

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k1802	<i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856	Additive composition Preparation of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856 containing a minimum of 3,6 × 10 ¹¹ CFU/g additive with a ratio 1:4 (7,2 x 10 ¹⁰ CFU <i>Bacillus subtilis</i> DSM 33862/g and 2,88×10 ¹¹ CFU <i>Lentilactobacillus buchneri</i> DSM 12856/g) Solid form ----- Characterisation of the active substance Viable cells of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856 -----	All animal species	-	-	-	<div>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</div> <div>2. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: 1x10⁸ CFU/kg fresh plant material.</div> <div>3. The additive shall only be used with easy and moderately difficult to ensile fresh plant material², with a dry matter range 32-65%.</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

² Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, <http://data.europa.eu/eli/reg/2008/429/oj>).

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		Analytical method¹ Identification of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856: - DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697) – Enumeration of <i>Bacillus subtilis</i> DSM 33862 in the feed additive: Spread plate method on tryptone soya agar (EN 15784) – Enumeration of <i>Lentilactobacillus buchneri</i> DSM 12856 in the feed additive: Spread plate (or pour plate) method on MRS agar (EN 15787)					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 skin and breathing protective equipment.	

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.