

## SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Subject:** Request for clarification on the meaning of the term "sprayable applications" for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide

### 1. Background

At the last Standing Committee and Working Party on Cosmetic Products of the 26<sup>th</sup> of June, the Commission has presented legislative proposals for the nano forms of Carbon Black CI 77266<sup>1</sup>, Titanium Oxide<sup>2</sup> and Zinc Oxide<sup>3</sup> based on the recent SCCS opinions. For these ingredients, the scientific conclusions clearly indicated that although these ingredients are considered safe for use, sprayable applications are of concern because of possible risks due to inhalation:

*"SCCS is of the opinion that the animal cancer data are relevant to humans and that the use of nano carbon black in sprayable applications is not recommended."*<sup>1</sup>

*"Therefore the SCCS does not recommend the use of nano TiO<sub>2</sub> in sprayable applications"*<sup>2</sup>

*"...the use of ZnO nanoparticles with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered not to pose a risk of adverse effects in humans after dermal application. This does not apply to other applications that might lead to inhalation exposure to ZnO nanoparticles (such as sprayable products)"*<sup>3</sup>

Member States asked a clarification by the SCCS for the meaning of the term "*sprayable applications/products*" in the conclusions of the safety assessments for Carbon Black CI 77266, Titanium Oxide and Zinc Oxide.

Generally speaking, the term spray is broad and includes:

- a) aerosols dispenser, for which there is the definition contained in Directive 75/324:  
*"non-reusable containers made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state";*
- b) spray bottles containing a pump that draws a liquid up from the bottom and forces it through a nozzle generating a stream or a mist.

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<sup>1</sup> SCCS/1515/13

<sup>2</sup> SCCS/1516/13

<sup>3</sup> SCCS/1489/12

In addition, according to literature "*aerosol*" indicates a suspension of solid or liquid particles in a gas (usually air) with particle size 2 nm to more than 100 µM while "*spray*" indicates a droplet aerosol formed by the mechanical breakup of a liquid with particles larger than a few micrometers.<sup>4</sup>

Many cosmetic products present on the market are dispensed through a mechanical pump that, instead of aerosol/nebulisation, produces a single dose of cream. Therefore, there is a need to clarify whether "*sprayable applications/products*" of the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide would also include these pump dispensers for creams.

For clarity of the next scientific opinions, a harmonised terminology could be adopted meaning with the term "spray" the production of aerosols and/or nebulisation and with "pump dispensers" the dispensing devices for single-dose cream.

## 2. Questions

- (1) *In light of the different definitions of spray, could the SCCS clarify the product types included in the term "sprayable applications/products" used in the conclusions of the safety assessments for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide?*
- (2) *For clarity of the future safety assessment, could the SCCS adopt a harmonised terminology that will allow a distinction between aerosol (with propellant), spray (spray bottles) and pump dispensers (single-dose cream)?*

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<sup>4</sup> Hinds, William C. (1999). *Aerosol Technology* (2nd ed.). Wiley - Interscience. ISBN 978-0-471-19410-1.