Scientific Literature Review Notice to Proceed – March 17, 2023

Ethyl Tafluprostamide and Isopropyl Cloprostenenate

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.

According to 2023 FDA VCRP data, Isopropyl Cloprostenenate is used in 3 total formulations of the product category “other eye makeup preparations.” There are no reported uses for Ethyl Tafluprostamide. A concentration of use survey is currently underway for these two ingredients.

Although use information has been reported for Isopropyl Cloprostenenate, an intensive search of the published information on this ingredient, as well as Ethyl Tafluprostamide, 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.

Both Ethyl Tafluprostamide and Isopropyl Cloprostenenate are synthetic prostaglandin analogs that are reported to function as hair conditioning agents in cosmetics. Ethyl Tafluprostamide is also reported to function as a nail conditioning agent. The minimal data found in the published literature include a case report indicating periorbital hollowing and skin discoloration following the use of a product containing Isopropyl Cloprostenenate, a report indicating periocular discoloration following use of a serum containing Isopropyl Cloprostenenate, and a study performed in male mice specifically evaluating the effects of Isopropyl Cloprostenenate on reproductive organs (general toxicological evaluations were not performed). Also found was a Scientific Committee on Consumer Safety (SCCS) opinion on prostaglandin and prostaglandin-analogs used in cosmetic products. This document contains minimal chemical/physical properties and impurities data on Ethyl Tafluprostamide and Isopropyl Cloprostenenate, predictive values for the dermal absorption and genotoxic potential of Isopropyl Cloprostenenate, as well as a summarized human eye irritation study in which subjects used an eyelash formulation containing 10% Isopropyl Cloprostenenate, a summarized clinical trial evaluating various ophthalmological parameters following exposure to Isopropyl Cloprostenenate, and summarized studies regarding ophthalmological parameters evaluated following exposure to Isopropyl Cloprostenenate in animal models. Based on the limited data, the SCCS was not able to conclude on the safety of Ethyl Tafluprostamide and Isopropyl Cloprostenenate.

All interested persons are provided 60 days from the above date (i.e., May 16, 2023) 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, which may be as soon as June 12-13, 2023. 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;
- Ocular toxicity/irritation 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, 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


