

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCT (SCCP)

Request for a scientific opinion: Request for a scientific opinion on Tea Tree Oil from the genus *Melaleuca*.

1. Background

The Scientific Committee on Consumer Product (SCCP) adopted a scientific opinion (SCCP/0834/04) on Tea Tree Oil (TTO) on its 2nd plenary meeting of 7 December 2004 with the following conclusion:

"The sparse data available suggest that the use of undiluted Tea Tree Oil as a commercial product is not safe. The safety dossier of Tea Tree Oil is incomplete. The stability of Tea Tree Oil in cosmetic formulations is questionable. A standardized method for the specification of Tea Tree Oil is needed. Industry should develop an analytical testing method based on typical degradation products to ensure and control the stability of the material. Skin and eye irritation was not assessed by adequate methods. There are relevant data gaps with regard to subchronic toxicity, percutaneous absorption, genotoxicity/carcinogenicity and reproductive toxicity. The safe use of Tea Tree Oil as cosmetic ingredient cannot be assessed. A complete dossier of a representative standardized material to all relevant toxicological endpoints is required by the end of 2005; an opinion based on the information available at that time will be given."

As a response to the above scientific opinion a complete new dossier was submitted by the end of March 2007.

Tea tree oil is the essential oil obtained from *Melaleuca alternifolia*, *Melaleuca linariifolia* and *Melaleuca dissitiflora* as well as other species of *Melaleuca* provided that the oil conforms to the requirements given in ISO 4730-2004.

The following types of application for cosmetic products are given in the dossier:

Skin - care products incl. post-waxing treatments up to 1.25%,

Hair - care products up to 2.0%

Nail - care products up to 20%

Oral hygiene up to 0.2%

Personal hygiene incl. shaving products up to 2%.

The undiluted might be used for other purposes as well i.e. aromatherapy.

2. Terms of reference

1. On the basis of the data provided, does the SCCP consider the use of Tea Tree Oil safe for the consumers when used in cosmetic products in concentrations as mentioned above?

2. Does the SCCP have any safety concerns for the use of Tea Tree Oil as an undiluted product?

3. Due to stability and auto-oxidation characteristics of tea tree oil upon use and storage does the SCCP find it important, for safety reasons, to have a date of minimum durability after opening on Tea Tree Oil products or any product containing Tea Tree Oil or any other recommendations?