



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10184/2016 ANNEX CIS
(POOL/E5/2016/10184/10184-EN
ANNEX CIS.doc)
[...](2016) **XXX** draft

ANNEX 1

ANNEX

to the

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

concerning the authorisation of 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran as feed additives 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									
2b03001	-	1,8-Cineole	<i>Additive composition</i> 1,8-Cineole <i>Characterisation of the active substance</i> 1,8-Cineole Produced by distillation from <i>Eucalyptus globulus</i> Purity: min. 98 % Chemical formula: C ₁₀ H ₁₈ O CAS number 470-82-6 FLAVIS No 03.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1,8-cineole in the feed additive and in feed flavouring premixtures. Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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: 5 mg/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%: 5 mg/kg"</div> <div>5. The functional group, the identification number, the name and the added amount</div>	[Publication Office insert date 10 years from the date of entry into force of the Regulation]

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									
								<div>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: 5 mg/kg.</div> <div>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, 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</div>	

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									
								breathing protection, safety glasses and gloves.	
2b13009	-	3,4-Dihydrocoumarin	<i>Additive composition</i> 3,4-Dihydrocoumarin <i>Characterisation of the active substance</i> 3,4-Dihydrocoumarin Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₉ H ₈ O ₂ CAS number 119-84-6 FLAVIS No 13.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3,4-dihydrocoumarin in the feed additive and in feed flavouring premixtures. Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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: 5 mg/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%: 5mg/kg "</div> <div>5. The functional group, the identification number, the name</div>	<i>[Publication Office insert date 10 years from the date of entry into force of the Regulation]</i>

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									
								<p>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: 5 mg/kg.</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, 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 breathing protection, safety</p>	

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									
								glasses and gloves.	
2b13037	-	2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran	<i>Additive composition</i> 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran <i>Characterisation of the active substance</i> 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₁₀ H ₁₈ O CAS number 16409-43-1 FLAVIS No 13.037 <i>Method of analysis</i> ⁽¹⁾ For the identification of 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran in the feed additive and flavouring premixtures. Gas chromatography mass spectrometry with retention	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: For pigs and poultry: 0.5 mg/kg, and for other species and categories: 0.3 mg/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% :</div>	[Publication Office insert date 10 years from the date of entry into force of the Regulation]

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									
			time locking GC-MS-RTL.					<div><div><div>– 0.5 mg/kg for pigs and poultry;</div><div>– 0.3 mg/kg for other species and categories."</div></div><div>5. The functional group, the 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 contents of the active substance in complete feedingstuff with a moisture content of 12% are exceeded:<div><div><div>– 0.5 mg/kg for pigs and poultry;</div><div>– 0.3 mg/kg for other species and categories.</div></div></div></div><div>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	

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									
								address potential risks by inhalation, 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 breathing protection, safety glasses and gloves.	
⁽¹⁾ = 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									