

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 | Other provisions | End of period of authorisation |
|--|-------------------------------------|--------------------------------|--|-------------------------------------|-------------|--|-----------------|---|---|
| | | | | | | Units of activity/kg of complete feedingstuff with a moisture content of 12% | | | |
| Technological additives: substances for reduction of the contamination of feed by mycotoxins: fumonisins | | | | | | | | | |
| 1m03i | - | Fumonisin esterase EC 3.1.1.87 | Additive composition: Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> (DSM 32159) containing a minimum of 3000U/g ¹ . ----- Characterisation of the active substance: Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> (DSM 32159) ----- Analytical method² 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. | All pigs All poultry species | - | 10 | | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to pelleting shall be indicated. 2. Recommended maximum dose: 300 U/kg of complete feedingstuff. 3. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed. ³ 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and | <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 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 European Union Reference Laboratory for Feed Additives: <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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| | | | | | | | | organisational measures to address potential risks concerning 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. | |
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