

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/344**  
**of 25 February 2021**  
**concerning the authorisation of sorbitan monolaurate as a feed additive for all animal species**

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup>.
- (2) Sorbitan monolaurate was authorised without a time limit as a feed additive for all animal species in accordance with Directive 70/524/EEC. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of sorbitan monolaurate as a feed additive for all animal species.
- (4) The applicant requested that additive to be classified in the additive category 'technological additives' and in the functional group 'emulsifiers'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 27 February 2019 <sup>(3)</sup> and 25 May 2020 <sup>(4)</sup> that, under the proposed conditions of use, sorbitan monolaurate does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is irritant to skin and eyes. 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 since sorbitan monolaurate is authorised as a food additive with an emulsifier function, the technological effect underlying its use as a food additive could reasonably be expected to be seen when used in feed. The Authority does not consider that there is a need for specific requirements of post-market 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.
- (6) The assessment of sorbitan monolaurate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of sorbitan monolaurate should be authorised.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of sorbitan monolaurate, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> *EFSA Journal* 2019;17(3):5651.

<sup>(4)</sup> *EFSA Journal* 2020;18(6):6162.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

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

*Article 2*

**Transitional measures**

1. The additive specified in the Annex and premixtures containing this additive, which are produced and labelled before 18 September 2021 in accordance with the rules applicable before 18 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additive as specified in the Annex which are produced and labelled before 18 March 2022 in accordance with the rules applicable before 18 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additive as specified in the Annex which are produced and labelled before 18 March 2023 in accordance with the rules applicable before 18 March 2021 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 3*

**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, 25 February 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

Identification number of the additive	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
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of technological additives. Functional group: emulsifiers</b>								
1c493	Sorbitan monolaurate	<p><i>Additive composition</i></p> <p>A preparation of sorbitan monolaurate containing ≥ 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters, esterified with fatty acids derived from coconut oil.</p> <p><i>Liquid form</i></p> <p><i>Characterisation of the active substance</i> Sorbitan monolaurate CAS number: 1338-39-2 C<sub>18</sub>H<sub>34</sub>O<sub>6</sub></p> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>For the characterisation of sorbitan monolaurate in the feed additive: — FAO JECFA Monograph 'Sorbitan Monolaurate'</p>	All animal species	-	-	85	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, 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.</li> </ol>	18 March 2031

<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>