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► **B**

**COMMISSION REGULATION (EC) No 903/2009**

**of 28 September 2009**

**concerning the authorisation of the preparation of ► M1 *Clostridium butyricum* FERM-BP 2789 ◀ as a feed additive for chickens for fattening (► M3 holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium ◀)**

(Text with EEA relevance)

(OJ L 256, 29.9.2009, p. 26)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011	L 102	10	16.4.2011
► <u>M2</u>	Commission Implementing Regulation (EU) No 357/2013 of 18 April 2013	L 109	22	19.4.2013
► <u>M3</u>	Commission Implementing Regulation (EU) 2017/1126 of 23 June 2017	L 163	13	24.6.2017

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**concerning the authorisation of the preparation of  
►M1 *Clostridium butyricum* FERM-BP 2789 ◄ as a feed  
additive for chickens for fattening (►M3 holder of authorisation  
Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV  
Belgium ◄)**

**(Text with EEA relevance)**

*Article 1*

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

## ANNEX

Identification number of the 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	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: gut flora stabilisers</b>									
4b1830	► <b>M3</b> Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium ◀	► <b>M1</b> <i>Clostridium butyricum</i> FERM-BP 2789 ◀	<p>Additive composition:</p> <p>Preparation of ► <b>M1</b> <i>Clostridium butyricum</i> FERM-BP 2789 ◀ containing a minimum of solid form <math>5 \times 10^8</math> CFU/g additive</p> <p>Characterisation of the active substance:</p> <p>► <b>M1</b> <i>Clostridium butyricum</i> FERM-BP 2789 ◀</p> <p>Analytical method <sup>(1)</sup>:</p> <p>Quantification: iron sulphite agar for the additive and premixtures and selective ► <b>M1</b> <i>Clostridium butyricum</i> FERM-BP 2789 ◀ agar for feedingstuffs</p> <p>Identification: pulsed-field gel electrophoresis (PFGE) method</p>	Chickens for fattening	—	► <b>M2</b> $2,5 \times 10^8$ ◀	—	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</li> <li>The use is allowed in feed containing the permitted coccidiostats: monensin sodium, diclazuril, maduramicin ammonium, robenidine, narasin, narasin/nicarbazin, semduramycin, decoquinat, ► <b>M1</b> monensin sodium or lasalocid ◀.</li> <li>For safety reasons: breathing protection shall be used during handling.</li> </ol>	19 October 2019

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Community Reference Laboratory: [www.irmm.jrc.be/crl-feed-additives](http://www.irmm.jrc.be/crl-feed-additives)