

ANNEX

Identi- fication number of the feed 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	Minimum content	Maximum content	Other provisions	End of period of authori- sation
						CFU/kg of complete feedingstuff with a moisture content of 12%		CFU/l of water for drinking			
Category: zootechnical additives. Functional group: gut flora stabilisers											
4b1708	Chr. Hansen A/S	<i>Enterococcus lactis</i> NCIMB 11181	Additive composition Preparation of <i>Enterococcus lactis</i> NCIMB 11181 containing a minimum of: Solid form: 5×10^{10} CFU/g additive; Solid water-soluble form: 2×10^{11} CFU/g additive. Characterisation of the active substance Viable cells of <i>Enterococcus lactis</i> NCIMB 11181 Analytical method ⁽¹⁾ Enumeration of the active substance in the feed additive, premixtures, compound feed and water: spread plate	Weaned piglets	-	1×10^{10}	-	5×10^9	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment and in water for drinking shall be indicated. 2. For weaned piglets up to 35 kg. 3. The water-soluble formulation of the additive shall be used via water for drinking. 4. For the use of the additive in water for drinking, a homogeneous dispersion of the additive shall be ensured. 5. For users of the additive and premixtures, feed business operators shall establish operational	[10 years from the date of entry into force of this Regula- tion. To be complet ed by the Service responsi ble for the publica- tion]

⁽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 using Bile Esculin Azide agar - EN 15788 Identification: Pulsed-Field Gel Electrophoresis (PFGE) - CEN/TS 17697 or DNA sequencing methods							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 eye (only for the solid formulation), breathing, and skin protective equipment.	
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						CFU/kg of complete feedingstuff with a moisture content of 12%			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1708	Chr. Hansen A/S	Enterococcus lactis NCIMB 11181	Additive composition Preparation of <i>Enterococcus lactis</i> NCIMB 11181 containing a minimum of: Solid form: 5×10^{10} CFU/g additive; Solid water-soluble form: 2×10^{11} CFU/g additive. Characterisation of the active substance Viable cells of <i>Enterococcus lactis</i> NCIMB 11181	Calves for rearing and for fattening	6 months	2×10^9	-	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 milk replacers for calves for rearing and for fattening. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	[10 years from the date of entry into force of this Regula- tion. To be complet ed by the

			<p>Analytical method ⁽²⁾ Enumeration of the active substance in the feed additive, premixtures, compound feed and water: spread plate method using Bile Esculin Azide agar - EN 15788</p> <p>Identification: Pulsed-Field Gel Electrophoresis (PFGE) - CEN/TS 17697 or DNA sequencing methods</p>					<p>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 eye (only for the solid formulation), breathing, and skin protective equipment.</p>	<p><i>Service responsible for the publication]</i></p>
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⁽²⁾ 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