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ANNEX

| Identifi-cation number of the additive | Name of the additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisa-tion | |
|--|----------------------|--|-------------------------------|-------------|---|-----------------|--|---|--|
| | | | | | mg/kg of complete feed with 12 % moisture content | | | | |
| Category: nutritional additives. Functional group: amino acids, their salts and analogues | | | | | | | | | |
| 3c384i | L-isoleucine | <p>Additive composition L-isoleucine Solid form</p> <p>Characterisation of the active substance L-isoleucine ≥ 90 % (on a dry matter basis) produced with <i>Escherichia coli</i> CCTCC M 20231916</p> <p>IUPAC name: (2S,3S)-2-amino-3-methylpentenoic acid</p> <p>Chemical formula: C₆H₁₃NO₂</p> <p>CAS number: 73-32-5</p> <p>Analytical method¹ For the identification of L- isoleucine in the feed additive:</p> | All animal species | - | - | - | <ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment and in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-isoleucine is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L- | [10 years from the date of entry into force of this Regulation. To be completed by the OP.] | |

¹ Details 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.

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| Category: nutritional additives. Functional group: amino acids, their salts and analogues | | | | | | | | | |
| | | <ul style="list-style-type: none"> – Food Chemical Codex "L-isoleucine monograph"; For the determination of isoleucine in the feed additive: <ul style="list-style-type: none"> – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD or IEC-VIS); For the determination of isoleucine in premixtures: <ul style="list-style-type: none"> – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) or – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009; For the determination of isoleucine in compound feed: <ul style="list-style-type: none"> – Ion-exchange chromatography coupled to post-column derivatisation and optical | | | | | <p>isoleucine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances².</p> <p>6. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air².</p> <p>7. 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 skin, eye and breathing protective equipment.</p> | | |

² Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

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| | | <p>detection (IEC-VIS), Commission Regulation (EC) No 152/2009;</p> <p>For the determination of isoleucine in water for drinking:</p> <p>– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS).</p> | | | | | | |