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EMA/HMPC/338914/2016  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Glycine max* (L.) Merr., oleum raffinatum

Final

Discussion in Working Party on European Union monographs and list (MLWP)	March 2014 November 2015 April 2016 May/June 2016
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 July 2016
End of consultation (deadline for comments) <sup>1</sup>	31 October 2016
Re-discussion in MLWP	November 2016
Adoption by HMPC	31 January 2017

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Glycine max</i> (L.) Merr., oleum raffinatum; Soiae oleum raffinatum; soya-bean oil, refined
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<sup>1</sup> No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



BG (bulgarski): Соево масло, рафинирано	LT (lietuvių kalba): Rafinuotas sojų aliejus
CS (čeština): čišťěný sójový olej	LV (latviešu valoda): sojas pupiņu eļļa, attīrīta
DA (dansk): Sojaolie, rensset	MT (Malti): żejt raffinat tas-sojja
DE (Deutsch): Raffiniertes Sojaöl	NL (Nederlands): soja olie
EL (elliniká): σογιέλαιο εξευγενισμένο	PL (polski): Olej sojowy rafinowany
EN (English): soya-bean oil, refined	PT (português): óleo de soja, refinado
ES (español): soja, aceite de, refinado	RO (română): ulei de soia, rafinat
ET (eesti keel): rafineeritud sojaõli	SK (slovenčina): sójový olej rafinovaný
FI (suomi): soijaöljy, puhdistettu	SL (slovenščina): rafinirano sojino olje
FR (français): soja (huile raffinée de)	SV (svenska): sojaolja, raffinerad
HR (hrvatski): sojino ulje, rafinirano	IS (íslenska):
HU (magyar): finomított szójaolaj	NO (norsk): rensset soyaolje
IT (italiano): olio di semi di soia raffinato	

# European Union herbal monograph on *Glycine max* (L.) Merr., oleum raffinatum

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>2,3</sup>

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC. <i>Glycine max</i> (L.) Merr., oleum raffinatum (soya-bean oil, refined) i) Herbal substance Not applicable ii) Herbal preparations Soya-bean oil, refined

## 3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for use as a bath additive.  The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the symptomatic relief of dry skin conditions associated with mild recurrent eczema.  The product is a traditional herbal medicinal product for use in the specified indication

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

<sup>3</sup> The material complies with the Ph. Eur. monograph (ref.: 1473).

Well-established use	Traditional use
	exclusively based upon long-standing use.

#### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p><b>Posology</b></p> <p>Liquid preparations containing 70–90% of soya-bean oil as bath additive 2–3 times per week</p> <p><i>Adolescents, adults and elderly</i></p> <p>Full bath (approximately 100–150 l): 15–45 ml</p> <p>Partial bath (approximately 25–50 l): 5–15 ml</p> <p>Partial bath (approximately 5 l): 1–2.5 ml</p> <p>Shower bath with direct application on skin: 20 ml</p> <p>In particularly dry skin, 2–3 times the above quantities can be used.</p> <p><i>Infants and children</i></p> <p>Children's bath (approximately 50 l): 20 ml</p> <p>Children's bath (approximately 25 l): 2.5–10 ml</p> <p>In particularly dry skin, 2–3 times the above quantities can be used.</p> <p><b>Duration of use</b></p> <p><u>Duration of bath:</u></p> <p><i>Adolescents, adults and elderly</i></p> <p>Maximum 20 minutes</p> <p><i>Infants and children</i></p> <p>A few minutes</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>Method of administration</b></p> <p>Use as bath additive.</p> <p><u>Bath temperature:</u></p> <p>Do not exceed 36 °C.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance, soya, peanut and to other plants of the Fabaceae (legume) family and to birch pollen.<sup>4</sup></p> <p>Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<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>Eye contact may cause keratitis and should be avoided. In cases of accidental eye contact, the eye should be rinsed immediately with cold water. If eye irritation remains, a doctor or a qualified health care practitioner should be consulted.</p>

### 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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

<sup>4</sup> In accordance with the 'Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein' (EMA/HMPC/138139/2005).

#### 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
	<p>Skin rashes and hypersensitivity reactions have been reported. The frequency is not known.</p> <p>Accidental eye contact may cause keratitis (see section 4.4 'Special warnings and precautions for use').</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### 4.9. Overdose

Well-established use	Traditional use
	<p>There are no known harmful effects resulting from excessive oil concentrations in the bath water.</p> <p>Accidental oral intake may lead to nausea, vomiting and diarrhoea. In case of vomiting aspiration could occur, therefore, vomiting should not be induced. If signs of aspiration occur, such as coughing, wheezing, fever, and chest discomfort, a doctor or a qualified health care practitioner should be consulted.</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.

## 5.2. Pharmacokinetic properties

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

## 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, unless necessary for the safe use of the product.</p> <p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

## 7. Date of compilation/last revision

31 January 2017