SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for a scientific opinion: Thioglycolic acid and its salts (CAS 68-11-1)

1. Background

Thioglycolic acid and its salts (including the ammonium salt) are currently regulated in the <u>Cosmetic</u> <u>Regulation 1223/2009</u> in Annex III entry 2a with the following restriction:

Thioglycolic acid and its salts may be used in:

- (a) Hair products:
- general use, max concentration allowed 8% (pH 7 to 9.5)
- professional use, max concentration allowed 11% (pH 7 to 9.5)
- (b) Depilatories, max concentration allowed 5% (pH 7 to 12.7)
- (c) Hair rinse-off products, max concentration allowed 2% (pH up to 9.5)

The above mentioned percentages are calculated as thioglycolic acid.

The previous EU Cosmetics Directive 76/768 of 27 July 1976 did not contain any definition of "hair" or "hair product", and therefore does not contain any specific requirements for the application of hair (care) products to eyelashes, except for a number of provisions relating to some specific substances. Hair dye products containing these substances must be labelled "Do not use to dye eyelashes and eyebrows" unless intended for professional use.

The Directive was replaced as from 11 July 2013 by the Cosmetic Regulation 1223/2009. The term "hair product", introduced in the preamble to Annexes II to VI of the EU Cosmetics Regulation, is defined as "a cosmetic product which is intended to be applied on the hair of head or face, except evelashes".

Thus, the use of thioglycolic acid and thioglycolates in hair products is in accordance with the new European cosmetics legislation, but the application of these products to eyelashes has been prohibited since 11 July 2013.

In order to ensure the legal compliance of these products, the applicant submitted a dossier for the safety assessment of thioglycolic acid and thioglycolates in cosmetic products used on eyelashes. It has been reported that eyelash-waving products based on thioglycolic acid derivatives are applied by professionals and during application a direct contact to the skin or eyes is avoided with the help of a sticking eyelash roll.

Furthermore, following concerns originally raised by Denmark regarding the local safety of "hair chemical removers" i.e. depilatory products containing thioglycolic Acid and its salts (thereafter designated as TGA), Cosmetics Europe* submitted a document containing post-marketing surveillance (PMS) data on these cosmetic products.

2. Terms of reference

- 1. Does the SCCS consider Thioglycolic acid and its salts (TGA) still safe for use as depilatories in cosmetic products in a concentration up 5.0% taking into account the data provided from Cosmetics Europe?
- 2. Taking into account the scientific data available, does SCCS consider Thioglycolic acid and its salts (TGA) safe for use on eyelashes (after mixing with oxidative hair dyes found safe for use in hair dye products) in concentrations up to 8% for general use and up to 11% for professional use applied on eyelashes?