COMMISSION IMPLEMENTING REGULATION (EU) 2022/272

of 23 February 2022

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae other than weaned piglets and sows, and dogs (holder of authorisation: Prosol S.p.A.)

(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 a preparation of *Saccharomyces cerevisiae* MUCL 39885. 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 the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae other than weaned piglets and sows, and dogs, to be classified in the category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 June 2021 ([2]) ([3]) that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that this preparation is considered as a potential skin and eye irritant and a skin and respiratory sensitiser. 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 the additive. The Authority also concluded that in the case of suidae, the preparation has the potential to be efficacious as a zootechnical additive in feedingstuffs and in the case of dogs, the preparation has the potential to be efficacious in improving the faecal consistency. The Authority does not consider that there is a need for specific requirements of postmarket monitoring. It also verified the report on the methods 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 the preparation of *Saccharomyces cerevisiae* MUCL 39885 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 'gut flora stabilisers', 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(7):6698.
([3]) *EFSA Journal* 2021;19(7):6699.

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, 23 February 2022.

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1710	Prosol S.p.A.	*Saccharomyces cerevisiae* MUCL 39885	*Additive composition* Preparation of *Saccharomyces cerevisiae* MUCL 39885 containing a minimum of: 1×10^9 CFU/g of additive Solid form *Characterisation of the active substance* Viable cells of *Saccharomyces cerevisiae* MUCL 39885 *Analytical method* (1) Enumeration: pour plate method using yeast extract glucose chloramphenicol agar (CGYE) (EN 15789) Identification: polymerase chain reaction (PCR) method	All Suidae other than for reproduction purposes and weaned piglets All Suidae for reproduction purposes other than sows Dogs	- - -	3×10^9 $6{,}4 \times 10^9$ 7×10^{10}	- - -	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalation or eyes exposure cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection.	16.3.2032

(1) 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