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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum

### Final

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<b>Keywords</b>	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or other species of <i>Melaleuca</i> , aetheroleum; Melaleucaae aetheroleum; Tea tree oil
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BG (bългарски): Чаено дърво, масло	IT (italiano): Melaleuca essenza
CS (čeština): silice kajeputu střídavolistého	LT (lietuvių kalba): Arbatmedžių eterinis aliejus
DA (dansk): Tetræolie	LV (latviešu valoda): Tējaskoka ēteriskā eļļa
DE (Deutsch): Teebaumöl	MT (malti): Żejt tal-Melaleuca
EL (elliniká): Μελαλεύκης αιθέριο έλαιο	NL (nederlands): Theeboomolie
EN (English): Tea tree oil	PL (polski): Olejek eteryczny drzewa herbacianego
ES (español): Melaleuca alternifolia, aceite esencial de	PT (português): Óleo essencial de melaleuca
ET (eesti keel): teepuuõli	RO (română):
FI (suomi): teepuuöljy	SK (slovenčina): Silica melaleuky
FR (français): Mélaleuca (arbre à thé) (huile essentielle de)	SL (slovenščina): eterično olje melalevke
HU (magyar): Teafa-olaj	SV (svenska): Teträdsolja
HR (hrvatska): eteričnog ulje australijskog čajevca	IS (íslenska):
	NO (norsk): Tetreolje

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## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or other species of <i>Melaleuca</i>, aetheroleum (tea tree oil)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Essential oil</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparation in liquid and semi-solid dosage forms for cutaneous use (indication 1-3) or in liquid dosage form for oromucosal use (indication 4).</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008: 1837).

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1) Traditional herbal medicinal product for treatment of small superficial wounds and insect bites.</p> <p>Indication 2) Traditional herbal medicinal product for treatment of small boils (furuncles and mild acne).</p> <p>Indication 3) Traditional herbal medicinal product for the relief of itching and irritation in cases of mild athlete's foot.</p> <p>Indication 4) Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose 0.03-0.07 ml of undiluted essential oil to be applied to the affected area using a cotton bud 1-3 times daily</p> <p>Liquid preparations containing 0.5% to 10% of essential oil to be applied to the affected area 1-3 times daily.</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose Oily liquid or semi-solid preparations containing 10% of essential oil, to be applied to the affected area 1-3 times daily or</p>

Well-established use	Traditional use
	<p>0.7-1 ml of essential oil stirred in 100 ml of lukewarm water to be applied as an impregnated dressing to the affected areas of the skin</p> <p>Undiluted essential oil to be applied to the boil using a cotton bud 2-3 times daily.</p> <p><b>Indication 3)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>Oily liquid or semi-solid preparations containing 10% of essential oil, to be applied on the affected area 1-3 times daily.</p> <p>0.17-0.33 ml of essential oil in an appropriate volume of warm water to cover the feet. Soak feet for 5-10 minutes a day.</p> <p>Undiluted essential oil to be applied to the affected area using a cotton bud 2-3 times daily.</p> <p><b>Indication 4)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>0.17-0.33 ml of essential oil to be mixed in 100 ml of water for rinse or gargle several times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p><b>Indication 1)</b></p> <p>If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indication 2) and 3)</b></p> <p>Not to be used for more than 1 month.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indication 4)</b></p> <p>If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a</p>

Well-established use	Traditional use
	<p>qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Indication 1), 2) and 3)</p> <p>Cutaneous use.</p> <p>Indication 4)</p> <p>Oromucosal use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance or to colophony.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>If a rash develops discontinue use.</p> <p>Not to be used orally or as inhalation.</p> <p>Not to be used in eyes or in ears.</p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 1)</p> <p>If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p> <p>In cases of severe acne a doctor or a qualified healthcare practitioner shall be consulted.</p> <p>Indication 3)</p> <p>For the eradication of fungal infection a doctor or a qualified healthcare practitioner shall be consulted.</p>

Well-established use	Traditional use
	Indication 4) Not to be swallowed.

#### **4.5. Interactions with other medicinal products and other forms of interaction**

Well-established use	Traditional use
	None reported.

#### **4.6. Fertility, pregnancy and lactation**

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.  No fertility data available.

#### **4.7. Effects on ability to drive and use machines**

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8. Undesirable effects**

Well-established use	Traditional use
	Adverse skin reactions including smarting pain, mild pruritus, burning sensation, irritation, itching, stinging, erythema, oedema (contact dermatitis) or other allergic reactions have been reported. The frequency is not known.  Burn-like skin reactions have been reported. The frequency is rare (<1/1000).  If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

## 4.9. Overdose

Well-established use	Traditional use
	<p>Cutaneous use: None reported.</p> <p>Oromucosal use:</p> <p>Accidental ingestion may cause central nervous system depression and muscle weakness. However, in adults these symptoms generally resolve within 36 hours.</p> <p>If ingestion occurs, the patient should be monitored and standard supportive treatment applied as required.</p> <p>In children, ingestion of tea tree oil is a medical emergency requiring immediate hospital treatment and respiratory support.</p>

## 5. Pharmacological properties

### 5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

### 5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

### 5.3. Preclinical safety data

Well-established use	Traditional use
	<p>Available data do not indicate a genotoxic potential of <i>Melaleuca aetheroleum</i>.</p> <p><i>Melaleuca aetheroleum</i> was not clastogenic using the chromosomal aberration test in human lymphocytes <i>in vitro</i> and not genotoxic in <i>in vivo</i> mouse micronucleus test (up to 1750 mg/kg). Ames test data are incomplete.</p> <p>Tests on reproductive toxicity and on carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Store in air-tight containers, protected from light and heat.  Proper storage and handling are needed to avoid the formation of oxidation products which have greater potential for skin sensitisation.

## 7. Date of compilation/last revision

24 November 2014