SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Zinc Pyrithione (ZPT) (CAS No 13463-41-7, EC No 236-671-3)

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

1. Background

The cosmetic ingredient Zinc Pyrithione (ZPT) (CAS No 13463-41-7, EC No 236-671-3) with the chemical name Bis[(2-pyridyl-1-oxo)-thio]zinc 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).

Zinc Pyrithione 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) and 2018 (SCCS/1593/2018). In particular, in the SCCS opinions from 2014 and 2018, Zinc Pyrithione was found safe as an antidandruff agent in rinse-off hair care products at a maximum concentration of 2.0%.

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


According to Article 15(2) of the Cosmetics Regulation, “The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:

(a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying

down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

(b) there are no suitable alternative substances available, as documented in an analysis of alternatives;

(c) the application is made for a particular use of the product category with a known exposure; and they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups”

In view of the above, regulatory measures must be adopted by the Commission services within 15 months of the classification as CMR 1A or 1B of the substance(s) concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

In April 2019, a safety dossier on ZPT was submitted by Cosmetics Europe to demonstrate the safety of the ingredient as an anti-dandruff in rinse-off hair products.

2. Terms of reference

(1) In view of the conditions laid out in Article 15(d) of the Regulation (EC) No 1223/2009 and taking into account the scientific data provided, does the SCCS consider Zinc Pyrithione safe when used as an anti-dandruff in rinse-off hair products up to a maximum concentration of 1%?

(2) Does the SCCS have any further scientific concerns with regard to the use of Zinc Pyrithione in cosmetic products?

3. Deadline: October 2019

4. Supporting documents:

- Dossier on the Safety of Zinc Pyrithione (ZPT) in Cosmetic Products

The SCCS approved this mandate by written procedure on 10 May 2019.