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ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi mum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of additive/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b61281-t	Omicha tincture	Additive composition Omicha tincture from the fruit of <i>Schisandra chinensis</i> (Turcz.) Baill. Liquid form Characterisation of the active substance Omicha tincture	Dogs	-	-	-	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 stability to heat treatment shall be indicated. 3. On the label of the additive, the following shall be indicated: “Recommended maximum content of the active substance per kg of	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]
			Cats	-	-	-		
			Horses	-	-	-		
			Poultry	-	-	-		

		Tincture as defined by the Council of Europe¹ obtained from the dried fruit of <i>Schisandra chinensis</i> (Turcz.) Baill. by extraction with water/ethanol solvent mixture, pressing and filtration. <u>Specifications</u> - Dry matter content: maximum 4 % - Sum of schisandrin and deoxyschisandrin: 0,01-0,15% - Organic acids: maximum 1,94 % - Dibenzocyclooctadiene lignans: maximum 0,135 % - Phenols: maximum 0,022 % Analytical method ⁽²⁾ For the determination of schisandrin and deoxyschisandrin (phytochemical markers) in the feed additive: - high performance liquid chromatography coupled with photometric detection (HPLC-UV)				complete feedingstuff with a moisture content of 12 %: - 12 mg for chickens for fattening, minor poultry for fattening and all poultry reared for laying or reared for breeding; - 18 mg for all poultry species for laying or breeding; - 16 mg for turkeys for fattening; - 47 mg for horses and for cats; - 56 mg for dogs.”. 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. 5. For users of the additive and premixtures, feed business operators shall establish	
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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

							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.	
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Identi- fication 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 authorisa- tion
					mg of additive/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b318-t	Ginseng tincture	Additive composition Ginseng tincture from the roots of <i>Panax ginseng</i> C.A.Mey. Liquid form Characterisation of the active substance Ginseng tincture Tincture as defined by the Council of Europe ³ obtained from the roots of <i>Panax ginseng</i> C.A.Mey by extraction with water/ethanol solvent mixture, pressing and filtration CoE number: 318 <u>Specifications</u> - Dry matter content: maximum: 6 % - Total ginsenosides: maximum 0,92 % - Sum of ginsenoside Rg1 and	Horses	-	-	-	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 stability to heat treatment shall be indicated. 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 %: - 48 mg for horses - 228 mg for dogs - 162 mg for cats” 4. The functional group, the identification number, the name and the added amount	[to be completed by the OP: insert precise date 10 years from the date of entry into force of this Regulation]
			Dogs	-	-	-		
			Cats	-	-	-		

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

		ginsenoside Rb1: 0,01-0,5 % - Phenols: maximum: 0,039 % - Dicarboxylic acids: maximum 0,33 % - Polyacetylenes (panaxynol and panaxydol): maximum 0,022 % Analytical method ⁽⁴⁾ For the determination of <i>ginsenoside-Rg1</i> and ginsenoside-Rb1 (phytochemical markers) in the feed additive: - high performance liquid chromatography coupled with photometric detection (HPLC-UV)				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. 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.	
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