Scientific Literature Review Notice to Proceed – May 19, 2020

Acryloyloxyethyl Phosphorylcholine Polymers

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 acryloyloxyethyl phosphorylcholine polymers (i.e., Acrylic Acid/Phosphorylcholine Glycol Acrylate Crosspolymer, C4-18 Alkyl Methacrylate/Methacryloyloxyethyl Phosphorylcholine Copolymer, Hydroxyethylcellulose/Phosphorylcholine Glycol Acrylate Copolymer, Phosphorylcholine Glycol Methacrylate/PEG-10 Dimethacrylate Crosspolymer, Polyphosphorylcholine Glycol Acrylate, Polyquaternium-10/Phosphorylcholine Glycol Acrylate Copolymer, Polyquaternium-51, and Polyquaternium-61), 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.

Acryloyloxyethyl phosphorylcholine polymers have been defined as amphiphilic block copolymers composed of poly(butyl acrylate) and poly(2-acryloyloxyethyl phosphorylcholine). Purity/impurities data on Polyquaternium-51, as well as data summaries (of acute oral toxicity, genotoxicity, skin irritation, skin sensitization, and ocular irritation) on Polyquaternium-61, were found among the available data that are accessible to the public. However, due to the insufficiency of these summaries, the limited available information has been deemed insufficient until pertinent study details are provided. It is also important to note that although skin penetration data and short-term toxicity data on a polymer that has the same CAS number as Polyquaternium-51 (i.e., poly(2-methacryloyloxyethyl phosphorylcholine-co-n-butyl methacrylate); CAS No. 125275-25-4) have been identified in the published literature, these data have been deemed insufficient for the safety assessment of acryloyloxyethyl phosphorylcholine polymers. All interested persons are provided 60 days from the above date (i.e., July 18, 2020) 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 monomer 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;

¹ Data summaries have been published in the published literature.
• 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.

1Because 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.