

## EN

ANNEX

Identifi- cation number of the additive	Name of the 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			
<b>Category: technological additives. Functional group: silage additives</b>								
1k1803	<i>Saccharomyces cerevisiae</i> NBRC 0203 and <i>Lacticaseibacillus rhamnosus</i> NBRC 3425	<p><b>Additive composition</b> Preparation of <i>Saccharomyces cerevisiae</i> NBRC 0203 and <i>Lacticaseibacillus rhamnosus</i> NBRC 3425 containing a minimum of <math>5 \times 10^3</math> CFU of <i>Saccharomyces cerevisiae</i> NBRC 0203 and <math>4 \times 10^7</math> CFU <i>Lacticaseibacillus rhamnosus</i> NBRC 3425/mL additive</p> <p>Liquid form</p> <p>-----</p> <p><b>Characterisation of the active substance</b> Viable cells of <i>Saccharomyces cerevisiae</i> NBRC 0203 and <i>Lacticaseibacillus rhamnosus</i> NBRC 3425</p> <p>-----</p>	All animal species	-	-	-	<ol style="list-style-type: none"> <li>In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</li> <li>Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: <math>4,0 \times 10^2</math> <i>Saccharomyces cerevisiae</i> NBRC 0203 and <math>3,2 \times 10^6</math> <i>Lacticaseibacillus rhamnosus</i> NBRC 3425 CFU/kg fresh plant material.</li> <li>The additive shall only be used with easy and moderately difficult to ensile fresh plant material<sup>2</sup>.</li> </ol>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

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		<p><b>Analytical method<sup>1</sup></b></p> <p>Identification of <i>Saccharomyces cerevisiae</i> NBRC 0203:</p> <ul style="list-style-type: none"> <li>- DNA sequencing methods or Polymerase Chain Reaction (PCR) - CEN/TS 15790</li> </ul> <p>Identification of <i>Lacticaseibacillus rhamnosus</i> NBRC 3425:</p> <ul style="list-style-type: none"> <li>- DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE) - CEN/TS 17697</li> </ul> <p>Enumeration of <i>Saccharomyces cerevisiae</i> NBRC 0203 in the feed additive:</p> <ul style="list-style-type: none"> <li>- Pour or spread plate method on YGC agar - EN 15789</li> </ul>				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, eye and breathing protective equipment.			

<sup>2</sup> 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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		Enumeration of <i>Lacticaseibacillus rhamnosus</i> NBRC 3425 in the feed additive: - Pour or spread plate method on MRS agar - EN 15787							