ANNEX

Identi- fication number Additive of the additive	Composition, chemical formula, description, analytical method	Specie s or catego ry of animal	Maxi mum age	complete f	ce/kg of eedingstuff noisture		Other provisions	End of period of authorisa- tion
Category of nutritional	additives. Functional group: vitamins, pro-vitamins and	chemicall	y well-def	ined substanc	es having sin	nilar	effect	
3a880 Biotin	Additive composition Biotin Characterisation of the active substance D-(+)-biotin C ₁₀ H ₁₆ N ₂ O ₃ S CAS number: 58-85-5 Biotin, solid form, produced by chemical synthesis Purity criteria: min. 97 % Analytical method ¹ For the determination of D-(+)-biotin in feed additive: potentiometric titration assay and optical rotation identification (European Pharmacopeia monograph 1073). For the determination of Biotin in the feed additive,	All animal species	-	-	-	1. 2. 3.	The additive may be used via water for drinking. 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. 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	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

¹Details 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

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Specie s or catego ry of animal	Maxi mum age	substan complete f with a r	Maximu m content active ce/kg of eedingstuff noisture of 12%	Other provisions	End of period of authorisa- tion
Category o	of nutritional a	dditives. Functional group: vitamins, pro-vitamins and	l chemicall	y well-def	ined substanc	es having sim	ilar effect	
		For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).						

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	of complete f	Maximum content substance/kg redingstuff are content of	Ot	her provisions	End of period of authorisa- tion
Category (of nutritional add	litives. Functional group: vitamins, pro-vitamins and chemica	lly well-def	ined substa	nces having sir	nilar effect			
3a880i	Biotin	Additive composition	All	-	-	-	1.	The additive may be used via	[10 years
		Preparation containing 2% of biotin Solid form Characterisation of the active substance D-(+)-biotin C ₁₀ H ₁₆ N ₂ O ₃ S CAS number: 58-85-5	animal species				2.	water for drinking. 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.	from the date of entry into force of this Regulation. To be completed by the OP]
		Biotin, solid form, produced by chemical synthesis Purity criteria: min. 97 %					3.	For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to	

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	of complete f	Maximum content substance/kg feedingstuff ure content of	Other provisions	End of period of authorisa- tion
Category o	f nutritional add	For the determination of Biotin in the feed additive, premixtures and compound feed: Reversed Phase High Performance Liquid Chromatography coupled to mass spectrometry (RP-HPLC-MS/MS). For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).	lly well-def	ined substa	nces having sin	nilar effect	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.	

²Details 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

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	of complete	Maximum content substance/kg feedingstuff ure content of		Other provisions	End of period of authorisa- tion
Category (of nutritional ad	ditives. Functional group: vitamins, pro-vitamins and chemica	illy well-def	ined substa	nces having si	nilar effect			
3a880ii	Biotin	Additive composition	All animal	-	-	-	1.	The additive may be used via water for drinking.	[10 years from the date
		Preparation containing 10% of biotin	species					water for drinking.	of entry into
		Solid form	species				2.	The directions for use of the	force of this
								additive and premixtures shall	Regulation.
								indicate the storage conditions,	To be
		Characterisation of the active substance						the stability to heat treatment	completed by
		D-(+)-biotin						and the stability in water for	the OP]
		$C_{10}H_{16}N_2O_3S$						drinking.	_
		CAS number: 58-85-5					_	D 04 112 1	
		Biotin, solid form, produced by chemical synthesis					3.	For users of the additive and	
		Purity criteria: min. 97 %						premixtures, feed business operators shall establish	
								operational procedures and	
		Analytical method ³						organisational measures to	
								address potential risks	
		For the determination of D-(+)-biotin in feed additive:						resulting from their use.	
		potentiometric titration assay and optical rotation						Where those risks cannot be	
		identification (European Pharmacopeia monograph 1073).						eliminated by such procedures	
		For the determination of Biotin in the feed additive,						and measures, the additive and	
		premixtures and compound feed: Reversed Phase High						premixtures shall be used with	
		Performance Liquid Chromatography coupled to mass						personal breathing protective	
		spectrometry (RP-HPLC-MS/MS).						equipment.	
		specialists (Id -III De-Ivio/Ivio).							

³Details 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

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	of complete f	Maximum content substance/kg Feedingstuff ure content of	Other provisions	End of period of authorisa- tion
Category o	f nutritional add	itives. Functional group: vitamins, pro-vitamins and chemica For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).	lly well-def	ined substa	nces having sin	nilar effect		