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**EURL Evaluation Report on the Analytical Methods
submitted in connection with the Application for the
Authorisation of Feed Additives according to
Regulation (EC) No 1831/2003**

Dossier related to: FAD-2010-0268
CRL/100306
FAD-2011-0011
CRL/100370

Product Name: Orthophosphoric acid (E 338)

Active Substance(s): Orthophosphoric acid

Rapporteur Laboratory: European Reference Laboratory
for Feed Additives (EURL-FA)
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Date: 16/09/2011

EXECUTIVE SUMMARY

In the current applications authorisation is sought, under article 4(1)^{1, 2} and under 10(2)² for *orthophosphoric acid* (E338) under the category "technological additives", functional group 1a "preservatives" according to the classification system of Annex I of Regulation (EC) No 1831/2003. According to both Applicants, the *feed additive* is a clear, colourless, odourless, viscous liquid with a purity ranging from 67 % to 85.7 %. Authorisation is sought for the use of the *feed additive* for all categories and species.

For the identification and quantification of the *orthophosphoric acid* in the *feed additive*, the EURL recommends for official control the internationally recognised JECFA Monograph 'Phosphoric acid' methods as suggested by the Applicant¹.

The unambiguous determination of *orthophosphoric acid* in *premixtures* and *feedingstuffs* is not achievable by analytical methods. Hence, the EURL does not recommend for official control any methods for the determination of *orthophosphoric acid* in *premixtures* and *feedingstuffs*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.

KEYWORDS

Orthophosphoric acid, all categories and species, technological additives, preservatives

¹ FAD-2010-0268

² FAD-2010-0011

1. BACKGROUND

In the current applications authorisation is sought, under article 4(1)^{1, 2} and under 10(2)² for *orthophosphoric acid* (E338) under the category "technological additives", functional group 1a "preservatives" according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1]. According to the both Applicants, the *feed additive* is clear, colourless, odourless, viscous liquid [2, 3]. According to the Applicant¹, the *feed additive* has a purity ranging from 67 % to 85.7 % [4].

Specifically, authorisation is sought for the use of the *feed additive* for all categories and species [1].

The *feed additive* is intended to be mixed into *premixtures*, *feedingstuff* and *water*. The Applicants did not suggest a minimum or maximum level [4], as are set in the previous regulations [5].

The Applicant² proposes a formulation of *orthophosphoric acid* absorbed on a silica carrier.

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and the tasks of the European Union Reference Laboratory concerning applications for authorisations of feed additives, the EURL is requested to submit a full evaluation report to the European Food Safety Authority for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *orthophosphoric acid*, and their suitability to be used for official controls in the frame of the authorisation, were evaluated.

3. EVALUATION

Identification /Characterisation of the feed additive

For the identification of *orthophosphoric acid* the EURL recommends the internationally recognised JECFA monograph methods ('phosphoric acid') [6], based on (i) selective reactions with *phosphate* (ii) *acidity* and (iii) *solubility*, as suggested by the Applicant [2].

¹ FAD-2010-0268

² FAD-2010-0011

Qualitative and quantitative composition of impurities in the additive

When required by EU legislation, analytical methods for official control of undesirable substances in the additive (e.g. arsenic, cadmium, lead, mercury, PAHs and dioxins) are available from the respective European Union Reference Laboratories [7].

Description of the analytical methods for the determination of the active substance in feed additive, premixtures and feedingstuffs

For the determination of *orthophosphoric acid* in the *feed additive*, the EURL recommends for official control the JECFA Monograph method [6], based on acid/base titration with 1 M sodium hydroxide and thymolphthalein as indicator, as suggested by the Applicant [2].

For the determination of *orthophosphoric acid* in *premixtures* and *feedingstuff*, Applicant comments [2]:

'The additive's main function as a preservative requires dissociation prior to action. Quantitative determination of the feedadditive, as such, in premixtures and feedingstuffs is therefore not possible. The total phosphorous content of premixtures and feedingstuffs can be quantified, however, the additive is not the only source of phosphorous in the diet of target animals,...'

The unambiguous determination of *orthophosphoric acid* in *premixtures* and *feedingstuffs* is not achievable by analytical methods. Hence, the EURL does not recommend for official control any methods for the determination of *orthophosphoric acid* in *premixtures* and *feedingstuffs*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of this authorisation the EURL recommends for official control:

- the JECFA Monograph method ('phosphoric acid') for the determination of *orthophosphoric acid* in *feed additive*

Recommended text for the register entry (analytical method)

For the determination of the *orthophosphoric acid* in the *feed additive*:

- titration with sodium hydroxide (JECFA monograph 'phosphoric acid')

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *orthophosphoric acid* have been sent to the European Union Reference Laboratory for Feed Additives. The dossier has been made available to the EURL by EFSA.

6. REFERENCES

- [1] Application, Reference SANCO/D2/BVP/ci(2011)452267
 - [2] *Technical dossier, Section II
 - [3] +Technical dossier, Section II
 - [4] *Application, Proposal for Register Entry – Annex A
 - [5] Official Journal of the European Union, C 50 of 25.2.2004, p. 1, *List of the authorised additives in feedingstuffs (1) published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs*
 - [6] JECFA Monograph 'Phosphoric acid', <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-312.pdf> (last visited 09/08/2011)
 - [7] Commission Regulation (EC) No 776/2006 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards to Community Reference Laboratories
- * Refers to Dossier No. FAD-2010-0268
+ Refers to Dossier No. FAD-2011-0011

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was European Reference Laboratory for Feed Additives, IRMM, Geel, Belgium. This report is in accordance with the opinion of the consortium of National Reference Laboratories as referred to in Article 6(2) of Commission Regulation (EC) No 378/2005, as last amended by Regulation (EC) No 885/2009.

8. ACKNOWLEDGEMENTS

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