

ANNEX

Identi- fication number of the additive	Name of the holder of authorisat ion	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi mum age	Mini- mum content	Maximu m content	Other provisions	End of period of authori sation
						CFU/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1707	Chevita Tierarzneim ittel GmbH	<i>Enterococcus lactis</i> DSM 10663	Additive composition Preparation of <i>Enterococcus lactis</i> DSM 10663 containing a minimum of: powder and granulated forms: 3,5 × 10 ¹⁰ CFU/g additive; coated form: 2 × 10 ¹⁰ CFU/g additive; liquid form: 1 × 10 ¹⁰ CFU/g additive Impurities: Nickel (in the liquid form) ≤ 0,69 mg/kg Characterisation of the active substance Viable cells of <i>Enterococcus lactis</i> DSM 10663 Analytical method ⁽¹⁾	Calves for rearing Suckling and weaned piglets Chickens for fattening Turkeys for fattening Cats Dogs	-	1 × 10 ⁹	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be used in suckling piglets ensuring a minimum dose of: 1 × 10 ⁹ CFU/piglet/day. 3. The additive may be used simultaneously only with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: semduramicin sodium, diclazuril, robenidine hydrochloride, maduramicin ammonium, decoquinat e, lasalocid A sodium or halofuginone. 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 breathing, eye and skin protective equipment. Particular attention shall be given to compliance with Union legislation on the protection of workers from the inhalation risks related to exposure to nickel.	[10 years from the date of entry into force of this Regulation. To be comple ted by the Service responsi ble for the publicati on]

⁽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

			Enumeration of <i>Enterococcus lactis</i> DSM 10663 in the feed additive, premixtures and compound feed: — Pour plate method using Bile Esculin Azide Agar (EN 15788) Identification of <i>Enterococcus lactis</i> DSM 10663: — Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697) or DNA sequencing methods						
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