

**COMMISSION IMPLEMENTING REGULATION (EU) 2019/892****of 28 May 2019****concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)****(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 <sup>(1)</sup>, 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 the preparation of *Saccharomyces cerevisiae* CNCM I-1079. That 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 the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species to be classified in the additive category 'zootechnical additives'.
- (4) That preparation was already authorised as a zootechnical additive for 10 years by Commission Implementing Regulation (EU) 2018/347 <sup>(2)</sup> for use with weaned piglets and sows, and by Commission Implementing Regulation (EU) 2017/1905 <sup>(3)</sup> for use with chickens for fattening and minor poultry species for fattening.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 November 2018 <sup>(4)</sup> that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1079 does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive has the potential to be efficacious in all pigs. 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.
- (6) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 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.
- (7) 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 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 67, 9.3.2018, p. 21).

<sup>(3)</sup> Commission Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 269, 19.10.2017, p. 30).

<sup>(4)</sup> EFSA Journal 2019;17(1):5535.

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*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, 28 May 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## 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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: gut flora stabilisers.**

4d1703	Danstar Ferment AG represented by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1079	<p><i>Additive composition</i></p> <p>Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1079 containing a minimum of:</p> <ul style="list-style-type: none"> <li>— <math>1 \times 10^{10}</math> CFU/g of additive (coated form);</li> <li>— <math>2 \times 10^{10}</math> CFU/g of additive (not-coated form).</li> </ul> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1079</p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009)</p> <p>Identification: polymerase chain reaction (PCR) method (CEN/TS) 15790:2008</p>	All pigs other than sows and weaned piglets All minor porcine species	—	$1 \times 10^9$		<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. 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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</li> </ol>	18 June 2029
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<sup>(1)</sup> 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>