

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1421**of 22 August 2022****concerning the authorisation of expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck as feed additives 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 an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Expressed orange essential oil, distilled orange essential oil and folded orange oil were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) 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 expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck for all animal species.
- (4) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The applicant requested those additives to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of these additives in water for drinking should not be allowed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 September 2021 ⁽³⁾ that, under the proposed conditions of use, expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck do not have adverse effects on animal health, consumer health or the environment. However, no conclusions could be drawn for dogs, cats, ornamental fish and ornamental birds not normally exposed to citrus by-products. The Authority also concluded that expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck should be considered as irritants to skin and eyes, and as skin and respiratory sensitisers. 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 additives.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2021;19(11):6891.

- (7) The Authority also concluded, that expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck are recognised to flavour food and their function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. 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.
- (8) The assessment of expressed orange essential oil, distilled orange essential oil and folded orange oils from *Citrus sinensis* (L.) Osbeck shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.
- (9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (10) The fact that the additives are not authorised for use as flavourings in water for drinking does not preclude their use in compound feed which is administered via water.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) 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

Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 12 March 2023 in accordance with the rules applicable before 12 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 12 September 2023 in accordance with the rules applicable before 12 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for 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, 22 August 2022.

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b143-eo	Expressed orange essential oil	<i>Additive composition</i> Expressed orange essential oil from fruit peels of <i>Citrus sinensis</i> (L.) Osbeck ⁽¹⁾ . Liquid form <i>Characterisation of the active substance</i> Essential oil derived by cold expression from fruit peel of <i>Citrus sinensis</i> (L.) Osbeck as defined by the Council of Europe ⁽²⁾ . In the volatile fraction:	Chickens for fattening and other minor poultry species for fattening Laying hens and other minor poultry species for laying and breeding purposes Turkeys for fattening	-	-	80	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other botanical additives is permitted provided that the amounts of perillaldehyde added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animal. 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 premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	12.9.2032
		d-Limonene: 93-97 % Myrcene: 1,5-3,5 % Sabinene: 0,1-1,0 % α-Pinene: 0,4-0,8 % Linalool: 0,1-0,7 % Decanal: 0,1-0,7 % Octanal: 0,1-0,6 %	All <i>Suidae</i> for fattening	-	-	172		
		Piglets of all <i>Suidae</i> species	-	-	144			

Perillaldehyde: < 0,05 % CAS number: 8028-48-6 Einecs number: 232-433-8 FEMA number: 2825 CoE number: 143 Analytical method ⁽³⁾ For the determination of d-limonene (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 3140)	Sows	-	-	200
	Ruminants	-	-	130
	Horses	-	-	230
	Rabbits Fish except ornamental fish	-	-	50
	Other species	-	-	50

⁽¹⁾ Synonyms: *Citrus sinensis* (L.) Pers., *Citrus aurantium* (L.) Dulcis.

⁽²⁾ Natural sources of flavourings – Report No 2 (2007).

⁽³⁾ 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

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b143-di	Distilled orange essential oil	Additive composition	Chickens for fattening and other minor poultry species for fattening	-	-	80	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other botanical additives is permitted provided that the amounts of perillaldehyde added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animals. 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 premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	12.9.2032
		Distillate (volatile fraction) of orange essential oil, which is obtained from fruit peel of <i>Citrus sinensis</i> (L.) Osbeck.						
		Liquid form						
		Characterisation of the active substance						
		Volatile fraction from the distillation of orange essential oil expressed (cold pressed), which is obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck as defined by the Council of Europe ⁽¹⁾ .						
		Turkeys for fattening						
		<i>Suidae</i>						
		d-Limonene: 93-97,5 %						
Myrcene: 1,5-3,5 %	Ruminants	-	-	130				
Sabinene: 0,2-1,0 %								
α-Pinene: 0,3-0,8 %								
Linalool: 0,05-0,5 %								
Octanal: 0,05-0,4 %	Horses	-	-	225				
Perillaldehyde: < 0,005 %								

	CAS number: 8028-48-6 CoE number: 143 <i>Analytical method</i> ⁽²⁾ For the determination of d-limonene (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 3140)	Rabbits	-	-	80	
		Fish except ornamental fish				
		Other species	-	-	80	

⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ 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

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b143-f	Folded orange oil	Additive composition	Chickens for fattening and other minor poultry species for fattening	-	-	15,5	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other botanical additives is permitted provided that the amounts of perillaldehyde added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animals. 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 premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	12.9.2032
		Folded oil obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck.						
		Liquid form	Laying hens and other minor poultry species for laying and breeding purposes	-	-	23,5		
		Characterisation of the active substance						
		Folded oil produced by the fractional distillation of an expressed orange essential oil obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck as defined by the Council of Europe ⁽¹⁾ .	Turkeys for fattening	-	-	21		
		Non-volatile fraction: 10,5 %	All <i>Suidae</i> for fattening	-	-	34		
		In the volatile fraction:	Piglets of all <i>Suidae</i> species	-	-	28,5		
		d-Limonene: 89-96 %						
		Decanal: 0,5-2 %	Sows	-	-	41,5		
		Linalool: 0,7-1,7 %	Calves (milk replacer)	-	-	66,5		
		Myrcene: 0,1-1,0 %						
		Geranial: 0,1-1,0 %						

	Perillaldehyde: < 0,3 % CAS number: 8028-48-6 FEMA number: 2822 <i>Analytical method ⁽²⁾</i> For the determination of d-limonene (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 3140)	Ruminants for fattening	-	-	62,5		
		Dairy ruminants	-	-	40,5		
		Horses	-	-	62,5		
		Rabbits	-	-	25		
		Fish except ornamental fish	-	-	70		
		Other species	-	-	15,5		

⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ 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

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b143-f-i	Folded orange oil	Additive composition	Chickens for fattening and other minor poultry species for fattening	-	-	5,5	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other botanical additives is permitted provided that the amounts of perillaldehyde added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animals. 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 premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	12.9.2032
		Folded oil obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck.						
		Liquid form	Laying hens and other minor poultry species for laying and breeding purposes	-	-	8		
		Characterisation of the active substance						
		Folded oil produced by the fractional distillation of an expressed orange essential oil obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck as defined by the Council of Europe ⁽¹⁾ .	Turkeys for fattening	-	-	7		
		Non-volatile fraction: 20,9 %						
		In the volatile fraction:	All <i>Suidae</i> for fattening	-	-	11,5		
		d-Limonene: 79-89 %						
		Decanal: 3,0-5,0 %	Piglets of all <i>Suidae</i> species	-	-	9,5		
		Linalool: 2,0-5,0 %						
Myrcene: 0,1-1,0 %	Sows	-	-	14				
Geranial: 0,5-1,8 %								
Perillaldehyde: < 0,6 %								

		CAS number: 8028-48-6 FEMA number: 2822	Calves (milk replacer)	-	-	23		
		<i>Analytical method</i> ⁽²⁾ For the determination of d-limonene (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 3140)	Ruminants for fattening	-	-	21,5		
			Dairy ruminants	-	-	14		
			Horses	-	-	21,5		
			Rabbits	-	-	8,5		
			Fish except ornamental fish	-	-	24,5		
			Other species	-	-	5,5		

⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ 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

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 additive/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b143-f-ii	Folded orange oil	<i>Additive composition</i> Folded oil obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck. Liquid form <i>Characterisation of the active substance</i> Folded oil produced by the fractional distillation of an expressed orange essential oil which is obtained from the fruit peel of <i>Citrus sinensis</i> (L.) Osbeck as defined by the Council of Europe ⁽¹⁾. Non-volatile fraction: 18 % In the volatile fraction: d-Limonene: 85-95 % Linalool: 0,5-4 % CAS number: 8028-48-6 FEMA number: 2822	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — Chickens for fattening and other minor poultry species for fattening, laying hens and other minor poultry species for laying and breeding purposes, turkeys for fattening, <i>Suidae</i>: 50 mg; — Calves (milk replacer): 70 mg; — Ruminants except sheep and goats: 60 mg; — Sheep and goats: 70 mg; — Fish, ornamental fish: 2 mg; — Other terrestrial animals: 50 mg'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.	12.9.2032

		<i>Analytical method</i> ⁽²⁾ For the determination of d-limonene (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 3140)					5. 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 premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ 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