

EN  
**ANNEX**

Identi- fication number of the additive	Name of the holder of authorisation	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 feedingstuff with a moisture content of 12%			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1830	Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium	<i>Clostridium butyricum</i> FERM BP-2789	<b>Additive composition</b>  Preparation of <i>Clostridium butyricum</i> FERM BP-2789 containing a minimum of 5 × 10 <sup>8</sup> CFU/g additive.  Solid form ----- <b>Characterisation of active substance</b>  Viable spores of <i>Clostridium butyricum</i> FERM BP-2789. ----- <b>Analytical method<sup>1</sup></b>  Enumeration: pour plate method based on ISO 15213 standard.  Identification: pulsed-field gel electrophoresis (PFGE) method	Chickens for fattening  Chickens reared for laying  Minor avian species (excluding laying birds)  Piglets and piglets of minor porcine species	-	2,5 × 10 <sup>8</sup>	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the permitted coccidiostats: decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramycin sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

<sup>1</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

				<p>Turkeys for fattening</p> <p>Turkeys reared for breeding</p>	-	$1,25 \times 10^8$	-	<p>organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</p>	
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