



SAGCS Final Opinion on HAA299 and HAA299 (nano)

# SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

## Final Opinion on HAA299 and HAA299 (nano) as UV Filters in Cosmetic Products.

### 1. Summary

- 1.1. 2-(4-(2-(4-Diethylamino-2-hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)-(4-diethylamino-2-hydroxyphenyl)-methanone [CAS: 919803-06-8; INCI: Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano); Common Name: HAA299] is not currently regulated under the UK Cosmetic Products Regulation No 1223/2009 (as amended) in either its nano or non-nano form.<sup>1</sup>
- 1.2. In order to be used within cosmetic products for sale on the GB market, novel substances that serve the function of a UV filter require positive approval and must be added to the list of approved UV filters within Annex VI of the UK Cosmetic Products Regulation.
- 1.3. A dossier has been submitted to OPSS to support the safe uses of HAA299 and HAA299 (nano) above a concentration of 10% in cosmetic products. OPSS requests that the SAG-CS assess the safety of HAA299 and HAA299 (nano) intended to be used as UV-filters in cosmetic products.

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<sup>1</sup> The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by [SI 696/2019 Product Safety and Metrology \(EU Exit\) Regulations](#). The full consolidated UK text will be available soon.



## **2. Presentation and Discussion by The Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)**

- 2.1. At their April 2022 meeting, the SAG-CS discussed a paper which focussed on the risks posed to health by the novel UV filters, HAA299 and HAA299 (nano), when used in cosmetic products.
- 2.2. Members noted that the applicant did not provide data to support the safe use of HAA299 and HAA299 (nano) at a level of “above 10%”, however sufficient data was available to assess the risk posed by HAA299 and HAA299 (nano) at a maximum concentration of 10%.
- 2.3. Members also noted that there is a lack of information and validation regarding the method available to determine the composition of products containing HAA299 and HAA299 (nano).
- 2.4. Members commented that the supplied particle size distribution of HAA299 (non-nano) implied that a portion of the material contains particles in the nanoscale. Members further discussed the formulation and potential contaminants of HAA299 (nano).
- 2.5. Members agreed that extrapolation of toxicological data from the non-nano form to the nano form of HAA299 was inappropriate.
- 2.6. Members discussed in-depth the available dermal absorption data and the suitability of use of a margin of safety (MoS) calculation for safety assessment of HAA299 and HAA99 (nano). The relevance of using a point of departure (PoD) based on the oral exposure route was further discussed owing to the major foreseeable exposure route being dermal application. Both HAA299 and HAA299 (nano) were of low aqueous solubility and demonstrated low dermal absorption and low systemic bioavailability.
- 2.7. The effects of inhalation of HAA299 and HAA299 (nano), such as lung inflammation, were discussed. Members acknowledged that short term studies showed that lung inflammation had improved several days after exposure had ceased but data were not available to support the safety of longer-term daily exposure to the lungs.
- 2.8. Limitations owing to precipitation were noted with respect to the supplied bone marrow micronucleus test. Overall, members considered that the available genotoxicity data were sufficient, and genotoxic potential was not expected owing to the low solubilities of HAA299 and HAA299 (nano).



### 3. Conclusions

*Members were satisfied that there was sufficient evidence to form an opinion at this stage.*

*Overall, the group concluded that the use of HAA299 and HAA299 (nano) can be considered safe up to a level of 10%, excluding use in spray and/or aerosol products.*

*The group concluded that there are no safe usage levels for either HAA299 and HAA299 (nano) in spray or aerosolised products owing to potential effects on the lungs.*

*The group clarified that the concentration of HAA299 in either form (non-nano and nano), when used either individually or when used in combination, must not exceed a total concentration of 10%.*

*The group highlighted a lack of information and validation regarding the method available to determine the composition of products containing HAA299 and HAA299 (nano).*

*The group wished to document that their assessment of HAA299 (nano) pertains only to particles with a median particle size of >50 nm according to number evaluation or >100 nm according to volume evaluation.*

**Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products**

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