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# COMMISSION IMPLEMENTING REGULATION (EU) 2024/997

## of 3 April 2024

## concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 18932 as a feed additive for all animal species

**(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 18932. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 18932 as a feed additive for use in feed and in water for drinking for all animal species, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 June 2023 ([2]) that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* CGMCC 18932 is safe for the target species, when supplemented to the diet in appropriate amounts according to the nutritional needs of the target species, and that it is safe for consumers and the environment. The Authority could not conclude on the potential of L-valine produced by *Corynebacterium glutamicum* CGMCC 18932 to be irritant to the skin or eyes or to be a dermal sensitiser but it concluded that exposure through inhalation is likely. The Authority further concluded that the substance is regarded as an efficacious source of the essential amino acid L-valine for non-ruminant animals and that for the substance to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that L-valine produced by *Corynebacterium glutamicum* CGMCC 18932 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance as a feed additive should be authorised. It is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids, in particular in the case of supplementation with L-valine via water for drinking. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2023;21(7):8104.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

**Entry into force**

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, 3 April 2024.

*For the Commission*
*The President*
Ursula VON DER LEYEN

ANNEX

| Identification number of the feed additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | mg/kg of complete feed with 12 % moisture content | | | |
| **Category: nutritional additives. Functional group: amino acids, their salts and analogues** | | | | | | | | |
| 3c373 | L-valine | *Additive composition*<br>L-valine with a minimum content of 98 % (on a dry matter basis) and a maximum content of 0,5 % water.<br><br>Solid form<br><br>*Characterisation of the active substance*<br>L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by *Corynebacterium glutamicum* CGMCC 18932<br><br>Chemical formula: $C_5H_{11}NO_2$<br><br>CAS number: 72-18-4<br><br>*Analytical method* (1)<br>For the identification of L-valine in the feed additive:<br>— Food Chemical Codex 'L-valine monograph'<br><br>For the quantification of valine in the feed additive:<br>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)<br><br>For the quantification of valine in premixtures and compound feed:<br>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (2) (Annex III, F) | All animal species | — | — | — | 1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water shall be indicated.<br><br>2. The additive may be used via water for drinking.<br><br>3. Declaration to be made on the label of the additive and premixtures:<br><br>'The supplementation with L-valine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.'<br><br>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. | 24 April 2034 |

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| | | For the quantification of valine in water:<br>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD) | | | | | | |

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

(2) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).





ELI: http://data.europa.eu/eli/reg_impl/2024/997/oj