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Committee for Herbal Medicinal Products (HMPC)

## Community list entry on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2013
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	9 July 2013
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 December 2013
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

<b>Keywords</b>	Herbal medicinal products; HMPC; Community list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; 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> ; Melaleucaae aetheroleum; Tea tree oil
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**Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum**

<b>Scientific name of the plant</b>	
<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>	
<b>Botanical family</b>	
Myrtaceae	
<b>Herbal substance</b>	
Not applicable.	
<b>Common name of herbal substance in all EU official languages</b>	
BG (bългарski): Чаено дърво, масло CS (čeština): silice kajerputu střídavolistého DA (dansk): Tetræolie DE (Deutsch): Teebaumöl EL (elliniká): Μελαλεύκης αιθέριο έλαιο EN (English): Tea tree oil ES (español): Melaleuca alternifolia, aceite esencial de ET (eesti keel): teepuuõl FI (suomi): teepuuöljy FR (français): Mèlaleuca (arbre à thé) (huile essentielle de) HU (magyar): Teafa-olaj HR (hrvatska): IT (italiano): Melaleuca essenza	LT (lietuvių kalba): Arbatmedžių eterinis aliejus LV (latviešu valoda): Tējaskoka ēteriskā eļļa MT (malti): Żejt tal-Melaleuca NL (nederlands): Theeboornolie PL (polski): Olejek eteryczny drzewa herbacianego PT (português): Óleo essencial de melaleuca RO (română): SK (slovenčina): Silica melaleuky SL (slovenščina): eterično olje melalevke SV (svenska): Teträdsolja IS (Íslenska): NO (norsk): Tetreolje
<b>Herbal preparation</b>	
Essential oil obtained by steam distillation from the foliage and terminal branchlets	
<b>European Pharmacopoeia monograph reference</b>	
Tee Tree Oil – Melalucae aetheroleum (01/2008:1837)	
<b>Indications</b>	
<b>Indication 1)</b> Traditional herbal medicinal product for treatment of small superficial wounds and insect bites.	
<b>Indication 2)</b> Traditional herbal medicinal product for treatment of small boils (furuncles and mild acne).	
<b>Indication 3)</b>	

<p>Traditional herbal medicinal product for the relief of itching and irritation in cases of mild athlete's foot.</p> <p><b>Indication 4)</b></p> <p>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 indication exclusively based upon long-standing use.</p>
<p><b>Type of tradition</b></p>
<p>European</p>
<p><b>Specified strength</b></p>
<p>Please see 'Specified posology'.</p>
<p><b>Specified posology</b></p>
<p><b>Indication 1)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Liquid preparations containing 0.5% to 10% of essential oil to be applied on the affected area 1-3 times daily.</p> <p><b>Indication 2)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Oily liquid or semi-solid preparations containing 10% of essential oil, to be applied on the affected area 1-3 times daily or</p> <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><b>Indication 3)</b></p> <p><i>Adolescents, adults and elderly</i></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><b>Indication 4)</b></p> <p><i>Adolescents, adults and elderly</i></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 'Special warnings and precautions for use').</p>
<p><b>Route of administration</b></p>
<p><b>Indication 1), 2) and 3)</b></p> <p>Cutaneous use.</p> <p><b>Indication 4)</b></p> <p>Oromucosal use.</p>

## Duration of use or any restrictions on the duration of use

### Indication 1)

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.

### Indication 2) and 3)

Not to be used for more than 1 month. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

### Indication 4)

If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

## Any other information necessary for the safe use

### Contraindications

Hypersensitivity to the active substance or to colophonium.

### Special warnings and precautions for use

The use in children under 12 years of age has not been established due to lack of adequate data..

Not to be used orally or as inhalation. Not to be used in eyes or in ears.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

### Indication 1)

Not to be used on burn wounds.

If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

### Indication 2)

In cases with severe acne a doctor or a qualified healthcare practitioner shall be consulted.

### Indication 3)

For the eradication of fungal infection a doctor or a qualified healthcare practitioner shall be consulted.

### Interactions with other medicinal products and other forms of interaction

None reported.

### Fertility, pregnancy and lactation

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.

**Effects on ability to drive and use machines**

No studies on the effect on the ability to drive and use machines have been performed.

**Undesirable effects**

Adverse skin reactions like smarting pain, mild pruritus, burning sensation, irritation, itching, stinging, erythema, oedema and allergic reactions have been reported. The frequency is not known.

Burn-like skin reaction has been reported. The frequency is rare (<1/1.000).

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

**Overdose**

Accidental poisonings following ingestion of 10-25 ml have shown that *Melaleuca aetheroleum* causes Central Nervous System depression and muscle weakness. However, these symptoms had generally resolved within 36 hours.

**Pharmaceutical particulars [If necessary]**

Store in air-tight containers, protected from light and heat.

Proper storage and handling should avoid the formation of oxidation products which have greater potential of skin sensitisation.

**Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]**

Not applicable.

**Date of compilation/Last revision**

9 July 2013