COMMISSION IMPLEMENTING REGULATION (EU) 2021/421

of 9 March 2021

concerning the authorisation of tincture derived from *Artemisia vulgaris* L. (mugwort tincture) 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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 4 October 2019 ([2]) and 1 July 2020 ([3]) that, under the proposed conditions of use the tincture derived from *Artemisia vulgaris* L. (mugwort tincture) does not have adverse effects on animal health, consumer health or the environment. The Authority indicated that no conclusions can be drawn on the additive's potential to be a dermal/eye irritant or a skin sensitiser. 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.

(5) The Authority also concluded, that *Artemisia vulgaris* L. and its extracts are universally 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. 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 tincture derived from *Artemisia vulgaris* L. (mugwort tincture) 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 substance should be authorised.

(7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(8) The fact that tincture derived from *Artemisia vulgaris* L. (mugwort tincture) is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(11):5879
([3]) EFSA Journal 2020;18(7):6206

HAS ADOPTED THIS REGULATION:

Article 1

The tincture derived from *Artemisia vulgaris* L. (mugwort tincture) specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed 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, 9 March 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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives									
Functional group: Flavouring compounds									
2b72-t	-	Mugwort tincture	*Additive composition* Tincture produced from the fragmented aerial parts of *Artemisia vulgaris* L. *Characterisation of the active substance* Tincture produced from the fragmented aerial parts of *Artemisia vulgaris* L by extended extraction with a water/ethanol mixture as defined *by the Council of Europe* ([1]). The specifications of the active substance are: Dry matter: 1,4-1,9 % Ash: 0,2-0,5 % Organic fraction: 1,13-1,65 %, of which — Total polyphenols:0,05-0,2 % — Phenolic acids 0,02-0,11 % — Chlorogenic acid: 0,0028-0,0136 % — α- and β-thujone: < 0,005 % — 1,8-cineole:0,005 % — Solvent (ethanol): 98,1-98,6 %	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 and premixtures the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 400 mg/kg' 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.	30.3.2031

			Liquid form CoE No 72 *Analytical method* (2) For the characterisation of the feed additive (Mugwort tincture): — gravimetric method for the determination of loss on drying and the ash content — spectrophotometric method for the determination of total polyphenols content — high performance thin layer chromatography (HPTLC) method for the determination of total phenolic acids, chlorogenic acid, alpha- and beta- thujones and eucalyptol					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 breathing protection, safety glasses and gloves.	

(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://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports