

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 |
|--|-------------------------------------|--|--|-------------------------------|-------------|--|---|---|--|
| | | | | | | Content of element (Cu) in mg/kg of complete feed with a moisture content of 12% | | | |
| Category of nutritional additives. Functional group: compounds of trace elements | | | | | | | | | |
| 3b415 | - | Copper chelate of lysine and glutamic acid | <p>Additive composition: Mixture of chelate of copper with lysine and chelate of copper with glutamic acid in a ratio of 1:1 as a powder with a copper content between 17 % and 19% and a maximum of 3% moisture</p> <p>-----</p> <p>Characterisation of the active substances: Chemical formulas: Copper-2,6-diaminohexanoic acid: C₆H₁₇ClCuN₂O₇S Copper-2-Aminopentanedioic acid: C₅H₉CuNNaO_{8.5}S</p> <p>-----</p> <p>Analytical methods*: For the quantification of the lysine and glutamic acid content in the feed additive:</p> <ul style="list-style-type: none">– ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) <p>For the quantification of total Cu in the feed additive:</p> <ul style="list-style-type: none">– inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15621) or– atomic absorption spectrometry, AAS (ISO 6869) <p>For proving the chelated structure of the feed additive:</p> <ul style="list-style-type: none">– mid-infrared (IR) spectrometry together | All animal species | - | - | Bovines: - Bovines before the start of rumination: 15 (total); - Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total) Piglets: - suckling and weaned up to 4 weeks after weaning: 150 (total). - from 5-th week after weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total). | <ol style="list-style-type: none">1. The additive shall be incorporated into feed in the form of a premixture.2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective | <i>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</i> |

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| | | | <p>with the determination of the content of the trace element and lysine and glutamic acid in the feed additive</p> <p>For the quantification of total Cu in premixtures:</p> <ul style="list-style-type: none"> – inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or – atomic absorption spectrometry, AAS (ISO 6869) or – inductively coupled plasma mass spectrometry, ICP-MS (EN 17053) <p>For the quantification of total Cu in feed materials and compound feed:</p> <ul style="list-style-type: none"> – inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or – atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C or ISO 6869) or – inductively coupled plasma mass spectrometry, ICP-MS (EN 17053) | | | | | <p>equipment.</p> <p>3. The following words shall be included in the labelling:</p> <ul style="list-style-type: none"> - For feed for ovines if the level of copper in the feed exceeds 10 mg/kg: ‘The level of copper in this feed may cause poisoning in certain breeds of sheep.’ - For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’ | |
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* 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>