

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 active substance of 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								
2a494	Lutein-rich extract	<b>Additive composition:</b> Lutein-rich extract of <i>Tagetes erecta</i> <i>Benzene</i> ≤ 2mg/kg ----- <b>Characterisation of the active substance:</b> Lutein from a saponified/isomerised extract of <i>Targetes erecta</i> (dried flowers petals) obtained via extraction and saponification: – Total carotenoids (TC):≥ 60g/kg – Lutein ≥ 75% of total carotenoids (TC) – Zeaxantin≥ 4% of total carotenoids (TC)  Chemical formula: C <sub>40</sub> H <sub>56</sub> O <sub>2</sub> CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form ----- <b>Analytical method<sup>1</sup></b> – For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xantophylls in the feed additive:	Poultry for fattening, (except turkeys) and minor poultry for fattening	-	-	80	<div>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</div> <div>2. Lutein-rich extract may be placed on the market and used as an additive consisting of a preparation.</div> <div>3. The mixture of lutein-rich extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xantophylls of 80 mg/kg of complete feed.</div> <div>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</div>	<div><i>[to be completed by the Service responsible for the publication: insert precise date]</i></div> <div>[10 years from the date of entry into force of this Regulation]</div>
			Poultry for laying (except turkeys) and minor poultry for laying	-	-	80		

<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>

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Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
		<div>high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) 231/2012 referring to FAO JECFA monograph ‘lutein from <i>Tagetes erecta</i>’ monograph No. 3 (2006), Combined Compendium for Food Additive Specifications</div> <div>– For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis)</div> <div>– For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64</div>					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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Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
		<p>spectrophotometry – Commission Directive 2008/128/EC referring to FAO JECFA monograph ‘lutein from <i>targetes erecta</i>’ monograph No. 3 (2006), Combined Compendium for Food Additive Specifications</p> <p>For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs:</p> <p>- High Performance Liquid Chromatography with visible detection (HPLC-Vis)</p> <p>For the determination of total carotenoids and xantophylls in premixtures and feedingstuffs:</p> <p>- Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64</p>		-	-	50 (alone or with other carotenoids)	including eye and skin protection.	