

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1247**of 19 July 2022****concerning the authorisation of Allura Red AC as a feed additive for small non-food producing mammals and ornamental birds****(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(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of Allura Red AC. 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 Allura Red AC as a feed additive for small non-food producing mammals and ornamental birds, to be classified in the category 'sensory additives' and in the functional group 'colourants'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 November 2021 ⁽²⁾ that, under the proposed conditions of use, Allura Red AC does not have adverse effects on animal health, consumer safety or the environment. The Authority could not conclude on the efficacy of Allura Red AC when used in feed for small non-food producing mammals and ornamental birds, considering the wide variety of feedingstuffs used in complete and complementary feed for small non-food producing mammals and ornamental birds, and the uncertainty of which concentration of Allura Red AC would result in a visible effect. However, the Authority also stated that for this additive, which is authorised in food and, where the function for feed is the same as that for food, no further demonstration of efficacy might be necessary. The Authority 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.
- (5) Moreover, Allura red AC is already authorised in feed for cats and dogs by Commission Implementing Regulation (EU) 2020/197 ⁽³⁾ and the Authority concluded, in its opinion of 24 April 2012 ⁽⁴⁾, that Allura Red AC is effective in colouring a typical feed for dogs at a minimum dose of 50 mg/kg, which is similar to the minimum levels proposed by the Authority for this use in small non-food producing mammals and ornamental birds.
- (6) In view of the above, the Commission therefore considers that there is sufficient evidence of the efficacy of this substance.
- (7) The assessment of Allura Red AC 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 as specified in the Annex to this Regulation.
- (8) 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 2021;19(12):6987.

⁽³⁾ Commission Implementing Regulation (EU) 2020/197 of 13 February 2020 concerning the authorisation of allura red AC as a feed additive for cats and dogs (OJ L 42, 14.2.2020, p. 4).

⁽⁴⁾ EFSA Journal 2012;10(5):2675.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants', 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, 19 July 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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a129	Allura Red AC	<p><i>Additive composition:</i> Allura Red AC described as the sodium salt as the principal component.</p> <p>Solid form (powder or granules)</p> <p><i>Characterisation of the active substance:</i> Allura Red AC consists essentially of disodium 2-hydroxy- 1-(2- methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.</p> <p>The calcium and the potassium salts are also permitted. Produced by chemical synthesis</p> <p>Purity criteria: content not less than 85 % total colouring matters, calculated as the sodium salt (assay) Water insoluble matter: ≤ 0,2 % Subsidiary colouring matters: ≤ 3 % Organic compounds other than colouring matters: — 6-hydroxy-2-naphthalene sulfonic acid, sodium salt: ≤ 0,3 %</p>	Guinea pig Chinchilla Degu Hamster Gerbil Chipmunk	-	-	500	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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, eyes and breathing protection.</p>	9 August 2032
			Ferrets Other small non-food producing mammals, except dogs and cats	-	-	99		
			Canaries Budgerigars Mynahs Toucans	-	-	45		
			Lovebirds	-	-	51		
			Cockatiels	-	-	79		
			Cockatoos	-	-	115		
			Amazons	-	-	145		
			Parrots	-	-	147		
			Yellow breast macaws	-	-	150		

	<ul style="list-style-type: none"> — 4-amino-5-methoxy-2- methylbenzene sulfonic acid: ≤ 0,2% — 6,6-oxybis (2-naphthalene sulfonic acid) disodium salt: ≤ 1 % <p>Unulfonated primary aromatic amines: ≤ 0,01 % (calculated as aniline) Ether extractable matter: ≤ 0,2 % from a solution of pH 7</p> <p>Chemical formula: C₁₈H₁₄N₂Na₂O₈S₂ CAS number: 25956-17-6 EINECS number: 247-368-0</p>	Blue-throated macaws	-	-	173		
		Hyacinth macaws	-	-	214		
		Other ornamental birds	-	-	45		
	<p><i>Analytical method</i> ⁽¹⁾</p> <p>For the quantification of Allura Red AC in the feed additive:</p> <ul style="list-style-type: none"> — spectrophotometry at 504 nm (Commission Regulation (EU) No 231/2012 referring to FAO JECFA monographs n. 1 (Vol. 4)) <p>For the quantification of Allura Red AC in feedingstuffs:</p> <ul style="list-style-type: none"> — high performance liquid chromatography coupled to tandem mass spectrometry (LC- MS/MS) 						

⁽¹⁾ 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