

EC Committee Begins Public Consultation on Preliminary Opinion on Fullerenes, Hydroxylated Fullerenes, and Hydrated Forms of Hydroxylated Fullerenes (Nano)

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The European Commission's (EC) Scientific Committee on Consumer Safety (SCCS) has begun a [public consultation](#) on its preliminary opinion on fullerenes, hydroxylated fullerenes, and hydrated forms of hydroxylated fullerenes (nano). The EC asked SCCS if it considers fullerenes, hydroxylated fullerenes, and hydrated forms of hydroxylated fullerenes safe when used in cosmetic products according to the maximum concentrations and specifications as reported via the Cosmetic Product Notification Portal (CPNP), taking into account reasonably foreseeable exposure conditions. SCCS states that having assessed the information provided by the notifiers, and the information available from published literature, it "has not been able to conclude on the safety of fullerenes and (hydrated) hydroxylated forms of fullerenes due to a number of uncertainties and data gaps in regard to physicochemical, toxicokinetic and toxicological aspects." SCCS indicated these uncertainties and data gaps in relevant sections of its preliminary opinion and states that they "must be addressed by the Notifiers to enable a conclusion on the safety of the materials for use in cosmetic products." SCCS notes that, in particular, it has not been able to conclude on the genotoxicity potential of fullerenes (C60 and C70). According to SCCS, "[t]he available evidence indicates that hydrated forms of hydroxylated fullerenes are genotoxic and hence SCCS considers them as not safe for use in cosmetic products." In view of equivalence, "the same concerns over genotoxicity potential also apply to hydroxylated fullerenes."

Based on the currently available scientific literature and SCCS' expert judgement, the EC requested that SCCS assess any further scientific concerns with regard to the use of fullerenes, hydroxylated fullerenes, and hydrated forms of hydroxylated fullerenes in cosmetic products and whether a potential risk to human health can be identified according to Article 16(6) of Regulation (EC) No. 1223/2009 (Cosmetics Regulation). SCCS states that in Annex 1 of its preliminary opinion, it notes the basis for concerns over risks that the use of fullerenes, hydroxylated fullerenes, and hydrated forms of hydroxylated fullerenes in cosmetic products may pose to the consumer. The preliminary opinion includes the following list of concerns:

- The potential presence of impurities, heavy metals, accompanying contaminants, and/or organic solvents in the notified nanomaterials;

- Lack of data on stability of hydroxylated fullerenes and their hydrated forms;
- The potential ability of fullerenes and derivatives to induce production of free oxyradicals when used in cosmetic products;
- Phototoxicity of hydroxylated fullerenes, with similar concerns for the hydrated forms of hydroxylated fullerenes;
- Sensitizing potential of hydroxylated fullerenes;
- Dermal absorption and systemic availability of the nanoparticles after use in cosmetic products;
- Distribution of systemically available fullerenes to various organs in the body and potential accumulation of the nanoparticles in certain organs, such as lungs and liver; and
- The available information does not allow SCCS to exclude genotoxic/carcinogenic potential of any of the materials assessed in the preliminary opinion.

Comments are due June 12, 2023.

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National Law Review, Volume XIII, Number 124

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