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COMMISSION IMPLEMENTING REGULATION (EU) 2018/1566

of 18 October 2018

concerning the authorisation of the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by ►C1 *Aspergillus orizae* (ATCC66222) ◄ as a feed additive for weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 1453/2004 (holder of authorisation Andrès Pintaluba S.A.)

(Text with EEA relevance)

(OJ L 262, 19.10.2018, p. 27)

Corrected by:

►C1 Corrigendum, OJ L 258, 7.8.2020, p. 51 (2018/1566)

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COMMISSION IMPLEMENTING REGULATION (EU) 2018/1566

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(Text with EEA relevance)

Article 1

Authorisation

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 the Annex.

Article 2

Amendment to Regulation (EC) No 1453/2004

In Annex II to Regulation (EC) No 1453/2004 entry E 1612 on the preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase and alpha-amylase is deleted.

Article 3

Transitional measures

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 8 May 2019 in accordance with the rules applicable before 8 November 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

Entry into force

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.

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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 activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1612i	Andrés 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 *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by ►**C1** *Aspergillus orizae* (ATCC66222) ◄ having respectively a minimum activity of. — Endo-1,3(4)-beta-glucanase 900 U ([1])/g; — Endo-1,4-beta-xylanase 1 000 U ([2])/g; — Alpha-amylase 3 000 U ([3])/g Solid form *Characterisation of the active substance* endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (NRRL 25541) and alpha-amylase produced by ►**C1** *Aspergillus orizae* (ATCC66222) ◄ *Analytical methods* ([4]) Determination in the feed additive of: — endo-1,3(4)-beta glucanase: colorimetric method based on the enzymatic reaction of glucanase on barley betaglucan substrate in the presence of 3,5-dinitrosalicylic acid (DNS) at pH 4,0 and 30 °C;	Weaned piglets Minor porcine species (weaned)		endo-1,3(4)-beta-glucanase 450 U beta-xylanase 500 U alpha-amylase 1 500 U		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment 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 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. 3. For use in weaned piglets until approximately 35 kg.	8 November 2028

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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 activity/kg of complete feedingstuff with a moisture content of 12 %			
			— 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. Determination of the active substances in premixtures and feedingstuffs: — 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 p-nitrophenylmaltoheptaoside.						

([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