

EN
ANNEX

Identi- fication 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 authorisa- tion
					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: Preparation of lutein-rich extract of <i>Tagetes erecta</i> L. with total carotenoids $\geq 0,5\%$ Benzene ≤ 2 mg/kg Hexane ≤ 290 mg/kg Solid or liquid form Characterisation of the active substance: Lutein from a saponified extract of <i>Tagetes erecta</i> L. (dried flowers petals) obtained via extraction with hexane and saponification: – Total carotenoids (TC): ≥ 60 g/kg – Lutein $\geq 75\%$ of total carotenoids (TC) – Zeaxanthin $\geq 4\%$ 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	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. The mixture of lutein-rich extract with other authorised carotenoids shall not exceed a total carotenoids content of 80 mg/kg of complete feed. 3. 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	16.08.2030
			Laying hens and minor poultry for laying	-	-	80		

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					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								
		Analytical method¹ For the determination of lutein, zeaxanthin and total carotenoids in the feed additive: – High performance liquid chromatography (HPLC) with spectrophotometry – FAO JECFA monograph “Lutein from <i>Tagetes erecta</i> ”, Combined Compendium of Food Additive Specifications For the determination of total carotenoids (including lutein) in premixtures and compound feed: – Reversed-phase high performance liquid chromatography (HPLC) coupled to UV detection - EN 17550						
2a161bi	Lutein/ zeaxanthin extract	Additive composition: Preparation of lutein/zeaxanthin extract of <i>Tagetes erecta</i> L. with total carotenoids ≥ 0,5% Benzene ≤ 2 mg/kg Hexane ≤ 290 mg/kg Solid or liquid form	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. The mixture of lutein/zeaxanthin extract with other authorised carotenoids	16.08.2030
			Laying hens	-	-	80		

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

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Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
		Characterisation of the active substance: Lutein/zeaxanthin saponified/isomerised extract from dried flowers petals of <i>Tagetes erecta</i> L. obtained via extraction with hexane, saponification and isomerisation: – Total carotenoids (TC) :≥ 60 g/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: C₄₀H₅₆O₂ Analytical method² For the determination of lutein, zeaxanthin and total carotenoids in the feed additive: - High performance liquid chromatography (HPLC) with spectrophotometry – FAO JECFA monograph “Lutein from <i>Tagetes erecta</i>”, Combined Compendium of Food Additive Specifications For the determination of total carotenoids (including lutein) in premixtures and compound feed: - Reversed-phase high performance	Minor poultry for laying	-	-	50	shall not exceed a total carotenoids 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. 3. 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.	

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		liquid chromatography (HPLC) coupled to UV detection - EN 17550						