

EN
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 (Mn) in mg/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: compounds of trace elements.									
3b509	-	Manganese chelate of lysine and glutamic acid	<p>Additive composition: Mixture of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with a manganese content between 15 and 17%, a lysine content between 20 and 21,5%, a glutamic acid content between 22 and 24%, a maximum of 3,5% moisture and a maximum of 4 ppm nickel.</p> <p>-----</p> <p>Characterisation of the active substances: Chemical formulas: Manganese-2,6- diaminohexanoic acid, chloride and hydrogen sulfate salt: C₆H₁₉ClN₂O₈SMn Manganese-2-aminopentanedioic acid, sodium and hydrogen sulfate salt: C₅H₁₀NNaO₉SMn</p> <p>-----</p> <p>Analytical methods*: For the quantification of total manganese in the feed additive and premixtures:</p> <ul style="list-style-type: none">- Atomic Absorption Spectrometry, AAS (EN ISO 6869); or- Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or- Inductively Coupled Plasma – Atomic Emission	All animal species	-	-	Fish: 100 (total) Other species: 150 (total)	<ol style="list-style-type: none">1. The additive shall be incorporated into feed in the form of a premixture.2. [Manganese 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 contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot	[10 years from the date of entry into force of this Regulation . To be completed by the Service responsible for the publication]

			<p>Spectrometry after pressure digestion, ICP-AES (EN 15621);</p> <p>For the quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> - Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C); or - Atomic Absorption Spectrometry, AAS (EN ISO 6869); or - Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or - Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621). <p>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 proving the chelated structure of the feed additive:</p> <ul style="list-style-type: none"> – mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive 					<p>be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</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>