

COMMISSION IMPLEMENTING DECISION (EU) 2016/1659**of 13 September 2016****amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products***(notified under document C(2016) 5748)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 24 November 2014 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, *aetheroleum* can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.
- (2) It is therefore appropriate to include *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and other species of *Melaleuca*, *aetheroleum* in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ⁽²⁾.
- (3) Decision 2008/911/EC should therefore be amended accordingly.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and II to Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 September 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42).

ANNEX

Decision 2008/911/EC is amended as follows:

(1) In Annex I, the following substance is inserted after *Hamamelis virginiana* L.:

'*Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum';

(2) In Annex II, the following is inserted after the entry *Hamamelis virginiana* L.:

'UNION LIST ENTRY ON MELALEUCA ALTERNIFOLIA (MAIDEN AND BETCH) CHEEL, M. LINARIIFOLIA SMITH, M. DISSITIFLORA F. MUELLER AND/OR OTHER SPECIES OF MELALEUCA, AETHEROLEUM

Scientific name of the plant

Melaleuca alternifolia (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and other species of *Melaleuca*

Botanical family

Myrtaceae

Common name in all EU official languages of herbal preparation

BG (bългарski): 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): Melaleuca (arbore de ceai) (ulei esențial)
FI (suomi): teepuuöljy	SK (slovenčina): Silica melaleuky
FR (français): Mélaleuca (arbre à thé) (huile essentielle de)	SL (slovensčina): eterično olje melalevke
HR (hrvatska): eteričnog ulje australijskog čajevca	SV (svenska): Teträdsolja
HU (magyar): Teafa-olaj	NO (norsk): Tetreolje

Herbal preparation

Essential oil

European Pharmacopoeia monograph reference

01/2008:1837

Indications

Indication (a)

Traditional herbal medicinal product for treatment of small superficial wounds and insect bites.

Indication (b)

Traditional herbal medicinal product for treatment of small boils (furuncles and mild acne).

Indication (c)

Traditional herbal medicinal product for the relief of itching and irritation in cases of mild athlete's foot.

Indication (d)

Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa.

The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

Type of tradition

European.

Specified strength

Please see 'Specified posology'.

Specified posology**Indication (a)**

Adolescents, adults and elderly

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.

Liquid preparations containing 0,5 % to 10 % of essential oil to be applied to the affected area 1-3 times daily.

Indication (b)

Adolescents, adults and elderly

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

0,7-1 ml of essential oil stirred into 100 ml of lukewarm water to be applied as an impregnated dressing to the affected areas of skin. Undiluted essential oil to be applied to the boil using a cotton bud 2-3 times daily.

Indication (c)

Adolescents, adults and elderly

Single dose

Oily liquid or semi-solid preparations containing 10 % of essential oil to be applied on the affected area 1-3 times daily. 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 daily.

Undiluted essential oil to be applied to the affected area using a cotton bud 2-3 times daily.

Indication (d)

Adolescents, adults and elderly

0,17-0,33 ml of essential oil to be mixed in 100 ml of water for rinse or gargle several times daily.

The use in children under 12 years of age is not recommended (see section 'Special warnings and precautions for use').

Route of administration**Indications (a), (b) and (c)**

Cutaneous use

Indication (d)

Oromucosal use.

Duration of use or any restrictions on the duration of use**Indication (a)**

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.

Indications (b) and (c)

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 (d)

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 colophony.

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.

If a rash develops, discontinue use.

Not to be used orally or as inhalation.

Not to be used in eyes or ears.

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

Indication (a)

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

Indication (b)

In cases of severe acne a doctor or a qualified health care practitioner shall be consulted.

Indication (c)

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

Indication (d)

Not to be swallowed.

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 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 (< 1/1 000).

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

Overdose

Cutaneous use:

None reported.

Oromucosal use:

Accidental overdose may cause central nervous system depression and muscle weakness. However, in adults these symptoms generally resolve within 36 hours.

If ingestion occurs, the patient should be monitored and standard supportive treatment applied as required.

In children, ingestion of tea tree oil is a medical emergency requiring immediate hospital treatment and respiratory support.

Pharmaceutical particulars (if necessary)

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.

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.
