

Official Journal

of the European Union

L 12



English edition

Legislation

Volume 53

19 January 2010

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 41/2010

of 18 January 2010

correcting the French, Latvian and Polish versions of Regulation (EC) No 546/2003 on certain notifications regarding the application of Council Regulations (EEC) No 2771/75, (EEC) No 2777/75 and (EEC) No 2783/75 in the eggs and poultrymeat sectors

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 192, in conjunction with Article 4 thereof,

Having regard to Regulation (EEC) No 2783/75 of the Council of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin ⁽²⁾, and in particular Article 10 thereof,

Whereas:

- (1) On 15 June 2009, the Commission adopted Regulation (EC) No 504/2009 ⁽³⁾ amending Regulation (EC) No 546/2003 ⁽⁴⁾. In the French, Latvian and Polish language versions of that Regulation, the term 'barn' was translated incorrectly and therefore a correction of

those three language versions is necessary. The other language versions are not affected.

- (2) Regulation (EC) No 546/2003 as amended by Regulation (EC) No 504/2009 should therefore be corrected accordingly.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

This correcting regulation concerns only the French, the Latvian and the Polish language versions.

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 January 2010.

For the Commission

José Manuel BARROSO

The President

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 282, 1.11.1975, p. 104.

⁽³⁾ OJ L 151, 16.6.2009, p. 22.

⁽⁴⁾ OJ L 81, 28.3.2003, p. 12.

COMMISSION REGULATION (EU) No 42/2010
of 15 January 2010
concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff⁽¹⁾, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column 1 of the table set out in the Annex should be classified under the CN code indicated in column 2, by virtue of the reasons set out in column 3 of that table.

(4) It is appropriate to provide that binding tariff information which has been issued by the customs authorities of Member States in respect of the classification of goods in the Combined Nomenclature but which is not in accordance with this Regulation can, for a period of three months, continue to be invoked by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽²⁾.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column 1 of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column 2 of that table.

Article 2

Binding tariff information issued by the customs authorities of Member States, which is not in accordance with this Regulation, can continue to be invoked for a period of three months under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 January 2010.

For the Commission,
On behalf of the President,
László KOVÁCS
Member of the Commission

⁽¹⁾ OJ L 256, 7.9.1987, p. 1.

⁽²⁾ OJ L 302, 19.10.1992, p. 1.

ANNEX

Description of goods	Classification (CN code)	Reasons
(1)	(2)	(3)
Product consisting of (% by weight): — barley grass, powdered 28,8 — honey 27,5 — wheatgrass, powdered 21,5 — alfalfa, powdered 21,5 — stearic acid 0,4 — pepper 0,25 — chromium picolinate 0,01 (corresponds to 8,7 µg Cr per tablet) The product is presented for retail sale, in tablet form and used as a food supplement (one tablet twice a day).	2106 90 98	Classification is determined by General Rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 2106, 2106 90 and 2106 90 98. The product does not meet the requirements of Note 2(b)(2) to Chapter 19 because of its composition, presentation and use as a food supplement. The product does not meet the requirements of Additional Note 1 to Chapter 30 as no statements on the use for specific diseases or the concentration of active substances are given. It should therefore not be considered as herbal medicinal preparation within the meaning of heading 3004. The product is therefore considered to be covered by the terms of heading 2106 as a food preparation not elsewhere specified or included and is used as dietary supplement indicated to maintain general health or well-being. (See also HSEN to heading 2106, second paragraph, number 16).

COMMISSION REGULATION (EU) No 43/2010**of 18 January 2010****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 19 January 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 January 2010.

*For the Commission,
On behalf of the President,*

Jean-Luc DEMARTY
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	IL	122,3
	JO	64,0
	MA	56,4
	TN	112,1
	TR	115,2
	ZZ	94,0
0707 00 05	EG	174,9
	JO	101,4
	MA	76,9
	TR	113,4
	ZZ	116,7
0709 90 70	MA	152,8
	TR	127,2
	ZZ	140,0
0709 90 80	EG	225,1
	ZZ	225,1
0805 10 20	EG	52,6
	IL	58,0
	MA	51,8
	TN	68,2
	TR	55,8
	ZZ	57,3
0805 20 10	MA	85,1
	ZZ	85,1
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	52,8
	EG	67,7
	HR	59,0
	IL	70,1
	JM	120,8
	TR	64,3
	ZZ	72,5
0805 50 10	EG	64,8
	IL	88,6
	TR	74,7
	US	87,7
	ZZ	79,0
0808 10 80	CA	75,3
	CL	60,1
	CN	91,3
	MK	24,7
	US	126,9
	ZZ	75,7
0808 20 50	CN	66,3
	US	101,4
	ZZ	83,9

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EU) No 44/2010**of 18 January 2010****on the issuing of import licences for applications lodged during the first seven days of January 2010
under tariff quotas opened by Regulation (EC) No 616/2007 for poultrymeat**

THE EUROPEAN COMMISSION,

Whereas:

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ⁽²⁾, and in particular Article 7(2) thereof,

Having regard to Commission Regulation (EC) No 616/2007 of 4 June 2007 opening and providing for the administration of Community tariff quotas in the sector of poultrymeat originating in Brazil, Thailand and other third countries ⁽³⁾, and in particular Article 5(5) thereof,

(1) Regulation (EC) No 616/2007 opened tariff quotas for imports of products in the poultrymeat sector.

(2) The applications for import licences lodged during the first seven days of January 2010 for the subperiod 1 April to 30 June 2010 relate, for some quotas, to quantities exceeding those available. The extent to which licences may be issued should therefore be determined and an allocation coefficient laid down to be applied to the quantities applied for,

HAS ADOPTED THIS REGULATION:

Article 1

The quantities for which import licence applications have been lodged pursuant to Regulation (EC) No 616/2007 for the subperiod 1 April to 30 June 2010 shall be multiplied by the allocation coefficients set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 19 January 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 January 2010.

*For the Commission,
On behalf of the President,*

Jean-Luc DEMARTY
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 142, 5.6.2007, p. 3.

ANNEX

Group No	Order No	Allocation coefficient for import licence applications lodged for the subperiod from 1.4.2010-30.6.2010 (%)
1	09.4211	0,432311
5	09.4215	12,484317

COMMISSION REGULATION (EU) No 45/2010
of 18 January 2010
amending Regulation (EU) No 39/2010 fixing the import duties in the cereals sector applicable from
16 January 2010

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1249/96 of 28 June 1996 laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 in respect of import duties in the cereals sector ⁽²⁾, and in particular Article 2(1) thereof,

Whereas:

- (1) The import duties in the cereals sector applicable from 16 January 2010 were fixed by Commission Regulation (EU) No 39/2010 ⁽³⁾.

- (2) As the average of the import duties calculated differs by more than EUR 5/tonne from that fixed, a corresponding adjustment must be made to the import duties fixed by Regulation (EU) No 39/2010.

- (3) Regulation (EU) No 39/2010 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Regulation (EU) No 39/2010 are hereby replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 19 January 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 January 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and
Rural Development

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 161, 29.6.1996, p. 125.

⁽³⁾ OJ L 11, 16.1.2010, p. 3.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 19 January 2010

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 10 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
1001 90 91	Common wheat seed	0,00
ex 1001 90 99	High quality common wheat, other than for sowing	0,00
1002 00 00	Rye	36,92
1005 10 90	Maize seed other than hybrid	18,54
1005 90 00	Maize, other than seed ⁽²⁾	18,54
1007 00 90	Grain sorghum other than hybrids for sowing	36,92

⁽¹⁾ For goods arriving in the Community via the Atlantic Ocean or via the Suez Canal the importer may benefit, under Article 2(4) of Regulation (EC) No 1249/96, from a reduction in the duty of:

- 3 EUR/t, where the port of unloading is on the Mediterranean Sea, or
- 2 EUR/t, where the port of unloading is in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or the Atlantic coast of the Iberian peninsula.

⁽²⁾ The importer may benefit from a flatrate reduction of EUR 24 per tonne where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

15.1.2010

1. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

(EUR/t)

	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾	Barley
Exchange	Minneapolis	Chicago	—	—	—	—
Quotation	155,97	101,75	—	—	—	—
Fob price USA	—	—	165,85	155,85	135,85	98,98
Gulf of Mexico premium	41,51	15,40	—	—	—	—
Great Lakes premium	—	—	—	—	—	—

⁽¹⁾ Premium of 14 EUR/t incorporated (Article 4(3) of Regulation (EC) No 1249/96).⁽²⁾ Discount of 10 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).⁽³⁾ Discount of 30 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

Freight costs: Gulf of Mexico–Rotterdam: 23,48 EUR/t

Freight costs: Great Lakes–Rotterdam: — EUR/t

DECISIONS

COUNCIL DECISION

of 18 January 2010

**appointing the members and alternate members of the Committee of the Regions for the period
from 26 January 2010 to 25 January 2015**

(2010/29/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 300(3) and 305 thereof, in conjunction with Article 8 of the Protocol on Transitional Provisions annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union,

Having regard to the proposals made by each Member State,

Whereas:

- (1) Article 300(3) of the Treaty on the Functioning of the European Union requires that members or alternate members of the Committee of the Regions, besides being representatives of regional or local bodies, 'either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly'.
- (2) Article 305 of the Treaty on the Functioning of the European Union provides for the members of the Committee and an equal number of alternate members to be appointed by the Council for five years in accordance with the proposals made by each Member State.
- (3) Article 8 of the Protocol on Transitional Provisions sets out the allocation of members of the Committee of the Regions.
- (4) As the term of office of the members and alternate members of the Committee of the Regions is due to expire on 25 January 2010, new members and alternate members should be appointed to the Committee of the Regions.
- (5) On 22 December 2009, the Council adopted the proposals of members and alternate members submitted by the Belgian, Bulgarian, Czech, Danish,

Estonian, Greek, Spanish, French, Italian, Cypriot, Latvian, Lithuanian, Luxembourg, Hungarian, Maltese, Dutch, Austrian, Polish, Portuguese, Romanian, Slovenian, Slovak, Finnish, Swedish and British Governments and the list containing 24 members and 23 alternate members submitted by the German Government ⁽¹⁾.

- (6) The members and alternate members proposed by the Irish government as well as one alternate member proposed by the German government, should now be appointed to the Committee of the Regions,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the period from 26 January 2010 to 25 January 2015:

- as members, the persons listed by Member State in Annex I,
- as alternate members, the persons listed by Member State in Annex II.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall enter into force on the date of its adoption.

Done at Brussels, 18 January 2010.

For the Council
The President
E. ESPINOSA

⁽¹⁾ OJ L 348, 29.12.2009, p. 22.

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Членове / Miembros / Členové / Medlemmer / Mitglieder / Liikmed / Μέλη / Members / Membres / Membri / Locekļi / Nariai / Tagok / Membri / Leden / Członkowie / Membros / Membri / Členovia / Člani / Jäsenet / Ledamöter

IRELAND

Mr Gerry BREEN

Member of Dublin City Council and Dublin Regional Authority

Ms Constance HANNIFY

Member of Offaly County Council and Midland Regional Authority

Mr Denis LANDY

Member of South Tipperary County Council and South East Regional Authority

Mr Declan MCDONNELL

Member of Galway City Council and West Regional Authority

Mr Patrick MCGOWAN

Member of Donegal County Council and Border Regional Authority

Mr Brian MEANEY

Member of Clare County Council and Mid-West Regional Authority

Ms Michelle MULHERIN

Member of Mayo County Council and West Regional Authority

Mr Paul O'DONOGHUE

Member of Kerry County Council and South West Regional Authority

Ms Fiona O'LOUGHLIN

Member of Kildare County Council and Mid-East Regional Authority

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Заместник-членове / Suplentes / Náhradníci / Suppleanter / Stellvertreter / Asendusliikmed / Αναπληρωτές / Alternates / Suppléants / Supplenti / Aizstājēji / Pakaitiniai nariai / Póttagok / Supplenti / Plaatsvervangers / Zastępcy / Suplentes / Supleanți / Náhradníci / Nadomestni člani / Varajäsenet / Suppleanter

DEUTSCHLAND

Herr Gustav BERGEMANN
Mitglied des Thüringer Landtags

IRELAND

Mr Terry BRENNAN
Member of Louth County Council

Ms Maria BYRNE
Member of Limerick City Council

Ms Mary FREEHILL
Member of Dublin City Council

Mr John LAHART
Member of South Dublin County Council

Mr Michael MCGREAL
Member of Roscommon County Council

Mr Niall MCNELIS
Member of Galway City Council

Mr John PENDER
Member of Carlow County Council

Ms Mary SHIELDS
Member of Cork City Council

Mr Barney STEELE
Member of Longford County Council

COMMISSION DECISION

of 9 December 2009

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

(notified under document C(2009) 9703)

(Text with EEA relevance)

(2010/30/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and 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 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) 'Eleutherococcus senticosus (Rupr. et Maxim.) Maxim' and 'Echinacea purpurea (L.) Moench' comply with the requirements set out in Directive 2001/83/EC. 'Eleutherococcus senticosus (Rupr. et Maxim.) Maxim' and 'Echinacea purpurea (L.) Moench' can be considered as herbal substances, herbal preparations or combinations thereof.

(2) It is therefore appropriate to include 'Eleutherococcus senticosus (Rupr. et Maxim.) Maxim' and 'Echinacea purpurea (L.) Moench' 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, 9 December 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 two substances are inserted after '*Calendula officinalis* L.':

- '*Echinacea purpurea* (L.) Moench'
 - '*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim'
-

ANNEX II

In Annex II to Decision 2008/911/EC, the following is inserted after the entry relating to '*Calendula officinalis* L':

'COMMUNITY LIST ENTRY ON ECHINACEA PURPUREA (L.) MOENCH, HERBA RECENS

Scientific name of the plant

Echinacea purpurea (L.) Moench

Botanical family

Asteraceae

Herbal substance

Purple coneflower herb

Common name in all EU official languages of herbal substance

BG (bългарски): пурпурна ехинацея, пресен стрък	LT (lietuvių kalba): rausvažiedžių ežiuolių žolė
CS (čeština): čerstvá nať třapatky nachové	LV (latviešu valoda): purpursarkanās ehinacejas laksti
DA (dansk): Purpursolhat, frisk urt	MT (malti): Echinacea Vjola
DE (Deutsch): Purpursonnenhutkraut, frisch	NL (nederlands): rood zonnehoeckruid
EL (elliniká): Πόα Εχινάκεας της πορφυράς	PL (polski): jeżówka purpurowa, świeże ziele
EN (English): purple coneflower herb	PT (português): Equinácea, partes aéreas floridas
ES (español): Equinácea purpúrea, partes aéreas incluidas sumidades floridas	RO (română): iarbă proaspătă de Echinacea, pâlăria soarelui
ET (eesti keel): punane siilkübar	SK (slovenčina): echinacea purpurová, čerstvá vňat'
FI (suomi): kaunopunahattu, tuore verso	SL (slovenščina): sveža zel škrlatne ehinaceje
FR (français): parties aériennes fraîches d'échinacée pourpre	SV (svenska): röd solhatt, färsk ört
HU (magyar): bíbor kasvirág virágos hajtása	IS (íslenska): Sólhattur
IT (italiano): Echinacea purpurea, pianta fresca	NO (norsk): Rød solhatt

Herbal preparation(s)

Expressed juice and dried expressed juice from fresh flowering aerial parts.

European Pharmacopoeia monograph reference

N/A

Indication(s)

Traditional herbal medicinal product for treatment of small superficial wounds.

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

Type of tradition

European.

Specified strength

10 to 20 g/100 g of expressed juice or equivalent amount of dried expressed juice in liquid or semi-solid dosage forms.

Specified posology

Adolescents over the age of 12 years, adults, elderly

Small amount of ointment is applied on the affected area 2-3 times a day.

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

Route of administration

Cutaneous use.

Duration of use or any restrictions on the duration of use

Do not use the medicinal product for more than 1 week.

If the symptoms persist during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Any other information necessary for the safe use

Contra-indications

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Special warnings and precautions for use

If signs of skin infection are observed, medical advice should be sought.

The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no data on cutaneous use during pregnancy or lactation.

Products containing Echinacea should not be applied to the breast of breastfeeding women.

Effects on ability to drive and use machines

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

Undesirable effects

Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) may occur.

The frequency is not known.

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

Overdose

No case of overdose has been reported.

COMMUNITY LIST ENTRY ON *ELEUTHEROCOCCUS SENTICOSUS* (RUPR. ET MAXIM.) MAXIM., RADIX**Scientific name of the plant***Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim.**Botanical family**

Araliaceae

Herbal substance

Eleutherococcus root

Common name in all EU official languages of herbal substance

BG (bългарски): елеутерокок, корен	LT (lietuvių kalba): Eleuterokokų šaknys
CS (čeština): eleuterokokový kořen	LV (latviešu valoda): Eleiterokoka sakne
DA (dansk): Russisk rod	MT (malti): Gherq ta' l-eleuterokokku
DE (Deutsch): Taigawurzel	NL (nederlands): Russische ginsengwortel
EL (elliniká): Ρίζα Ελευθεροκόκκου	PL (polski): korzeń eleuterokoka
EN (English): Eleutherococcus root	PT (português): Raiz de Ginseng Siberiano
ES (español): Eleuterococo, raíz de	RO (română): Rădăcină de ginseng siberian
ET (eesti keel): eleuterokokijuur	SK (slovenčina): Všehojovcový koreň
FI (suomi): venäjänjuuren juuri	SL (slovenščina): korenina elevterokoka
FR (français): racine d'éleuthérocoque (racine de ginseng sibérien)	SV (svenska): Rysk rot
HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)	IS (íslenska): Síberíu ginseng, rót
IT (italiano): Eleuterococco radice	NO (norsk): Russisk rot

Herbal preparation(s)

Comminuted herbal substance for preparation of a herbal tea

Liquid extract (1:1, ethanol 30-40 % v/v)

Dry extract (13-25: 1, ethanol 28-40 % v/v)

Dry extract (17-30: 1, ethanol 70 % v/v)

Dry aqueous extract (15-17:1)

Tincture (1:5, ethanol 40 % v/v)

European Pharmacopoeia monograph reference

Eleutherococcus — Eleutherococci radix (ref.: 01/2008: 1419 corrected 6.0)

Indication(s)

Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness.

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

Type of tradition

Chinese, European.

Specified strength

Not applicable.

Specified posology

Adolescents over 12 years of age, adults, elderly

Herbal preparations.

Daily dose.

Comminuted herbal substance as herbal tea: 0,5-4 g.

Tea preparation: 0,5 to 4 g of comminuted herbal substance for infusion in 150 ml of boiling water.

Dosage frequency: 150 ml of tea infusion should be divided in one to three doses taken during the day.

Liquid extract: 2-3 ml.

Dry extracts (ethanol 28-70 % v/v) corresponding to 0,5-4 g dried root.

Dry aqueous extract (15-17:1): 90-180 mg.

Tincture: 10-15 ml.

The daily dose can be taken in one to three doses.

The use is not recommended in children under 12 years 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 months.

If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Any other information necessary for the safe use*Contra-indications*

Hypersensitivity to the active substance.

Arterial hypertension.

Special warnings and precautions for use

The use in children under 12 years of age is not recommended because sufficient experience is not available.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified healthcare 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

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

Undesirable effects

Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

Overdose

No case of overdose has been reported.'

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