

ENANNEXPart I

Identifi-cation number of the feed additive	Name of the holder of authorisa-tion	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi-mum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
						CFU/kg of complete feed with a moisture content of 12%			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1897	Biomin GmbH	<i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351	<p>Additive composition</p> <p>Preparation of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 containing a minimum total in coated formulation: 4.0×10^{10} CFU/g additive (1.3×10^{10} <i>Enterococcus faecium</i> DSM 33761, 1.3×10^{10} <i>Pediococcus acidilactici</i> DSM 33758, 1.2×10^{10} <i>Bifidobacterium animalis</i> DSM 16284, 1.0×10^9 <i>Limosilactobacillus reuteri</i> DSM 33751 and 1.0×10^9 <i>Ligilactobacillus salivarius</i> DSM 16351).</p> <p>Solid form</p> <p>Characterisation of the active substance</p> <p>Viable cells of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351.</p>	Poultry for fattening and reared for laying or reproduction	-	1×10^8	-	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 may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: nicarbazin, diclazuril, decoquinate and halofuginone. 3. 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.	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]

		<p><i>Analytical method (1)</i></p> <p>For the identification of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351:</p> <ul style="list-style-type: none"> — DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)- CEN/TS 17697 <p>For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures and compound feed:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788) <p>For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures and compound feed:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15786) <p>For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures and compound feed:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15785) <p>For the enumeration of <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 in the feed additive, premixtures and compound feed:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15787) 				
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⁽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

Part II

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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	
						CFU/l of water for drinking				
Category: zootechnical additives. Functional group: gut flora stabilisers.										
4b1897i	Biomin GmbH	<i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351	<p>Additive composition Preparation of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 containing a minimum total in non-coated formulation: 1.0×10^{11} CFU/g additive (3.3×10^{10} <i>Enterococcus faecium</i> DSM 33761, 3.3×10^{10} <i>Pediococcus acidilactici</i> DSM 33758, 3.0×10^{10} <i>Bifidobacterium animalis</i> DSM 16284, 2.5×10^9 <i>Limosilactobacillus reuteri</i> DSM 33751 and 2.5×10^9 <i>Ligilactobacillus salivarius</i> DSM 16351). Solid form</p> <p>Characterisation of the active substance Viable cells of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351.</p> <p>Analytical method (2) For the identification of <i>Enterococcus faecium</i></p>	Poultry for fattening and reared for laying or reproduction	-	5×10^7	-	1. In the directions for use of the additive, the storage conditions and the stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: nicarbazin, diclazuril, decoquinate and 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.	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]	

(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

		<p>DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351:</p> <ul style="list-style-type: none"> — DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)-CEN/TS 17697 <p>For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures, compound feed and water:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788) <p>For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures, compound feed and water:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15786) <p>For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures, compound feed and water:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15785) <p>For the enumeration of <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 in the feed additive, premixtures, compound feed and water:</p> <ul style="list-style-type: none"> — Spread plate (or pour plate) method on MRS agar (EN 15787) 					
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