

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Request for a scientific opinion on the preservative Zinc pyrithione (CAS 13463-41-7; EU 236-671-3) submission II (P81)

1. Background

Zinc pyrithione (ZPT) (CAS 13463-41-7; EU 236-671-3) with the chemical name: Bis[(2-pyridyl-1-oxo)-thio]zinc was introduced into the Cosmetics Directive as a preservative by Directive 82/368/EEC. It was authorised as a preservative at the maximum concentration of 0.5% with the limitation "*Authorized in products rinsed off after use, forbidden in products for oral hygiene*".

Back in 1984 (17/12/1984) the Scientific Committee on Cosmetology (SCC) concluded in its opinion XI/389/84 concerning the use of pyrithione zinc in hair-care preparations not rinsed off after use: "*The Committee notes that the use of pyrithione zinc is allowed as a preservative in products rinsed off after use at a maximum concentration of 0.5% in the finished product.*

The Committee finds that the substance is highly toxic, and cannot agree to recommend any extension of its use unless percutaneous absorption in man can be shown not to occur in normal skin, nor under conditions of inflammation or abrasion."

Submission I for Zinc pyrithione was submitted in July 2000 by COLIPA¹.

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) adopted its opinion (SCCNFP/0671/03) on 17th December 2002 with the conclusion: "*The SCCNFP is of the opinion that zinc pyrithione does not pose a health risk when used:*

- *for non-preservative purposes in cosmetic rinse-off and leave-on hair care products at a maximum concentration of 1.0 % and 0.1 %, respectively; or,*
- *for preservative purposes in cosmetic rinse-off hair care products at a maximum concentration of 1.0 %.*

Zinc pyrithione should not be used in products for oral hygiene."

Zinc pyrithione is currently regulated as a preservative in rinse-off products (excluding oral hygiene products) in a concentration up to 0.5% in general and up to 1.0% in hair products (annex VI/1, 8). Furthermore zinc pyrithione is also allowed in a concentration up to 0.1% in leave-on hair products. (annex III/1, 101)

In the present submission by Colipa (submission II), which is a supplemental dossier to submission I, the applicant applies for an extension of the authorised concentration from 1.0% to 2.0% in rinse-off antidandruff hair care products.

¹ COLIPA - European Cosmetics Toiletry and Perfumery Association

2. Terms of reference

Based on the scientific data provided, does the SCCS consider that zinc pyrithione, when used in a concentration up to 2.0% as anti-dandruff agent in rinse-off hair care products, is safe for the consumer? [The request should be seen as additional to the currently authorized use]