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►**B**

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1097

of 24 July 2020

concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

(Text with EEA relevance)

(OJ L 241, 27.7.2020, p. 23)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2021/420 of 9 March 2021	L 83	16	10.3.2021

▼B

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1097

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(Text with EEA relevance)

Article 1

The substances specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants: (ii) substances which, when fed to animals, add colours to food of animal origin’, are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The authorised substances specified in the Annex shall not be used in water for drinking

Article 3

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 16 February 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 16 August 2021 in accordance with the rules applicable before 16 August 2020 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 4

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.

▼M1

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 total carotenoids/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
2a161b	Lutein-rich extract	*Additive composition* Lutein-rich extract of *Tagetes erecta* Benzene ≤ 2mg/kg *Characterisation of the active substance* Lutein from a saponified extract of *Tagetes erecta* (dried flowers petals) obtained via extraction and saponification: — Total carotenoids (TC):≥ 60g/kg — Lutein ≥ 75 % of total carotenoids (TC) — Zeaxanthin≥ 4 % of total carotenoids (TC) Chemical formula: $C_{40}H_{56}O_2$ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form *Analytical method* (1) — For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) No 231/2012 referring to FAO JECFA monograph 'lutein from *Tagetes erecta*' monograph No 3 (2006), Combined Compendium for Food Additive Specifications	Chickens for fattening and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein-rich extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein-rich extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 80 mg/kg of complete feed. 4. 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 and skin protection	30.3.2031
			Laying hens and minor poultry for laying.	-	-	80		

▼M1

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 total carotenoids/kg of complete feedingstuff with a moisture content of 12 %			
		— For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis) — For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64						
2a161bi	Lutein/zeaxanthin extract	*Additive composition* Lutein/zeaxanthin extract of *Tagetes erecta.* Benzene ≤ 2mg/kg	Chickens for fattening and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein/zeaxanthin extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein/zeaxanthin extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of: a. 80 mg/kg of complete feed for chickens for fattening, minor poultry for fattening and laying hens. b. 50 mg/kg of complete feed for minor poultry for laying.	30.3.2031
		Characterisation of the active substance Lutein/zeaxanthin saponified/isomerised extract of *Tagetes erecta* (dried flowers petals) obtained via extraction, saponification and isomerisation: — Total carotenoids (TC):≥ 60g/kg — Lutein ≥ 37 % of TC; — Zeaxanthin ≥ 36 % of TC. Liquid form CAS number 127-40-2(lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Chemical formula: $C_{40}H_{56}O_2$	Laying hens			80		
			Minor poultry for laying.			50		
		Analytical method ([1]) For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive:		-	-			

▼M1

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 total carotenoids/kg of complete feedingstuff with a moisture content of 12 %			
		— High Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Directive 2008/128/EC referring to FAO JECFA monograph 'lutein from *Tagetes erecta*' monograph No 3 (2006), Combined Compendium for Food Additive Specifications For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: — High Performance Liquid Chromatography with visible detection (HPLC-Vis) For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: — Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64					4. 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 and skin protection.	

([1]) 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