



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for a scientific opinion on Phenylene Bis-Diphenyltriazine (CAS No 55514-22-2) (S86). Submission II.

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

Following submission I on Phenylene Bis-Diphenyltriazine to assess its safety for use in cosmetic products, the SCCS concluded in its opinion in July 2015 (SCCS/1556/15) that:

The following conclusions apply to Phenylene bis-diphenyltriazine with median particle size distribution (number-sized) around 130-170 nm or larger.

1. Does the SCCS consider Phenylene bis-diphenyltriazine, S86, safe for use as a UV-filter in sunscreen products in a concentration up to 10.0% taking into account the scientific data provided?

The SCCS considers Phenylene bis-diphenyltriazine, S86, not safe for use as a UV-filter in sunscreen products in a concentration up to 10.0% taking into account the scientific data provided.

SCCS cannot exclude that Phenylene bis-diphenyltriazine may have a genotoxic potential.

2. Does the SCCS have any further scientific concerns with regard to the use of Phenylene bis-diphenyltriazine, S86, as a UV-filter in sunscreen and/or other cosmetic products?

An adequate physico-chemical characterisation should be provided.

The tests conducted on eye irritation and skin sensitisation are considered inconclusive.

The phototoxicity potential can as yet not be excluded.

This Opinion does not apply to inhalation exposure of Phenylene bis-diphenyltriazine since no adequate information on chronic or sub-chronic toxicity after inhalation was provided.

The SCCS noted that due to the poor biodegradation potential and the very high octanol-water partition coefficient, long-term effects or bioaccumulation of Phenylene bis-diphenyltriazine, S86, in the environment cannot be excluded. The use of Phenylene bis-diphenyltriazine as an ingredient in sunscreen products might lead to environmental exposure.

In March 2017, in light of the opinion SCCS/1556/15, the cosmetics company Pierre Fabre transmitted a new safety dossier (submission II) on Phenylene Bis-Diphenyltriazine that addresses the major issues raised by the SCCS notably i) additional physico-chemical characterization studies, ii) additional toxicity studies in line with the required guidelines (studies were performed according GLP) and iii) finally the file was rewritten focusing on the active ingredient to be more in line with normal practice.

2. Terms of reference

1. *In light of the new data provided, does the SCCS consider Phenylene Bis-Diphenyltriazine, S86 safe for use as a UV-filter in sunscreen products in a concentration up to 5.0%?*
2. *Does the SCCS have any further scientific concerns with regard to the use of Phenylene Bis-Diphenyltriazine, S86 as a UV-filter in sunscreen and/or other cosmetic products*

3. Deadline: February 2018

4. Supporting documents:

- "Dossier on the Safety of Phenylene bis-diphenyltriazine (S86, WP30, CAS 55514-22-2) - Submission II"
- Folder Zip "References"

The SCCS approved this mandate by written process on 7 September 2017.