

Scientific Literature Review Notice to Proceed – February 20, 2025

Dimer Dilinoleates

Cosmetic Ingredient Review (CIR) Procedures call for the development of a review of the available scientific literature for each cosmetic ingredient (and wherever appropriate, closely related ingredients) on the basis of the annual priority list. The Scientific Literature Review (SLR) shall consist of a bibliography of relevant scientific literature, study reports that have been submitted by interested parties, and a description of each literature reference or submitted study report.

The ingredients included in this report are:

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 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.¹ The 2023 VCRP data also reported Dimer Dilinoleyl Dimer Dilinoleate to have the most reported uses, in 28 formulations, most of which were in lipsticks;² the results of the concentration of use survey conducted by the Council in 2022 indicate Dimer Dilinoleyl Dimer Dilinoleate is used at up to 22% in lipsticks.³

Although use information has been reported for this ingredient group, an extensive search of the published literature on these ingredients resulted in insufficient information to justify preparation of a formal SLR. CIR, therefore, is issuing this SLR Notice to Proceed (NTP) to alert interested parties that a safety assessment is being prepared and significant data needs remain.

All of the ingredients in this report are dimer dilinoleates. Each ingredient is a mixture of esters formed from the reaction of straight-chain or branch-chain alkyl alcohols with dilinoleic acid. The precursor core, dilinoleic acid, is produced by catalytic dimerization of linoleic acid. The dimer dilinoleates are mainly reported to function as hair conditioning agents, skin-conditioning agents, and viscosity increasing agents in cosmetic products.⁴ The Panel has previously reviewed the related ingredients, dialkyl dimer dilinoleates, and concluded that the 8 ingredients in that safety assessment are safe in cosmetics in the present practices of use and concentration.⁵ (The full report can be found on the CIR website (<https://cir-reports.cir-safety.org/>).

All interested persons are provided 60 days from the above date (i.e., April 21, 2025) to submit comments and/or published or unpublished data.* A draft report will be prepared, and reviewed by the Expert Panel for Cosmetic Ingredient Safety at a future meeting. If data are provided in response to this SLR NTP, those data will be incorporated into that draft report.

Given that this notice is being issued because of a general absence of information, CIR is seeking information in a wide range of 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

Please forward relevant data and comments to Dr. Bart Heldreth, Executive Director. This notice was prepared, and the search indicated above was performed, by Christina Burnett, M.S., Senior Scientific Analyst/Writer.

*Because all unpublished data submitted to CIR will be evaluated in public meetings and may be included in the final published safety assessment, CIR may not accept any confidential or proprietary data or information that cannot be made public. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient.

REFERENCES

1. 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].
2. 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].
3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Categories: Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate and Related Ingredients. [Unpublished data submitted by the Personal Care Products Council on July 5, 2022.].
4. Nikitakis J, Kowcz A. 2025. Web-Based International Cosmetic Ingredient Dictionary and Handbook. <https://incipedia.personalcarecouncil.org/winci/> Last Updated: 2025. Date Accessed: February 13, 2025.
5. 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.