

THE NATIONAL LAW REVIEW

EC Committee Accepting Comment on Preliminary Opinion on Solubility of Synthetic Amorphous Silica

Wednesday, March 20, 2019

On March 15, 2019, the European Commission's (EC) Scientific Committee on Consumer Safety (SCCS) published its [preliminary opinion on the solubility of synthetic amorphous silica \(SAS\)](#). The EC asked whether the SCCS considers that SAS are soluble (100 milligram per liter (mg/L) or higher) or degradable/non-persistent in biological systems in light of the nanomaterial definition of the Cosmetics Regulation. Having considered the data provided in this dossier and that available in published literature, the SCCS concluded that:

1. The solubility values for hydrophilic SAS materials have been reported to range from 22 mg/L to 225 mg/L for the solubility tests performed in aqueous media, or following the enhanced Organization for Economic Cooperation and Development (OECD) Test Guideline (TG) 105 (0.5 percent ethanol). The latter protocol has been noted to increase the solubility by a factor of ten for some hydrophilic SAS materials.
2. The solubility values of hydrophobic surface-treated SAS materials have been reported to range from 0.4 to 180 mg/L for solubility tests performed in aqueous media, or following a modified enhanced OECD TG 105 protocol (*i.e.*, using ten percent ethanol). The latter protocol has been noted to strongly increase the solubility of some hydrophobic SAS materials (by a factor up to 173).

The preliminary opinion states that the hydrophilic and hydrophobic SAS materials can therefore be regarded as "insoluble" (*i.e.*, below 100 mg/L) to "very slightly soluble" (*i.e.*, 100 mg/L to 1,000 mg/L) based upon the terminology used in USP 38 and USP 38 NF33. According to the preliminary opinion, in regard to the nanomaterial definition in the Cosmetics Regulation, none of the SAS materials (hydrophilic or hydrophobic) included in the dossier can be regarded as soluble. No data were provided to help establish whether the SAS materials could be regarded as degradable/non-persistent in biological systems.

The EC asked whether SCCS could indicate to which kind of silica this solubility applies. The preliminary opinion states that the solubility values reported in the dossier are applicable when SAS materials are subject to the following conditions:

- Hydrophilic SAS: Silica and hydrated silica when solubilized in aqueous media containing up to 0.5 percent ethanol;
- Hydrophobic surface treated SAS: When solubilized in aqueous media containing up to ten percent ethanol;
- At temperatures between 19.5 to 20.5°C;
- With a pH level of between three and eight; and
- Over a period between three days (hydrophilic SAS) up to 49 days (hydrophobic SAS).

The EC asked whether SCCS has any further scientific concerns with regard to the solubility of SAS. SCCS states



Article By [Carla N. Hutton](#)
[Lynn L. Bergeson](#)
[Bergeson & Campbell, P.C.](#)
[Nano and Other Emerging Chemical Technologies Blog](#)
[Environmental, Energy & Resources](#)
[Global](#)
[European Union](#)

that the solubility values considered in its opinion may not be valid in situations where the SAS materials are formulated/used under conditions that are different from those used in the solubility tests — e.g., when used in a less/non aqueous formulation, or at a different temperature. According to SCCS, in the context of the definition of nanomaterial under the Cosmetics Regulation, which relates to insoluble materials in conjunction with other size/particle related parameters, the question of solubility of a nano-structured material needs to be seen in perspective for use in cosmetics. For nano-structured materials, with the exception of the materials that are completely soluble, SCCS states that “it is important to establish whether a proportion of these materials would still exist in undissolved form comprising nanoparticles, at the given use level in a cosmetic formulation.” SCCS noted that the protocols used for solubility tests have a strong influence on the solubility of SAS materials. Comments on the preliminary opinion are due **May 17, 2019**.

© 2019 Bergeson & Campbell, P.C.

Source URL: <https://www.natlawreview.com/article/ec-committee-accepting-comment-preliminary-opinion-solubility-synthetic-amorphous>