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ANNEX

Identification number of the feed additive	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 additive/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b188-t	Clove tincture	Additive composition Tincture from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merr. & L.M. Perry ¹ Liquid form	All animal species except <i>Equidae</i>	-	-	50	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]

¹ Synonym: *Eugenia caryophyllata* Thunb.

	<p>Characterisation of active substance</p> <p>Clove tincture</p> <p>Tincture as defined by the Council of Europe² obtained from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merr. & L.M. Perry by extended extraction with a water/ethanol solvent mixture, pressing and filtration.</p> <p>CoE number: 188</p> <p><u>Specifications</u></p> <ul style="list-style-type: none"> - Dry matter content: 1,57–1,77% - Total polyphenols³: ≤ 0,541% - Flavonoids: ≤ 0,0418% - Eugenol: ≤ 0,00497% - Eugenyl acetate: < 0,00017 mg/mL - Methyleugenol: ≤ 0,00022% - Estragole: ≤ 0,00009% <p>Analytical method⁽⁴⁾</p>	<i>Equidae</i>	-	-	200	<p>to heat treatment shall be indicated.</p> <p>3. Mixture of clove tincture with other botanical additives is permitted provided that the amounts of methyleugenol and estragole in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended content for the species or animal category.</p> <p>4. 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</p>
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² Natural sources of flavourings – Report No 2 (2007).

³ Expressed as gallic acid equivalent (GAE)

⁴ 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

		<p>For the characterisation of the feed additive:</p> <ul style="list-style-type: none"> - spectrophotometry for the determination of total polyphenols and total flavonoids - gas chromatography coupled with flame ionisation detection (GC-FID) for the determination of eugenol (phytochemical marker), estragole, methyleugenol and eugenyl acetate 					breathing equipment.	protective	
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