

ANNEX

Identi- fication 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 authori- sation
						Units of activity /kg of complete feedingstuff with a moisture content of 12%			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1612	Andrès Pintaluba S.A.	Endo-1,3(4)- beta-glucanase EC 3.2.1.6 Endo-1,4-beta- xylanase EC 3.2.1.8 Alpha-amylase EC 3.2.1.1	Additive composition: Preparation of endo-1,3(4)-beta- glucanase and endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (NRRL 25541) and alpha-amylase produced by <i>Aspergillus niger</i> (ATTC66222) having respectively a minimum activity of: -Endo-1,3(4)-beta-glucanase 275 U ¹ /g; - Endo-1,4-beta-xylanase 400 U ² /g; - Alpha-amylase 3100 U ³ /g Solid form Characterisation of the active substance: endo-1,3(4)-beta-glucanase and endo- 1,4-beta-xylanase produced by <i>Aspergillus niger</i> (NRRL 25541) and alpha-amylase produced by <i>Aspergillus niger</i> (ATTC66222 Analytical methods⁴ Determination in the feed additive of: - endo-1,3(4)-beta glucanase: colorimetric method based on the	Weaned piglets		endo-1,3(4)- beta- glucanase 450 U beta- xylanase 500 U alpha- amylase 1500 U		1. In the directions for use of the additive and premixtures, the storage conditions and stability to pelleting shall be indicated. 2. 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	[To be completed by the Service responsible for the publication: insert precise date 10 years from the date of entry into force of this Regula- tion]

¹ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4.0 and 30 °C;

² 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from rye arabinoxylan per minute at pH 4.0 and 30 °C;

³ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from wheat starch per minute at pH 5.0 and 30 °C.

⁴ 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>

			<p>enzymatic reaction of glucanase on barley betaglucon substrate in the presence of 3,5-dinitrosalicylic acid (DNS) at pH 4.0 and 30 °C;</p> <ul style="list-style-type: none"> - endo-1,4-β-xylanase in the feed additive: colorimetric method based on the enzymatic reaction of xylanase on rye arabinoxylan substrate in the presence of DNS at pH 4.0 and 30 °C; - alpha-amylase: colorimetric method based on the enzymatic reaction of amylase on wheat starch substrate in the presence of DNS at pH 5.0 and 30 °C. <p>Determination of the active substances in premixtures and feedingstuffs:</p> <ul style="list-style-type: none"> - Colorimetric method measuring depolymerised soluble fragments released by action of glucanase on azo-barley-glucan; - Colorimetric method measuring depolymerised soluble fragments released by action of endo-1,4-β-xylanase on azo-xylan; - Colorimetric method measuring depolymerised soluble fragments released by action of amylase on oligosaccharide “non-reducing-end blocked p-nitrophenyl maltoheptaoside. 	Minor porcine species (weaned)		<p>endo-1,3(4)-beta-glucanase 450 U</p> <p>beta-xylanase 500 U</p> <p>alpha-amylase 1500 U</p>		<p>eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including skin, eyes and breathing protections.</p>	
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