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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	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg betaine/kg of complete feed with a moisture content of 12 %		mg betaine/l of water for drinking			
Category: nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect										
3a920	Betaine anhydrous	Additive composition	Poultry	-	-	2 000	-	1 000	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Simultaneous use of this additive in water for drinking and in feed is not permitted. 4. 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	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]
		Betaine anhydrous								
		Solid form	Pigs	-	-	2 000	-	700		
		Characterisation of the active substance	Calves for rearing	-	-	2 000	-	250		
		Betaine anhydrous (2-(trimethylazaniumyl)acetate) ≥ 97% (on anhydrous basis), produced by chemical synthesis or by extraction from sugar beet molasses or vinasses (by-products of sugar production).	All other animal species	-	-	2 000	-	-		
		C ₅ H ₁₁ NO ₂								
CAS number: 107-43-7										

		Method of Analysis¹ For the determination of betaine anhydrous in the feed additive, premixtures, compound feed and water: High- Performance Liquid Chromatography with refractive index detection (HPLC-RI).							skin, eye and breathing protective equipment. 5. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of betaine administered via water for drinking is not higher than what it would be if fed at the maximum content of 2 000 mg/kg complete feed.	
3a920i	Betaine anhydrous	Additive composition Preparation containing a minimum of betaine anhydrous of 96% Solid form Characterisation of the active substance Betaine anhydrous (2-(trimethylazaniumyl)acetate) ≥ 97% (on anhydrous basis), produced by chemical synthesis or by extraction from sugar beet molasses or vinasses by-products of sugar production. C ₅ H ₁₁ NO ₂ CAS number: 107-43-7	Poultry Pigs Calves for rearing All other animal species	- - - -	- - - -	2 000 2 000 2 000 2 000	- - - -	1 000 700 250 -	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Simultaneous use of this additive in water for drinking and in feed is not permitted. 4. 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	<i>[10 years from the date of entry into force of this Regulation.</i> <i>To be completed by the Service responsible for the publication]</i>

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_en

		Method of Analysis¹ For the determination of betaine anhydrous in the feed additive, premixtures, compound feed and water: High- Performance Liquid Chromatography with refractive index detection (HPLC-RI).							skin, eye and breathing protective equipment. 5. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of betaine administered via water for drinking is not higher than what it would be if fed at the maximum content of 2 000 mg/kg complete feed.	
3a920ii	Liquid betaine	Additive composition Preparation containing ≥ 38 % of betaine Liquid form Characterisation of the active substance Betaine anhydrous (2-(trimethylazaniumyl)acetate) produced by extraction from sugar beet molasses or vinasses (by-products of sugar production). C ₅ H ₁₁ NO ₂ CAS number: 107-43-7 Method of Analysis¹ For the determination of betaine anhydrous in the feed additive, premixtures, compound feed and water: High- Performance Liquid Chromatography with	Poultry Pigs Calves for rearing All other animal species	- - - -	- - - -	2 000 2 000 2 000 2 000	- - - -	1 000 700 250 -	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Simultaneous use of this additive in water for drinking and in feed is not permitted. 4. 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. 5. Taking account of the actual intake of water for drinking relative to feed by the animals,	<i>[10 years from the date of entry into force of this Regulation.</i> <i>To be completed by the Service responsible for the publication]</i>

		refractive index detection (HPLC-RI).							it shall be ensured that the amount of betaine administered via water for drinking is not higher than what it would be if fed at the maximum content of 2 000 mg/kg complete feed.	
3a925	Betaine hydrochloride	Additive composition Betaine hydrochloride Solid form Characterisation of the active substance Betaine hydrochloride (carboxymethyl)trimethylazanium chloride ≥ 98 % (on anhydrous basis), produced by chemical synthesis. Chemical formula: C₅H₁₁NO₂·HCl CAS number: 590-46-5 Method of Analysis¹ For the determination of betaine hydrochloride in the feed additive: - Titration with perchloric acid (US Pharmacopeia 31, Betaine hydrochloride monograph.); or - High Performance Liquid Chromatography	Poultry Pigs Calves for rearing All other animal species	- - - -	- - - -	2 000 2 000 2 000 2 000	- - - -	1 000 700 250 -	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Simultaneous use of this additive in water for drinking and in feed is not permitted. 4. 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. 5. Taking account of the actual intake of water for drinking relative to feed by the animals, it shall be ensured that the amount of betaine administered via water for drinking is not higher than what it would be if	<i>[10 years from the date of entry into force of this Regulation.</i> <i>To be completed by the Service responsible for the publication]</i>

		with refractive index detection (HPLC-RI). For the determination of betaine hydrochloride in premixtures, compound feed and water: High-Performance Liquid Chromatography with refractive index detection (HPLC-RI).							fed at the maximum content of 2 000 mg/kg complete feed.	
3a925i	Betaine hydrochloride	Additive composition Preparation containing a minimum of betaine hydrochloride of 95 % Solid form Characterisation of the active substance Betaine hydrochloride (2-(trimethylazaniumyl) acetate hydrochloride) ≥ 98 % (on anhydrous basis), produced by chemical synthesis. Chemical formula: $C_5H_{11}NO_2 \cdot HCl$ CAS number: 590-46-5 Method of Analysis¹ For the determination of betaine hydrochloride in the feed additive:	Poultry Pigs Calves for rearing All other animal species	-	-	2 000	-	1 000	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Simultaneous use of this additive in water for drinking and in feed is not permitted. 4. 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. 5. Taking account of the actual intake of water for drinking	<i>[10 years from the date of entry into force of this Regulation.</i> <i>To be completed by the Service responsible for the publication]</i>

		- Titration with perchloric acid (US Pharmacopeia 31, Betaine hydrochloride monograph.); or - High Performance Liquid Chromatography method with refractive index detection (HPLC-RI). For the determination of betaine hydrochloride in premixtures, compound feed and water: High-Performance Liquid Chromatography with refractive index detection (HPLC-RI).							relative to feed by the animals, it shall be ensured that the amount of betaine administered via water for drinking is not higher than what it would be if fed at the maximum content of 2 000 mg/kg complete feed.	
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