

ENANNEXPart I

| Identi- fication number of the feed additive | Name of the holder of authori- sation | 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 | 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 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). Solid form 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. | Poultry for fattening and reared for laying or reproducti- on | - | 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 Regula- tion. To be completed by the Service responsi- ble for the publica- tion] |

| | | | | | | | | | |
|--|--|--|---|--|--|--|--|--|--|
| | | | <p>Analytical method ⁽¹⁾</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> <p>— DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)-CEN/TS 17697</p> <p>For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures and compound feed:</p> <p>— Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)</p> <p>For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures and compound feed:</p> <p>— Spread plate (or pour plate) method on MRS agar (EN 15786)</p> <p>For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures and compound feed:</p> <p>— Spread plate (or pour plate) method on MRS agar (EN 15785)</p> <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> <p>— Spread plate (or pour plate) method on MRS agar (EN 15787)</p> | | | | | | |
|--|--|--|---|--|--|--|--|--|--|

⁽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

| Identi- fication number of the feed additive | Name of the holder of author isation | 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 authoris ation |
|--|---|---|--|---|--------------------|--------------------------------|--------------------|--|--|
| | | | | | | 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 | 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 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. Analytical method (2) For the identification of <i>Enterococcus faecium</i> | Poultry for fattening and reared for laying or reproducti on | - | 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 Regula- tion. To be completed by the Service responsi- ble for the publica- tion] |

⁽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> <p>— DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)-CEN/TS 17697</p> <p>For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures, compound feed and water:</p> <p>— Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)</p> <p>For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures, compound feed and water:</p> <p>— Spread plate (or pour plate) method on MRS agar (EN 15786)</p> <p>For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures, compound feed and water:</p> <p>— Spread plate (or pour plate) method on MRS agar (EN 15785)</p> <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> <p>— Spread plate (or pour plate) method on MRS agar (EN 15787)</p> | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|