

EN

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxim um age	Minimu m content	Maximu m 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								
2b282-eo	Peppermint essential oil	Additive composition Essential oil from the aerial parts of <i>Mentha</i> × <i>piperita</i> L. (basionym: <i>Mentha aquatica</i> × <i>Mentha spicata</i> L.) Liquid form	All animal species	-	-	-	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]

	<p>Characterisation of active substance</p> <p>Peppermint essential oil</p> <p>Essential oil, as defined by the Council of Europe¹, obtained from the aerial parts (the leaves with or without the flowers) of <i>Mentha × piperita</i> L. by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation.</p> <p>CAS number: 8006-90-4 EINECS: 308-770-2 FEMA number: 2848 CoE number: 282</p> <p><u>Specifications</u></p> <p>Menthol: 30-55 % Menthone: 13-32 % <i>d,l</i>-Isomenthone: 1,5-10 % Menthyl acetate: 2-10 % 1,8-Cineole (eucalyptol): 2-8 % Pulegone: ≤ 1,72 % Menthofuran: ≤ 4,54 % β-thujone: ≤ 0,01 % Coumarin: ≤ 0,001% Estragole: ≤ 0,001%</p>				<p>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 complete feedingstuff with a moisture content of 12%: 12 mg.”</p> <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 level on the label of the premixture would result in exceeding the level 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</p>	
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¹ Natural sources of flavourings - Report No. 2 (2007).

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.

		Analytical method⁽²⁾ For the determination of menthol and menthone (phytochemical markers) in the feed additive: – Gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 856)				procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	
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					mg of additive/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b415-co	Clary sage essential oil	Additive composition Essential oil from flowering stems of <i>Salvia sclarea</i> L. Liquid form Characterisation of active substance Clary sage essential oil Essential oil, as defined by the Council of Europe ³ , obtained from from fresh or dried flowering stems of <i>Salvia sclarea</i> L.by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation. CAS number: 8016-63-5 EINECS: 283-911-8 FEMA number: 2321 CoE number: 415	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 conditions and the stability to heat treatment shall be indicated.</div> <div>3. On the label of the additive, the following shall be indicated: "Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12%: - 7 mg for turkeys for fattening; - 5 mg for chickens for fattening and minor poultry for fattening; - 5 mg for all poultry reared for laying or breeding;</div>	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]

³ Natural sources of flavourings - Report No. 2 (2007).

		<p><u>Specifications</u></p> <p>Linalyl acetate: 55-78%</p> <p>Linalool: 6,5-25 %</p> <p>Germacra-1(10),4(14),5-triene: 1-12%</p> <p>α-Terpineol: 0-5 %</p> <p>Analytical method⁽⁴⁾</p> <p>For the determination of linalyl acetate and linalool (phytochemical marker) in the feed additive:</p> <ul style="list-style-type: none"> - gas chromatography coupled with flame ionization detection (GC-FID) (European Pharmacopoeia monograph 1850) 				<ul style="list-style-type: none"> - 5 mg for ornamental birds; - 8 mg all poultry for laying or breeding, - 11 mg for pigs for fattening; - 9 mg for piglets (suckling and weaned) of all <i>Suidae</i>; - 9 mg for pigs for fattening of minor <i>Suidae</i>; - 14 mg for all <i>Suidae</i> for reproduction; - 15 mg for calves for fattening up to 6 months; - 15 mg for sheep and goats; - 15 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; - 13 mg for all other ruminants and all other <i>Camelidae</i>; - 10 mg for <i>Equidae</i>; - 8 mg for <i>Leporidae</i>; - 20 mg for salmonids and minor fin fish; - 20 mg for dogs; - 20 mg for ornamental fish; 	
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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.

						<ul style="list-style-type: none"> - 4 mg for cats; - 4 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 level on the label of the premixture would result in exceeding the level 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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Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxim um age	Minimu m content	Maximu m 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								
2b414-eo	Sage essential oil	Additive composition Essential oil from the fresh leaves of <i>Salvia officinalis</i> L. Liquid form Characterisation of active substance Sage essential oil Essential oil, as defined by the Council of Europe ⁵ , obtained the fresh leaves of <i>Salvia officinalis</i> L. by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation. CAS number: 8022-56-8 EINECS: 283-291-0 FEMA number: 3001 CoE number: 414	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 conditions and the stability to heat treatment shall be indicated.</div> <div>3. On the label of the additive, the following shall be indicated: "Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12%: - 3 mg for turkeys for fattening; - 3 mg for chickens for fattening and minor poultry for fattening;</div>	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]

⁵ Natural sources of flavourings - Report No. 2 (2007).

		<p><u>Specifications</u></p> <p>α-Thujone: 18-27% Camphor: 4-24,5% 1,8-Cineole (eucalyptol): 5,5-13% β-Thujone: 3-7%</p> <p>Analytical method⁽⁶⁾</p> <p>For the determination of camphor, alpha-thujone and beta-thujone (phytochemical markers) in the feed additive: – Gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 9909)</p>				<ul style="list-style-type: none"> - 3 mg for all poultry reared for laying or breeding; - 3 mg for ornamental birds; - 4 mg for all poultry for laying or breeding; - 6 mg for pigs for fattening; - 5 mg for piglets (suckling and weaned) of all <i>Suidae</i>; - 5 mg for pigs for fattening of minor <i>Suidae</i>; - 7 mg for all <i>Suidae</i> for reproduction; - 11 mg for calves for fattening up to 6 months; - 10 mg for sheep and goats; - 10 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; - 7 mg for all other ruminants and all other <i>Camelidae</i>; - 10 mg for <i>Equidae</i>; - 4 mg for <i>Leporidae</i>; 	
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⁶ 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"> - 11 mg for salmonids and minor fin fish; - 12 mg for dogs; - 20 mg for ornamental fish; - 2 mg for cats; - 2 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 level on the label of the premixture would result in exceeding the level 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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