78	51614		F	57	0	0	0	0	0	0	0	0	0	0	-	0	-
79	21911		F	65	0	0	0	0	0	0	0	0	0	0	-	0	-
80	54295		M	23	±	0	0	0	0	0	0	0	0	0	-	0	-
81	53585		F	36	0	0	0	0	0	0	0	0	0	0	-	0	-
82	52076		M	59	0	0	0	0	0	0	0	0	0	0	-	0	-
83	52444		F	55	0	0	0	0	0	0	0	0	0	0	-	0	-
84	30021		F	47	0	0	0	0	0	0	0	0	0	0	-	0	-
85	49353		F	47	0	0	0	0	0	0	0	0	0	0	-	0	-
86	53897		F	32	0	0	0	0	0	0	0	0	0	0	-	0	-
87	34459		M	56	0	0	0	0	0	0	0	0	0	0	-	0	-
88	54264		F	33	0	0	0	0	0	0	±	0	0	0	0 ♦	0	0 ♦
89	51657		M	57	0	0	0	0	0	0	0	0	0	0	-	0	-
90	50411		F	58	0	0	0	0	0	0	0	0	0	0	-	0	-
91	54249		M	22	0	0	0	0	0	0	0	0	0	0	-	0	-
92	53993		M	31	0	0	0	0	0	X	X	X	X	X	X	X	X
93	54297		M	33	0	0	0	0	0	0	0	0	0	0	-	0	-
94	34458		F	68	0	0	0	0	0	0	0	0	0	0	-	0	-
95	54246		M	41	X	X	X	X	X	X	X	X	X	X	X	X	X
96	53014		M	18	0	0	0	0	0	0	0	0	0	0	-	0	-
97	47921		F	63	0	0	0	0	0	0	0	0	0	0	-	0	-
98	47318		F	54	0	0	0	0	0	0	0	0	0	0	-	0	-
99	25910		F	62	0	0	0	0	0	0	X	X	X	X	X	X	X
100	53131		F	52	0	0	0	0	0	0	0	0	0	0	-	0	-

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	SGS	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
101	38892	[redacted]	F	62	0	0	0	0	0	0	0	0	0	0	-	0	-
102	32934		F	67	0	0	0	0	0	0	0	0	0	0	-	0	-
103	49917		F	21	0	0	0	0	0	X	X	X	X	X	X	X	X
104	42751		M	56	0	0	0	0	0	0	0	0	0	0	-	0	-
105	43211		M	37	0	0	0	0	X	X	X	X	X	X	X	X	X
106	54063		F	47	X	X	X	X	X	X	X	X	X	X	X	X	X
107	50051		F	63	0	0	0	0	0	0	0	0	0	0	-	0	-
108	53869		F	51	0	0	0	0	0	0	0	0	0	0	-	0	-
109	40248		F	60	0	0	0	0	0	0DR	0	0	0	0	-	0	-
110	54167		F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
111	48679		F	57	0	0	0	0	0	0	0	0	0	0	-	0	-
112	49426		M	54	0	0	0	0	0	0	0	0	0	0	-	0	-
113	29042		F	41	0	0	0	0	0	0	0	0	0	0	-	0	-
114	50883		M	52	0	0	0	0	0	0	0	0	0	0	-	0	-
115	52320		M	39	0	0	0	X	X	X	X	X	X	X	X	X	X
116	53377		F	43	0	X	X	X	X	X	X	X	X	X	X	X	X
117	30536		F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
118	49685		F	28	X	X	X	X	X	X	X	X	X	X	X	X	X
119	53834		F	42	0	0	0	0	0	0	0	0	0	0	-	0	-
120	49440		F	42	0	0	0	0	0	X	X	X	X	X	X	X	X
121	38653		F	52	0	0	0	0	0	0	0	0	0	0	-	0	-
122	47885		F	47	X	X	X	X	X	X	X	X	X	X	X	X	X
123	54308		M	51	X	X	X	X	X	X	X	X	X	X	X	X	X

[redacted]

[redacted]

SCORING SYSTEM*:

0	=	No visible reaction
±	=	Faint, minimal erythema
1	=	Erythema
2	=	Intense erythema
3	=	Intense erythema, induration, vesicles
4	=	Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	=	Edema
DR	=	Dryness
P	=	Peeling
S	=	Staining
^	=	Hyperpigmentation / Hypopigmentation
TR	=	Tape Reaction
C	=	Change of test site
N9R	=	No 9th reading
-	=	No patch application and / or reading
X	=	Discontinued
♦	=	This subject was requested to return for an additional scoring due to a reaction to a different test material

*International Contact Dermatitis Research Group System: Fisher, Alexander A., *Contact Dermatitis*, Lea & Febiger, Philadelphia, 2008: p 27. (Modified)

[redacted]

Lip Treatment
leave-on
Dimer Dilinoleyl Dimer Dilinoleate 19%
undiluted
no irritation or sensitization

Distributed for Comment Only -- Do Not Cite or Qu

[redacted]

Subject Number	Day1*	Induction Phase 1	2	3	4	5	6	7	8	9	Virgin Challenge Site Day 1*	Day 3
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0[m]	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	WC
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0*	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0[m]	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	WITHDREW CONSENT										
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0
28	0	WITHDREW CONSENT										
29	0	0	0	0	0	0	0	0	0	0	0	0

Day 1* = Supervised removal
m = Additional makeup day granted at the discretion of the clinic supervisor
WC = Withdrew Consent
* = Late observation (see deviation)

[redacted]

[redacted]

Subject Number	Induction Phase									Virgin Challenge Site	
	Day1*	1	2	3	4	5	6	7	8	9	Day 1* Day 3
30	0	0	0	0	0	0	0	0	0	0	0 0
31	0	0	0	0	0	0	0	0	0	0	0 0
32	0	0	0	0	0	0	0	0	0	0	0 0
33	0	0	0	0	0	0	0	0	0	0	0 0
34	0	0	0	0	0	0	0	0	0	0	0 0
35	0	0	0	0	0	0	0	0	0	0	0 0
36	0	0	0	0	0	0	0	0	0	0	0 0
37	0	0	0	0	0	0	0	0	0	0	0 0
38	0	0	0	0	0	0	0	0	0	0	0 0
39	0	0	0	0	0	0	0	0	0	0	0 0
40	0	0	0	0	0	0	0	0	0	0	0 0
41	0	0	0	0	0	0	0	0	0	0	0 0
42	0	0	0	0	0	0	0	0	0	0	0 0
43	0	0	0	0	0	0	0	0	0	0	0 0
44	0	0	0	0	0	0	0	0	0	0	0 0
45	0	0	0	0	0	0	0	0	0	0	0 0
46	0	0	0	0	0	0	0	0	0	0	0 0
47	0	0	0	0	0	0	0	0	0	0	0 0
48	0	0	0	0	0	0	0	0	0	0	0 0
49	0	0	0	0	0	0	0	0	0	0	0 0
50	0	0	0	0	0	0	0	0	0	0	0 0
51	0	0	0	0	0	0	0	0	0	0	0 0
52	0	0	0	0	0	0	0	0	0	0	0 0
53	0	0	0	0	0	0	0	0	0	0	0 0
54	0	0	0	0	0	0	0	0	0	0	0 0
55	0	0	0	0	0	0	0	0	0	0	0 0
56	0	0	0	0	0	0	0	0	0	0	0 0

Day 1* = Supervised removal

[redacted]

[redacted]

2012

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate
Lip Balm
Leave-on 3%
undiluted
did not cause
sensitization

TABLE I: SUMMARY OF REACTIONS

TOTAL NUMBER OF SUBJECTS ENROLLED: 120
TOTAL NUMBER OF SUBJECTS COMPLETED: 106

Reaction	Induction Reading									Challenge Reading			
Grade	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**1**	**2**	**3**	**4**
0	115	113	111	110	109	109	108	108	108	106	102	103	105
±							1	1	1	1	4	3	1
1													
1E													
2													
2E													
3													
4													
-													
N9R													
Total	115	113	111	110	109	109	109	109	109	107	106	106	106

SCORING SYSTEM:

0	= No visible reaction
±	= Faint, minimal erythema
1	= Erythema
2	= Intense erythema, induration
3	= Intense erythema, induration, vesicles
4	= Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	= Edema
-	= No reading
N9R	= No 9th reading

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
1	39590	[redacted]	F	25	0	0	0	0	0	0	0	0	0	0	0	0	0
3	16498	[redacted]	M	59	0	0	0	0	0	0	0	0	0	0	0	0	0
5	38466	[redacted]	F	61	0	0	0	0	0	0	0	0	0	X	X	X	X
7	39267	[redacted]	M	47	0	0	0	0	0	0	0	0	0	0	0	0	0
9	39228	[redacted]	F	66	0	0	0	0	0	0	0	0	0	0	±	0	0
11	28896	[redacted]	F	63	0	0	0	0	0	0	0	0	0	0	0	±	±
13	36471	[redacted]	M	49	0	0	0	0	0	0	0	0	0	0	0	0	0
15	35878	[redacted]	F	56	0	0	0	0	0	0	0	0	0	0	0	0	0
17	23147	[redacted]	M	50	0	0	0	0	0	0	0	0	0	0	0	0	0
19	33796	[redacted]	M	42	0	0	0	0	0	0	0	0	0	0	0	0	0
21	39561	[redacted]	F	38	0	0	0	0	0	0	0	0	0	0	0	0	0
23	39606	[redacted]	M	46	0	0	0	0	0	0	0	0	0	0	0	0	0
25	30680	[redacted]	M	51	0	0	0	0	0	0	0	0	0	0	0	0	0
27	33673	[redacted]	F	19	0	0	0	0	0	0	0	0	0	0	0	0	0
29	36260	[redacted]	F	36	0	0	0	0	0	0	0	0	0	0	0	0	0
31	38890	[redacted]	M	60	0	0	0	0	0	0	0	0	0	0	0	0	0
33	34911	[redacted]	F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
35	39157	[redacted]	F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
37	16040	[redacted]	F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
39	39552	[redacted]	F	44	0	0	0	0	0	0	0	0	0	0	0	±	0
41	30807	[redacted]	F	48	0	0	0	0	0	0	0	0	0	0	0	0	0
43	31777	[redacted]	F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
45	32066	[redacted]	F	48	0	0	0	0	0	0	0	0	0	0	0	0	0
[redacted]			F	21	0	0	X	X	X	X	X	X	X	X	X	X	X
[redacted]			F	65	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	[redacted]	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
51	25030		F	54	0	0	0	0	0	0	0	0	0	0	0	0	0
53	21973		F	64	0	0	0	0	0	0	0	0	0	0	0	0	0
55	22717		F	59	0	0	0	0	0	0	0	0	0	0	0	0	0
57	31988		F	48	0	0	0	0	0	0	0	0	0	0	0	0	0
59	33776		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
61	36932		F	20	0	0	0	0	0	0	0	0	0	0	0	0	0
63	27546		M	56	0	0	0	0	0	0	0	0	0	0	0	0	0
65	37706		M	29	0	0	0	0	0	0	0	0	0	0	0	0	0
67	32077		F	21	0	0	0	0	0	0	0	0	0	0	0	0	0
69	30228		F	57	0	0	X	X	X	X	X	X	X	X	X	X	X
71	37670		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
73	37718		F	33	0	0	0	0	0	0	0	0	0	0	0	0	0
75	24696		F	60	X	X	X	X	X	X	X	X	X	X	X	X	X
77	39600		M	65	0	0	0	0	0	0	0	0	0	0	0	0	0
79	37509		F	61	0	0	0	0	0	0	0	0	0	0	0	0	0
81	39609		M	41	0	0	0	0	0	0	0	0	0	0	0	0	0
83	28848		F	56	0	0	0	0	0	0	±	±	±	0	±	±	0
85	37585		F	54	0	0	0	0	0	0	0	0	0	0	0	0	0
87	37663		M	49	0	0	0	0	0	0	0	0	0	0	0	0	0
89	17882		M	51	0	0	0	0	0	0	0	0	0	0	±	0	0
91	36802		M	64	0	0	0	0	0	0	0	0	0	0	0	0	0
93	39622		F	61	0	0	0	0	0	0	0	0	0	0	0	0	0
95	33015		M	54	0	0	0	0	0	0	0	0	0	0	0	0	0
97	24741		F	52	0	0	0	0	0	0	0	0	0	0	0	0	0
99	38873		F	37	0	0	0	X	X	X	X	X	X	X	X	X	X

[redacted]

Distributed for Comment Only -- Do Not Cite or Quote

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
101	39324	[redacted]	F	40	0	0	0	0	0	0	0	0	0	±	0	0	0
103	36232		F	54	0	0	0	0	0	0	0	0	0	0	0	0	0
105	39582		M	25	0	0	0	0	0	0	0	0	0	0	0	0	0
107	38777		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
109	28542		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
111	32311		M	21	0	0	0	0	0	0	0	0	0	0	0	0	0
113	32959		F	50	0	0	0	0	0	0	0	0	0	0	0	0	0
115	30489		M	25	0	0	0	0	0	0	0	0	0	0	0	0	0
117	33786		M	50	0	0	0	0	0	0	0	0	0	0	0	0	0
119	31309		M	63	0	0	0	0	0	0	0	0	0	0	0	0	0
121	38898		F	31	0	0	0	0	0	0	0	0	0	X	X	X	X
123	21149		F	66	0	0	0	0	0	0	0	0	0	0	0	0	0
125	39628		M	20	X	X	X	X	X	X	X	X	X	X	X	X	X
127	35182		F	30	0	0	0	0	0	0	0	0	0	0	0	0	0
129	28785		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
131	33727		F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
133	35218		F	50	0	0	0	0	0	0	0	0	0	0	0	0	0
135	38659		F	24	0	0	0	0	0	0	0	0	0	0	0	0	0
137	39189		F	20	X	X	X	X	X	X	X	X	X	X	X	X	X
139	12143		M	45	0	0	0	0	0	0	0	0	0	0	0	0	0
141	37677		M	58	0	X	X	X	X	X	X	X	X	X	X	X	X
143	28507		M	50	0	X	X	X	X	X	X	X	X	X	X	X	X
145	37340		F	50	0	0	0	0	0	0	0	0	0	0	0	0	0
147	29939		M	43	0	0	0	0	0	0	0	0	0	0	0	0	0
149	38231		M	40	0	0	0	0	0	0	0	0	0	0	0	0	0

[redacted]

Distributed for Comment Only -- Do Not Cite or Quote

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
151	15970	[redacted]	F	23	0	0	0	0	0	0	0	0	0	0	0	0	0
153	26520		F	47	0	0	0	0	0	0	0	0	0	0	X	X	X
155	24284		M	51	0	0	0	0	X	X	X	X	X	X	X	X	X
157	30242		F	41	0	0	0	0	0	0	0	0	0	0	0	0	0
159	16559		M	36	0	0	0	0	0	0	0	0	0	0	0	0	0
161	23494		F	60	0	0	0	0	0	0	0	0	0	0	0	0	0
163	38084		M	55	0	0	0	0	0	0	0	0	0	0	0	0	0
165	38976		F	33	0	0	0	0	0	0	0	0	0	0	0	0	0
167	23022		F	58	0	0	0	0	0	0	0	0	0	0	0	0	0
169	19863		F	55	0	0	0	0	0	0	0	0	0	0	0	0	0
171	21423		M	57	0	0	0	0	0	0	0	0	0	0	0	0	0
173	38974		M	31	0	0	0	0	0	0	0	0	0	0	0	0	0
175	20460		F	52	0	0	0	0	0	0	0	0	0	0	0	0	0
177	39604		F	21	0	0	0	0	0	0	0	0	0	0	0	0	0
179	32885		M	54	0	0	0	0	0	0	0	0	0	0	0	0	0
181	30003		F	29	0	0	0	0	0	0	0	0	0	0	0	0	0
183	39090		F	48	0	0	0	0	0	0	0	0	0	0	0	0	0
185	20133		F	34	0	0	0	0	0	0	0	0	0	0	0	0	0
187	39300		F	53	0	0	0	0	0	0	0	0	0	0	0	0	0
189	30780		M	48	0	0	0	0	0	0	0	0	0	0	0	0	0
191	21750		F	31	0	0	0	0	0	0	0	0	0	0	0	0	0
193	31323		F	37	0	0	0	0	0	0	0	0	0	0	0	0	0
195	35168		F	52	0	0	0	0	0	0	0	0	0	0	0	0	0
197	36898		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
199	39634		F	19	X	X	X	X	X	X	X	X	X	X	X	X	X

Distributed for Comment Only -- Do Not Cite or Quote

[redacted]

[redacted]

TABLE II: INDIVIDUAL SUBJECT DATA

(see Scoring System, page 11)

					Induction Reading									Challenge Reading			
Sub	HRL	Ini	Sex	Age	1	2	3	4	5	6	7	8	9	1	2	3	4
201	29041	[redacted]	F	40	0	0	0	0	0	0	0	0	0	0	0	0	0
203	21559		F	63	0	0	0	0	0	0	0	0	0	0	±	0	0
205	34426		F	44	0	0	0	0	0	0	0	0	0	0	0	0	0
207	39580		F	23	0	0	0	0	0	0	0	0	0	0	0	0	0
209	16913		F	54	0	0	0	0	0	0	0	0	0	0	0	0	0
211	35640		F	57	0	0	0	0	0	0	0	0	0	0	0	0	0
213	38508		F	19	0	0	0	0	0	0	0	0	0	0	0	0	0
215	32343		F	55	0	0	0	0	0	0	0	0	0	0	0	0	0
217	34994		F	25	0	0	0	0	0	0	0	0	0	0	0	0	0
219	38658		F	56	0	0	0	0	0	0	0	0	0	0	0	0	0
221	28515		F	51	0	0	0	0	0	0	0	0	0	0	0	0	0
223	26620		F	27	0	0	0	0	0	0	0	0	0	0	0	0	0
225	34725		F	36	0	0	0	0	0	0	0	0	0	0	0	0	0
227	39638		M	32	X	X	X	X	X	X	X	X	X	X	X	X	X
229	15850		F	33	0	0	0	0	0	0	0	0	0	0	0	0	0
231	23224		F	42	0	0	0	0	0	0	0	0	0	0	0	0	0
233	32269		F	59	0	0	0	0	0	0	0	0	0	0	0	0	0
235	06915		F	61	0	0	0	0	0	0	0	0	0	0	0	0	0
237	22086		F	49	0	0	0	0	0	0	0	0	0	0	0	0	0
239	35986		M	22	0	0	0	0	0	0	0	0	0	0	0	0	0

Distributed for Comment Only -- Do Not Cite or Quote

[redacted]

[redacted]

SCORING SYSTEM*:

0	=	No visible reaction
±	=	Faint, minimal erythema
1	=	Erythema
2	=	Intense erythema
3	=	Intense erythema, induration, vesicles
4	=	Severe reaction with erythema, induration, vesicles, pustules (may be weeping)
E	=	Edema
DR	=	Dryness
P	=	Peeling
S	=	Staining
^	=	Hyperpigmentation
C	=	Change of test site
N9R	=	No 9th reading
-	=	No reading
X	=	Discontinued

*International Contact Dermatitis Research Group System: Fisher, Alexander A., *Contact Dermatitis*, Lea & Febiger, Philadelphia, 1986: p 26

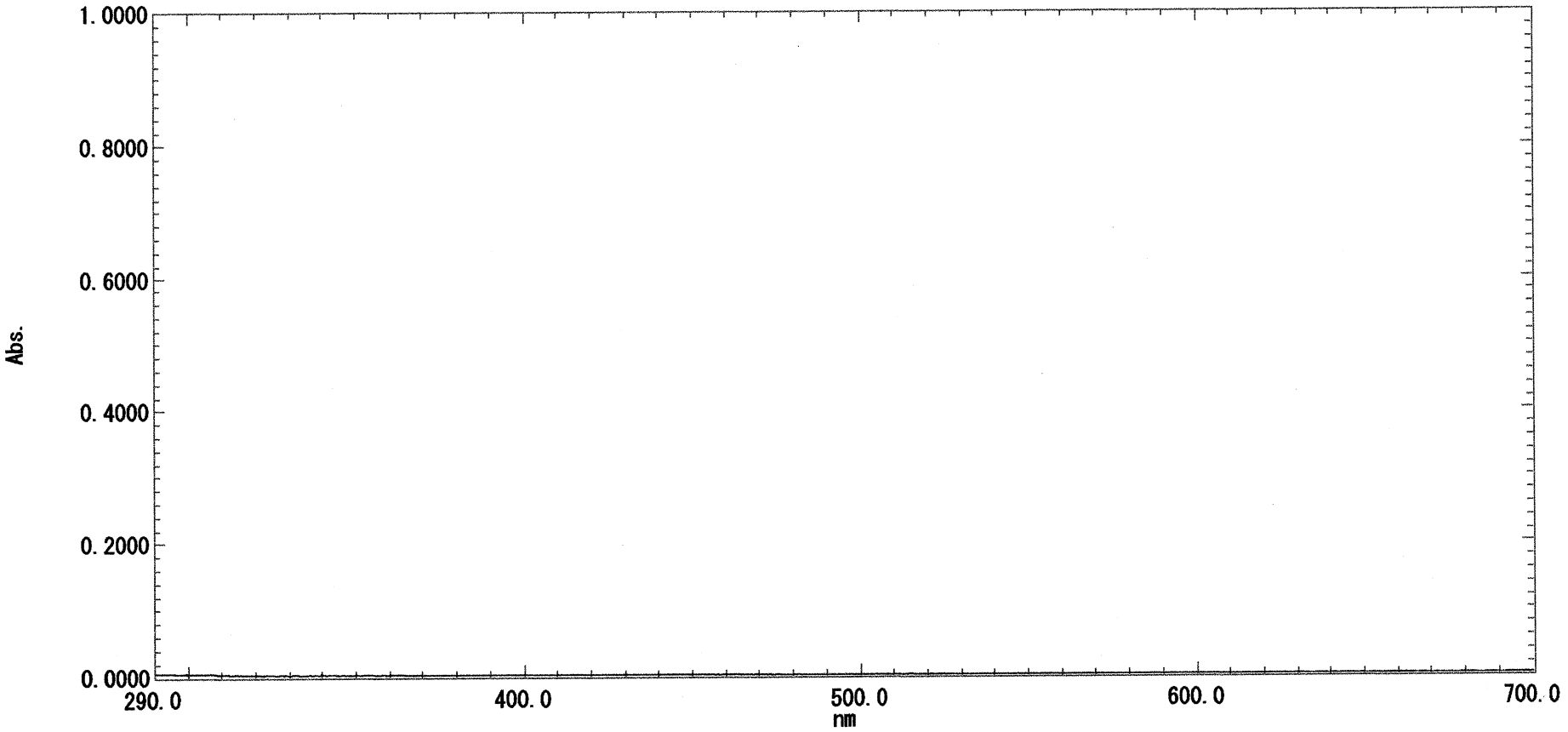
Distributed for Comment Only -- Do Not Cite or Quote

[redacted]

Distributed for Comment Only -- Do Not Cite or Quote

2025/01/29 16:32:45

UV spectrum of LUSPLAN DD-DA7 Dimer Dilinoleyl Dimer Dilinoleate NIPPON FINE CHEMICAL CO., LTD.



LUSPLAN DD-DA7_Lot.T2306201 - RawData

Lot. T2306201

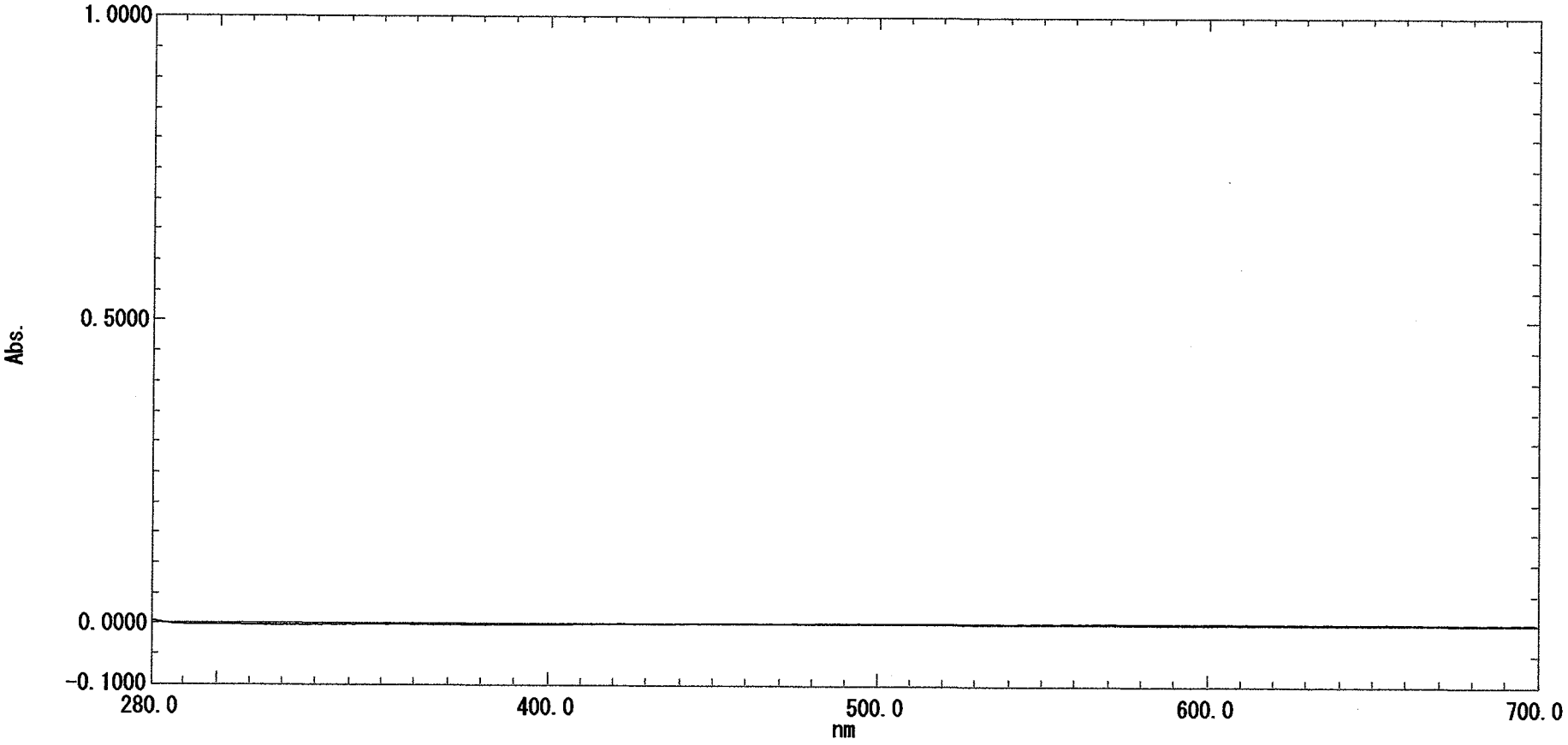
Concentration : 100ppm

Distributed for Comment Only -- Do Not Cite or Quote

2025/03/24 15:51:11

UV spectrum of LUSPLAN PI-DA Phytosteryl Isostearyl Dimer Dilinoleatae

NIPPON FINE CHEMICAL CO., LTD.



Lot. 241009

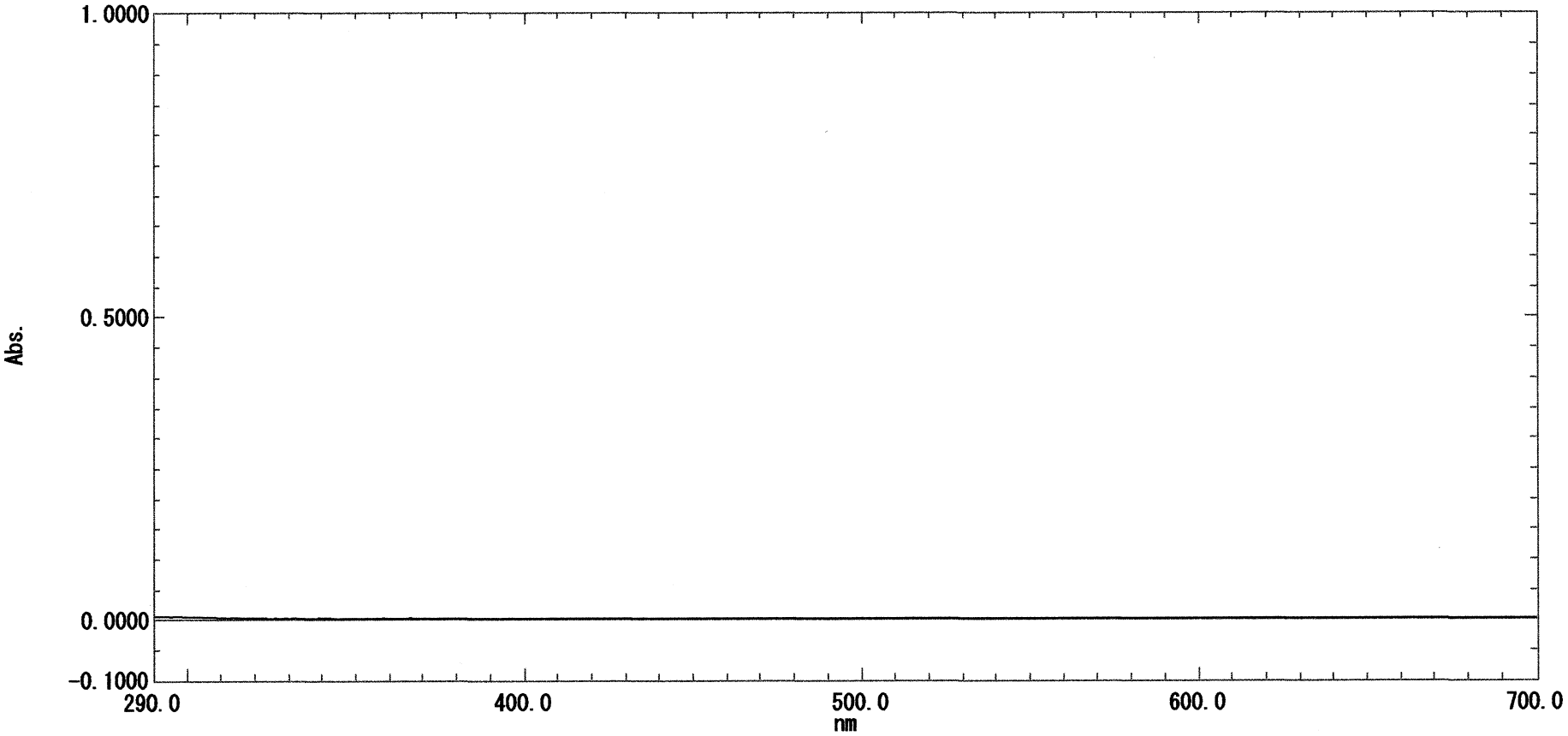
Concentration : 100ppm

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate
Distributed for Comment Only -- Do Not Cite or Quote

2023/07/20 17:34:41

UV spectrum of Plandool-G

NIPPON FINE CHEMICAL CO., LTD.



Lot. T2205215

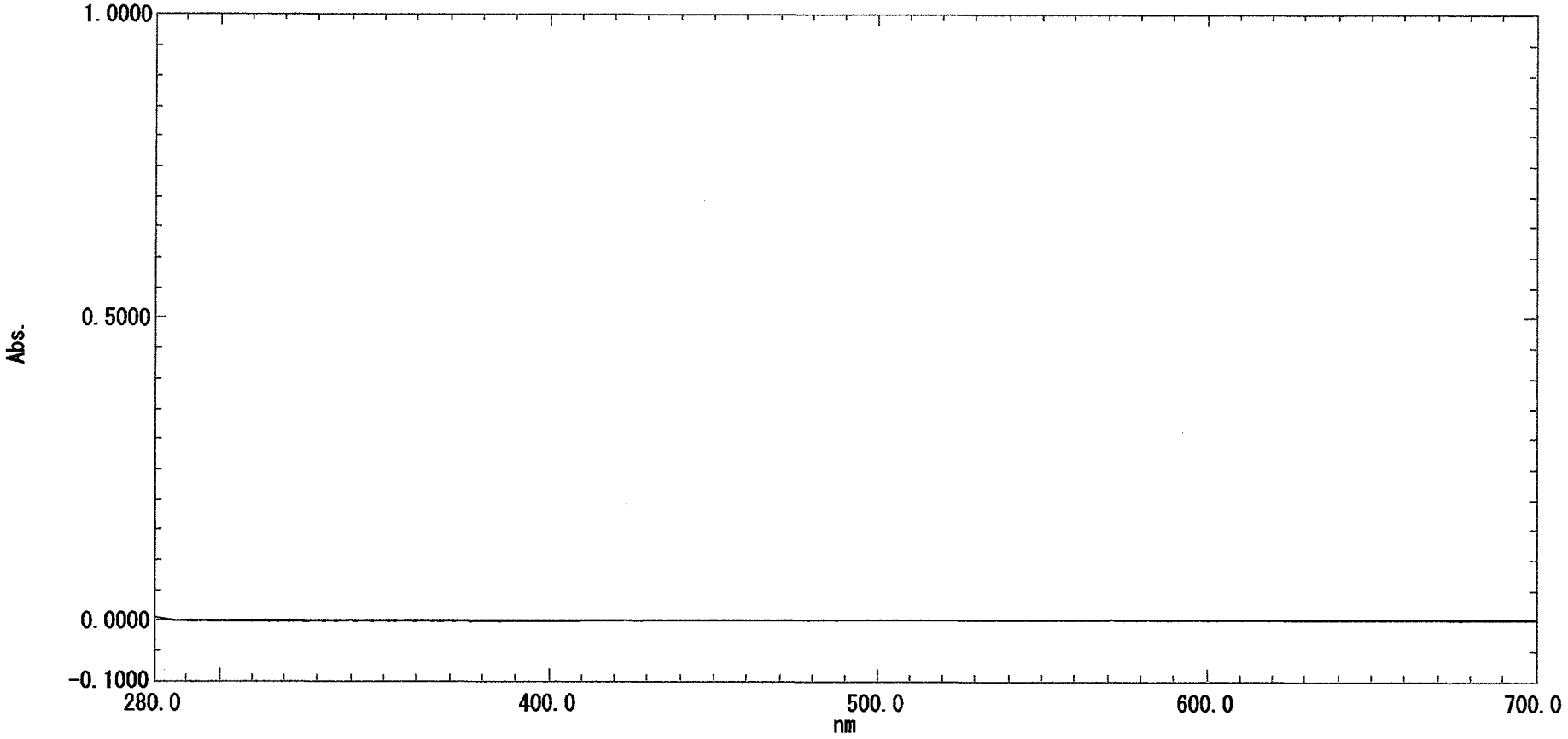
Concentration : 100ppm

Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate
Distributed for Comment Only -- Do Not Cite or Quote

2025/03/24 15:41:59

UV spectrum of Plandool-H

NIPPON FINE CHEMICAL CO., LTD.



Lot. T2411225

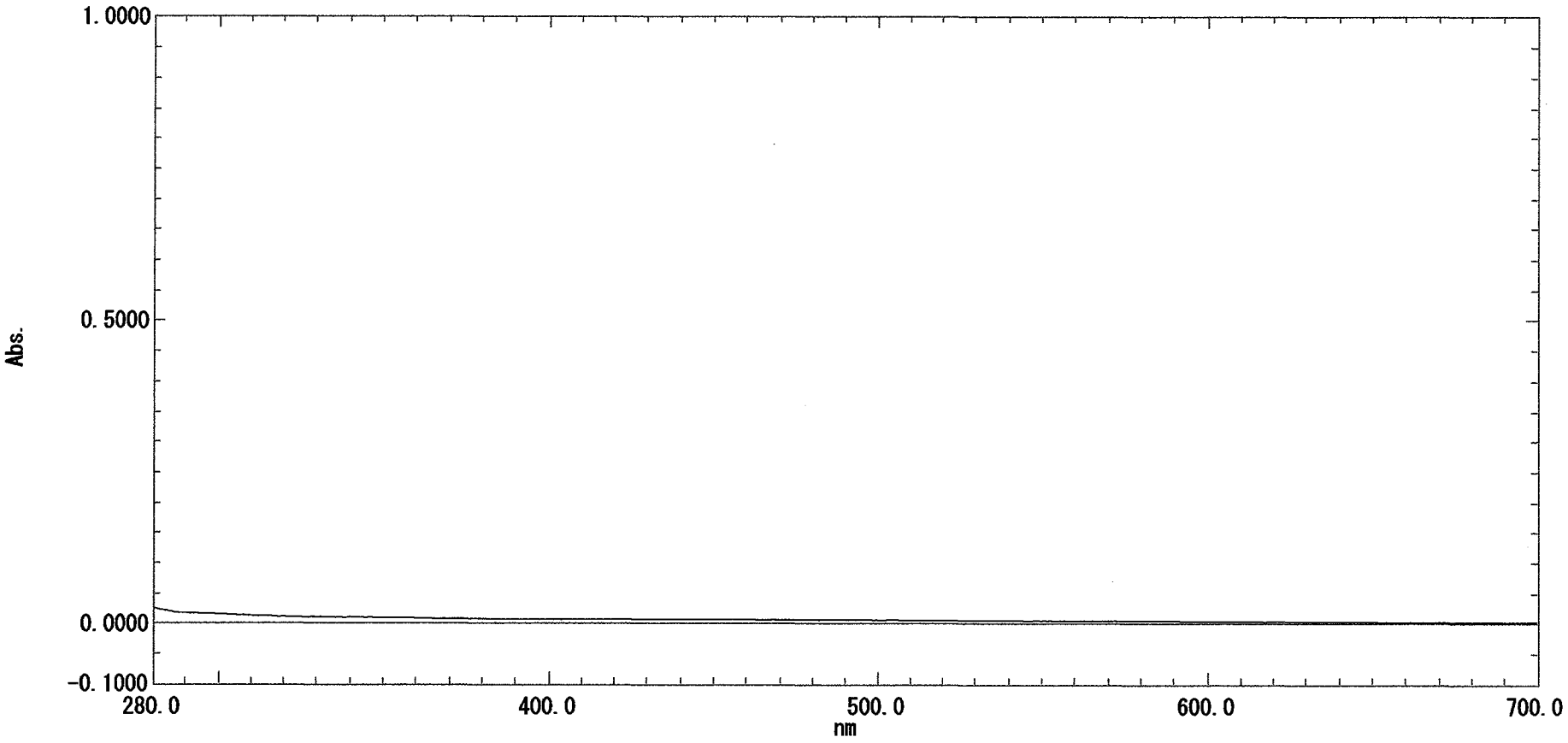
Concentration : 100ppm

Bis-Behenyl/Phytosteryl Dimer Dilinoleate
Distributed for Comment Only -- Do Not Cite or Quote

2025/03/24 16:00:18

UV spectrum of Plandool-PB

NIPPON FINE CHEMICAL CO., LTD.



Lot. TBG-858

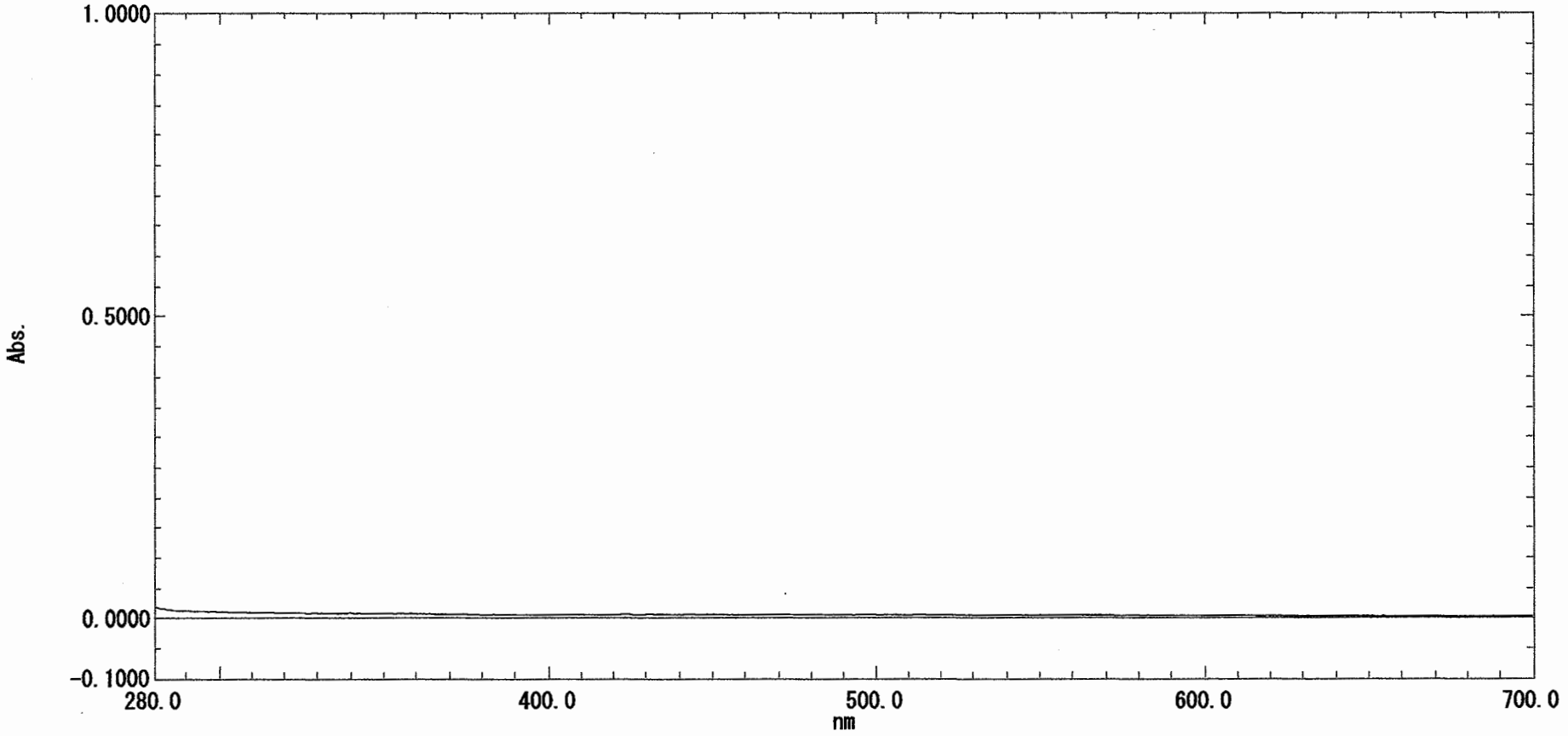
Concentration : 100ppm

Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate
Distributed For Comment Only -- Do Not Cite or Quote

2025/03/24 16:11:56

UV spectrum of Plandool-S

NIPPON FINE CHEMICAL CO., LTD.



Lot. 250108

Concentration : 100ppm

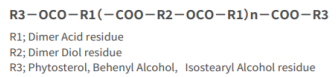
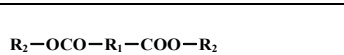
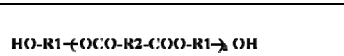
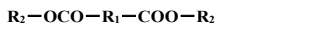
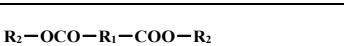
Distributed for Comment Only -- Do Not Cite or Quote

NIPPON FINE CHEMICAL CO., LTD.
日本精化株式会社
2-4-9, Bingomachi, Chuo-ku, Osaka, 541-0051, Japan
Phone: +81-6-6231-4781 Fax: +81-6-6231-4787

18-Apr-2025

Nippon Fine Chemical Co., Ltd.
COSMETIC INGREDIENTS LABORATORY
Manager
Toru Shimizu

The information of dimer dilinoleate ingredients

INCI	Products	Chemical structure	UV spectra	Method of Manufacture	Impurities	Safety data (Test guideline (Test conditions), Test concentration, Test date, Results)	Reference
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Plandool™-G	 R1; Dimer Acid residue R2; Dimer Diol residue R3; Phytosterol, Behenyl Alcohol, Isostearyl Alcohol residue	Almost no UV absorption (Data attached)	Raw materials→Reaction→Purification →Filtration→Packaging	Hevy metal: 20ppm Max. Arsenic: 2ppm Max.	Acute Oral Toxicity: OECD TG423, 100%, 2004.05.05, LD50>2000mg/kg Primary Skin Irritation: OECD TG404, 100%, 2004.05.05, NON IRRITANT Skin Sensitization: OECD TG406, 25%, 2004.03.30, NON-SENSITIZER Eye Irritation: OECD TG405, 100%, 2004.11.27, PRACTICALLY NON IRRITANT Eye Irritation: Eye irritation study using EpiOcular corneal model, 100%, 2005.12.30, NON IRRITANT Mutagenicity: OECD TG471, 100%, 2004.06.11, NEGATIVE Genotoxicity: Chromosome aberration test using mammalian cell culture, 100%, 2010.10.11, NEGATIVE Human 24hr Closed Patch: 45 subjects, 100%, 2004.02.26, NEGATIVE RIPT (Repeated Insult Patch Test): 42 subjects, 100%, 2024.11.05, NEGATIVE	Unpublished data (NIPPON FINE CHEMICAL original)
Bis-Behenyl/Phytosteryl Dimer Dilinoleate	Plandool™-PB	 R1 : Dimer acid residue R2 : Phytosterol residue or Behenyl alcohol residue	Almost no UV absorption (Data attached)	Raw materials→Reaction→Purification →Filtration→Packaging	Hevy metal: 20ppm Max. Arsenic: 2ppm Max.	Mutagenicity: Ames Test, 100%, 2019.03.05, NEGATIVE	Unpublished data (NIPPON FINE CHEMICAL original)
Dimer Dilinoleyl Dimer Dilinoleate	LUSPLAN™ DD-DA5 LUSPLAN™ DD-DA7	 R1 : Dimer diol residue R2 : Dimer acid residue	Almost no UV absorption (Data attached)	Raw materials→Reaction→Purification →Filtration→Packaging	Hevy metal: 20ppm Max. Arsenic: 2ppm Max.	LUSPLAN DD™-DA5 Acute Oral Toxicity: OECD TG423, 100%, 2001.03.02, LD50>2500mg/kg Primary Skin Irritation: OECD TG404, 100%, 2001.03.02, MILD IRRITANT Skin Sensitization: OECD TG406, 100%, 2001.03.02, NON-SENSITIZER Eye Irritation: OECD TG405, 100%, 2001.03.02, MINIMAL IRRITANT Eye Irritation: Eye irritation study using EpiOcular corneal model, 100%, 2005.12.30, NON IRRITANT Mutagenicity: OECD TG471, 100%, 2001.01.01, NEGATIVE Human Closed Patch: 42 subjects, 100%, 2001.02.16, NEGATIVE LUSPLAN™ DD-DA7 Eye Irritation: OECD TG491, 100%, 2021.11.16, NO CATEGORY	Unpublished data (NIPPON FINE CHEMICAL original)
Phytosteryl/Isostearyl/Cetyl/Stearyl/ Behenyl Dimer Dilinoleate	Plandool™-H Plandool™-S	 R1 : Dimer acid residue R2 : Phytosterol residue, Behenyl alcohol residue, Stearyl alcohol residue, Cetryl alcohol residue or Isostearyl alcohol residue	Almost no UV absorption (Data attached)	Raw materials→Reaction→Purification →Filtration→Packaging	Hevy metal: 20ppm Max. Arsenic: 2ppm Max.	Plandool™-H Acute Oral Toxicity: OECD TG423, 100%, 2003.05.27, LD50>2500mg/kg Primary Skin Irritation: OECD TG404, 100%, 2002.08.30, NON IRRITANT Cumulative skin irritation study using guinea pigs: 100%, 2004.05.10, NON IRRITANT Skin Sensitization: OECD TG406, 100%, 2002.10.16, NON-SENSITIZER Eye Irritation: OECD TG405, 100%, 2002.10.14, MINIMAL IRRITANT Mutagenicity: OECD TG471, 100%, 2003.05.01, NEGATIVE Genotoxicity: Chromosome aberration test using mammalian cell culture, 100%, 2004.05.10, NEGATIVE Human 24hr Closed Patch: 45 subjects, 100%, 2002.10.31, NEGATIVE Plandool™-S Acute Oral Toxicity: OECD TG423, 100%, 2002.10.14, LD50>2500mg/kg Primary Skin Irritation: OECD TG404, 100%, 2002.10.02, NON IRRITANT Skin Sensitization: OECD TG406, 100%, 2002.10.16, NON-SENSITIZER Eye Irritation: OECD TG405, 100%, 2002.10.14, MINIMAL IRRITANT Mutagenicity: OECD TG471, 100%, 2002.09.05, NEGATIVE Human 24hr Closed Patch: 45 subjects, 100%, 2002.10.31, NEGATIVE	Unpublished data (NIPPON FINE CHEMICAL original)
Phytosteryl Isostearyl Dimer Dilinoleate	LUSPLAN™ PI-DA	 R1 : Dimer acid residue R2 : Phytosterol residue or Isostearyl alcohol residue	Almost no UV absorption (Data attached)	Raw materials→Reaction→Purification →Filtration→Packaging	Hevy metal: 20ppm Max. Arsenic: 2ppm Max.	Acute Oral Toxicity: OECD TG423, 100%, 2000.02.22, LD50> 2000 mg/kg Primary Skin Irritation: OECD TG404, 100%, 2000.02.22, MILD IRRITANT Cumulative skin irritation study using guinea pigs: 100%, 2000.06.27, PRACTICALLY NON IRRITANT Skin Sensitization: OECD TG406, 100%, 2000.02.22, NON-SENSITIZER Eye Irritation: OECD TG405, 100%, 2000.02.22, MINIMAL IRRITANT Mutagenicity: OECD TG471, 100%, 2000.07.25, NEGATIVE Genotoxicity: Chromosome aberration test using mammalian cell culture, 100%, 2001.02.28, NEGATIVE Human 24hr Closed Patch: 45 subjects, 100%, 1999.12.21, NEGATIVE	Unpublished data (NIPPON FINE CHEMICAL original)

Concentration of Use by FDA Product Category[1]*

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

Ingredient	Product Category	Maximum Concentration of Use
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Eyebrow pencils	0.88-4.8%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Eye shadows	3.6-12.6%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Blushers and rouges	12%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Face powders	1.4-1.6%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Foundations Traditional	13%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Lipstick	15.1-30%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Face and neck products (not spray) Leave-on	0.6-3%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Body and hand products (not spray)	3%
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	Moisturizing products (not spray)	3.4%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Eyebrow pencils	0.15-2.5%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Eyeliners	0.98-11.7%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Eye shadows	1.4-7%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Eyelash and eyebrow preparations	4%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Other eye makeup preparations	2.1%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Hair conditioners Rinse-off	1.6%

[1] The new FDA cosmetic product categories under MoCRA were used for this survey.

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Tonics, dressings, and other hair grooming aids	1.6%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Blushers and rouges	2.9%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Face powders	0.4-2.9%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Foundations Traditional	 0.5%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Lipstick	3-30.1%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Shaving cream	0.6%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Face and neck products (not spray) Leave-on Rinse-off	 0.4-3% 0.2%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Moisturizing products (not spray)	1-3%
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate	Paste masks and mud packs	3.6%
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	Blushers and rouges	6.7%
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	Lipstick	4.7-8.9%
Dimer Dilinoleyl Dimer Dilinoleate	Eyebrow pencils	10%
Dimer Dilinoleyl Dimer Dilinoleate	Eye shadows	1.5-2%
Dimer Dilinoleyl Dimer Dilinoleate	Mascaras	0.8-3%
Dimer Dilinoleyl Dimer Dilinoleate	Eyelash and eyebrow preparations	2%
Dimer Dilinoleyl Dimer Dilinoleate	Blushers and rouges	7-8%
Dimer Dilinoleyl Dimer Dilinoleate	Foundations Traditional	 0.1-4.3%
Dimer Dilinoleyl Dimer Dilinoleate	Lipstick	11.3-48.7%
Dimer Dilinoleyl Dimer Dilinoleate	Face and neck products (not spray) Leave-on	 3.2%
Dimer Dilinoleyl Dimer Dilinoleate	Night products (not spray)	3.2%
Dimer Dilinoleyl Dimer Dilinoleate	Other skin care preparations	6%
Phytosteryl Isostearyl Dimer Dilinoleate	Face powders	0.099%
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate	Lipstick	10%

*The ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

Information collected in 2025
Table prepared: March 27, 2025