

COMMISSION DECISION

of 28 July 2009

amending the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2009) 5804)

(Text with EEA relevance)

(2010/28/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 16(f) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 10 January 2008 and 6 March 2008 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Calendula officinalis* L and *Pimpinella anisum* L comply with the requirements set out in Directive 2001/83/EC. *Calendula officinalis* L and *Pimpinella anisum* L can be considered as herbal substances, herbal preparations or combinations thereof.
- (2) It is therefore appropriate to include *Calendula officinalis* L and *Pimpinella anisum* L in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established in Annex I to 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

Decision 2008/911/EC is amended as follows:

1. Annex I is amended in accordance with Annex I to this Decision.
2. Annex II is amended in accordance with Annex II to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 July 2009.

For the Commission

Günter VERHEUGEN

Vice-President

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 328, 6.12.2008, p. 42.

ANNEX I

In Annex I to Decision 2008/911/EC, the following is inserted:

- ‘*Calendula officinalis* L’ is inserted before *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* (Bitter fennel, fruit),
 - ‘*Pimpinella anisum* L’ is inserted after *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (Sweet fennel, fruit).
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ANNEX II

In Annex II to Decision 2008/911/EC, the following is inserted:

— ‘*Calendula officinalis* L’ is inserted before *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* (Bitter fennel, fruit)

‘COMMUNITY LIST ENTRY ON CALENDULA OFFICINALIS L

Scientific name of the plant

Calendula officinalis L.

Botanical family

Asteraceae

Herbal substance

Calendula flower

Common name in all EU official languages of herbal substance

BG (bългарски): Невен, цвят	LT (lietuvių kalba): Medetkų žiedai
CS (čeština): Měsíčkový květ	LV (latviešu valoda): Klīģerītes ziedi
DA (dansk): Morgenfrueblomst	MT (malti): Fjura calendula
DE (Deutsch): Ringelblumenblüten	NL (nederlands): Goudsbloem
EL (elliniká): Άνθος καλέντουλας	PL (polski): Kwiat nagietka
EN (English): Calendula flower	PT (português): Flor de calêndula
ES (español): Flor de caléndula	RO (română): Floare de gălbenele (calendula)
ET (eesti keel): Saialilleõisik	SK (slovenčina): Nechtíkový kvet
FI (suomi): Tarhakehäkukan kukka	SL (slovenščina): Cvet vrtnega ognjiča
FR (français): Souci	SV (svenska): Ringblomma, blomma
HU (magyar): A körömvirág virága	IS (íslenska): Morgunfrú, blóm
IT (italiano): Calendula fiore	NO (norsk): Ringblomst

Herbal preparation(s)

- A. Liquid extract (DER 1:1), extraction solvent ethanol 40-50 % (v/v).
- B. Liquid extract (DER 1:1,8-2,2), extraction solvent ethanol 40-50 % (v/v).
- C. Tincture (DER 1:5), extraction solvent ethanol 70-90 % (v/v).

European Pharmacopoeia monograph reference

Calendula flower – *Calendulae flos* (01/2005:1297)

Indication(s)

- (a) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds.
- (b) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.

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

Type of tradition

European

Specified strength

Please see "Specified posology".

Specified posology

Herbal preparations:

A. Liquid extract (DER 1:1)

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

B. Liquid extract (DER 1:1,8-2,2)

In semi-solid dosage forms: amount equivalent to 2-5 % herbal substance.

C. Tincture (DER 1:5)

In compresses diluted at least 1:3 with freshly boiled water.

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

As a gargle or mouth rinse in a 2 % solution.

2 to 4 times daily

Indication (a)

The use is not recommended in children under 6 years of age (see below "Special warnings and precautions for use").

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available (see below "Special warnings and precautions for use").

Route of administration

Cutaneous and oromucosal use.

Duration of use or any restrictions on the duration of use

Compresses: remove after 30-60 minutes

All herbal preparations: If the symptoms persist after 1 week 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 members of the *Asteraceae* (*Compositae*) family.

Special warnings and precautions for use

Indication (a)

The use in children under 6 years of age is not recommended because there is no experience available.

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available.

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

Interactions with other medicinal products and other forms of interaction

None reported.

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.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Skin sensitisation. The frequency is not known.

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

Overdose

None reported.

- 'Pimpinella anisum L' is inserted after *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (Sweet fennel, fruit)

'COMMUNITY LIST ENTRY ON PIMPINELLA ANISUM L**Scientific name of the plant**

Pimpinella anisum L.

Botanical family

Apiaceae

Herbal substance

Aniseed

Common name in all EU official languages of herbal substance

BG (bългарски): Анасон, плод	LT (lietuvių kalba): Anyžių sėklos
CS (čeština): Anýzový plod	LV (latviešu valoda): Anīsa sēklas
DA (dansk): Anisfrø	MT (malti): Frotta tal-Anisi
DE (Deutsch): Anis	NL (nederlands): Anijsvrucht
EL (elliniká): Γλυκάνισο	PL (polski): Owoc anyżu
EN (English): Aniseed	PT (português): Anis
ES (español): Fruto de anís	RO (română): Fruct de anason
ET (eesti keel): Aniiis	SK (slovenčina): Anízový plod
FI (suomi): Anis	SL (slovenščina): Plod vrtnega janeža
FR (français): Anis (fruit d)	SV (svenska): Anis
HU (magyar): Ánizsmag	IS (íslenska): Anís
IT (italiano): Anice (Anice verde), frutto	NO (norsk): Anis

Herbal preparation(s)

Dried aniseed, comminuted or crushed

European Pharmacopoeia monograph reference

Anisi fructus (01/2005:0262)

Indication(s)

- (a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- (b) Traditional herbal medicinal product used as an expectorant in cough associated with cold.

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

Type of tradition

European

Specified strength

Please see "Specified posology"

Specified posology

Adolescents over 12 years of age, adults, elderly:

Indications (a) and (b)

1 to 3,5 g of whole or (freshly (*)) comminuted or crushed aniseed in 150 ml of boiling water as a herbal tea
3 times daily

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

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Not to be taken for more than 2 weeks.

If the symptoms persist 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 *Apiaceae* (*Umbelliferae*) (caraway, celery, coriander, dill and fennel) or to anethole.

Special warnings and precautions for use

The use is not recommended in children under 12 years of age due to the lack of adequate data for safety assessment.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no data from the use of aniseed in pregnant patients.

It is unknown if aniseed constituents are excreted in human breast milk.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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

Allergic reactions to aniseed affecting the skin or the respiratory system may occur. The frequency is not known.

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

Overdose

No case of overdose has been reported.

(*) For commercial preparations of comminuted or crushed aniseed the applicant must carry out appropriate stability testing related to the content of essential oil components.'
