

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Submission III 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (CAS No 103597-45-1) (S79)

1. Background

The substance 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (MBBT) (CAS No 103597-45-1), Methylene bis-benzotriazolyl tetramethylbutylphenol (INCI) (COLIPA S79) is currently regulated in Entry 23 Annex VI of the Cosmetics Regulation (EC) 1223/2009 with the maximum concentration of 10% in cosmetic products such as sunscreens, day care products and skin lightening products. The safety of mentioned use conditions was confirmed by the Scientific Committee on Cosmetic Products and Non-Food (SCCNFP) in 1998 following submission I by COLIPA¹ (SCCNFP/0080/98)².

Submission II on MBBT was submitted to the Scientific Committee on Consumer Safety (SCCS) in January 2013 to assess the safety of its nano form. The SCCS opinion concluded that:

"Since no appropriate data on genotoxicity of nano form of MBBT were provided, no conclusion on the safety of this substance can be drawn. However regarding systemic effects there seems no concern for the dermal application of nano-sized MBBT." (SCCS/1443/11)³

In August 2014 BASF has transmitted a new safety dossier that summarizes analytical and toxicological results obtained for genotoxicity studies performed with nano and non-nano forms of MBBT.

2. Terms of reference

- (1) *In light of the new data provided, does the SCCS consider Methylene bis-benzotriazolyl tetramethylbutylphenol (CAS No 103597-45-1) safe when used in cosmetic products in its nano forms under the current use conditions up to a maximum of 10%?*
- (2) *Does the SCCS have any further scientific concern regard the use of Methylene bis-benzotriazolyl tetramethylbutylphenol in cosmetic products?*

¹COLIPA - today Cosmetics Europe,- European Cosmetics Toiletry and Perfumery Association

²http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out55_en.htm

³ http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_129.pdf

3. Deadline:

4. Supporting documents

1. UV filter 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) COLIPA n° S79 Submission III. July 2014