# Commission Implementing Regulation (EU) 2019/8 of 3 January 2019 concerning the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2019/8

of 3 January 2019

concerning the authorisation of hydroxy analogue of methionine and its calcium salt 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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for use in feed for all animal species. 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 hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 20 February 2018[(2)] that, under the proposed conditions of use, hydroxy analogue of methionine and its calcium salt does not have an adverse effect on animal health, human health or the environment.

(5) The Authority also concluded that the additive is an effective source of methionine for all animal species and that, even though the ruminal degradation of the additive in ruminants is lower than that of DL-methionine, the additive should be protected against degradation in the rumen.

(6) The Authority does 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/8. (See end of Document for details)*

(7) The assessment of this additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

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

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 a feed 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 January 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/8. (See end of Document for details)*

ANNEX

| **Identification number of the additive** | **Name of the holder of authorisation** | **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 a moisture content of 12 %** | | | |
| Category of nutritional additives. Functional group: amino acids, their salts and analogues | | | | | | | | | |
| 3c310 | — | Hydroxy analogue of methionine and its calcium salt | *Additive composition* Preparation of hydroxy analogue of methionine and calcium salt of hydroxy analogue of methionine, having a minimum content of hydroxy analogue of methionine of 88 % and a minimum content of calcium of 8 %. *Characterisation of the active substances:* Hydroxy analogue of methionine: | All animal species | — | — | — | 1. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use, in particular considering that it is corrosive to skin and eyes. Where those risks cannot be eliminated or | 24 January 2029 |

**a** Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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|---|---|---|---|---|---|---|---|---|---|
| | | | | IUPAC name: 2-hydroxy-4-(methylthio)butanoic acid<br>CAS number 583-91-5<br>Chemical formula: $C_5H_{10}O_3S$<br>calcium salt of hydroxy analogue of methionine: IUPAC name 2-hydroxy-4-(methylthio)butanoic acid, calcium salt<br>CAS number 4857-44-7<br>Chemical formula: $(C_5H_9O_3S)_2Ca$ | | | reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including safety glasses and gloves.<br>2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. | |
| | | | *Analytical method*[a]: For the determination of hydroxy analogue of methionine in the additive:<br>— | Titrimetry, potentiometric titration after oxidation | | | | 3. Declaration to be made on the label of the additive and premixture: content of | |

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