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Scientific Committee on Consumer Safety
Email: [SANCO-C2-SCCS @ ec.europa.eu](mailto:SANCO-C2-SCCS@ec.europa.eu)

To Whom It May Concern:

RE: Comments on: Opinion on Carbon Black (nano-form)

These comments are submitted on behalf of the PETA International Science Consortium, Ltd., which directs the scientific and regulatory expertise of PETA U.S. and its international affiliates to promote reliable and relevant strategies that eliminate the use of animals in experiments and coordinates the affiliates' funding of non-animal method development. We thank the Scientific Committee on Consumer Safety (SCCS) for the opportunity to comment on the 'Opinion on Carbon Black (nano-form)'.

We agree with the SCCS opinion that acute oral toxicity and absorption through intact skin are unlikely to be of concern with the use of carbon black in cosmetic products. We also agree with the SCCS that the literature currently available provides limited information on the potential of carbon black to cause skin sensitization in case of damaged skin or to initiate or promote tumors. However, we are concerned that the criticism by SCCS of specific studies might be perceived as a need for new hazard assessment studies by regulators and manufacturers. Since animal studies for chemicals used in cosmetics are banned in the EU, we recommend adding to this report information regarding the non-animal methods available to address any perceived data gaps. For instance, in addition to the many *in vitro* Organization for Economic Cooperation and Development (OECD) test guidelines, the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM) has recommended a number of *in vitro* assays which, when used in conjunction with existing knowledge regarding nano-based phenomenon and properties, could yield valuable information regarding potential toxicological effects [1]. Following are a few recent EURL ECVAM recommendations:

- Acute Oral Toxicity: The 3T3 Neutral Red Uptake (3T3 NRU) cytotoxicity assay [2] is used to assess the overt cytotoxicity of substances not requiring classification for acute oral toxicity.
- Skin Sensitization: The Direct Peptide Reactivity Assay (DPRA) for Skin Sensitization [3] is an *in chemico* assay to test peptide reactivity of chemicals. The adverse outcome pathway for skin sensitization leading to Allergic Contact Dermatitis (ACD) in humans starts with initial event of haptentation [4]. This assay can assess the ability of the chemical to covalently bind to peptides on the skin, making it very useful for quick detection of chemicals which can cause skin sensitization. The DPRA can be used in a tiered testing strategy with the KeratinoSensTM assay [5].
- Carcinogenicity: The Cell Transformation Assay (CTA) for carcinogenicity testing based on the Bhas 42 cell line [6] is a cell-

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based assay that can detect the ability of the chemical to initiate or promote cancer. Like other CTAs, such as Syrian Hamster Embryo Cells (SHE) and the BALB/c 3T3 Mouse Fibroblast Cell Line [7], this assay could be used to replace animal testing in the area of carcinogenicity.

Furthermore, based on the SCCS Nano-Guidance [8], attention should also be paid to the physicochemical characterization of nanomaterials to assess the potential risk due to its nano-related properties, behavior, and effects. With regards to carbon black and its application in cosmetic products, studies should be done to analyze its lifecycle changes, such as agglomeration, deagglomeration etc. Acellular techniques such as suspending carbon black in the relevant exposure solutions, including emulsifiers, over a course of relevant time points and temperature conditions could provide useful information on the extent of deagglomeration. This approach is similar to issues described in a current OECD document which states that the interaction between nano-objects in a formulation should be studied in conjunction with interaction of nanomaterials with components of the formulation [9].

Sincerely,



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6. *EURL- ECVAM (2013) recommendation on the Cell Transformation Assay based on the Bhas 42 cell line. http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-recommendations/eurl-ecvam-recommendation-on-the-cell-transformation-assay-based-on-the-bhas-42-cell-line.*
7. *EURL-ECVAM (2011) recommendation concerning the cell transformation assays using Syrian hamster embryo cells (SHE) and the BALB/c 3T3 mouse fibroblast cell line for in vitro carcinogenicity testing. Annex I: ESAC opinion on the ESAC peer review of an ECVAM-coordinated prevalidation study concerning three protocols of the cell transformation assay (CTA) for in vitro carcinogenicity testing. http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-recommendations/cta-recommendation.*
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