

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/702

of 5 May 2022

concerning the authorisation of great mullein tincture as a feed additive for certain 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of great mullein tincture. That 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 great mullein tincture as a feed additive for all animal species, to be classified in the category 'sensory additives' and in the functional group 'flavouring compounds'.
- (4) The applicant requested great mullein tincture 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 great mullein tincture in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 November 2019 ⁽²⁾ and 24 June 2021 ⁽³⁾ that, under the proposed conditions of use, great mullein tincture does not have adverse effects on animal health, consumer health or the environment. However, no conclusions could be drawn for long-living animals (pets and other non-food producing animals, horses and animals for reproduction). The Authority also concluded that in the absence of data, great mullein tincture should be considered as 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.

⁽¹⁾ OJL 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2019;17(12):5910.

⁽³⁾ EFSA Journal 2021;19(7):6711.

- (6) The Authority further concluded, that great mullein tincture is recognised to flavour food and its 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.
- (7) The assessment of great mullein 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 the substance should be authorised as specified in the Annex to this Regulation.
- (8) The fact that great mullein 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,

HAS ADOPTED THIS REGULATION:

Article 1

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

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 May 2022.

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 additive/kg of complete feed with a moisture content of 12 % | | | |

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

| | | | | | | | | | |
|------------|---|------------------------|--|---|--|---|----|--|-------------|
| 2b475(m)-t | - | Great mullein tincture | <p><i>Additive composition</i></p> <p>Great mullein tincture derived from <i>Verbascum thapsus</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Great mullein tincture derived from <i>Verbascum thapsus</i> L. as defined by the Council of Europe ⁽¹⁾.</p> <p>Dry matter: ≤ 3 % Solvent (water/ethanol): ≤ 97,5 % Ash: ≤ 0,3 % Aucubin: ≤ 0,006 %</p> <p>Polyphenols: ≤ 0,22 % Total flavonoids (chlorogenic acid equivalents): ≤ 0,10 %</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the characterisation of great mullein tincture:</p> | <p>Chickens for fattening</p> <p>Turkeys for fattening</p> <p>Pigs for fattening</p> <p>Calves for fattening Lambs and kids for fattening</p> <p>Salmonids, except for reproduction purposes</p> <p>Rabbits for fattening</p> | | - | 50 | <ol style="list-style-type: none"> The additive shall be incorporated into the feed in the form of a premixture. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. Mixture with other botanical additives is permitted provided that the amounts of aucubin in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category. 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 and eye protection. | 26 May 2032 |
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| | | | <ul style="list-style-type: none"> — 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. | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

⁽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>.