

EN

**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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU /kg of complete feedingstuff with a moisture content of 12%		CFU /l of water for drinking			
Category of zootechnical additives. Functional group: gut flora stabilisers.											
4b1700i	Chr.Hansen A/S	<i>Bacillus subtilis</i> (DSM 5750) and <i>Bacillus licheniformis</i> (DSM 5749)	<b>Additive composition</b> Preparation of <i>Bacillus subtilis</i> (DSM 5750) and <i>Bacillus licheniformis</i> (DSM 5749) containing a minimum of 3.2x10 <sup>10</sup> CFU /g of additive (1:1 ratio) Solid form  ----- <b>Characterisation of the active substance:</b> Viable spores of <i>Bacillus subtilis</i> (DSM 5750) and <i>Bacillus licheniformis</i> (DSM 5749)  ----- <b>Analytical method</b> <sup>1</sup> Identification and enumeration of <i>Bacillus subtilis</i> (DSM	Suckling piglets	-	1.3 x 10 <sup>9</sup>	-	6.5x 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. The additive may be used in water for drinking. 3. For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured. 4. The additive shall be administered to lactating sows simultaneously with the suckling piglets 5. 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 Service responsible for the publication.]

<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>5750) and <i>Bacillus licheniformis</i> (DSM 5749) in the feed additive, premixtures, feedingstuffs and water:</p> <ul style="list-style-type: none"> <li>- Identification: Pulsed Field Gel Electrophoresis (PFGE)</li> <li>- Enumeration: Spread plate method using tryptone soya agar - EN 15784.</li> </ul>							<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 and skin protection.</p>	
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