

ANNEX

PAFF 15-16/02/2024

Identification 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	2020Other provisions	End of period of authorisation
						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											
4b1890	Biomin GmbH	<i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus faecium</i> DSM 21913	<p>Additive composition Preparation of <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus faecium</i> DSM 21913 containing a minimum of 10×10^9 CFU/g additive (3:1:6 ratio) Solid form</p> <p>Characterisation of the active substance Viable spores of <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus</i></p>	<p>All poultry species for fattening</p> <p>All poultry species reared for laying</p> <p>All poultry species reared for breeding</p>	-	1×10^8	-	5×10^7	-	<p>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. The additive may be used via water for drinking.</p> <p>3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: maduramicin ammonium, diclazuril, robenidine hydrochloride, decoquinat, narasin, nicarbazin, a combination of narasin with nicarbazin.</p> <p>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential</p>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</i>

			<p><i>faecium</i> DSM 21913</p> <p>Analytical method ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697.</p> <p>Enumeration in the feed additive, premixtures, compound feed and water of:</p> <ul style="list-style-type: none"> - <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284: spread plate method EN 15785 - <i>Ligilactobacillus salivarius</i> DSM 16351: spread plate method EN 15787 - <i>Enterococcus faecium</i> DSM 21913: spread plate method EN 15788 								<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 breathing and skin protective equipment.</p>	
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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