

EN

ANNEX

Identifi- cation number of the feed additive	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimu	Maximum content	Other provisions	End of period of authorisation
					m content	mg active substance/kg of complete feed with a moisture content of 12%		
Category: Nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect								
3a836	‘Cyanocob alamin’ or ‘Vitamin B ₁₂ ’	Additive composition: Cyanocobalamin Solid form Characterisation of the active substance: Cyanocobalamin $C_{63}H_{88}CoN_{14}O_{14}P$ CAS number: 68-19-9 Purity: ≥96% on dry basis; loss of drying 12% Produced by fermentation with <i>Ensifer adhaerens</i> CGMCC 19596	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 2. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 040 IU/m ³ air ² . 3. For users of the additive and	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

² The exposure is calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2023;21(4):7972)

	<p>Analytical method¹</p> <p>For the quantification of cyanocobalamin in the feed additive: European Pharmacopoeia method (Eur. Ph. 0547) based on spectrophotometry (UV/VIS)</p> <p>For the quantification of cyanocobalamin in compound feed: reversed phase high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV)</p>						premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 and skin protective equipment.	
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¹ 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>