

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/107****of 23 January 2020****concerning the authorisation of ponceau 4R as a feed additive for dogs, cats and ornamental fish****(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 <sup>(1)</sup>, 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. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup>.
- (2) Ponceau 4R was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for ornamental fish belonging to the group 'colourants, including pigments', under the heading 'other colourants'. It was also authorised without a time limit as a feed additive for dogs and cats belonging to the group 'colourants, including pigments', under the heading 'colouring agents authorised for colouring foodstuffs by Community rules'. The additive was subsequently entered in the Register of feed additives as an existing product, 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 ponceau 4R as a feed additive for ornamental fish and for dogs and cats. The applicant requested the additive to be classified in the additive category 'sensory additive' and in the functional group 'colourants'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2018 <sup>(3)</sup> that, under the proposed conditions of use, ponceau 4R does not have an adverse effect on animal health. It also concluded that the inhalation exposure to additive is regarded as hazardous for the user of the additive and that no conclusion could be drawn on the irritancy potential to skin or eyes and on the skin 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. In accordance with Commission Regulation (EC) No 429/2008 <sup>(4)</sup>, phase I of the environmental risk assessment has determined that ponceau 4R, as an additive intended for non-food producing animals, is exempted from further assessment due to the unlikelihood of a significant environmental effect, there being no scientifically-based evidence for concern having been identified by the Authority in its above-mentioned opinion. The Authority also stated that for this additive, which is also authorised in food, where the function is the same as that for feed, no further demonstration of efficacy might be necessary. However, the Authority, considering the wide variety of feedingstuffs, requested further demonstration. The applicant demonstrated the efficacy in a typical feed matrix for 50 mg/kg but also indicated that for other matrixes (colour in petfood may range from almost white to dark brown) lower levels may be used specially in pale matrixes (the applicant provided in the dossier some evidence for lower levels). As the recommended maximum level proposed by the Authority for this additive is similar to the levels authorised for food in different types of products, the Commission considered that there is sufficient evidence of the efficacy of this substance. 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.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

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

<sup>(3)</sup> *EFSA Journal* 2018; 16(3):5222.

<sup>(4)</sup> Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

- (5) The assessment of ponceau 4R 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 additive should be authorised as specified in the Annex to this Regulation.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) 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 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*

**Transitional measures**

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 13 August 2020 in accordance with the rules applicable before 13 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substance specified in the Annex which are produced and labelled before 13 February 2022 in accordance with the rules applicable before 13 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

*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, 23 January 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## 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 of active substance of kg of complete feedingstuff with a moisture content of 12 %			

**Category: Sensory additives. Functional group: Colourants.** (i) substances that add or restore colour in feedingstuffs

2a124	Ponceau 4R	<p><i>Additive composition</i> Ponceau 4R described as the sodium salt as the principal component. Solid form (powder or granules)</p>	Cats	—	—	31	<p>1. In the directions for use of the additive and premixture, 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 eye, skin, oral and breathing protection.</p>	13 February 2030
		<p><i>Characterisation of the active substance as the sodium salt</i> Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also permitted Chemical formula: <math>C_{20}H_{11}N_2O_{10}S_3Na_3</math> Solid form (powder or granules) produced by chemical synthesis CAS No: 2611-82-7 Purity criteria — Total colouring matters calculated as the sodium salt <math>\geq 80</math> % (assay); — Subsidiary colouring matter <math>\leq 1</math> %; — Organic compounds other than colouring matters <math>\leq 0,5</math> %; — Unsulfonated primary aromatic amines (calculated as aniline) <math>\leq 0,01</math> %.</p>	Dogs	—	—	37		
		<p><i>Analytical method <sup>(1)</sup></i> For the quantification of total colouring matters content of ponceau 4R in the feed additive: Spectrophotometry at 505 nm and titration with Titanous chloride as described in Commission Regulation (EU) No 231/2012 referring to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4); and the Monograph No 11 (2011) 'Ponceau 4R'. For the quantification of ponceau 4R in feedingstuffs:</p>						

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 of active substance of kg of complete feedingstuff with a moisture content of 12 %			
		High performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)						

**Category: Sensory additives. Functional group: Colourants.** (iii) substances which favourably affect the colour of ornamental fish or birds

2a124	Ponceau 4R	<p><i>Additive composition</i> Ponceau 4R described as the sodium salt as the principal component. Solid form (powder or granules)</p> <p><i>Characterisation of the active substance as the sodium salt</i> Ponceau 4R consists essentially of trisodium 2-hydroxy-1-(4-sulfonato-1-naphthylazo) naphthalene-6,8-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components The calcium and the potassium salts are also permitted Chemical formula: <math>C_{20}H_{11}N_2O_{10}S_3Na_3</math> Solid form (powder or granules) produced by chemical synthesis CAS No: 2611-82-7 Purity criteria — Total colouring matters calculated as the sodium salt <math>\geq 80</math> % (assay); — Subsidiary colouring matter <math>\leq 1</math> %; — Organic compounds other than colouring matters <math>\leq 0,5</math> %; — Unsulfonated primary aromatic amines (calculated as aniline) <math>\leq 0,01</math> %.</p> <p><i>Analytical method <sup>(1)</sup></i> For the quantification of total colouring matters content of ponceau 4R in the feed additive: Spectrophotometry at 505 nm and titration with Titanous chloride as described in Commission Regulation (EU) No 231/2012 referring to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4); and the Monograph No 11 (2011) 'Ponceau 4R'. For the quantification of ponceau 4R in feeding-stuffs:</p>	Ornamental fish	—	—	137	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</li> <li>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 eye, skin, oral and breathing protection.</li> </ol>	13 February 2030
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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 of active substance of kg of complete feedingstuff with a moisture content of 12 %			
		High performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)						

(<sup>1</sup>) 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>