EC Committee Publishes Final Opinion on Copper (Nano) and Colloidal Copper (Nano)

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On March 5, 2021, the European Commission's (EC) Scientific Committee on Consumer Safety (SCCS) published its <u>final opinion on copper (nano)</u> and <u>colloidal copper (nano)</u>. According to the final opinion, nine manufacturers notified the EC about 36 different products containing nanosized copper. After initial evaluation and a request for additional information, two manufacturers withdrew their products from the notification, and these seven products were excluded from evaluation, resulting in the final evaluation of 29 nanosized copper products produced by seven manufacturers. For three different copper nanomaterials, notification files were provided. The final opinion states that for all three copper nanomaterials, "the notified files were insufficient regarding their characterisation and for conducting a safety evaluation." All copper nanomaterials claimed to have antimicrobial activity. Most files contained declarations of safety without any supporting data or documentation, however, and based on the provided information, the final opinion states that it is not possible to perform a safety assessment on them.

The EC asked whether SCCS considers the nanomaterials copper and colloidal copper safe when used in leave-on and rinse-off dermal and oral cosmetic products at a maximum concentration of 1% (for both copper and colloidal copper) and with certain specifications, taking into account reasonably foreseeable exposure conditions. SCCS states that it considered all the information provided by the notifiers and "is of the opinion that it is not possible to carry out safety assessment of the nanomaterials Copper and Colloidal Copper due to the limited or missing essential information." SCCS notes that much of the information provided on toxicity relates to copper as such, "and in the absence of full study reports, it is not possible to determine the relevance of the data for nano-forms of copper under the current evaluation." SCCS states that "[a]dequate information on various aspects both for the nanomaterial characterisation and the toxicological evaluation including experiment performance and experimental data obtained need to be provided."

The EC also asked whether SCCS has any further scientific concerns with regard to the use of copper and colloidal copper in nano form in cosmetic products. According to the final opinion, the information provided by the notifiers and obtained from scientific literature suggests possible systemic uptake of copper nanoparticles (and/or ionic copper), "which may lead to accumulation in certain organs — notably the liver and spleen." The final opinion notes that in addition, the available data

indicate potential mutagenic/genotoxic and immunotoxic/nephrotoxic effects of copper nanomaterials. The final opinion states that these indications "raise an alert that warrants further safety evaluation of copper nanomaterials used as cosmetic ingredients." SCCS details its concerns for consumer safety in this regard in Annex II of the final opinion.

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National Law Review, Volume XI, Number 67

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