



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for an Addendum to the scientific opinion on the safety of Zinc Pyrithione (CAS 13463-41-7).

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

The cosmetic ingredient 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".

ZPT has been subject to different safety evaluations by the SCC in 1984 (XI/389/84), SCCNFP in 2002 (SCCNFP/0671/03) and the SCCS in 2014 (SCCS/1512/13).

In particular, in the opinion of 2002, experts assessed ZPT safe for the consumer as antidandruff agent in rinse-off hair care products at a maximum concentration of 1.0% and later in 2014 safe at 2.0%.

ZPT 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 V/8). Furthermore, ZPT is also allowed in a concentration up to 0.1% in leave-on hair products (Annex III/101).

A CLH dossier was submitted in October 2016 by the Swedish Chemicals Agency ("KEMI") to ECHA to support the harmonised classification and labelling of ZPT as a CMR 1B.

As new studies are available and used in the CLH report for ZPT, the Swedish Medical Products Agency have asked for a re-assessment of the safety of ZPT as an anti-dandruff agent in rinse-off hair care products at a maximum concentration of 2.0%.

2. Terms of reference

- 1. In light of the new evidence available, does the SCCS still consider that zinc pyrithione, when used in a concentration up to 2.0% as an anti-dandruff agent in rinse-off hair care products, is safe for the consumer as concluded in SCCS/1512/13?*

2. *If not, does the SCCS consider that zinc pyrithione, when used in a concentration up to 1.0% as an anti-dandruff agent in rinse-off hair care products, is safe for the consumer as is the current situation?*
3. *Does the SCCS have any further scientific concerns regarding the use of zinc pyrithione in cosmetic products?*

3. **Deadline:** February 2018

4. **Supporting documents:**

- confidential studies

The SCCS approved this mandate by written process on 24 October 2017.