

## ANNEX

Identifi- cation number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maxi- mum age	Minimum content	Maxim um content	Other provisions	End of period of authori- sation
						mg/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: amino acids, their salts and analogues.									
3c392	-	L-cystine	<b>Additive composition:</b> Powder with a minimum content of 98% L-cystine  ----- <b>Characterisation of the active substance:</b> L-cystine produced by fermentation with <i>Pantoea ananatis</i> NITE BP-02525 IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanylpropanoic acid CAS number: 56-89-3 Chemical formula: C <sub>6</sub> H <sub>12</sub> N <sub>2</sub> O <sub>4</sub> S <sub>2</sub>  ----- <b>Analytical method<sup>1</sup>:</b> For the identification of L-cystine in the feed additive: – Food Chemical Codex "L-cystine monograph" For the quantification of cystine in the feed additive and premixtures: – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), as described in EN ISO 17180 For the quantification of cystine in premixtures, compound feed and feed materials:	All animal species	-	-	-	<div>1. L-cystine may be placed on the market and used as an additive consisting of a preparation.</div> <div>2. The additive can be also used via water for drinking.</div> <div>3. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment.</div> <div>4. In the directions for use of the additive and premixture, the storage conditions, the stability</div>	<div>[10 years from the date of entry into force of this Regulation.</div> <div>To be completed by the Service responsible for the publication]</div>

<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>

			<div>– ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009<sup>2</sup> (Annex III, F)</div> <div>For the quantification of cystine in water:</div> <div>– ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), as described in EN ISO 13903 or Commission Regulation (EC) No 152/2009 (Annex III, F)</div>					<div>to heat treatment and the stability in water for drinking shall be indicated.</div> <div>5. Declaration to be made on the label of the additive and premixture: ‘- The supplementation with L-cystine, shall depend on the requirements of the target animals for sulphur- containing amino acids and the level of other sulphur-containing amino acids in the ration. - The supplementation with L-cystine, in particular via water for drinking, should take into account all amino acids in the animals’ diet in order to avoid imbalances.’</div>	
Category: Sensory additives. Functional group: Flavouring compounds									
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 of active substance/kg of complete feed with a moisture content of 12%			
3c392	-	L-cystine	<b>Additive composition:</b> Powder with a minimum content of 98% L-cystine -----	All animal species	-	-	-	1. L-cystine may be placed on the market and used as an additive consisting of a preparation.	[10 years from the date of entry into force of this Regulation.

<sup>2</sup> OJ L 54, 26.2.2009, p. 1.

			<p><b>Characterisation of the active substance:</b>  L-cystine produced by fermentation with  <i>Pantoea ananatis</i> NITE BP-02525  IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanylpropanoic acid  CAS number: 56-89-3  Chemical formula: C<sub>6</sub>H<sub>12</sub>N<sub>2</sub>O<sub>4</sub>S<sub>2</sub></p> <p>-----</p> <p><b>Analytical method<sup>3</sup>:</b>  For the determination of L-cystine in the feed additive:  – Food Chemical Codex "L-cystine monograph"  For the quantification of cystine in the feed additive and premixtures:  – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), as described in EN ISO 17180</p>					<ol style="list-style-type: none"> <li>2. The additive shall be incorporated into the feed in the form of a premixture.</li> <li>3. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated.</li> <li>4. On the label of the additive the following shall be indicated:  "Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12%: 25 mg/kg".</li> <li>5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12% is exceeded: 25 mg/kg.</li> <li>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational</li> </ol>	<p><i>To be completed by the Service responsible for the publication]</i></p>
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<sup>3</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>

								measures to address potential risks by inhalation. 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.	
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