

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Climbazole (CAS 38083-17-9) COLIPA P64

1. Background

Climbazole, with the chemical name 1-(4-chlorophenoxy)-1-imidazol-1-yl-3,3-dimethyl-2-butanone, is currently regulated in the Cosmetics Directive as a preservative in Annex VI, entry 32, with a maximum authorized concentration of 0.5%.

In opinion SCCP/1204/08, adopted on 21 February 2009, the SCCP concluded that:

- *“The use of Climbazole as a preservative at a maximum concentration of 0.5% in all cosmetic products cannot be considered safe. However, when used as a preservative in hair cosmetics and face cosmetics at 0.5%, climbazole does not pose a risk to the health of the consumer”;*
- *“the (non-preservative) use of Climbazole in rinse-off hair cosmetics up to a maximum concentration of 2.0% does not pose a risk to the health of the consumer”;*
- *“The non-preservative use of Climbazole in hair cosmetics and face cosmetics at 0.5% does not pose a risk to the health of the consumer. The use of Climbazole at 0.5% in leave-on products other than those mentioned above, however, is not considered safe”.*

In this opinion, the SCCP also remarked that no specific information regarding the potential development of (cross-) resistance had been provided.

A working document proposing to restrict the use of Climbazole as suggested by the SCCP was put forward by the Commission in October 2009. Member States declared concerns in relation to possible induction by climbazole of antimicrobial resistance and cross-resistance to antimicrobial medicinal products and asked the Commission to consult EMA on the issue.

In addition, at the time of the public consultation to evaluate the economic impact of the restriction, one company claimed use of climbazole in an additional type of products (i.e. foot care).

The Commission subsequently consulted EMA and issued a mandate to the SCCS to evaluate the safety of the additional use in foot care products. The CHMP/EMA Innovation Task Force (ITF) concluded in its scientific opinion that *'in view of its mechanism of action, the use of climbazole in cosmetic products may increase the risk of cross-resistance to other azole antifungals used as medicinal products, the greatest concern being the possible effect of climbazole on microbiota on the human skin and the possibility for development of cross-resistance for other azole antifungals, especially in immunocompromised individuals.'*

2. Terms of reference

The SCCS is asked to answer the following questions:

1. *In light of the EMA opinion and the information contained therein, can climbazole still be considered safe for use as an ingredient in cosmetic products?*
2. *If the answer to question 1 is yes, does the SCCS consider that any aspects of the previous assessment of climbazole needs to be revised on the basis of the dossier produced by EMA on this ingredient?*
3. *If the answer to question 1 is yes, does the SCCS consider that Climbazole is safe for the consumers, when used up to a concentration of 0.5% in foot care products in addition to the previous evaluated uses (i.e. hair cosmetics and face cosmetics up to 0.5%, rinse-off hair cosmetics up to 2.0%)*
4. *Does the SCCS have any further scientific concern with regard to the use of climbazole in cosmetic products?*