



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 January 2011  
EMA/HMPC/534924/2010  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L. M. Perry, floris aetheroleum

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 November 2010 January 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
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 June 2011
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 herbal monographs; traditional use; <i>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry, floris aetheroleum; Caryophylli floris aetheroleum; clove oil
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BG (bългарski): CS (čeština): DA (dansk): DE (Deutsch): Gewürznelkenöl EL (elliniká): EN (English): clove oil ES (español): ET (eesti keel): FI (suomi): FR (français): Clou de girofle (huile essentielle de) HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): <i>IS (íslenska):</i> <i>NO (norsk):</i>
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# Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L. M. Perry, floris aetheroleum

## 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>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry, floris aetheroleum (clove oil)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Essential oil obtained by steam distillation from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparation in liquid dosage forms for dental and oromucosal use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008:1091).

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p data-bbox="810 441 967 470"><b>Indication 1)</b></p> <p data-bbox="810 499 1422 595">Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.</p> <p data-bbox="810 624 967 654"><b>Indication 2)</b></p> <p data-bbox="810 683 1362 779">Traditional herbal medicinal product for the temporary relief of toothache due to a dental cavity.</p> <p data-bbox="810 808 1422 904">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 data-bbox="810 1102 935 1131"><b>Posology</b></p> <p data-bbox="810 1160 967 1189"><b>Indication 1)</b></p> <p data-bbox="810 1218 1034 1247"><i>Adults and elderly</i></p> <p data-bbox="810 1276 1394 1335">Mouth washes corresponding to 1–5% essential oil. Apply several times daily.</p> <p data-bbox="810 1364 1422 1460">The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1489 967 1518"><b>Indication 2)</b></p> <p data-bbox="810 1547 1034 1576"><i>Adults and elderly</i></p> <p data-bbox="810 1606 1394 1664">Undiluted essential oil or solutions in a strength up from 50% or gels in a strength of 20%.</p> <p data-bbox="810 1693 1362 1751">Repeat administration after 20 minutes, then every 2 hours if necessary.</p> <p data-bbox="810 1780 1422 1877">The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1906 1015 1935"><b>Duration of use</b></p> <p data-bbox="810 1964 967 1993"><b>Indication 1)</b></p>

Well-established use	Traditional use
	<p>Not to be used for more than 1 week.</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>Indication 2)</p> <p>Not to be used for more than 1 week.</p> <p>The relief of toothache by clove essential oil is only a provisional measure. Dental attention should be sought as soon as possible.</p> <p><b>Method of administration</b></p> <p>Indication 1)</p> <p>Oromucosal use.</p> <p>Indication 2)</p> <p>Dental use.</p> <p>A small piece of cotton wool should be soaked in the undiluted oil or in a diluted solution; semi-solid dosage forms should be placed on a cotton bud. Cotton bud or cotton wool should be accurately directed to the decayed part of the tooth.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance(s) or to Peru balsam.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p>

Well-established use	Traditional use
	Avoid contact with gums.

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

Well-established use	Traditional use
	None reported.

#### ***4.6. 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.

#### ***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
	Mucosal irritations and allergic reactions have been reported. The frequency is not known.  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
	No case of overdose from oromucosal or dental use has been reported.  After oral administration of 5-10 ml of clove oil in children below 2 years of age, life threatening conditions were observed.  Overdose may lead to CNS depression, urinary abnormalities, anion gap acidosis, deterioration of liver function, coma, seizure and low blood glucose levels. Treatment should be supportive

Well-established use	Traditional use
	and symptomatic; there have been reports in the literature that N-acetylcysteine has been successfully used as an antidote.

## 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>Not required as per Article 16c (1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>Eugenol, the main component of clove oil, showed equivocal results in several test systems for genotoxicity and carcinogenicity.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity of the entire clove oil have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

27 January 2011