

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) Submission II (S79)

1. Background

2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (CAS No 103597-45-1), Methylene bis-benzotriazolyl tetramethylbutylphenol (INCI) listed in Annex VII as reference number 23, has been used as UV filter in sunscreens, day care products and skin lightening products.

Submission I for Methylene bis-benzotriazolyl tetramethylbutylphenol was submitted in 1998 by COLIPA¹.

The Scientific Committee on Cosmetic Products and Non-Food expressed its opinion (SCCNFP/0080/98) with the following conclusions:

"The SCCNFP is of the opinion that Methylene bis-benzotriazolyl tetramethylbutylphenol is safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%".

After a SCCNFP opinion, 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) S79 was requested for inclusion in Annex VII, part 1 – List of UV filters which Cosmetic Products may contain – to Council Directive 76/768/EEC.

As a result of the recast of the European Cosmetic Directive (76/768/EEC) into the Cosmetic Regulation (EC No. 1223/2009) a new description will be necessary for this chemical. According to the description stated in the Cosmetic Regulation under article 2 this material could fulfil the definition of a nanomaterial. Based on this new definition supplementary data on the material on its nano form, was submitted by the applicant.

According to the applicant, the current submission II takes into account the available information on the nano-form of this ingredient.

2. Terms of reference

- (1) *Does the SCCS consider 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) in its nano form safe for use as a UV-filter with a concentration up to 10 % in cosmetic products taking into account the scientific data provided?*
- (2) *Does the SCCS have any further scientific concern with regard to the use of 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) in its nano form in cosmetic products?*