



## Commentary

## Opinion of the scientific committee on consumer safety (SCCS) – Opinion on the safety of cosmetic ingredient phenylene bis-diphenyltriazine (CAS No 55514-22-2) - S86

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## ABSTRACT

Based on the data provided in the dossier, the SCCS considers Phenylene Bis-Diphenyltriazine, S86, safe for use as a UV-filter in sunscreen products at a concentration up to 5%. Because of the insoluble nature of S86 and as no data were provided on safety via inhalation exposure, the SCCS considers its use safe only in dermally applied products and not in products that would lead to inhalation exposure.

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

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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 characterisation 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.

Based on the data provided in the dossier, the SCCS considers Phenylene Bis-Diphenyltriazine, S86, safe for use as a UV-filter in sunscreen products at a concentration up to 5%.

Because of the insoluble nature of S86 and as no data were provided on safety via inhalation exposure, the SCCS considers its use safe only in dermally applied products and not in products that would lead to inhalation exposure.

Phenylene Bis-Diphenyltriazine (S86) may contain impurities (NMP and hydrazine), which are classified as CMR 1B and identified in the EU as SVHC. Therefore, the level of NMP and hydrazine should be kept at trace levels.

Potential effects of Phenylene Bis-Diphenyltriazine (S86) on the environment have not been assessed by SCCS.

#### **Transparency document**

Transparency document related to this article can be found online at <https://doi.org/10.1016/j.yrtph.2018.09.006>.

#### **Reference**

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