

ANNEX

Identification number of the additive	Name of the 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 feed with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a820	‘Thiamine hydrochloride’ or ‘Vitamin B ₁ ’	Additive composition Thiamine hydrochloride Solid form Characterisation of active substance Thiamine hydrochloride Chemical formula: C ₁₂ H ₁₇ CIN ₄ OS•HCl CAS number: 67-03-8 Purity: minimum 98,5% on anhydrous basis Produced by chemical synthesis Analytical method¹ For the characterisation of thiamine hydrochloride in the feed additive: - high performance liquid chromatography with UV detection (HPLC-UV) — US Pharmacopeia (‘thiamine hydrochloride’ monograph). For the quantification of thiamine hydrochloride in premixtures: - ion-exchange high performance liquid chromatography coupled to UV detector (HPLC- UV) - <u>VDLUFA</u> Bd. III, 13.9.1, or	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water shall be indicated. 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 breathing, eye and skin protective equipment.	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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>.

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Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
		<p>— reversed phase high performance liquid chromatography coupled to fluorescence detection (HPLC-FLD) - decree 20.2.2006, Official Italian Journal No 50, 1.3.2006.</p> <p>For the quantification of thiamine hydrochloride in compound feed:</p> <p>- reversed phase high performance liquid chromatography coupled to fluorescence detection (HPLC-FLD) - decree 20.2.2006, Official Italian Journal No 50, 1.3.2006.</p> <p>For the quantification of thiamine hydrochloride in water for drinking:</p> <p>- reversed phase high performance liquid chromatography with post-column derivatisation and fluorescence detection (HPLC-FLD).</p>						

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					mg of active substance/kg of complete feed with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a821	‘Thiamine mononitrate’ or ‘Vitamin B ₁ ’	Additive composition Thiamine mononitrate Solid form Characterisation of active substance Chemical formula: C ₁₂ H ₁₇ N ₄ OS•NO ₃ CAS number: 532-43-4 Purity: minimum 98 % on anhydrous basis Produced by chemical synthesis Analytical method² For the characterisation of thiamine mononitrate in the feed additive: - high performance liquid chromatography with UV detection (HPLC-UV) — US Pharmacopeia (‘thiamine mononitrate’ monograph). For the quantification of mononitrate in premixtures: - ion-exchange high performance liquid chromatography coupled to UV detector (HPLC- UV) - VDLUFA Bd. III, 13.9.1, or — reversed phase high performance liquid chromatography coupled to fluorescence detection (HPLC-FLD) - decree 20.2.2006, Official Italian Journal No 50, 1.3.2006.	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water shall be indicated. 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 breathing, eye and skin protective equipment.	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
		For the quantification of thiamine mononitrate in compound feed: - reversed phase high performance liquid chromatography coupled to fluorescence detection (HPLC-FLD) - decree 20.2.2006, Official Italian Journal No 50, 1.3.2006. For the quantification of thiamine mononitrate in water for drinking: - reversed phase high performance liquid chromatography with post-column derivatisation and fluorescence detection (HPLC-FLD).						