

ANNEX

| Identifi-cation number of the additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maxi-mum age | Minimum content | Maximum content | Other provisions | End of period of authorisa-tion |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------|-----------------------------------------------------------------------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| | | | | | mg of active substance/kg of complete feedingstuff with a moisture content of 12% | | | |
| Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect | | | | | | | | |
| 3a841 | “Calcium D-pantothenate” or “vitamin B ₅ ” | <p>Additive composition Calcium D-pantothenate.</p> <p>Characterisation of the active substance Calcium D-pantothenate Chemical formula: Ca[C₉H₁₆NO₅]₂ CAS number: 137-08-6 Calcium D-pantothenate, solid form, produced by chemical synthesis.</p> <p>Purity criteria:</p> <ol style="list-style-type: none"> 1. Min. 98 % (on dry basis) 2. Max. 0,5 % 3-aminopropionic acid. <p>Analytical method¹</p> <ul style="list-style-type: none"> – For the determination of Calcium D-pantothenate in the feed additive: potentiometric titration with perchloric acid and identification by specific optical rotation - European Pharmacopoeia Monograph 0470. – For the determination of Calcium D-pantothenate in premixtures, compound feed and water for drinking: High Performance | All animal species | - | - | - | <ol style="list-style-type: none"> 1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. 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 breathing, eye and skin protective equipment. | [10 years from the date of entry into force of this Regulation. To be completed by the OP] |

¹Details 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

Kommenterede [AR1]: The applicant request to include water in the method of analysis. EURL has verified and can assure that the method proposed for premixtures and compound feed works also for water, therefore I included water. The applicant will be warned that for the next time he needs to provide data for validation of the method.

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| | | | | | mg of active substance/kg of complete feedingstuff with a moisture content of 12% | | | |
| Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect | | | | | | | | |
| | | Liquid Chromatography coupled to mass spectrometry (HPLC-MS). | | | | | | |