

## 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/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a841	“Calcium D-panthotenate” or “vitamin B <sub>5</sub> ”	<p><b>Additive composition</b></p> <p>Calcium D-pantothenate.</p> <p><b>Characterisation of the active substance</b></p> <p>Calcium D-pantothenate</p> <p>Chemical formula: Ca[C<sub>9</sub>H<sub>16</sub>NO<sub>5</sub>]<sub>2</sub></p> <p>CAS number: 137-08-6</p> <p>Calcium D-pantothenate, solid form, produced by chemical synthesis.</p> <p>Purity criteria:</p> <div><div>1.</div><div>Min. 98 % (on dry basis);</div></div> <div><div>2.</div><div>Max. 0,5 % 3-aminopropionic acid.</div></div> <p><b>Analytical method <sup>1</sup></b></p> <div><div>–</div><div>For the determination of Calcium D-pantothenate in the feed additive: potentiometric titration with perchloric acid and identification by specific optical rotation (European Pharmacopoeia Monograph 0470);</div></div> <div><div>–</div><div>For the determination of Calcium D-pantothenate in water, premixtures and compound feed: High Performance Liquid Chromatography coupled to mass spectrometry (HPLC-MS).</div></div>	All animal species	-	-	-	<div><div>1.</div><div>The additive may be used via water for drinking.</div></div> <div><div>2.</div><div>The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking.</div></div> <div><div>3.</div><div>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 personal breathing protective equipment.</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

<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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Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a842	“D- Panthenol” or “vitamin B <sub>5</sub> ”	<b>Additive composition</b>  D-Panthenol  <b>Characterisation of the active substance</b>  D-Panthenol  Chemical formula: C <sub>9</sub> H <sub>19</sub> NO <sub>4</sub>  CAS number: 81-13-0  D-Panthenol, liquid form, produced by chemical synthesis.  Purity criteria:  1. Min. 98 % on anhydrous basis (water < 1 %) 2. Max. 0,5 % 3-aminopropionic acid.  <b>Analytical method <sup>2</sup></b>  — For the determination of D- panthenol in the feed additive: titration with perchloric acid and potassium hydrogen phthalate and identification by specific optical rotation and infrared spectroscopy (European Pharmacopoeia monograph 0761).  — For the determination of D- panthenol in water: Reverse Phase High-Performance Liquid Chromatography, coupled to UV detector (RP-HPLC-UV).	All animal species	-	-	-	1. The additive may be used via water for drinking.  2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking.  3. 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 personal skin, eye and breathing protective equipment.	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

<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).

