

ANNEX

Identification number of the additive	Name of the holder of authorisation	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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12%			
Category of nutritional additives. Functional group: compounds of trace elements									
3b615	-	Zinc chelate of lysine and glutamic acid	<p>Additive composition: Mixture of chelates of zinc with lysine and chelates of zinc with glutamic acid in a ratio of 1:1 as a powder with a zinc content between 17 % and 19% and a maximum of 3% moisture</p> <p>-----</p> <p>Characterisation of the active substances: Chemical formulas: Zinc-2,6-diaminohexanoic acid: C₆H₁₉ClN₂O₈SZn Zinc-2-aminopentanedioic acid: C₅H₈NNaO₈SZn</p> <p>-----</p> <p>Analytical methods*: For the quantification of the lysine and glutamic acid content in the feed additive:</p> <ul style="list-style-type: none">– ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) <p>For the quantification of total zinc in the feed additive:</p> <ul style="list-style-type: none">– inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15621) or– atomic absorption spectrometry, AAS (ISO 6869) <p>For proving the chelated structure of the feed additive:</p> <ul style="list-style-type: none">– mid-infrared (IR) spectrometry together	All animal species	-	-	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	<ol style="list-style-type: none">1. The additive shall be incorporated into feed in the form of a premixture.2. Zinc chelate of lysine and glutamic acid may be placed on the market and used as an additive consisting of a preparation.3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall	<i>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</i>

			<p>with the determination of the content of the trace element and lysine and glutamic acid in the feed additive</p> <p>For the quantification of total zinc in premixtures:</p> <ul style="list-style-type: none"> – inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or – atomic absorption spectrometry, AAS (ISO 6869) or – inductively coupled plasma mass spectrometry, ICP-MS (EN 17053) <p>For the quantification of total zinc in feed materials and compound feed:</p> <ul style="list-style-type: none"> – inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or – atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or – inductively coupled plasma mass spectrometry, ICP-MS (EN 17053) 					<p>be used with appropriate personal protective equipment, including breathing protection.</p>	
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* 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>