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**European Union Reference Laboratory for Feed Additives**

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

**Natrolite-phonolite**  
*(FAD-2010-0061; CRL/100073)*





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

Dossier related to: **FAD-2010-0061 - CRL/100073**

Name of Feed Additive: ***Phil 75***<sup>®</sup>

Active Agent (s): **Natrolite-phonolite E566**

Rapporteur Laboratory: **European Union Reference Laboratory for  
Feed Additives (EURL-FA)  
Geel, Belgium**

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Report checked by: **Piotr Robouch (EURL-FA)**  
Date: **23/03/2015**

Report approved by: **Christoph von Holst**  
Date: **25/03/2015**

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## EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 10(2) and 13 for *natrolite-phonolite*, under the category/functional group 1(i) 'technological additives'/ 'anticaking agents', according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species.

The *feed additive* is odourless pale yellow powder obtained by grinding mineral-based substances derived from volcanic rocks. The *feed additive* consists of natural mixture of aluminium silicates, natrolite, feldspar and alkaline, alkaline-earth and aluminium hydro-silicates. According to the Applicant, the *feed additive* contains at least 50 % zeolites from which the main constituents are phillipsite, chabazite and analcime. The *feed additive* is intended to be used directly in *feedingstuffs* to ensure flowability within the storage silos. The Applicant proposed an inclusion level of *feed additive* in complete *feedingstuffs* ranging from 10 to 25 g/kg.

For the characterisation of the *feed additive* the Applicant submitted the international CEN standard EN 13925 method based on X-ray diffraction (XRD). Even though no performance characteristics are provided, the EURL recommends for official control the internationally recognised CEN standard EN 13925 for the characterisation of *natrolite-phonolite*.

The Applicant provided no experimental data or any analytical method for the determination of the *natrolite-phonolite* in *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrix is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of *natrolite-phonolite* in *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

*Natrolite-phonolite*, *Phil 75*<sup>®</sup>, technological additives, anticaking agents, all animal species

## 1. BACKGROUND

In the current application authorisation is sought under articles 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) and 13 (modifications of authorisations ) for *natrolite-phonolite*, under the category/functional group 1(i) 'technological additives/'anticaking agents', according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species [1,2].

The *feed additive* is odourless pale yellow powder obtained by grinding mineral-based substances derived from volcanic rocks. The *feed additive* consists of natural mixture of aluminium silicates, natrolite, feldspar and alkaline, alkaline-earth and aluminium hydro-silicates [3]. According to the Applicant, the *feed additive* contains at least 50 % zeolites from which the main constituents are phillipsite, chabazite and analcime [3]. The *feed additive* is intended to be used directly in *feedingstuffs* to ensure flowability within the storage silos. The Applicant proposed an inclusion level of *feed additive* in complete *feedingstuffs* ranging from 10 to 25 g/kg [2].

## 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 *natrolite-phonolite* 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*

#### *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, mycotoxins and dioxins) are available from the respective European Union Reference Laboratories [4].

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

For the characterisation of the *feed additive* the Applicant submitted the international CEN standard EN 13925 method based on X-ray diffraction (XRD) [5]. The Applicant submitted

experimental data obtained analysing 10 samples originating from different batches/lots. The following compositions were reported [6]:

phillipsite ranging from 44 to 28 %,  
chabazite ranging from 10 to 25 %, and  
analcime ranging from 1 to 4 % ,

where the sum of these constituents was always above 51%, thus complying with the composition specification requested ( $\geq 50$  %) [2]. However, the applicant did not provide results from elemental analysis.

Even though no performance characteristics are provided, the EURL recommends for official control the internationally recognised CEN standard EN 13925 for the characterisation of *natrolite-phonolite*.

The Applicant provided no experimental data or any analytical method for the determination of the *natrolite-phonolite* in *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrix is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of *natrolite-phonolite* in *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**

The EURL recommends for official control the internationally recognised CEN standard, EN 13925, for the characterisation of *feed additive*.

As the quantification of *natrolite-phonolite* added to *feedingstuffs* is not achievable experimentally, the EURL cannot recommend any method for official control in this matrix.

##### ***Recommended text for the register entry (analytical method)***

Characterisation of *the feed additive*:

- X-ray diffraction (XRD) – EN 13925

#### **5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL**

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *natrolite-phonolite* (*Phil 75*<sup>®</sup>) 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/G1: Forw. Appl. 1831/0025-2014
- [2] \*Application, Proposal for Register Entry
- [3] \*Technical dossier, Section II: Identity, characterisation and conditions of use of the additive; methods of analysis
- [4] 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
- [5] Non-destructive testing. X-ray diffraction from polycrystalline and amorphous materials. General principles, EN 13925
- [6] \*Technical dossier, Section II, Annex II.1.3  
\*Refers to Dossier no: FAD-2010-0061

## 7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was European Union 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

The following National Reference Laboratories contributed to this report:

- Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby Fødevarestyrelsen, Ringsted<sup>1</sup> DK
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena (DE)
- RIKILT-Instituut voor Voedselveiligheid, Wageningen (NL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Freistaat Sachsen, Nossen<sup>2</sup> (DE)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)
- Państwowy Instytut Weterynaryjny, Puławy (PL)

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