



2024/980

3.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/980

of 2 April 2024

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cats (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 a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cats, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 June 2021 ⁽²⁾ and of 26 September 2023 ⁽³⁾ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 is safe for cats. It also concluded that the preparation of *Saccharomyces cerevisiae* MUCL 39885 is considered a potential skin and eye irritant and a skin and respiratory sensitiser. The Authority further concluded that the preparation of *Saccharomyces cerevisiae* MUCL 39885, has the potential to be efficacious as a zootechnical additive for cats when added to feed at 7×10^{10} CFU/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning the same additive are valid and applicable for the current application.
- (6) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* MUCL 39885 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for cats. 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.
- (7) 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2021;19(7):6699.

⁽³⁾ EFSA Journal 2023;21(10):8358.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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.

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, 2 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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	<i>Saccharomyces cerevisiae</i> MUCL 39885	Additive composition Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885 containing a minimum of: 1 × 10 ⁹ CFU/g of additive Solid form Characterisation of the active substance Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885 Analytical method ⁽¹⁾ Identification: polymerase chain reaction (PCR) method – CEN/TS 15790. Enumeration in feed additive and compound feed: Pour or spread plate method (EN 15789).	Cats	—	7 × 10 ¹⁰	—	1. In the directions for use of the additive and premixture, 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 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 breathing, eye and skin protective equipment.	23 April 2034

⁽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