
Natrolite-phonolite
(FAD-2010-0238; CRL/100234)

Dossier related to: FAD-2010-0238 - CRL/100234
Name of Feed Additive: Natrolite-phonolite E566
Active Agent (s): Natrolite-phonolite
Rapporteur Laboratory: European Union Reference Laboratory for Feed Additives (EURL-FA) Geel, Belgium
Report prepared by: Zigmas Ezerskis
Report checked by: Piotr Robouch (EURL-FA) 03/09/2015
Report approved by: Christoph von Holst 04/09/2015
EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 10(2) 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.

According to the Applicant the *feed additive* is an odourless grey-brown 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 content of natrolite (zeolite) in the *feed additive* is ranging from 43 to 46.5 %.

The *feed additive* is intended to be used directly in *feedingstuffs* or through *premixtures* to ensure flowability within the storage silos. The Applicant proposed a maximum inclusion level of the *feed additive* in complete *feedingstuffs* of 25 g/kg.

For the characterisation of the *feed additive (natrolite-phonolite)* the Applicant suggested X-Ray diffraction (XRD) analysis to determine the main mineralogical components. This method - described in the EN 13925 standard - was previously recommended by the EURL in the frame of the evaluation of FAD-2010-0061. Four main mineralogical compositions were reported for four typical natrolite-phonolite samples: natrolite, K-feldspar, āgirinaugit, and wollastonite. In addition, the Applicant applied X-Ray fluorescence spectrometry (XRF) as described in the ISO 29581-2 standard and reported elemental composition for the *feed additive* consisting of SiO$_2$, Al$_2$O$_3$, CaO, Na$_2$O, K$_2$O and Fe$_2$O$_3$.

Based on the available experimental data, the EURL recommends for official control the XRD and XRF methods described in the EN 13925 and the ISO 29581-2 standards for the characterisation of the *feed additive*.

The unambiguous determination of the *feed additive* added to *premixtures* and *feedingstuffs* is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the determination of *natrolite-phonolite* 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**

*Natrolite-phonolite*, 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) 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].

According to the Applicant the feed additive is an odourless grey-brown powder obtained by grinding mineral-based substances derived from volcanic rocks [3]. The feed additive consists of natural mixture of aluminium silicates, natrolite, feldspar and alkaline, alkaline-earth and aluminium hydro-silicates [2,3]. According to the Applicant, the content of natrolite (zeolite) in the feed additive ranges from 43 to 46.5 % [3]. The feed additive is intended to be used directly in feedingstuffs or through premixtures to ensure flowability within the storage silos. The Applicant proposed a maximum inclusion level of the feed additive in complete feedingstuffs of 25 g/kg [2].

Note: The EURL evaluated another natrolite-phonolite dossier (FAD-2010-0061).

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 (natrolite-phonolite)* the Applicant suggested using an X-Ray diffraction (XRD) analysis to determine its main mineralogical components [2,3]. This method - described in the EN 13925 standard [5] - was previously recommended by the EURL in the frame of the evaluation of FAD-2010-0061 [6].

The following main mineralogical compositions were reported for four typical natrolite-phonolite samples [7]:

- **natrolite**: 43.1 - 46.3%
- **K-feldspar**: 27.1 - 35.2%
- **ägirinaugit**: 9.6 - 11.6%
- **wollastonite**: 6.6 - 12.2%

In addition, the Applicant applied X-Ray fluorescence spectrometry (XRF) as described in the ISO 29581-2 standard [8] and derived the following "observed" elemental composition for the *feed additive* [3], which are compared to "typical" natrolite-phonolite compositions [7] in the table hereafter:

<table>
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<tr>
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<tbody>
<tr>
<td>SiO₂</td>
<td>47.2 - 50.8 %</td>
<td>48.2 - 50.6 %</td>
</tr>
<tr>
<td>Al₂O₃</td>
<td>16.3 - 18.6 %</td>
<td>17.4 - 18.6 %</td>
</tr>
<tr>
<td>CaO</td>
<td>6.2 - 8.7 %</td>
<td>6.7 - 8.5 %</td>
</tr>
<tr>
<td>Na₂O</td>
<td>5.3 - 7.5 %</td>
<td>5.5 - 8.2 %</td>
</tr>
<tr>
<td>K₂O</td>
<td>4.4 - 6.1 %</td>
<td>4.1 - 5.7 %</td>
</tr>
<tr>
<td>Fe₂O₃</td>
<td>4.1 - 4.5 %</td>
<td>3.9 - 4.3 %</td>
</tr>
</tbody>
</table>

Based on the available experimental data, the EURL recommends for official control the XRD and XRF methods described by the EN 13925 and the ISO 29581-2 standards for the characterisation of the *feed additive*.

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

The EURL recommends for official control two internationally recognised standards: - EN 13925, based on X-ray diffraction (XRD); and - ISO 29581-2, based on X-ray fluorescence spectrometry (XRF) for characterisation of the feed additive (natrolite-phonolite).

The unambiguous quantification of the feed additive added to premixtures and feedingstuffs is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the quantification of natrolite-phonolite in premixtures and feedingstuffs.

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

Characterisation of the feed additive:
- X-ray diffraction (XRD) – EN 13925; and
- X-ray fluorescence spectrometry (XRF) – ISO 29581-2

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of natrolite-phonolite 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

[2] *Application, Proposal for Register Entry
[3] *Technical dossier, Section II: Identity, characterisation and conditions of use of the additive; methods of analysis
[7] *Technical dossier, Section II – Annex_IL_1_8

*Refers to Dossier no: FAD-2010-0238
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:

- RIKILT Wageningen UR, Wageningen (NL)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Państwowy Instytut Weterynaryjny, Pulawy (PL)