

SCHEDULE 9

Regulation 3

Authorisation of a preparation of 6-phytase (EC 3.1.3.26) (identification number 4a32) as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows, minor porcine species for fattening or reproduction

The preparation of 6-phytase (EC 3.1.3.26), belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive nutrition in accordance with the specifications in the following table.

<i>Additive</i>	6-phytase (EC 3.1.3.26)
<i>Identification number of the additive</i>	4a32
<i>Authorisation holder</i>	Huvepharma EOOD
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (DSM 32854) with a minimum activity of: <ul style="list-style-type: none"> — 5 000 FTU/g⁽¹⁾ in granular form — 5 000 FTU/g in coated form — 5 000 FTU/g in liquid form.
<i>Characterisation of the active substance(s)</i>	6-phytase (EC 3.1.3.26) produced by fermentation with <i>Komagataella phaffii</i> (DSM 32854).
<i>Analytical methods</i> ⁽²⁾	For quantification of phytase activity in the feed additive: <ul style="list-style-type: none"> — Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with the VDLUFA Method Book, Volume III (3rd edition 1976, revised), Method No. 27.1.4⁽³⁾.
	For quantification of phytase activity in premixtures: <ul style="list-style-type: none"> — Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with VDLUFA, Method Book, Volume III, (3rd edition 1976, revised), Method No. 27.1.3⁽⁴⁾.
	For quantification of phytase activity in feed materials and compound feed: <ul style="list-style-type: none"> — Colorimetric method based on the enzymatic reaction of phytase on the phytate in accordance with BS EN ISO 30024:2009⁽⁵⁾.
<i>Species or category of animal</i>	<ul style="list-style-type: none"> — All poultry species — Ornamental birds — Piglets — Pigs for fattening — Sows — Minor porcine species for fattening or reproduction.
<i>Maximum age</i>	Not applicable
<i>Minimum content</i> ⁽⁶⁾	250 FTU

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Maximum content</i> ⁽⁶⁾	No maximum
<i>Other provisions</i>	In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

- (1) FTU means phytase enzyme units. One FTU is the amount of enzyme that releases 1 micromole (μm) of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5.5 and 37°C.
- (2) Details of the analytical methods set out in the document referenced “Ares(2020)762221 - 06/02/2020“ and last updated 4th May 2020. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0052>.
- (3) The Association of German Agriculture Analytical and Research Institutes (VDLUFA) Method Book, Volume III, New Single Methods 2016, the Chemical Analysis of Feedingstuff (ISBN 978 3 941273 14 6) is available at the following address: Method book Volume III Feedingstuffs (vdlufa.de). For access to a translated version of Part 27.1.4 contact the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.
- (4) The Association of German Agriculture Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 8th supplement 2012, the Chemical Analysis of Feedingstuff (ISBN 978 3 941273 14 6) is available at the following address: Method book Volume III Feedingstuffs (vdlufa.de). For access to a translated version of Part 27.1.3 contact the Food Standards Agency, Foss House, Kings Pool, 1-2 Peasholm Green, York, YO1, 7PR.
- (5) BS EN ISO 30024:2009. “*Animal feeding stuffs – Determination of phytase activity*”. Published by the International Organization for Standardization on 30th September 2009 (ISBN 978 0 580 62651 7). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (6) Content of 6-phytase: units of activity/kg of complete feed with a moisture content of 12 %.