

EN

ANNEX

Identification 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 authorisation
					mg of additive/kg of complete feed with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b353-eo	Patchouli essential oil	<p>Additive composition</p> <p>Essential oil from the leaves of <i>Pogostemon cablin</i> Benth.</p> <p>Liquid form</p> <p>Characterisation of active substance</p> <p>Patchouli essential oil:</p> <p>Essential oil, as defined by the Council of Europe (CoE)¹, obtained from the dried leaves of <i>Pogostemon cablin</i></p>	All animal species	-	-	-	<p>1. The additive shall be incorporated into the feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>3. On the label of the additive, the following shall be indicated: “Recommended maximum content of the active substance per kg of</p>	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]

¹ Natural sources of flavourings – Report No 2 (2007).

		<p>Benth. by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation.</p> <p>CAS number: 8014-09-3 EINECS number: 282-493-4 FEMA number: 2838 CoE number: 353</p> <p><u>Specifications</u> Patchouli alcohol: 27-35% 1(5),11-Guaiadiene: 11-16% β-Caryophyllene: 2-5% α-Bulnesene: 13-21%</p> <p>Analytical method ⁽²⁾ For the determination of patchouli alcohol (phytochemical marker) in the feed additive: - gas chromatography coupled with flame ionisation detection (GC–FID) (ISO 3757)</p>				<p>complete feed with a moisture content of 12 %:</p> <ul style="list-style-type: none"> - 7,5 mg for turkeys for fattening; - 7,5 mg for chickens for fattening and minor poultry for fattening; - 7,5 mg for all poultry reared for laying or breeding; - 7,5 mg for ornamental birds; - 7,5 mg for all poultry for laying or breeding; - 7,5 mg for pigs for fattening; - 24 mg for piglets (suckling and weaned) of all <i>Suidae</i>; - 24 mg for pigs for fattening of minor <i>Suidae</i>; - 35 mg for all <i>Suidae</i> for reproduction; - 60 mg for calves for fattening up to 6 months; - 53 mg for sheep and goats; - 53 mg for cattle for fattening, other ruminants for fattening except sheep, goats and calves for fattening up to 6 months; <i>Camelidae</i> for fattening; - 34 mg for all other ruminants; all other <i>Camelidae</i>; 	
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² 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.

							<ul style="list-style-type: none"> - 7,5 mg for <i>Equidae</i>; - 7,5 mg for <i>Leporidae</i>; - 7,5 mg for salmonids and minor fin fish; - 7,5 mg for dogs; - 7,5 mg for cats; - 7,5 mg for ornamental fish; - 7,5 mg for other species and categories.”. <p>4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, where the use levels on the label of the premixture would result in exceeding the levels referred to in point 3.</p> <p>5. 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.</p>	
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