

COMMISSION IMPLEMENTING REGULATION (EU) 2021/658**of 21 April 2021****concerning the authorisation of essential oil from *Origanum vulgare* L. subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) 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 ⁽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. Article 4(1) of that Regulation provides for the authorisation of additives.
- (2) In accordance with Article 4(1) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of essential oil from *Origanum vulgare* L. subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) as a feed additive for all animal species.
- (3) The applicant requested the additive to be classified in the additive category 'sensory additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 November 2017 ⁽²⁾ and 4 July 2019 ⁽³⁾ that, under the proposed conditions of use, the essential oil from *Origanum vulgare* L. subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) does not have an adverse effect on animal health, consumer health or the environment. It also concluded that the additive is considered as a potential irritant to skin and eye and a potential respiratory and skin sensitiser in susceptible individuals. 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 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) Article 5(2)(b) of Regulation (EC) No 1831/2003 lays down that additives may not be presented in a manner which may mislead the user. This concerns in particular the presentation of the effects of an additive taking account of the category and group for which it has been authorised. The additive concerned contains some components such as carvacrol and thymol for which zootechnical effects have been demonstrated in certain additives already authorised. In order to prevent that the proposed level of use of 150 mg/kg complete feed is exceeded, having an effect for which this additive is not authorised, it is necessary to establish a maximum content as condition of use of the additive in feed.
- (6) The assessment of that substance shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of essential oil from *Origanum vulgare* L. subsp. *hirtum* (Link) letsw. Var. Vulkan (DOS 00001) should be authorised as specified in the Annex to this Regulation.
- (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⁾ OJL 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2017;15(12):5095.⁽³⁾ EFSA Journal 2019;17(7):5794.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', 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, 21 April 2021.

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 active substance/kg of complete feedingstuff with a moisture content of 12 %			

Category: Sensory additives**Functional group: Flavouring compounds**

2b317eo	—	Essential oil from <i>Origanum vulgare</i> L., subsp. <i>hirtum</i> , (Link) letsw. Var. Vulkan (DOS 00001)	<p><i>Additive composition</i></p> <p>Essential oil from <i>Origanum vulgare</i> L. subsp. <i>hirtum</i> (Link) letsw. Var. Vulkan (DOS 00001).</p> <p><i>Characterisation of the active substance</i></p> <p>Essential oil as defined by the Council of Europe ⁽¹⁾</p> <ul style="list-style-type: none"> — 60-65 % carvacrol; — 1-3 % thymol — 4-9 % γ-terpinene — 5-10 % p-cymene — < 5 % linalool — 2-5 % β caryophyllene — < 1,5 % α-terpinene — < 2 % terpinen-4-ol — 0,3-1,0 % <i>trans</i> sabinene hydrate <p>CoE No: 317 CAS number: 336185-21-8 FEMA: 2660</p> <p><i>Method of analysis</i> ⁽²⁾</p> <p>For the identification of the major constituents and for the quantification of the phytochemical marker (carvacrol) in the feed additive:</p>	All animal species	—	—	150	<ol style="list-style-type: none"> 1. The additive shall be incorporated into feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The mixture of Essential oil from <i>Origanum vulgare</i> L. subsp. <i>hirtum</i> (Link) letsw. Var. Vulkan (DOS 00001) with other authorised additives obtained from <i>Origanum vulgare</i> L. shall not be allowed in feedingstuffs. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and 	12 May 2031
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			<p>— gas chromatography coupled to mass spectrometry and flame ionisation detection (GC-MS and GC-FID)</p> <p>For the determination of Oregano essential oil in premixtures:</p> <p>— water-steam distillation combined with gas chromatography coupled to mass spectrometry and flame ionisation detection (GC-MS and GC-FID)</p>					<p>premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.</p>	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ Details of the methods of analysis are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>