RISK PROFILE

Tea tree oil – TTO

CAS No. 85085-48-9, 68647-73-4, and 8022-72-8

Date of reporting 10.08.2012

Content of document

1. Identification of substance

Chemical name (IUPAC):	Melaleuca Alternifolia Leaf Oil is the oil distilled from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INCI	Tea Tree Oil (primary name); *Melaleuca alternifolia* (Tea tree) Leaf Oil (INCI)[1] The European Inventory (CosIng) contains 7 *Melaleuca alternifolia* ingredients (INCI names), including oil, water and powder forms. (Annex 6)
Synonyms	
CAS No.	85085-48-9 /68647-73-4 /8022-72-8, cf. also SCCP/1155/08 (Annex 6)
EINECS No.	285-377-1
Molecular formula	As to major constituents confer SCCP/1155/08
Chemical structure	For chemical structures of the main constituents of TTO (Annex 1A), see excerpt from SCCP opinion on TTO, SCCP/1155/08 (pp. 8).
Molecular weight	TTO is a mixture of several constituents, with the molecular weights of the main constituents ranging from 134 – 222 g/mol; Annex 1A.

[1] cf. SCCP opinions SCCP/0843/04 and SCCP/1155/08 and TTO monograph (Council of Europe, 2001). See also excerpt from Cosing database (Annex 6).

Contents (if relevant)	TTO consists of more than 100 constituents (mainly mono-terpenes, sesquiterpenes and their alcohols). ISO 4730:2004 specifies levels of 14 major components (80-90% of the oil). *Terpinen-4-ol*, which is said to be responsible for most of the antimicrobial activity, has to be maintained at a minimum level of 30%, cf. German regulation (BfR, 2003). See also **SCCP/1155/08**, **SCCP/0843/04** and Annex 1B.
Physiochemical properties	See TTO monograph (Council of Europe, 2001) and SCCP opinions on TTO, SCCP/0843/04 and SCCP/1155/08 (section 3.1).

2. Uses and origin

Uses	➢ **Cosmetic products:** *Functions according to* • CosIng database[2]: - Antioxidant – Inhibits reactions promoted by oxygen, thus avoiding oxidation and rancidity - Perfuming – Used for perfume and aromatic raw materials • Others: Other functions and uses[3] (**SCCP/1155/2008**, pp. 14; TTO monograph, Council of Europe, 2001). *Concentrations of TTO being applied* "*TTO is not currently subject to any constraint for the use in cosmetic products. It is sold undiluted and highly concentrated to the public. Furthermore, the oil is used as ingredient of cosmetics*" (**SCCP/1155/08**, pp. 14). According to the Australian Tea Tree Industry Association (ATTIA) / Rural Industry Research and Development Corporation (RIRDC), typical concentration of TTO in cosmetic products are: • moisturisers (1.25%) • body lotions (1.25%) • shampoos and conditioners, mouth washes (0.2%) • face cleansing washes (0.7%) • hand washes (0.7%) • soaps (2%) • foot sprays (2%) • foot powders (1%) • shaving products (2%) • post-waxing treatments (1.25%) and • deodorants (2%).

[2] Applicable to the *Melaleuca Alternifolia* **leaf oil**. For CosIng functions of other parts of the plant, see Annex 6.
[3] No cosmetic function was provided by the applicant: Australian Tea Tree Industry Association (ATTIA), SCCP/1155/08 (pp. 14).

	RIRDC [online]. *Frequency of use* The Environmental Working Group (EWG) cosmetic database lists 910 cosmetic products containing TTO (i.e. *Melaleuca Alternifolia* (Tea Tree) Leaf Oil): • facial moisturizer/ treatment (91 products) • moisturizer (91 products) • facial cleanser (88 products) • toners/ astringents (60 products) (EWG's Skin Deep [online]) A survey by the Swedish Medicinal Products Agency (MPA) in 1999 revealed 112 products containing TTO at concentrations of 0.3% to 100% (TTO monograph, Council of Europe, 2001). The German codecheck.info database (search phrase: "Melaleuca Alternifolia") lists 532 cosmetic products. ➢ **Food** There are no natural food sources of tea tree oil. Several incidences of oral poisoning in children and adults have been reported, but no deaths (cited in Carson et al., 2006). Because of its toxicity, TTO should never be swallowed (American Cancer Society [online]). ➢ **Medicinal products** It should be noted that TTO does not have marketing authorization as a pharmaceutical product. Because TTO is an unproven treatment, there is no established dose, but for certain medical conditions with possible benefits, TTO is used at concentrations in the range of 5-100%: - Nail fungus (*onychomycosis*): 100% TTO solution applied twice daily for six months. - Athlete's foot (*tinea pedis*): 25% or 50% TTO solution applied twice daily for one month has been used. 10% TTO cream applied twice daily for one month has also been used. - Acne: 5% TTO gel applied daily. MedlinePlus [online]. The Swedish MPA has registered three TTO containing products as "natural medicinal products (**SCCP/1155/2008**, pp. 14). In the UK, "Melaleuca Oil" is on "list B: consolidated list of substances which are present in authorized medicines for general sale" (MHRA [online]). ➢ **Other products**
Origin Natural (exo /endo) Synthetic	TTO is the oil obtained by steam distillation of the foliage and terminal branchlets of *Melaleuca alternifolia*, Melaleuca linariifolia and Melaleuca dissitiflora, as well as other species of Melaleuca (Carson et al., 2006; BfR, 2003). The *M. alternifolia* species is unique to Australia and native to Northern New South Wales. See also SCCP opinion **SCCP/1155/08.**

3. Regulation

Norway	Area of allowance[4]: Special limitations:	Mouth care products (max 0.5 %; w/w) All other cosmetics (max. 2 %) Must not be used in products meant for children less than 12 years old
EU	No regulation	
Rest of the world	No regulation	

4. Relevant toxicity studies

Absorption Skin GI tractus	TTO is not a single chemical but a mixture - some constituents are known to penetrate the skin, whereas others do not. Extrapolations from *in vitro* tests of the constituents of TTO with potentially varying bioavailabilities need to be considered with caution (Nielsen, 2008). Both exposure time and type of formulation have significant influence on dermal absorption of TTO (**SCCP/1155/2008**, pp. 28; see Annex 2). In an *in vitro* human epidermal skin model, only two components of TTO were able to penetrate the entire thickness of the epidermal preparation: terpinen-4-ol and α-terpineol. Both substances reached the subcutaneous fat layer within 1 h and 2 h, respectively, whereas some of the other components were detectable at lower levels upon prolonged exposure (**SCCP/1155/08**, pp. 26). Clinical data support the notion that percutaneous absorption of some constituents of TTO could lead to a considerable systemic exposure from cosmetic products, but the magnitude remains uncertain. **SCCP/1155/08** (pp. 36) concluded in 2008 that*: "Should reliable data on percutaneous absorption covering relevant concentrations and cosmetic formulations be provided, the SCCP anticipates a reassessment of the safety of tea tree oil".* SCCS also commented that*: "None of the available studies were adequate to assess exposure (magnitude) of TTO from cosmetic products" (*SCCP/1155/08). For (*hypothetical) exposure estimation*, two skin penetration studies are cited in the SCCP opinion **SCCP/1155/08** (pp. 42) (Cross & Roberts, 2005; Cross et al., 2008), with a measured ***dermal absorption rate of 3% for TTO***. Other dermal absorption studies of different components of TTO are briefly reviewed in **SCCP/1155/08** (pp. 25 –pp. 28).
Distribution	Cf. SCCP/1155/08 and TTO monograph (Council of Europe, 2001).
Metabolism	Cf. SCCP/1155/08 and TTO monograph (Council of Europe, 2001).
Excretion	Cf. SCCP/1155/08 and TTO monograph (Council of Europe, 2001).
Local toxic effects	***Taken from SCCP/1155/08 and TTO monograph (Council of Europe,***

[4] Cf. The Norwegian Cosmetics Regulation. Products containing TTO at higher levels used to fall under the regulations of medicinal products in general. In Norway, products cannot be sold as cosmetic products claiming at the same time an effect against acne (TTO monograph, Council of Europe, 2001, pp. 2 and Appendix 5 therein: "New regulations in Nordic countries", pp. 9 – 10).

Irritation Sensitivity	***2001)*** SCCP found that neat TTO and formulations containing 5% TTO can exhibit skin irritancy (**SCCP/1155/08**, pp. 18). Moreover, neat TTO is a sensitizer in humans (pp. 25). The specific concentration responsible for inducing sensitization is not known. The TTO monograph submitted by the Norwegian delegation in 2001, indicates that ***only products having a conc. of 2% or more seem to cause skin reactions*** ((Council of Europe, 2001: pp. 24). The reports concerned mainly contact dermatitis and eczema (27 out of 33 cases). Several other studies are cited in the SCCP report (pp. 24-25). It is likely that the occurrence of TTO sensitization is underreported, and therefore the incidence may be more common than the few reports in the medical literature is suggesting (Council of Europe, 2001: pp. 4). The same conclusion was reached in a literature study in which the extent of contact allergy related to use of natural medicinal products (e.g. TTO) was surveyed (Ahlin et al., 2011). Whereas fresh TTO seems to possess only a weak sensitizing potential, oxidation of oil constituents increases their ability to act as a strong allergens. It is not fully understood which of the constituents in TTO is responsible for sensitization. In one study, oxidized TTO was 3 times more potent than fresh oil. A study by Hausen et al. (1999) suggests that increases in peroxides are important to explain the potential of TTO to cause sensitization / allergy. Neat TTO is also known as a moderately potent allergen (LLNA E3: 4 – 24%) – 3 times more potent on long term storage under conditions that promote formation of peroxides (Selvaag et al., 1994). TTO can cross-react with colophony (widespread use in adhesives, such as sticking plasters), cf. Appendix III in the TTO monograph for more details (Council of Europe, 2001). On the basis of the toxicological data provided by Silano and Patri (cited in Council of Europe, 2001: Appendix III), oral care products containing no more than 0.5% TTO and other cosmetics containing nor more than 2-3% TTO appears to be safe. "COLIPA recommends that *TTO should not be used at concentrations greater than 1% in cosmetic products*. "When formulating Tea Tree Oil in a cosmetic product, companies should consider that the sensitization potential increases if certain constituents of the oil become oxidized. To reduce the formation of these oxidation products, manufacturers should consider the use of antioxidants and/or specific packaging to minimize exposure to light." (**SCCP/1155/2008**, pp. 15).
Systemic toxic effects Acute	**Taken from SCCP/0843/04 and SCCP/1155/08** Albino rabbits exposed to TTO (2000 mg/ kg bw), once for 24 h, did not exhibit signs of toxicity. The LD_{50} was >5000 mg /kg bw (2/10 deaths). Cases of TTO toxicosis have been reported in dogs and cats following dermal application for therapeutic reasons (**SCCP/1155/08**, pp. 16). Typical signs of neurotoxicity were observed, such as depression, weakness, incoordination, ataxia, and muscle tremors. No acute inhalation toxicity was evident in response to exposure with TTO/etanol/CO_2 in rats, but methodological weaknesses with the study were noted **(SCCP/1155/08**, pp. 17). The LD_{50} for TTO in rats is 1.9 - 2.6 ml neat (i.e. 100%) TTO/kg

Repeated dose	(equivalent to 2300 mg/kg bw). Rats ingesting doses of ≥ 1.5 g/kg TTO appeared ataxic and lethargic (cited in Carson et al., 2006). No repeated dose toxicity study of TTO itself was provided prior to the publication of **SCCP/1155/08** (pp. 28-30), and the effects of chronic exposure still remain uncharacterized. However, NOAELS of six out of eight major constituents of TTO (max. content of 5% or more) have been estimated, and is briefly summarized in the table below (**SCCP/1155/08**,pp. 30): **Compound** / **Max. Content in TTO (%)** / **Established or Estimated NOAEL (mg/kg bw/day)** Terpinen-4-ol / 48 / 400 1,8-Cineole (eucalyptol) / 15 / 300 α-Terpinene / 13 / 60 Cumene / p-Cymene / 8 / 75 α-Terpineol / 8 / 500 α-Pinene / 6 / 250 Terpinolene / 5 / no data γ-Terpinene / 28 / no data Based on the available information on repeated dose systemic toxicity of TTO constituents, the SCCP opinion (pp. 30) estimated a derived **NOAEL for TTO of 117 mg /kg bw /day** for renal effects.
Mutagenicity /genotoxicity	No mutagenic effects of TTO or some of its constituents have been demonstrated, but it is cautioned that the antimicrobial activity of TTO reduces the relevance of the results obtained with bacterial test systems (**SCCP/1155/08**, pp. 31-32).
Carcinogenicity	No data
Reprotoxicity / teratogenicity	No data on teratogenicity for TTO are available. However, there are some data from studies of substances with structural and chemical similarities to major components of TTO; e.g. α-terpinene. SCCP comments that a definite NOAEL for reproductive toxicity cannot be assessed, but that a NOAEL for α-terpinene of 30 mg/kg bw /day as a representative of TTO is a conservative estimate (SCCP/1155/08, pp. 33).
Other effects	***Estrogen-like effects*** Henley et al. (2007) reported that prepubertal gynecomastia (excessive development of the breast in the male) is linked to topical use of lavendar oil and TTO containing products. While both oils demonstrated estrogen-like activity in vitro by inducing growth in MCF-7 cells, no estrogenic activity has been found for the main constituents of TTO known to penetrate human skin (i.e. terpinen-4-ol, α-terpineol and eucalyptol). **SCCP/1155/08** commented: "*An estrogenic potential of TTO was shown in vitro. No in vivo studies are available to elucidate the relevance of this finding for the in vivo situation. Since the hormonal active ingredients of TTO were shown not to penetrate the skin, the hypothesized correlation of the finding of 3 cases of gynecomastia to the topical use of Tea Tree Oil is considered implausible*" (pp. 33). See also Section 6 in the present risk profile (below). Nielsen (2008) found that TTO clearly demonstrated estrogenic potency, confirming the observation by Henley et al. (2007). However, *none of the TTO constituents*, previously *identified as penetrating the skin*, were estrogenic (Nielsen, 2008). Thus, these data indicate that the absorption profile of the individual constituents of TTO differs from their respective

	estrogenic potencies. ***Methyl eugenol*** The conclusion of the SCCP (SCCP/1155/2008) opinion is as follows – three last paragraphs: "Methyl eugenol was reported as a minor constituent of Tea Tree Oil; the content should be indicated. According to the opinion SCCNFP/0373/00 on methyleugenol in fragrances the content in finished leave-on products should not exceed 0.0002% (2 ppm) and in rinse-off products 0.001% (10 ppm). Following topical application of Tea Tree Oil and Tea Tree Oil containing products, percutaneous absorption of some constituents may occur, leading to a considerable systemic exposure, especially from neat oil, body lotion and foot spray/powder (see appendix). Because of inadequate dermal absorption studies available, the magnitude of systemic exposure to Tea Tree Oil from cosmetic products is uncertain. Only worst case estimations for NOAELs for general systemic and reproductive toxicity can be made. A Margin of Safety has not been calculated and the safety of Tea Tree Oil cannot be assessed. Should there be reliable data on percutaneous absorption covering relevant concentrations and cosmetic formulations a reassessment of the safety of Tea Tree Oil is envisaged by the SCCP". ***Update - methyl eugenol as a minor constituent of TTO***: To our knowledge the European Commission has since the publication of the SCCP opinion in 2008 not received any new data from industry that could enable the SCCP /SCCS to update its risk evaluation of TTO in cosmetics. Peak assignment by GC-MS and co-elution with a standard facilitated the GC-FID determination of 128 commercial samples. Inter-laboratory confirmation was achieved using GC-MS with selected ion monitoring. These determinations indicated that the methyl eugenol content of TTO ranged from less than 0.01% to 0.06% (mean 0.02%) (Southwell et al., 2011). The study quantifies previously stated trace amounts of methyl eugenol in TTO and found that levels are *20 times less that reports in the 2008 SCCP opinion*, with a mean value of 209 ppm and maximum not exceeding 600 ppm in commercial distillations. The critical toxic effect of methyl eugenol is carcinogenicity (i.e. hepatocellular carcinomas). Thus, on the basis of the NTP study (2000) it is calculated that a lifetime dose of **0.4 μg/kg bw/d** methyleugenol will represent a lifetime cancer risk of 10^{-5} (Sanner et al., 2001)[5]. *Calculations*: Since no data on percutaneous absorption is available, the default value of 100% is used (SCCS (2010). The above exposure will thus represent the daily systemic exposure dose (SED).

[5] "T25 method" [Sanner et al. 2001] is the default method for quantitative risk assessment of carcinogens in the EU (EChA 2008b, cited in SCCS/1501/12).

	• **Body lotion** (leave-on): 1.25% TTO (body lotion) typical concentration Calculated relative daily exposure of product: 123.20 mg/kg bw/day Concentration of ingredient in product: 1.25% = 0.0125 Mean concentration of methyl eugenol in TTO: 0.02% = 0.0002 Dermal absorption (SCCS default value): 100%% = 1 SED = 123200 x 0.0125 x 0.0002 x 1 = 0.3 µg /kg bw /day **Lifetime cancer risk**: (0.3/0.4) 10^{-5} = **$\underline{0.75 \times 10^{-5}}$** • **Hand wash** (rinse-off): Use level: 2.0% TTO; illustrative use level Calculated relative daily exposure of product[6]: 3.33 mg/kg bw/day Concentration of ingredient in product: 2.0% = 0.02 Mean concentration of methyl eugenol in TTO: 0.02% = 0.0002 Dermal absorption (SCCS default value): 100% = 1 SED = 3330 x 0.02 x 0.0002 x 1 = 0.0132 µg/kg bw/day **Lifetime cancer risk**: (0.01/0,4) x 10^{-5} = **$\underline{0.03 \times 10^{-5}}$** *Foods and supplements*: The predominant source of exposure to methyleugenol in the general population is expected to be its naturally occurring presence in food and beverages, with smaller contributions from cosmetics (Methyleugenol assessment report 2010, Canada [online]; IARC monograph [online]). Thus, methyleugenol is a naturally occurring flavor and fragrance found in a large variety of food sources, including spices, herbs, fruits and it is also a component in natural essential oils of plant origin. Recent estimates put the daily per capita consumption of methyleugenol at 0.26 µg/kg bw.

5. Exposure estimate and critical NOAEL / NOEL

NOAEL/NOEL critical	The SCCP report states that data are inadequate for safety evaluation, including calculation of the MoS. However, a **NOAEL of 117 mg/kg bw/day** is chosen for illustrative purposes in the risk assessment calculations below.
Exposure cosmetic products	For assessment of systemic exposure dose (SED), typical concentrations of TTO in cosmetic products are used for the calculations; cf. section 2 ("Uses and origin") and "Exposure estimates using the absorption as % of applied dose" (Annex 3 – table taken from **SCCP/1155/08**, pp. 42). • **Hand wash soap, solid**

[6] Estimated daily exposure level of cosmetic product types according to Colipa data (SCCS, 2010).

	Use level: 2.0% TTO; typical use level. Calculated relative daily exposure of product[7]: 3.33 mg/kg bw/day Concentration of ingredient in product: 2.0% = 0.02 Dermal absorption (SCCS default value): 100% = 1 SED = A (mg/kg bw/day) x C(%)/100 x Dap (%)/100 = 3.33 mg/kg bw/day x 0.02 x 1 = **0.067 mg/kg bw/day** • **Shampoo** 2.0% TTO (anti-dandruff shampoo) as a typical use level Calculated relative daily exposure of product: 1.51 mg/kg bw/day Concentration of ingredient in product: 2.0% = 0.02 Dermal absorption (SCCS default value): 100%% = 1 SED = A (mg/kg bw/day) x C(%)/100 x Dap (%)/100 = 1.51 mg/kg bw/day x 0.02 x 1 = **0.030 mg/kg bw/day** • **Total body** 1.25% TTO (body lotion) – typical use level Calculated relative daily exposure of product : 123.20 mg/kg bw/day Concentration of ingredient in product: 1.25% = 0.0125 Dermal absorption (SCCS default value): 100%% = 1 SED = A (mg/kg bw/day) x C(%)/100 x Dap (%)/100 = 123.20 mg/kg bw/day x 0.0125 x 1 = **1.54 mg/kg bw/day** • **Deodorant stick /roller (solid)** 2.5% TTO as illustrative example Calculated relative daily exposure of product: 22.08 mg/kg bw/day Concentration of ingredient in product: 2.5% = 0.025 Dermal absorption (SCCS default value): 100%% = 1 SED = A (mg/kg bw/day) x C(%)/100 x Dap (%)/100 = 22.08 mg/kg bw/day x 0.025 x 1 = **0.55 mg/kg bw/day** • **Mouthwash** 0.2% TTO (mouth wash) as illustrative example Calculated relative daily exposure of product: 32.54 mg/kg bw/day Concentration of ingredient in product: 0.2% = 0.002 Dermal absorption (SCCS default value): 100%% = 1 SED = A (mg/kg bw/day) x C(%)/100 x Dap (%)/100 = 32.54 mg/kg bw/day x 0.002 x 1 = **0.065 mg/kg bw/day** • **Foot powder** 1% TTO (foot powder) as illustrative example Amount applied (SCCS default value): 1 mg/cm^2 Surface area feet (**RIVM** default value)[8]: 100 cm^2 Body weight: 60 kg (women) Total amount applied of product: 1 mg/cm^2 x 100 cm^2 = 100 mg

[7] Estimated daily exposure level of cosmetic product types according to Colipa data (SCCS, 2010).
[8] Surface area of feet: 1170 cm^2. It is assumed that the cream is applied to 100 cm^2 of the skin of the feet (RIVM).

	Daily exposure (female, 60 kg): 100 mg/60 kg = 1.67 mg/kg bw/day Frequency of application: 2/day Dermal absorption (SCCS default value): 100% = 1 Concentration of ingredient in the product: 1% = 0.01 Retention factor: 1.0 SED= 1.67 mg/kg bw/day x 2 x 1.0 x 0.01 x 1.0 **= 0.033 mg/kg bw/day** **Overall SED from cosmetic products:** Hand wash soap + Shampoo + Body lotion + Deodorant stick + Foot powder + Neat TTO (nails): 0.067 + 0.030 + 1.54 + 0.55 + 0.033 + 1.67 = 2.22 mg/kg bw/day
Margin of Safety (MoS)	MoS (NOAEL / SED): NOAEL = 117 mg/kg bw/day **MoS for total body:** SED = 1.54 mg/kg bw/day MoS = 117 / 1.54 = **76.0** **MoS for mouth wash:** SED = 0.065 mg/kg bw/day MoS = 117 / 0.065 = 1**798** **MoS for hand wash soap (solid):** SED = 0.067 mg/kg bw/day MoS = 117 / 0.067 = 1**757** **MoS for shampoo:** SED = 0.03 mg/kg bw/day MoS = 117 / 0.03 = **3900** **MoS for deodorant stick / roller:** SED = 0.55 mg/kg bw/day MoS = 117 / 0.55 = **213** **MoS for foot powder:** SED = 0.033 mg/kg bw/day MoS = 117 / 0.033 = **3545** **Overall MoS (cosmetics):** SED = 2.22 MoS = 117 / 2.22 = **53** For calculation of MoS based on a worst case scenario and hypothetical exposure data, see Section 8, “Conclusions 2”.

6. **Other sources of exposure than cosmetic products**

Food stuffs	There is no natural food sources of tea tree oil, and because of its toxicity, TTO should never be swallowed (American Cancer Society [online]).

Pharmaceuticals	TTO does not have marketing authorization as a pharmaceutical product[9].
Other sources	
Adverse side effects - from uses other than cosmetics	*Oral poisoning*: TTO intoxication has been reported to cause drowsiness, confusion, hallucinations, coma, unsteadiness, weakness, vomiting, diarrhea, stomach upset, blood cell abnormalities, and severe rashes. Oral poisoning in humans tends to be more dramatic in children because of their lower body weight. Among 787 cases reported to the American Poison control centers surveillance system in 2003, 518 (65.8%) occurred in children less than 6 years of age, 57 in those aged 6-19, and 212 were in adults older than 19 years. Thus, TTO should be kept away from pets and children and/or stored in bottles with child-resistant cap (SCCP/1155/08; Hammer et al., 2006; Carson et al., 2006;American Cancer Society [online]). *Endocrine disruption*: A study by Henley et al. (2007) reported that breast enlargement in boys who have not yet reached puberty ("prepubertal gynecomastia") is linked to lavender oil and TTO. The study, published in the highly respected 'New England Journal of Medicine' has been disputed and criticized both on methodological grounds and for making medically related conclusions about TTO based on a single individual (i.e. the study involved 3 boys - only one of whom used products containing TTO). In all cases, the prepubertal gynecomastia reversed after several months. Lavender and TTO have been found to have some hormone-like effects; i.e. they have effects similar to estrogen (female sex hormones) and also block or decrease the effect of androgens (male sex hormones). (Nielsen, 2008; Henley & Korach, 2010). On the other hand, *none of the TTO constituents*, previously *identified as penetrating the skin*, were estrogenic (Nielsen, 2008). Thus, the clinical relevance of these findings, if any, are unknown. *Medicinal uses:* For side effects of TTO in connection with medicinal use, cf. TTO monograph (Council of Europe, 2001, pp. 3 – 4). The clinical relevance of *in vitro* estrogenic activity of TTO. The American Cancer Society recommends that patients with tumors that need estrogen to grow avoid using lavender and TTO (American Cancer Society [online]). Among 124 volunteers receiving treatment for mild-to-moderate acne (Basset et al., 1990), side effects like smarting, itching, dry skin and erythema were mentioned by 79% of patients treated with BP (benzoyl peroxide) and 44% of patients treated with TTO (BfR opinion, 2003).

[9] The Swedish MPA has registered three TTO containing products as "natural medicinal products" (**SCCP/1155/2008**, pp. 14; Ahlin et al., 2011). "Melaleuca Oil "is on a consolidated list of substances which are present in authorised medicines for general sale" in the UK (MHRA [online]).

7. Assessment

General toxicity
The SCCP opinion (**SCCP/1155/08**) states that data are inadequate for safety evaluation, including calculation of the MoS.

Although no repeated dose toxicity study with TTO itself is available, NOAELs have been estimated for some of its major constituents. In the current hypothetical risk profile of TTO, we have chosen to use a deduced NOAEL of 117 mg /kg bw /day for the renal effects of TTO.

Mutagenicity /Carcinogenicity
No mutagenic or carcinogenic effects of TTO have been reported. The content of methyl eugenol may, however, implicate an unacceptable lifetime risk for cancer in case the content substantially exceeds measured levels.

Cosmetics
Skin /eye irritation, dermal sensitisation

TTO is a skin sensitizer: neat TTO and certain formulations at concentrations of 5% or more can induce skin (and eye?) irritation. Skin sensitization may be enhanced by irritancy.

Diverging results have been observed in human studies, ranging from no irritation with diluted or neat TTO, to skin irritation in response to cosmetic formulations containing 5% TTO. Oxidized TTO has been shown to be 3 times more potent sensitizer than fresh oil. It is not fully understood which of the constituents of TTO is responsible for sensitization. However, oxidation caused by exposure of the oil to atmospheric oxygen, light, humidity, and heat, all seem to contribute to the production of degradation products with sensitizing capability. Also the vehicle used for formulations of cosmetic products may be of importance (**SCCP/1155/08**, pp. 34).

According to *Bundesinstitut für Risikobevertung* (Bfr) and *The European Cosmetic Toiletry and Perfumery Association* ("*Colipa"*), not more than 1% should be used in cosmetics because of the potential for skin irritancy and sensitization. Moreover, Colipa stated that companies should take into account "*that the sensitization potential increases if certain constituents of the oil become oxidized*". (Opinion SCCP/1155/08).

The TTO monograph (Council of Europe, 2001) indicates that *only products having a conc. of 2% TTO or more seem to cause skin reactions* (pp. 24).

In the current Norwegian regulation, *oral care products containing no more than 0.5% TTO and other cosmetics no more than 2% TTO are allowed, with the special limitation that TTO must not be used in products meant for children less than 12 years old*. These limits have been set observing the sensitizing effect of the TTO.

An internet search of TTO in cosmetic products (Annex 7) revealed that products containing 5-6% TTO, and even neat (100%) TTO, are sold without restrictions on the EU/EØS market.

Food
TTO is not naturally present in food.

Medicinal products
In Sweden, TTO is one out of four registered medicinal natural products with sensitizing /allergic poteintial (Ahlin et al., 2011).

Total exposure
The systemic exposure dose of TTO is mainly due to topical cosmetic products, as it is toxic if ingested orally. However, it is allowed in oral hygiene products (mouth-wash).

For example, a worst case scenario of TTO exposure for a person using various leave-on cosmetic products e.g. body lotion (1.54 mg/kg bw/day) + deodorant stick /roller (0.55 mg/kg bw/day) + foot powder (0.033 mg/kg bw/day) = 2.12 mg/kg bw/day. This equals **MoS** = 117/2.12 = **55.1**, which is lower than the acceptable MoS = 100.

If neat TTO for treatment of foot fungus (a medicinal product in virtue of claim) is also contributing to the exposure (SED = 1.67 mg/kg bw/day), the MoS is decreased even further (MoS = 117 / (2.12 +1.67) = 117 / 3.79 = **30.9**).

Methyl eugenol:
Methyl eugenol is a minor constituent of TTO and is present at mean levels of 200 ppm in commercial tea tree oils (Southwell et al., 2011).

We assessed the toxicity of methyl eugenol (at a typical level of 200 ppm) in TTO for cosmetic products individually or in combination, and found that a typical level of 200 ppm methyl eugenol (in TTO) resulted in a calculated lifetime cancer risk of 1.065×10^{-5} (excluding neat TTO for toe nails). The concentration premise then used was 1.25% in body lotion and 2 % in hand wash products.

This level does not substantially exceed an acceptable cancer risk of 1×10^{-5}. Higher concentration levels than the ones mentioned would increase the lifetime risk for cancer above the acceptance level.

8. Conclusions

The risk assessment calculations are based on a deduced NOAEL value for TTO of 117 mg/kg bw/day (adverse renal effects in animal experiments)[10], a default skin penetration rate of 100% (assumed to be very conservative)[11], and 100% oral bioavailability. The calculated use levels of TTO (%) complies with the requirement that the MoS must be above 100 in order for these usages to be safe.

Maximum use levels:

Leave-on products:

Body lotion:	(1.25 x 76.0) / 100	= 1.0%
Deodorant stick /roller:	(2.5 x 213) / 100	= 2.0% (calculated value of 5.3%)[12]
Foot powder:		= 1.0%

Rinse-off products at the indicated use levels are safe:

MoS for mouth wash:	0.2% TTO
MoS for hand wash soap (solid):	2.0% TTO
MoS for shampoo:	2.0% TTO

- All other products: 0 %

Following topical application of TTO, percutaneous adsorption of some constituents is likely to occur, especially for various leave-on products. At the recommended levels, i.e. much lower concentrations than frequently found in the marketplace (Annex 7), we would assume that problems with allergic skin dermatitis and sensitization are avoided.

Purity requirements:
The suspected carcinogenic substance *methyl eugenol* should not exceed 200 ppm (or 0.02%) as a minor constituent of TTO – and the content should be indicated in the ingredient list.

To reduce the formation of *oxidation products* of TTO, due to aged or improperly stored oil with a much higher sensitizing potential than the pure unmodified oil, manufacturers should consider the use of antioxidants and/or specific packaging to minimize exposure to light **(SCCP/1155/2008**, pp. 15).

Remarks:
Poisoning: in young children, inadvertent ingestion of small amounts of tea tree oil has produced confusion, ataxia, and drowsiness.

Labeling: The different products should be labeled with following warning texts – “Keep out of reach for children”.

Special limitations:
Must not be used in products meant for children less than 12 years old.

[11] The magnitude of systemic exposure to TTO is uncertain because dermal absorption studies are inadequate. Only worst case estimations for NOAELs for general systemic and reproductive toxicity can be made.
[12] Our recommendations are in line with the monograph on TTO (Council of Europe, 2001), which indicates that only products having a conc. of more than 2% TTO seem to cause skin reactions (pp. 24).

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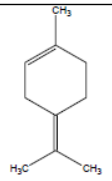
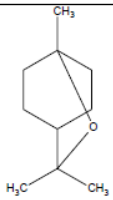
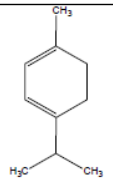
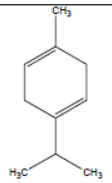
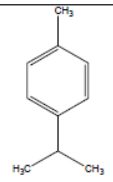
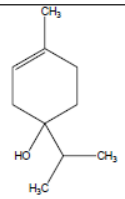
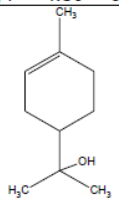
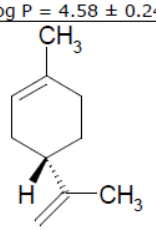
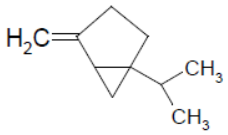
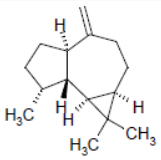
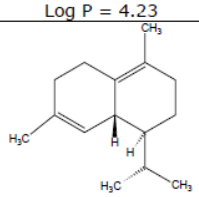
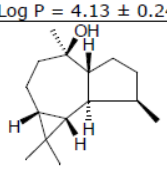
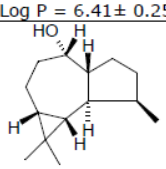
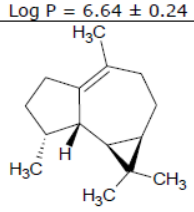
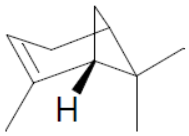
10. Annexes

Annex 1A: [Taken from SCCP/1155/2008 (pp. 8)]

Figure 1: Chemical structures of the main constituents of Tea Tree Oil

 Terpinolene ($C_{10}H_{16}$) MW=136 Log P = 4.52 ± 0.22	 1,8-Cineole ($C_{10}H_{18}O$) MW=160 Log P = 2.82 ± 0.27	 *a*-Terpinene ($C_{10}H_{16}$), MW=136 Log P = 4.52 ± 0.22
 *γ*-Terpinene ($C_{10}H_{16}$) MW=136 Log P = 4.36 ± 0.24	 *p*-Cymene ($C_{10}H_{14}$) MW=134 Log P = 4.58 ± 0.24	 (+)-Terpinen-4-ol ($C_{10}H_{18}O$) MW=154 Log P = 4.52 ± 0.22
 (+)-*α*-Terpineol ($C_{10}H_{18}O$) MW=160 Log P = 2.73 ± 0.22	 D-Limonene ($C_{10}H_{16}$) MW=136.24 Log P = 4.23	 (+)-Sabinene ($C_{10}H_{16}$) MW=136.23 Log P = 4.13 ± 0.24
 (+)-Aromadendrene ($C_{15}H_{24}$) MW=204.35 Log P = 6.41± 0.25	 δ-Cadinene ($C_{15}H_{24}$) MW=204 Log P = 6.64 ± 0.24	 (-)-Globulol ($C_{15}H_{26}O$) MW=222.37 Log P = 4.81 ± 0.26
 (+)-Viridiflorol ($C_{15}H_{26}O$) MW=222.37 Log P = 4.81 ± 0.26	 (+)-ledene (syn. viridiflorene) ($C_{15}H_{24}$) MW=204	 α-Pinene ($C_{10}H_{16}$) MW=136.23 Log P = 4.37± 0.24

Annex 1B: [Taken from SCCP/08438/2004 (pp. 4)]

The International Standard ISO 4730-2004 specifies the major constituents of TTO.

The monoterpenes terpinen-4-ol, α-terpinene, α-terpinene, 1,8-cineole, p-cymene, α-terpineol, α-pinene, terpinolenes, limonene and sabinene account for 80 - 90% of the oil.

Table 1: Chromatographic profile of Tea Tree Oil according to ISO/FDIS 4730:2004

Component	**Minimum (%)**	**Maximum (%)**
α-Pinene	1	6
Sabinene	trace	3.5
α-Terpinene	5	13
Limonene	0.5	1.5
p-Cymene	0.5	8
1,8-Cineole (eucalyptol)	trace	15
γ-Terpinene	10	28
Terpinolene	1.5	5
Terpinen-4-ol	30	48
α-Terpineol	1.5	8
Aromadendrene	trace	3
Ledene (syn. viridoflorene)	trace	3
δ-Cadinene	trace	3
Globulol	trace	1
Viridiflorol	trace	1

Annex 2: [Taken from SCCP/1155/2008 (pp. 28)]

Table 3: Overview on dermal absorption studies of Tea Tree Oil, values for terpinen-4-ol

Source	Dermal absorption (µg/cm²)	Study details
A Cross et al. 2008 (Ref. 65, 66)	a) 213 b) 24.6	Human epidermal skin *in vitro* a) neat Tea Tree Oil b) Tea Tree Oil 20 % ethanolic solution; finite dose (10 mg/cm²) 24 h exposure
B Reichling et al. 2006 (Ref. 69)	1509	Human epidermal skin *in vitro* Tea Tree Oil 5 % in an ambiphilic cream Infinite dose conditions, 24 exposure (calculated)
C Cal et al. 2006a,b,c Ref. 78-81	530	Human skin *in vitro* Tea Tree Oil 5 % in a hydrogel Infinite dose conditions, 4 h exposure
D Cal et al. 2006d, 2007 Ref. 82, 83	110 (Stratum corneum only)	Human skin *in vivo* Tea Tree Oil 5 % in a hydrogel Infinite dose conditions, 1 h exposure

In the studies with infinite dose conditions (B, C, D) using the same concentration of 5% Tea Tree Oil in water containing formulations, a nearly linear relationship between exposure time and dermal absorption is apparent. In one study (study A) an adequate exposure dose, but no relevant cosmetic formulation was investigated. These studies also demonstrated that the type of formulation has a significant influence on dermal absorption of Tea Tree Oil. Overall, none of the available studies is adequate as a sound basis for assessment of exposure to Tea Tree Oil from cosmetic products.

Annex 3: [Taken from SCCP/1155/2008 (pp. 42)]

8.2.2. Exposure estimation using the percentage of applied substance

The rate of absorption of Tea Tree Oil was measured to be about 3% in the percutaneous absorption study submitted in the current dossier (see reference 65 and 66). The daily exposure was calculated for the various product types. This was adjusted for the skin retention factor according to SCCP Notes of Guidance. Where retention factors were not stipulated by the SCCP, a value of 0.01 was used for rinse-off products and a value of 1 was used for leave-on products. The Table contains the exposure estimates for the various product types. Systemic exposure estimates between 0.0017 and 3.33 mg/kg/day were obtained.

Table: Exposure estimates using the absorption as % of applied dose

Use	Concentration (%)	Amount applied (mg)	Retention Factor	Systemic Exposure Dose (mg/kg/day)
100% Tea Tree Oil	100	200	1	3.33
Bath additive	15	10,000	0.01	0.25
Cleansing Face Wash	0.7	5,000	0.01	0.006
Anti-Dandruff Shampoo	2.0	8,000	0.01	0.027
Deodorant stick/roller	2.5	500	1	0.21
Foot Powder	1.0	2,000	1	0.33
Foot Spray	2.0	2,000	1	0.67
Body Lotion	1.25	8,000	1	1,67
Hand Wash	0.7	3,000	0.01	0.0035
Mouthwash	0.2	10,000	0.1	0.033
Hand wash soap solid	2.0	500	0.01	0.0017

Comment of the SCCP

From the table above it can be deduced that following topical application of Tea Tree Oil and Tea Tree Oil containing products percutaneous absorption of some constituents occurs leading to a considerable systemic exposure, especially from neat Tea Tree Oil, body lotion and foot spray/powder.

Annex 4: [Taken from SCCP/1155/2008 (pp. 30)]

NOAELs

Comment of the SCCP

No repeated dose toxicity study with Tea Tree Oil itself was performed. However, data and read-across considerations were provided regarding the systemic toxicity of some constituents or related compounds. There are 8 major constituents of Tea Tree Oil with a maximum content of 5% and more are: terpinen-4-ol (max. 48%), γ-terpinene (max. 28%), 1,8-cineole (eucalyptol, max. 15%), α-terpinene (max. 13%), p-cymene (max. 8 %), α-terpineol (max. 8%), α-pinene (max. 6%) and terpinolene (max. 5%). For these constituents, the following NOAELS were established or estimated:

Compound	Max. Content in TTO (%)	Established or Estimated NOAEL (mg/kg bw/day)
Terpinen-4-ol	48	400
1,8-Cineole (eucalyptol)	15	300
α-Terpinene	13	60
Cumene / p-Cymene	8	75
α-Terpineol	8	500
α-Pinene	6	250
Terpinolene	5	no data
γ-Terpinene	28	no data

Annex 5:

Toxicity

Organism	Test Type	Route	Reported Dose (Normalized Dose)	Effect	Source
child	TDLo	oral	500uL/kg (0.5mL/kg)	BEHAVIORAL: "HALLUCINATIONS, DISTORTED PERCEPTIONS" BEHAVIORAL: ATAXIA	Journal of Toxicology, Clinical Toxicology. Vol. 32, Pg. 461, 1994. Link to PubMed
child	TDLo	oral	500uL/kg (0.5mL/kg)	BEHAVIORAL: SLEEP BEHAVIORAL: ATAXIA	Veterinary and Human Toxicology. Vol. 37, Pg. 557, 1995. Link to PubMed
man	TDLo	oral	21uL/kg (0.021mL/kg)	BLOOD: CHANGES IN CELL COUNT (UNSPECIFIED) SKIN AND APPENDAGES (SKIN): "DERMATITIS, ALLERGIC: AFTER SYSTEMIC EXPOSURE" SKIN AND APPENDAGES (SKIN): "DERMATITIS, OTHER: AFTER SYSTEMIC EXPOSURE"	Medical Journal of Australia. Vol. 159, Pg. 830, 1993.
rabbit	LDLo	skin	5gm/kg (5000mg/kg)		Food and Chemical Toxicology. Vol. 26, Pg. 407, 1988.
rat	LD50	oral	1900mg/kg (1900mg/kg)		Food and Chemical Toxicology. Vol. 26, Pg. 407, 1988.

Annex 6: Nomenclature /CAS # (CosIng).

		Total: 7
#	INCI Name/Substance Name	Restriction/ Annex-Part-Ref #
1.	MELALEUCA ALTERNIFOLIA FLOWER/LEAF/STEM EXTRACT	
2.	MELALEUCA ALTERNIFOLIA LEAF	
3.	MELALEUCA ALTERNIFOLIA LEAF EXTRACT	
4.	MELALEUCA ALTERNIFOLIA LEAF OIL	
5.	MELALEUCA ALTERNIFOLIA LEAF POWDER	
6.	MELALEUCA ALTERNIFOLIA LEAF WATER	
7.	MELALEUCA ALTERNIFOLIA LEAF/ROSMARINUS OFFICINALIS LEAF/THYMUS VULGARIS LEAF EXTRACT	
		Total: 7

Ingredient: MELALEUCA ALTERNIFOLIA FLOWER/LEAF/STEM EXTRACT

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA FLOWER/LEAF/STEM EXTRACT
Description	Melaleuca Alternifolia Flower/Leaf/Stem Extract is an extract of the leaves, flowers and stems of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9
EINECS/ELINCS #	285-377-1
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• SKIN CONDITIONING
SCCS opinions	
Identified INGREDIENTS or substances e.g.	
Current Version	v.2
Other Versions	v.1

Ingredient: MELALEUCA ALTERNIFOLIA LEAF

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF
Description	Melaleuca Alternifolia Leaf is the plant material obtained from the cut leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9
EINECS/ELINCS #	285-377-1
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• ABRASIVE • SKIN CONDITIONING
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

Ingredient: MELALEUCA ALTERNIFOLIA LEAF EXTRACT

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF EXTRACT
Description	Melaleuca Alternifolia Leaf Extract is is an extract of the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9
EINECS/ELINCS #	285-377-1
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• PERFUMING • SKIN CONDITIONING
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

Ingredient: MELALEUCA ALTERNIFOLIA LEAF OIL

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF OIL
Description	Melaleuca Alternifolia Leaf Oil is the oil distilled from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9 / 8022-72-8 / 68647-73-4
EINECS/ELINCS #	285-377-1 / - / -
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• ANTIOXIDANT • PERFUMING
SCCS opinions	• 0843/04 - Opinion on Tea Tree Oil • 1155/08 - Opinion on Tea Tree Oil
Identified INGREDIENTS or substances e.g.	

Ingredient: MELALEUCA ALTERNIFOLIA LEAF POWDER

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF POWDER
Description	Melaleuca Alternifolia Leaf Powder is the powder obtained from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9
EINECS/ELINCS #	285-377-1
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• ABRASIVE
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

Ingredient: MELALEUCA ALTERNIFOLIA LEAF WATER

Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF WATER
Description	Melaleuca Alternifolia Leaf Water is an aqueous solution of the steam distillates obtained from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae
INN Name	
Ph. Eur. Name	
CAS #	85085-48-9
EINECS/ELINCS #	285-377-1
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• ANTIMICROBIAL • ANTISEBORRHOEIC • ASTRINGENT • TONIC
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

Ingredient: MELALEUCA ALTERNIFOLIA LEAF/ROSMARINUS OFFICINALIS LEAF/THYMUS VULGARIS LEAF EXTRACT Cosmetics Directive (v.1)

INCI Name	MELALEUCA ALTERNIFOLIA LEAF/ROSMARINUS OFFICINALIS LEAF/THYMUS VULGARIS LEAF EXTRACT
Description	Melaleuca Alternifolia Leaf/Rosmarinus Officinalis Leaf/Thymus Vulgaris Leaf Extract is the extract of the leaves of Melaleuca alternifolia, Rosmarinus officinalis and Thymus vulgaris
INN Name	
Ph. Eur. Name	
CAS #	-
EINECS/ELINCS #	-
Chemical/IUPAC Name	
Cosmetic Restriction	
Other Restriction(s)	
Functions	• SKIN CONDITIONING
SCCS opinions	
Identified INGREDIENTS or substances e.g.	

Annex 7: TTO cosmetic products

Examples of uses for tea tree oil (TTO) in cosmetic products on the market – retrieved 07.09.2011

Bing image search: tea tree oil
Hits: 80000
http://www.bing.com/images/search?q=tea+tree+oil&FORM=BIFD#x0y0