

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
						mg/kg of complete feed with a moisture content of 12%			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical performance).									
4d22	Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU	Iron(III) citrate chelate	<p>Additive composition:</p> <p>Iron(III) citrate chelate as a powder with a minimum iron(III) content of 16,5%, a maximum iron content of 23%, a maximum nickel content of 50 ppm and a maximum of 10% moisture.</p> <p>-----</p> <p>Characterisation of the active substance:</p> <p>2-hydroxy-1,2,3-propanetricarboxylic acid iron(III)</p> <p>Chemical formula: C₆H₅FeO₇</p> <p>CAS number: 3522-50-7.</p> <p>-----</p> <p>Analytical method¹</p> <p>For the quantification of total iron in the feed additive:</p> <ul style="list-style-type: none">- inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510); or- inductively coupled plasma-atomic emission spectrometry, ICP-AES with pressure digestion (EN 15621);- atomic absorption spectrometry, AAS (EN ISO 6869); <p>For the quantification of citrate in the</p>	Piglets and minor porcine species (suckling and weaned)	-	500	-	<p>1. The additive shall be incorporated into feed in the form of a premixture.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including safety glasses and gloves.</p> <p>3. The amount of iron contained in the additive shall be taken into</p>	<p>[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication]</p>

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>

			<p>feed additive:</p> <ul style="list-style-type: none"> - ion-exchange high performance liquid chromatography (HPLC) coupled to ultraviolet (UV) detection; <p>For the determination of the added content of iron(III) citrate chelate in premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"> - enumeration of colour coated particles of the marker present at fixed mass ratio in the feed additive. 					<p>consideration for the calculation of the total iron content of the feed.</p>	
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