



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10212/2016 ANNEX CIS
(POOL/E5/2016/10212/10212-EN
ANNEX CIS.doc)
[...](2016) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

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

concerning the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening and a preparation of montmorillonite-illite for all animal species as feed additives

ANNEX I

Identi- fication number of the additive	Additive	Chemical formula, description, methods of analysis	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%			
Technological additives: anti-caking agents								
1g598	Dolomite-magnesite	<p>Additive composition Preparation of natural mixture of: Dolomite and magnesite ≥ 40% (having a minimum content of: carbonates 24%) -----</p> <p>Characterisation of the active substance <u>Dolomite</u> CAS number 16389-88-1 (CaMg)(CO₃)₂ <u>Magnesite</u> CAS number 546-93-0 MgCO₃ <u>Talc</u> (hydrated silicates of magnesium) CAS number 14807-96-6 Mg₃Si₄O₁₀(OH)₂ Talc ≥35% <u>Chlorite</u> (aluminium–magnesium) CAS number 1318-59-8 (Mg,Fe,Al)₆(Si, Al)4O₁₀(OH)₈ Iron (structural) 6 % (average) Chlorite ≥16% Free quartz and asbestos -----</p> <p>Analytical method¹ Characterisation of the feed additive: - X-ray diffraction (XRD) together with - Atomic absorption spectrophotometry (AAS)</p>	Dairy cows and other ruminants for dairy production Weaned Piglets Pigs for fattening	-	5000	20000	<ol style="list-style-type: none">For use in weaned piglets until 35 kg.In the labelling the following shall be indicated:” The additive is rich in (inert) Iron”For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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.	<p><i>[to be completed by the Service responsible for the publication: insert precise date]</i></p> <p>[10 years from the date of entry into force of this Regulation]</p>

¹ Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

ANNEX II

Identi- fication number of the additive	Additive	Chemical formula, description, methods of analysis	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%			
Technological additives: binders								
1g557	Montmorillonite-Illite	Additive composition Preparation of montmorillonite-Illite mixed layer clay mineral: phyllosilicates ≥75% Characterisation of active substance Phyllosilicates ≥75%: ≥ 35 % montmorillonite-illite (swellable) ≥ 30 % illite/muscovite ≤ 15 % kaolinite(non-swellable) Quartz ≤ 20 % Iron (structural) 3.6 % (average) ----- Analytical method ² For the determination in feed additive: - X-ray diffraction (XRD) - Inductively coupled plasma atomic emission spectroscopy (ICP-AES)	All animals species	-	10 000	20 000	1. The instructions for use shall indicate the following: - ‘The simultaneous oral use with macrolides shall be avoided’; - ‘In addition, for poultry, the simultaneous use with robenidine shall be avoided’. 2. In the labelling the following shall be indicated:” The additive is rich in (inert) Iron” 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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.	<i>[to be completed by the Service responsible for the publication: insert precise date]</i> [10 years from the date of entry into force of this Regulation]
Technological additives: anti-caking agent								
1g557	Montmorillonite-Illite	Additive composition Preparation of montmorillonite-Illite mixed layer clay mineral: phyllosilicates ≥75% Characterisation of active substance Phyllosilicates ≥75%: ≥ 35 % montmorillonite/illite (swellable) ≥ 30 % illite/muscovite	All animals species	-	20 000	20 000	1. Indicate in the instructions for use: - ‘The simultaneous oral use with macrolides shall be avoided’; - in poultry: ‘The simultaneous use with robenidine shall be avoided’. 2. In the labelling the following shall be indicated:” The additive is rich in (inert) Iron 3. For users of the additive and premixtures,	<i>[to be completed by the Service responsible for the publication: insert precise date]</i> [10 years from the date of

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Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

Identification number	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation of this Regulation]
		<p>≤ 15 % kaolinite (non-swellable) Quartz ≤ 20 % Iron (structural) 3.6 % (average)</p> <p>-----³</p> <p>Analytical method³</p> <p>For the determination in feed additive:</p> <ul style="list-style-type: none"> - X-ray diffraction (XRD) - Inductively coupled plasma atomic emission spectroscopy (ICP-AES) 					<p>feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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.</p>	

³ Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>