



2023/2734

8.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2734

of 7 December 2023

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* DBVPG 48 SF as a feed additive for horses, dairy ruminants and pigs (holder of authorisation: Mazzoleni 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* DBVPG 48 SF as a feed additive. 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* DBVPG 48 SF as a feed additive for horses, ruminants and all pigs, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers' as regards horses, and in the functional group 'other zootechnical additives' as regards ruminants and pigs.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 March 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF is safe for horses, ruminants and all pigs, consumers and the environment. It also concluded that the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF is not irritant to the eyes and skin but should be considered a respiratory sensitiser, while it could not conclude on the skin sensitisation potential of that preparation. The Authority further concluded that the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF has the potential to be efficacious at the proposed conditions of use for horses, dairy ruminants and all pigs, but was not in the position to conclude on the efficacy of that preparation for ruminants other than dairy ruminants. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority 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 applicant committed on 13 June 2023 to submit supplementary information with a view to demonstrate the efficacy of the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF for ruminants other than dairy ruminants.
- (6) In view of the above, the Commission considers that the preparation of *Saccharomyces cerevisiae* DBVPG 48 SF satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003 for horses, dairy ruminants and all pigs. Accordingly, the use of that preparation should be authorised for horses, dairy ruminants and all pigs. 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.

⁽²⁾ EFSA Journal 2023;21(4):7971.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional groups 'digestibility enhancers' and 'other zootechnical additives', 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, 7 December 2023.

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 of zootechnical additives. Functional group: digestibility enhancers									
4d24	Mazzoleni S.p.A.	<i>Saccharomyces cerevisiae</i> DBVPG 48 SF	<i>Additive composition</i> Preparation of <i>Saccharomyces cerevisiae</i> DBVPG 48 SF with a minimum concentration of: 1 × 10 ⁹ CFU/g of additive. Solid forms. <i>Characterisation of the active substance</i> Viable cells of <i>Saccharomyces cerevisiae</i> DBVPG 48 SF. <i>Analytical method</i> ⁽¹⁾ — Identification: polymerase chain reaction (PCR) method – CEN/TS 15790 — Enumeration in the feed additive, premixtures and compound feed: pour or spread plate method (EN 15789)	Horses	-	3 × 10 ⁹	-	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 and skin protective equipment.	28 December 2033

Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)

4d24	Mazzoleni S.p.A.	<i>Saccharomyces cerevisiae</i> DBVPG 48 SF	Additive composition Preparation of <i>Saccharomyces cerevisiae</i> DBVPG 48 SF with a minimum concentration of: 1×10^9 CFU/g of additive. Solid forms.	Dairy cows All minor dairy ruminants	-	4×10^8	-	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 and skin protective equipment.	28 December 2033
			Characterisation of the active substance Viable cells of <i>Saccharomyces cerevisiae</i> DBVPG 48 SF. Analytical method ⁽¹⁾ — Identification: polymerase chain reaction (PCR) method – CEN/TS 15790 — Enumeration in the feed additive, premixtures and compound feed: pour or spread plate method (EN 15789)	Pigs for fattening Piglets (suckling and weaned) Minor porcine species (suckling piglets, weaned piglets and pigs for fattening)		4×10^9			
				Sows for reproduction Minor porcine species (sows for reproduction)		6×10^9			

⁽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