

ANNEX

| Identification number of the 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 authorisation |
|---|--|---|-------------------------------|-------------|-------------------------------------|-----------------|---|---|
| | | | | | Units of activity/kg fresh material | | | |
| Category of technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: fumonisins | | | | | | | | |
| 1m03i | Fumonisin esterase <i>EC 3.1.1.87</i> | <p>Additive composition: Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 containing a minimum of 3 000 U/g¹.</p> <p>-----</p> <p>Characterisation of the active substance: Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159.</p> <p>-----</p> <p>Analytical method²</p> <p>- For the determination of fumonisin esterase activity: High Performance Liquid Chromatography coupled with a tandem mass spectrometry. (HPLC-MS/MS) method based on the quantification of the tricarballic acid released from the action of the enzyme on fumonisin B1 at pH 8,0 and 30 °C.</p> | All animal species | - | 40 | - | <ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The use of the additive at this minimum dose is only allowed in silages. It is also not allowed in other fermented feeds 3. Recommended maximum dose: 300 U/kg of fresh material. 4. The use of the additive is allowed in feedingstuffs complying with Union legislation on undesirable substances in animal feed³. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or | <p><i>[to be completed by the Service responsible for the publication: insert precise date]</i></p> <p><i>[10 years from the date of entry into force of this Regulation]</i></p> |

¹ 1 U is the enzymatic activity that releases 1 µmol tricarballic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8,0 with 0,1 mg/ml bovine serum albumin at 30 °C.

² 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>

³ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

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| | | | | | | | reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. | |