



Council of the
European Union

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COVER NOTE

From:	European Commission
To:	General Secretariat of the Council
No. Cion doc.:	D036697/03 - Annex 1
Subject:	ANNEXES to the COMMISSION REGULATION (EU) No .../.. amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of L-leucine as a carrier for table-top sweeteners in tablets

Delegations will find attached document D036697/03 - Annex 1.

Encl.: D036697/03 - Annex 1



Brussels, **XXX**
SANCO/11503/2014 ANNEX
(POOL/E3/2014/11503/11503-EN
ANNEX.doc) D036697/03
[...] (2014) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) No .../..

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of L-leucine as a carrier for table-top sweeteners in tablets

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) In Part B, in Section 3 ‘Additives other than colours and sweeteners’, the following new entry is inserted after the entry for food additive E 640:

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E 641	L-leucine
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"

- (2) In part E, in food category 11.4.3 ‘Table-top sweeteners in tablets’, the following new entry is inserted after the entry for food additive E 640:

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	E 641	L-leucine	50 000		
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for E 640:

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E 641 L-LEUCINE	
Synonyms	2-Aminoisobutylic acid; L-2-Amino-4-methylvaleric acid; alpha-Aminoisocaproic acid; (S)-2-Amino-4-methylpentanoic acid; L-Leu
Definition	
Einecs	200-522-0
CAS number	61-90-5
Chemical name	L-Leucine; L-2-Amino-4-methylpentanoic acid
Chemical formula	C ₆ H ₁₃ NO ₂
Molecular Weight	131,17
Assay	Content not less than 98,5 % and not more than 101,0 % on the anhydrous basis
Description	White or almost white crystalline powder or shiny flakes
Identification	
Solubility	Soluble in water, acetic acid, dilute HCl and alkaline hydroxides and carbonates; slightly soluble in ethanol
Specific rotation	$[\alpha]_D^{20}$ between + 14,5° and + 16,5° (4 % solution (anhydrous basis) in 6N HCl)
Purity	
Loss on drying	Not more than 0,5 % (100 - 105 °C)
Sulphated Ash	Not more than 0,1 %
Chlorides	Not more than 200 mg/kg
Sulphates	Not more than 300 mg/kg
Ammonium	Not more than 200 mg/kg
Iron	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

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