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COMMISSION IMPLEMENTING REGULATION (EU) 2016/997

of 21 June 2016

concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation ►M1 Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V. ◄)

(Text with EEA relevance)

(OJ L 164, 22.6.2016, p. 4)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2019/221 of 6 February 2019	L 35	28	7.2.2019

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COMMISSION IMPLEMENTING REGULATION (EU) 2016/997

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(Text with EEA relevance)

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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
						Units of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Zootechnical additives. Functional group: digestibility enhancers									
4a15	►**M1** Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V. ◄	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	*Additive composition* Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (ATCC SD 2106) having respectively a minimum activity of 12 200 U ([1])/g and 1 520 U ([2])/g. Solid and liquid form. *Characterisation of the active substance* Endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (ATCC SD 2106). *Analytical methods* ([3]) Characterisation of the active substance in the additive, premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of endo-1,4-β-xylanase from azurine cross-linked wheat arabinoxylan substrates;	Lactating sows (including minor porcine species) Minor porcine species weaned and for fattening	—	Endo-1,4-beta-xylanase 1 220 U Endo-1,3(4)-beta-glucanase 152 U Endo-1,4-beta-xylanase 610 U Endo-1,3(4)-beta-glucanase 76 U	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heating treatment. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	12 July 2026

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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
						Units of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			— colorimetric method measuring water soluble dye released by action of endo-1,3(4)-β-glucanase from azurine cross-linked barley β — glucan substrates.						

([1]) 1 U is the amount of enzyme which releases 0,48 μmol of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4,2 and 50 °C.
([2]) 1 U is the amount of enzyme which releases 2,4 μmol of reducing sugar (glucose equivalent) per minute from glucan of barley at pH 5,0 and 50 °C.
([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