

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1431

of 1 September 2021

concerning the authorisation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for weaned piglets (holder of the authorisation DSM Nutritional Products Ltd, represented in the Union by DSM Nutritional Products Sp. z o.o.)

(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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of muramidase produced by *Trichoderma reesei* DSM 32338. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ⁽²⁾ that, under the proposed conditions of use, muramidase produced by *Trichoderma reesei* DSM 32338 does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the additive should be considered a potential respiratory and skin sensitiser and a potential skin and eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of that additive. The Authority concluded that the additive has the potential to be efficacious as a zootechnical additive in weaned piglets. 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.
- (5) The assessment of muramidase produced by *Trichoderma reesei* DSM 32338 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) 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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(3):6452.

Article 2

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, 1 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						Unit of activity/kg of complete feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of the feed to gain ratio).									
4d16	DSM Nutritional Products Ltd. represented in the Union by DSM Nutritional Products Sp. z o.o.	Muramidase (EC 3.2.1.17)	<p>Additive composition Preparation of muramidase (EC 3.2.1.17) (lysozyme) produced by <i>Trichoderma reesei</i> (DSM 32338) having a minimum activity of 60 000 LSU(F) ⁽¹⁾ /g. Solid and liquid forms.</p> <p>Characterisation of the active substance: Muramidase (EC 3.2.1.17) (lysozyme) produced by <i>Trichoderma reesei</i> (DSM 32338).</p> <p>Analytical method ⁽²⁾ For the quantification of muramidase: fluorescence-based enzyme assay method that determines the enzyme-catalyzed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6,0 and 30 °C.</p>	Piglets (weaned)	-	50 000 LSU(F)	65 000 LSU(F)	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. 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. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protections.</p>	22.9.2031

⁽¹⁾ 1 LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12,5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6,0 and 30 °C by a value that corresponds to the fluorescence of approximately 0,06 nmol fluorescein isothiocyanate isomer.

⁽²⁾ 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>.