

## Scientific Literature Review Notice to Proceed - July 2, 2019

### Polysilicone-11

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 Polysilicone-11, an intensive search of the published information on this ingredient 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.

Polysilicone-11 is a crosslinked dimethyl siloxane formed by the reaction of Bis-Vinyldimethicone and Hydrogen Dimethicone. Except for some very limited summary information on tumorigenesis and dermal irritation (information which may or may not be relevant to the *crosslinked* polymer), no relevant information was found in the published literature. All interested persons are provided 60 days from the above date (i.e., **August 31, 2019**) to submit comments and/or published or unpublished data.<sup>1</sup> A draft report will be prepared, and reviewed by the CIR Expert Panel 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 impurity 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 Priya Cherian, Scientific Analyst/Writer.*

<sup>1</sup>Because all unpublished data submitted to CIR will be evaluated in public meetings and may be included in the CIR final published safety assessment, CIR may not accept any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.