



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10386/2016 ANNEX CIS  
(POOL/G1/2016/10386/10386-EN  
ANNEX CIS.doc)  
**[...]**(2016) **XXX** draft

ANNEX 1

## **ANNEX**

**to the**

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**concerning the authorisation of tannic acid as a feed additive for all animal species**

## 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 of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds									
2b16080	-	Tannic acid	<i>Additive composition</i> Tannic acid <i>Characterisation of the active substance</i> Tannic acid Produced by extraction from different botanical sources. Purity: min. 93% Chemical formula: C <sub>76</sub> H <sub>52</sub> O <sub>46</sub> CAS number 72401-53-7 FLAVIS 16.080 <i>Method of analysis</i> <sup>(1)</sup> For the determination of tannic acid, in the feed additive: Qualitative colorimetric precipitation tests (Ph. Eur. 6 <sup>th</sup> edition, monograph 1477) and quantitative gravimetric method (FAO JECFA tannic acid monograph). For the identification of tannic acid (as gallic acid) in the	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</div> <div>3. The recommended maximum content of the active substance shall be: 15mg/kg of complete feedingstuff with a moisture content of 12%.</div> <div>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%:15mg/kg "</div> <div>5. The functional group, the</div>	<i>[Publication Office insert date 10 years from the date of entry into force of the Regulation]</i>

			premixture of flavourings: Reversed Phase High Performance Liquid Chromatography coupled to UV detector( RP-HPLC-UV)					identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12% is exceeded: 15 mg/kg. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by dermal contact 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 safety glasses and gloves.	
<sup>(1)</sup> = Details of the analytical methods are available at the following address of the Reference Laboratory: <a href="https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports">https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports</a>									