

ANNEX

Identi- fication number of the feed additive	Name of the holder of authorisation	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 authoris- ation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a1604i	Adisseo France S.A.S.	Endo-1,3(4)- beta- glucanase (EC 3.2.1.6) Endo-1,4- beta-xylanase (EC 3.2.1.8)	Additive composition Preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced with <i>Talaromyces versatilis</i> IMI CC 378536 having a minimum activity of: — solid form: endo-1,3(4)-beta-glucanase 30 000 VU ⁽¹⁾ /g and endo-1,4-beta- xylanase 22 000 VU/g; — liquid form: endo-1,3(4)-beta-glucanase 7 500 VU/ml and endo-1,4- beta-xylanase 5 500 VU/ml. Characterisation of the active substance Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-xylanase (EC 3.2.1.8) produced with <i>Talaromyces versatilis</i> IMI CC 378536 Analytical method ⁽²⁾	All poultry species Piglets (weaned) Pigs for fattening Sows	-	Endo-1,3(4)- beta-glucanase 1 500 VU Endo-1,4-beta- xylanase 1 100 VU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2.For use in sows from one week before farrowing to whole lactation period. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 breathing and	[10 years from the date of entry into force of this Regulatio n. To be complete d by the Service responsib le for the publica- tion]

⁽¹⁾ 1 unit of glucanase or xylanase activity is the amount of enzyme which hydrolyzes the substrate (barley betaglucan and wheat arabinoxylan, respectively), reducing the viscosity of the solution, to give a change in relative fluidity of 1 (dimensionless unit)/min at 30 °C and pH 5,5.

⁽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.

			<p>For the quantification of endo-1,3(4)- beta-glucanase activity in the feed additive, premixture and compound feed:</p> <p>— viscosimetric method based on decrease in viscosity produced by action of endo-1,3(4)-beta-glucanase on the glucan substrate barley betaglucan at pH = 5,5 and 30 °C.</p> <p>For the quantification of endo-1,4-beta-xylanase activity in the feed additive, premixture and compound feed:</p> <p>— viscosimetric method based on decrease in viscosity produced by action of endo-1,4-beta-xylanase on the xylan containing substrate (wheat arabinoxylan).</p>					<p>skin (only for the solid formulations of the additive) protective equipment.</p>	
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