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COMMISSION IMPLEMENTING REGULATION (EU) 2018/338

of 7 March 2018

concerning the authorisation of a preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) as feed additive for chickens for fattening, chickens reared for laying, pigs for fattening, sows, minor porcine species for fattening or for reproduction, turkeys for fattening, turkeys reared for breeding, all other avian species (excluding laying birds) and weaned piglets (holder of the authorisation BASF SE)

(Text with EEA relevance)

(OJ L 65, 8.3.2018, p. 17)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2019/1290 of 31 July 2019	L 203	6	1.8.2019

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COMMISSION IMPLEMENTING REGULATION (EU) 2018/338

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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 activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a27	BASF SE	6-phytase EC 3.1.3.26	*Additive composition:* Preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) with a minimum content of: Solid form: 5 000 FTU ([1])/g Liquid form: 5 000 FTU/g *Characterisation of the active substance:* 6-phytase produced by *Aspergillus. niger* (DSM 25770) *Analytical method* ([2]): For the quantification of phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate For the quantification of phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on the phytate — VDLUFA 27.1.3	Pigs for fattening Sows Minor porcine species for fattening or for reproduction	—	100 FTU		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 breathing protection. 3. For use in weaned piglets up to 35 kg.	28.3.2028
				Weaned piglets		125 FTU			
				Chickens for fattening Chickens reared for laying		►**M1** 125 FTU ◄			
				Turkeys for fattening Turkeys reared for breeding All other avian species (excluding laying birds)		125 FTU			

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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 %			
			For the quantification of phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate — EN ISO 30024						

([1]) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C
([2]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports