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)

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.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/160. (See end of Document for details)

- (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.

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

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ANNEX

Identifica Niom e	Additive Comp	osi Sipa çies	Maxim	uMinimunMaxim	u 10 ther	End
number of the	chemi	calor	age	content content	provisio	nsf
of the holder		la,categor	y	mg of additive/		period
additive of	descri			kg of complete		of
authori	sation analyt	i¢a a nimal		feedingstuff		authorisation
	metho	d		with a		
				moisture		
				content of 12		
				%		

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

4d19	Biomin		Additive			75	125	1.	2 16
	GmbH	oil,	composi						Hadoruary
		caraway	Preparati	on					2020 tions
		oil,	of:						for
		carvacro	l,—	essential					use
		methyl		oils					of
		salicylat	e	of					the
		and L-		oregano					additive
		menthol		(Origani	ım				and
				vulgare					premixtures,
				L.)					the
				(60-80)					storage
				mg/					conditions
				g) g					and
				and					stability
				caraway					to
				seed					heat
				(Carum					treatment
				carvi					shall
				L.)					be
				(5-10					indicated.
				mg/				2.	For
				g),					users
				carvacro	1				of
				(60-80m					the
				g),					additive
				methyl					and
				salicylat	e				premixtures,
				(10-40					feed
				mg/					business
				g)					operators
				and					shall
				L-					establish
				menthol					operational
				(30-55					procedures
				mg/					and
				g)					organisationa

a 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

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Solid		measures
form		to
Chanadaniadian		address
Characterisation		potential
of the active		risks
		resulting
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oil		use.
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vulgare		those
L.)		risks
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8007-11-2)		eliminated
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of		to
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of		minimum
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mg/g;		such
Caraway		procedures
seed oil		and
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L.)		additive
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		with
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		equipment,
mg/g; Carvacrol		including
oil		skin
(CAS		and
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≥ 99 %		
with a		
content		
of		
carvacrol		
of		
95-140		
mg/g		
(from		
(110111		

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	oregano			
	and			
	pure			
	carvacro	1);		
	Methyl			
	salicylate			
	(CAS			
	number:			
	119-36-8	,		
	L-			
	Menthol			
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	number:			
	2216-51-	8).		
	Analytic	al		
	method ^a			
	Quantific			
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	flame			
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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) EFSA Journal 2019;17(4):5688.

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