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 (SCCS)

Request for a scientific opinion: UV-filter HAA299 (nano) [INCI name: 'Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine'] [chemical name: '2-(4-(2-(4-Diethylamino-2 hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)-(4-diethylamino-2-hydroxyphenyl)-methanone'](CAS 1419401-88-9). Submission II

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

1. Background

HAA299 (nano) with the chemical name '2-(4-(2-(4-Diethylamino-2 hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)-(4-diethylamino-2-hydroxyphenyl)-methanone' and INCI name 'Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine' (CAS 919803-06-8) is a cosmetic ingredient with the reported functions of UV-filter. Currently HAA299 normal form and nano form is not regulated under the Cosmetic Regulation (EC) No. 1223/2009.

In 2009, Commission' services received a dossier from industry to support the safe use of HAA299 (micronized and non-micronized) in cosmetic products, which was further substantiated with additional information in 2012. In its corresponding opinion (SCCS/1533/14), the SCCS concluded that *"the use of non-nano HAA299 (micronised or non-micronised, with median particle size distribution around 134 nm or larger, as measured by FOQELS) at a concentration up to 10% as an UV-filter in cosmetic products, does not pose a risk of systemic toxicity in humans".*

In addition, SCCS stated that "*[the Opinion]…covers the safety evaluation of HAA299 in non-nano form. The opinion does not cover the safety evaluation of HAA299 which is composed of nano particles*' and highlighted that *'[the Opinion]…does not apply to inhalation exposure of HAA299 since no information on chronic or sub-chronic toxicity after inhalation is provided".*

With the current submission, received in September 2020, and in view of the previous SCCS opinion (SCCS/1533/14) on the normal form of HAA299, the applicant requests to assess the safety of HAA299 (nano) intended to be used as UV-filter up to a maximum concentration of 10%.

2. Terms of reference

(1) In light of the data provided, does the SCCS consider HAA299 (nano) safe when used as a UV-filter in cosmetic products up to a maximum concentration of 10%?

(2) In view of the previous SCCS opinion (SCCS/1533/14) does the SCCS consider HAA299 non-nano and nano form safe when used as a UV-filter in cosmetic products up to a maximum concentration of 10%?

(3) In case the SCCS finds HAA299 (nano) not safe, does it still uphold the conclusions of the SCCS/1533/14 opinion with regard to the safe use of HAA299 non-nano form?

(4) Does the SCCS have any further scientific concerns (on human health) with regard to the use of HAA299 (nano) in cosmetic products?

3. Deadline: 9 months

The SCCS adopted this mandate at the SCCS plenary meeting on 27-28 October 2020.