

COMMISSION IMPLEMENTING REGULATION (EU) 2020/160**of 5 February 2020****concerning the authorisation of the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol as a feed additive for weaned piglets (holder of authorisation Biomin GmbH)****(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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of a preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 ⁽²⁾ that, under the proposed conditions of use, the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that exposure to users by inhalation is unlikely and that no conclusion could be drawn on skin or eyes sensitisation. 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 concluded that the additive has the potential to be efficacious in improving zootechnical performance. 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.
- (5) The assessment of the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol 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 'other zootechnical additives', 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 2019;17(4):5688.

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, 5 February 2020.

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
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

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

4d19	Biomin GmbH	Oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol	<p>Additive composition Preparation of:</p> <ul style="list-style-type: none"> — essential oils of oregano (<i>Origanum vulgare</i> L.) (60-80 mg/g) and caraway seed (<i>Carum carvi</i> L.) (5-10 mg/g), — carvacrol (60-80mg/g), methyl salicylate (10-40 mg/g) and L-menthol (30-55 mg/g) <p>Solid form</p> <p>Characterisation of the active substance: Oregano oil (<i>Origanum vulgare</i> L.) (CAS number: 8007-11-2) with a content of linalool of 1,8-16 mg/g; Caraway seed oil (<i>Carum carvi</i> L.) (CAS number: 8000-42-8) with a content of D-carvone of 2,5-6,5 mg/g; Carvacrol oil (CAS number: 499-75-2) ≥ 99 % with a content of carvacrol of 95-140 mg/g (from oregano and pure carvacrol); Methyl salicylate (CAS number: 119-36-8); L-Menthol (CAS number: 2216-51-8).</p> <p>Analytical method ⁽¹⁾ Quantification of the active substances in the feed additive: gas chromatography coupled with flame ionisation detection (GC-FID).</p>	Weaned piglets	—	75	125	<ol style="list-style-type: none"> 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 organisational measures to address potential risks resulting from its 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 skin and eye protections. 	26 February 2030
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⁽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>