Commission Regulation (EU) 2015/649 of 24 April 2015 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 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/649

of 24 April 2015

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Articles 10(3), 14 and 30(5) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)], and in particular Article 7(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) Commission Regulation (EU) No 231/2012[(3)] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(4) On 9 September 2010 an application for authorisation of the use of L-leucine as a carrier (tableting aid) for table-top sweeteners in tablets was submitted by Germany where such use was authorised. That application has been made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) There is a technological function and need for the use of L-leucine in table-top sweeteners in tablets. L-leucine is homogeneously mixed with sweeteners before pressing tablets from the mixture and it aids tableting by ensuring that the tablets do not remain stuck to the pressing tools.

(6) The European Food Safety Authority ('the Authority') evaluated the safety of amino acids and related substances when used as flavouring substances and expressed its opinion on 29 November 2007[(4)]. The Authority concluded that the human exposure to

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/649. (See end of Document for details)*

amino acids through food is in orders of magnitude higher than the anticipated levels of exposure from their use as flavouring substances and that nine of the substances, including L-leucine, were not of safety concern at their estimated levels of intake as flavouring substances.

(7) It was demonstrated in the application that even a high consumption of sweetener tablets would not exceed 4 % of the intake quantity recommended for L-leucine.

(8) Therefore, it is appropriate to authorise the use of L-leucine as a carrier for table-top sweeteners in tablets as specified in Annex I to this Regulation and to assign E 641 as an E-number to that food additive.

(9) The specifications for L-leucine should be included in Regulation (EU) No 231/2012 when it is included in the Union lists in Annex II to Regulation (EC) No 1333/2008 for the first time. In this regard it is appropriate to take into account the purity criteria of the European Pharmacopoeia for L-leucine.

(10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of 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, 24 April 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/649. (See end of Document for details)*

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:

E 641	L-leucine

(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:

	E 641	L-leucine	50 000		

ANNEX II

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

E 641 L-LEUCINE	
Synonyms	2-Aminoisobutylacetic 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	$C_6H_{13}NO_2$
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 °C – 105 °C)