

ANNEX

| Identification number of the feed 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 |
|---|----------------------------|---|--|-------------|--|-----------------|---|--|
| | | | | | mg active substance/kg of complete feed with a moisture content of 12% | | | |
| Category: Nutritional additives . Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect | | | | | | | | |
| Sub classification: vitamin D | | | | | | | | |
| 3a670a | 25-Hydroxy cholecalciferol | <p>Additive composition: Preparation with a maximum content of 1.25% of 25-hydroxycholecalciferol.</p> <p>Solid form</p> <p>Characterisation of the active substance: 25-Hydroxycholecalciferol. Its precursor compound, 5,7,24-cholestatrienol, is produced with Saccharomyces cerevisiae CBS 146008. After extraction, the precursor is converted chemically to</p> | Chickens for fattening | | | 0,100 | <ol style="list-style-type: none"> The additive shall be incorporated in feedingstuffs via the use of a premixture. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol | [10 years from the date of entry into force of this Regulation – Precise date to be completed by the OP] |
| | | | Turkeys for fattening | | | 0,100 | | |
| | | | Other poultry | | | 0,080 | | |
| | | | Pigs | | | 0,050 | | |
| | | | Bovines and ovines Ruminants other than | | | 0,100 0,05 | | |

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| | | <p>25-hydroxy-pro-vitamin D₃, which is further transformed photochemically to 25-hydroxycholecalciferol.</p> <p>C₂₇H₄₄O₂.H₂O</p> <p>CAS number: 63283-36-3</p> <p><u>Purity criteria</u></p> <ul style="list-style-type: none"> - 25-hydroxycholecalciferol >94% - other sterol derivatives ≤ 1% each - erythrosine < 5 mg/kg <p>Analytical method¹</p> <p>For the determination of 25-hydroxycholecalciferol in the feed additive: Ultra Performance Liquid Chromatography coupled to spectrophotometric detection (UPLC-UV)</p> <p>For the determination of 25-hydroxycholecalciferol in premixtures: High Performance Liquid Chromatography coupled to</p> | bovines and ovines | | | | <p>(vitamin D₃) per kg of complete feedingstuff:</p> <ul style="list-style-type: none"> - ≤ 0,125 mg² (equivalent to 5 000 IU of cholecalciferol) for chickens for fattening and turkeys for fattening, - ≤ 0,080 mg³ (equivalent to 3 200 IU of cholecalciferol) for other poultry, - ≤ 0,050 mg⁴ (equivalent to 2 000 IU of cholecalciferol) for pigs, - ≤ 0,100 mg⁵ (equivalent to 4 000 IU of cholecalciferol) for milk replacers for calves, | |
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¹Details 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>.

² 40 IU cholecalciferol (vitamin D₃) = 0,001 mg cholecalciferol (vitamin D₃).

³ 40 IU cholecalciferol (vitamin D₃) = 0,001 mg cholecalciferol (vitamin D₃).

⁴ 40 IU cholecalciferol (vitamin D₃) = 0,001 mg cholecalciferol (vitamin D₃).

⁵ 40 IU cholecalciferol (vitamin D₃) = 0,001 mg cholecalciferol (vitamin D₃).

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| | | <p>spectrophotometric detection (HPLC-UV)</p> <p>For the determination of 25-hydroxycholecalciferol in compound feed and in low concentrated premixtures: High Performance Liquid Chromatography coupled to tandem mass spectrometry (HPLC-MS/MS)</p> | | | | | <ul style="list-style-type: none"> - $\leq 0,100 \text{ mg}^6$ (equivalent to 4 000 IU of cholecalciferol) for bovines and ovines, - $\leq 0,05 \text{ mg}^7$ (equivalent to 2 000 IU of cholecalciferol) for ruminants other than bovines and ovines. <p>4. The simultaneous use of the additive with glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract shall not be permitted.</p> <p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by</p> | |
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⁶ 40 IU cholecalciferol (vitamin D₃) = 0,001 mg cholecalciferol (vitamin D₃).

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| | | | | | | | such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment. | |
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