

EN  
**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   |
|--|-------------------------------------|--------------|---|-------------------------------|-------------|---|-----------------|--|--|
|  |                                     |              |   |                               |             | mg/kg of complete feed with a moisture content of 12% |                 |  |  |
| Category: nutritional additives. Functional group: amino acids, their salts and analogues. |                                     |              |   |                               |             |   |                 |  |  |
| 3c440  | -                                   | L-tryptophan | <b>Additive composition:</b><br>Powder with a minimum of 98 % L-tryptophan on a dry matter basis and a maximum moisture content of 1%.<br>Maximum content of 10 mg/kg 1,1'-ethylidene-bis-L-tryptophan (EBT)<br>-----<br><b>Characterisation of the active substance:</b><br>L-tryptophan produced by fermentation with <i>Escherichia coli</i> KCCM 80210<br>Chemical formula: C <sub>11</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub><br>CAS No: 73-22-3<br>-----<br><b>Analytical methods<sup>1</sup>:</b><br>For the identification of L-tryptophan in the feed additive:<br>– Food Chemical Codex ‘L-tryptophan monograph’.<br>For the determination of tryptophan in the feed additive and premixtures: | All species                   | -           | -   | -               | 1. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, skin or eyes contact. 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, gloves and safety glasses. | [10 years from the date of entry into force of this Regulation.<br>To be completed by the Service responsible for the publication] |

<sup>1</sup> 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>

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|  |  |  | <ul style="list-style-type: none"> <li>– High performance liquid chromatography with fluorescence detection (HPLC-FLD)</li> <li>– EN ISO 13904.</li> </ul> <p>For the determination of tryptophan in compound feed and feed materials:</p> <ul style="list-style-type: none"> <li>– High performance liquid chromatography with fluorescence detection (HPLC-FLD); Commission Regulation (EC) No 152/2009 (Annex III, G).</li> </ul> |  |  |  |  | <p>2. The <u>feed business operator placing the additive on the market shall ensure that its</u> endotoxin content <del>of the additive</del> and its dusting potential <del>shall ensure</del> a maximal endotoxin exposure of 1600 IU endotoxins/m<sup>3</sup> air<sup>2</sup>.</p> <p>3. For ruminants, L-tryptophan shall be rumen protected.</p> <p>4. The labelling of the additive and premixtures shall indicate the following:<br/>"The supplementation with L- tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances."</p> |  |
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<sup>2</sup> Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).