



Commentary

Opinion of the Scientific Committee on Consumer safety (SCCS) – Second revision of the opinion on carbon black, nano-form, in cosmetic products



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Carbon Black, CI 77266, CAS no. 1333-86-4, EC no. 215-609-9, listed in Annex IV as reference number 126 of the Cosmetic Regulation (EC) No. 1223/2009, is used as colorant in cosmetic products.

According to the applicant the ingredient Carbon Black CI 77266 has a long history of use as a cosmetic colorant. Typical uses of Carbon Black are in different types of cosmetic products, typical use concentrations range from 0.001% to 10% with 0.001% for skin products, 5% for nail enamels and mascaras and up to 10% for other eye decorative products such as eyeliners, eye pencils and eye shadows.

As a result of the recast of the European Cosmetic Directive (76/768/EEC) into the Cosmetic Regulation (EC) No. 1223/2009 a new description will be necessary for this chemical.

According to the definition established in the Cosmetic Regulation under art. 2.(k), this material is a nanomaterial. Based on this new definition, specific data on the material in its nano form was submitted by the applicant.

Reportedly, the present dossier evaluates the safety of Carbon

Black/CI 77266 taking into account most recent recommendations for the safety evaluation of nanomaterials. These recommendations include the SCCS “Guidance on the safety assessment of nanomaterials in cosmetics” (SCCS/1484/12) as well as ECHA “Recommendations for nanomaterials applicable to Chapter R7a Endpoint specific guidance” (ECHA, 2012¹).

Regarding the tests for nanomaterials, the review of health effects-related testing guidelines concluded that, in general, the OECD guidelines are applicable for investigating the health effects of nanomaterials, but specific attention needs to be given to the physicochemical characteristics of the test material, including such characteristics in the actual dosing solution (OECD, 2009; OECD 2010; OECD, 2012²; REACH nano-consultation, 2011³).

The current submission I- according to Cosmetics Europe - provides an overall safety assessment for this ingredient in nano-form, which takes into account the available information.

On the basis of the available evidence, the SCCS has concluded that the use of carbon black CI 77266 in nano-structured form, with a size of 20 nm or larger at a concentration up to 10% as a colorant in cosmetic products, is considered to not pose any risk of adverse effects in humans after application on healthy, intact skin.

This opinion, however, does not apply to applications that might lead to inhalation exposure to carbon black nanoparticles, where the preparation might lead to inhalable particles.

The purity of carbon black nanomaterials used in cosmetic products should be >97%. The impurity profile of carbon black should be comparable with those nanomaterials tested for toxicity in this submission should comply with the EU specifications of carbon black materials as used in food contact materials, and should also comply with FDA specifications with respect to carbon

¹ http://echa.europa.eu/documents/10162/13632/appendix_r7a_nanomaterials_en.pdf.

² <http://www.oecd.org/science/nanosafety/47104296.pdf>.

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:EN:PDF>.

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black produced by furnace method.⁴

In the evidence provided in the submission, imaging was considered the only practical method by the applicant for investigating skin penetration. The use of this method is considered by the SCCS as only semi-quantitative. Other methods need to be explored.

This opinion is based on the currently available scientific evidence, which shows an overall lack of dermal absorption of carbon black nanoparticles. If any new evidence emerges in the future to show that the carbon black nanoparticles used in cosmetic products can penetrate skin (healthy, compromised, sunburnt or damaged skin) to reach viable cells, then the SCCS may consider revising this assessment.

Since the skin absorbance studies have only been performed with carbon black nanoparticles ≥ 20 nm, the current opinion

applies to nano-structured form of carbon black with a particle size of 20 nm or larger. Additional information will be required on the use of carbon black with particles smaller than 20 nm size intended for use in cosmetic products.

Transparency document

Transparency document related to this article can be found online at <http://dx.doi.org/10.1016/j.yrtph.2016.02.021>.

Reference

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_144.pdf

⁴ Ash content $\leq 0.15\%$, total sulfur $\leq 0.65\%$, total PAH ≤ 500 ppb and benzo(a) pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, As ≤ 3 ppm, Pb ≤ 10 ppm, and Hg ≤ 1 ppm.