

## EN

ANNEX

Ident-ification number of the additive	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi-mum age	Minimu-m content	Maximu-m content	Other provisions	End of period of authorisa-tion	
					mg of active substance/kg of complete feed with a moisture content of 12%				
<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect</b>									
3a160	Beta-carotene	<b>Additive composition</b> Beta-carotene Solid form Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg of the additive.  <b>Characterisation of the active substance</b> Beta-carotene $C_{40}H_{56}$ CAS number: 7235-40-7 Beta-carotene, solid form, produced by chemical synthesis.  <i>Purity criteria:</i> — (assay) min. 96 % total colouring matters (dried substance) expressed as beta-carotene, — carotenoids other than beta-carotene ≤ 3 % of total colouring matters.	Calves (milk replacers)	-	-	50	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated.  [10 years from the date of entry into force of this Regulation. To be completed by the OP]		
			Other animal species and categories	-	-	-			

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<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect</b>								
		<p><b>Analytical method<sup>1</sup></b></p> <p>For the determination of beta-carotene in the feed additive:</p> <ul style="list-style-type: none"> <li>- Spectrophotometry – Food Chemical Codex “β-Carotene monograph”.</li> </ul> <p>For the determination of beta-carotene in premixtures and compound feed:</p> <ul style="list-style-type: none"> <li>- Reversed-phase high performance liquid chromatography (HPLC) coupled to UV detection – EN 17550.</li> </ul>						

<sup>1</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

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<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect</b>								
3a160i	Beta-carotene	<p><b>Additive composition</b>            Preparation of beta-carotene with a minimum of 10% of beta-carotene.            Solid form            Triphenylphosphine oxide (TPPO)            ≤ 100 mg/kg of the additive.</p> <p><b>Characterisation of the active substance</b>            Beta-carotene  <math>C_{40}H_{56}</math>            CAS number: 7235-40-7            Beta-carotene, solid form, produced by chemical synthesis.</p> <p><b>Purity criteria:</b>            — (assay) min. 96 % total colouring matters (dried substance) expressed as beta-carotene,            — carotenoids other than beta-carotene            ≤ 3 % of total colouring matters.</p> <p><b>Analytical method<sup>2</sup></b>            For the determination of beta-carotene in the feed additive:            - Spectrophotometry</p>	Calves (milk replacers)  Other animal species and categories	-  -	50	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions and the 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 their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.</li> </ol>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>	

<sup>2</sup> 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

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					mg of active substance/kg of complete feedingstuff with a moisture content of 12%				
<b>Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect</b>									
		For the determination of beta-carotene in premixtures and compound feed: - Reversed-phase high performance liquid chromatography (HPLC) coupled to UV detection - EN 17550							