

ANNEX

Identi- fication 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								
3c354	L-histidine monohydrochloride monohydrate	Additive composition L-histidine monohydrochloride monohydrate Solid form Characterisation of the active substance L-histidine monohydrochloride monohydrate ≥ 98 % with a minimum content of 72% histidine (on a dry matter basis), produced with <i>Escherichia coli</i> CCTCC M 20241089 Histamine ≤ 100 ppm IUPAC name: (2 <i>S</i>)-2-amino-3-(1 <i>H</i> - imidazol-5-yl) propanoic acid hydrate hydrochloride Chemical formula: C ₆ H ₉ N ₃ O ₂ ·HCl·H ₂ O CAS number: 5934-29-2 Analytical method¹ For the identification of <i>L-histidine monohydrochloride monohydrate</i> in the feed additive: – Food Chemical Codex “L-histidine	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability 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-histidine monohydrochloride monohydrate is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L- histidine monohydrochloride monohydrate, in particular via water for drinking, shall take <td>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</td>	[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.

		monohydrochloride monograph”. For the determination of <i>histidine</i> in the <i>feed additive</i>: – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD or IEC-VIS). For the determination of histidine in premixtures: – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009² For the determination of histidine in compound feed: – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Regulation (EC) No 152/2009. For the determination of histidine in water for drinking: – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS). For the determination of histamine in the feed additive: – High performance liquid					into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.’ 6. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air³. 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.	
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² Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009; ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

³ 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).

		chromatography coupled with spectrophotometric detection (HPLC- UV).						
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