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Scientific Literature Review Notice to Proceed – October 7, 2021

Phytosteryl Glutamates

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.

For the phytosteryl glutamates **(i.e., Phytosteryl/Octyldodecyl Lauroyl Glutamate, Phytosteryl/Behenyl/Octyldodecyl/Isostearyl Lauroyl Glutamate, and Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate)**, an intensive search of the published information 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.

The 3 phytosteryl glutamates comprise phytosterol and fatty alkyl esters of lauroyl glutamic acid. Safety test data on these ingredients were not found in the published literature. All interested persons are provided 60 days from the above date (i.e., **December 6, 2021**) to submit comments and/or published or unpublished data.[1] A draft report will be prepared, and reviewed by the Expert Panel for Cosmetic Ingredient Safety at a future meeting.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 composition and structure, method of manufacture, and impurities data (including residual free alcohol and acid content);
- Toxicokinetic data relevant to routes of exposure expected with cosmetic use;
- Short-term, subchronic, and chronic dermal/oral toxicity data;
- Developmental and reproductive toxicity data;
- Genotoxicity data;
- Carcinogenicity data;
- Dermal irritation and sensitization data at maximum reported use concentrations;
- 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, CIR. This notice was prepared, and the search indicated above was performed, by Wilbur Johnson, Jr., Senior Scientific Analyst.

[1]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
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1620 L Street, NW, Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(Email) cirinfo@cir-safety.org (CIR Website) www.cir-safety.org
(Expert Panel Website) www.ingredientsafetyexpertpanel.org