

EN

ANNEX

| Identifi- cation 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 authori- sation |
|---|---|---|---|-------------------------------------|----------------|---|--------------------|---|---|
| | | | | | | CFU /kg of complete feedingstuff with a moisture content of 12% | | | |
| Category of zootechnical additives. Functional group: gut flora stabilisers | | | | | | | | | |
| 4b1823 | Kemin Europa N.V. | <i>Bacillus subtilis</i> ATCC PTA-6737 | Additive composition: Preparation of <i>Bacillus subtilis</i> (ATCC PTA-6737) containing a minimum of 1x10 ¹⁰ CFU/g additive Solid form ----- Characterisation of the active substance: Viable spores of <i>Bacillus subtilis</i> (ATCC PTA-6737) ----- Analytical method ¹ Enumeration: spread plate method using tryptone soya agar with pre heat- treatment of feed samples. Identification: pulsed-field gel electrophoresis (PFGE) method. | Sows | - | 1x 10 ⁸ | - | <div>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</div> <div>2. The additive shall be added to diets of sows from 3 weeks before parturition until weaning of piglets.</div> <div>3. For users of the additive and premixtures, feed</div> | <i>[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication]</i> |

¹ 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>

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| | | | | | | | | business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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. | |
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