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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

Vermiculite

(FEED- 2023-16782; CRL/230004)

European Union Reference Laboratory
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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

Dossier related to:	**FEED-2023-16782 - CRL/230004**
Name of Product :	***Vermiculite***
Active Agent (s):	**Vermiculite**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA)** **JRC Geel, Belgium**
Report prepared by:	**Stefano Bellorini**
Report checked by: Date:	**María José González de la Huebra** **19/12/2023**
Report approved by: Date:	**Christoph von Holst** **19/12/2023**

EXECUTIVE SUMMARY

In the current application an authorisation is sought under Article 4 for *vermiculite*, under the category/functional group 1(i) 'technological additives' / 'binders' and 'anticaking agents', according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species and categories.

According to the Applicant, *vermiculite* is a magnesium aluminium iron silicate powder mainly consisting of (w/w) 20-40 % Magnesium oxide (MgO), 7-15 % of Aluminium oxide (Al_2O_3), 4-10 % of Iron oxide (Fe_2O_3) and 35-45 % of Silicon dioxide (SiO_2). The *feed additive* is intended to be used for all monogastric species through complementary feed, *premixtures* or directly added to *compound feed*. The Applicant proposed a maximum dose corresponding to 50 g/kg *feed additive* in *feed*.

As the unambiguous determination of *vermiculite* or the *feed additive* added to *premixtures* and *compound feed* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control for the determination of *vermiculite* in the *feed additive*, *premixture*s and *compound feed*.

For the elemental characterisation of a similar *feed additive*, the EURL recommended for official control the EN ISO 12677 method based on X-Ray Fluorescence (XRF) spectrometry. Furthermore, the Applicant, in the frame of the studies supporting the present dossier, applied the EN ISO 12677 method presenting satisfactory results.

Based on the experimental evidence presented the EURL recommends for official control the EN ISO 12677 method based on X-Ray Fluorescence (XRF) spectrometry for the elemental characterisation of the *feed additive*

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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

KEYWORDS

Vermiculite, technological additives, binders and anticaking agents, all animal species.

1. BACKGROUND

In the current application an authorisation is sought under Article 4(1) (new feed additive) for *vermiculite*, under the category/functional group 1(i) 'technological additives' / 'binders' and 'anticaking agents', according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the *feed additive* for all animal species and categories [1,2].

According to the Applicant, *vermiculite* is a grey magnesium aluminium iron silicate powder consisting of (w/w) [2,3]:

- 20-40 % of Magnesium oxide (MgO)
- 7-15 % of Aluminium oxide (Al_2O_3)
- 4-10 % of Iron oxide (Fe_2O_3)
- 35-45 % of Silicon dioxide (SiO_2)

It also contains (expressed as mass fraction) 0.5-5 % of Calcium oxide (CaO) and a maximum content of 6 and 1 % respectively of Potassium oxide (K_2O) and Sodium oxide (Na_2O) [3].

The *feed additive* is intended to be used for all monogastric species through complementary feed, *premixtures* or directly added to *compound feed.* The Applicant indicated a maximum dose corresponding to 50 g/kg *feed additive* in *feed* [2,4]. Furthermore, it is specified a typical inclusion level of 10 g/kg *feed additive* in *feed* [4].

Note: An authorisation was sought under article 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *vermiculite* (formerly listed as *feed additive* as E561). In the frame of dossier FAD-2010-0128, the EURL evaluated the analytical methods for the official control issuing the corresponding report [5].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761, 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 *vermiculite* and their suitability to be used for official controls in the frame of the authorisation were evaluated.

3. EVALUATION

Description of the analytical methods for the determination of the active substance in the feed additive, premixtures, compound feed and when appropriate water (section 2.6.1 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

As the unambiguous determination of *vermiculite* or the *feed additive* added to *premixtures* and *compound feed* is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control for the determination of *vermiculite* in the *feed additive*, *premixture*s and *compound feed*.

Methods of analysis for the determination of the residues of the additive in food (section 2.6.2 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

An evaluation of corresponding methods of analysis is not relevant for the present application.

Identification/Characterisation of the feed additive (section 2.6.3 of the dossier - Annex II of Commission Regulation (EC) No 429/2008

For the characterisation of the *feed additive* the Applicant submitted an analytical method based on X-Ray Fluorescence Spectroscopy (XRF) [6]. The method is routinely performed by a laboratory accredited for this specific analysis by the United Kingdom Accreditation Service (UKAS) [7].

The procedure described for the analysis of pressed powders trace elements/fused beads is very similar to the one specified in the protocol of the EN ISO 12677 method. This standard, based on XRF, has been already recommended by the EURL for the elemental characterisation of a similar *feed additive* [8,9].

When applying the EN ISO 12677 method, the powdered sample is fused with a suitable flux to destroy its mineralogical and particulate composition. The resultant melt is cast into the shape of a glass bead which is then introduced into an XRF spectrometer. The intensities of the fluorescent X-rays of the elements in the bead are measured and the chemical composition of the sample is determined by using calibration graphs or equations applying corrections for inter-elemental effects [8].

Furthermore, the Applicant, in the frame of the batch to batch variation experiments, presented satisfactory results applying the EN ISO 12677 method [3,10].

Based on the experimental evidence presented the EURL recommends for official control the EN ISO 12677 method based on XRF spectrometry for the elemental characterisation of the *feed additive*.

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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of the current authorisation the EURL recommends for official control the EN ISO 12677 method based on X-ray fluorescence (XRF) spectrometry for the elemental characterisation of the *feed additive*.

As the unambiguous determination of *vermiculite* in the *feed additive* added to *premixtures* or *compound feed* is not achievable experimentally, the EURL cannot recommend any method for official control in these matrices.

Recommended text for the register entry (analytical method)

For the characterisation of the *feed additive*:

- X-ray fluorescence (XRF) spectrometry (EN ISO 12677)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *vermiculite* 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] Forwarding of applications for authorisation of feed additives in accordance with Regulation (EC) No 1831/2003 – E-Submission Food Chain platform: https://webgate.ec.europa.eu/esfc/#/applications/46183 https://open.efsa.europa.eu/questions/EFSA-Q-2023-00391
[2] *Application, Annex 1
[3] *Technical dossier, Sect_2.1-2.2_Identity_II.1.3 Qualitative and quantitative composition
[4] *Technical dossier, Sect_2.5_Conditions_II.5.1 Proposed mode of use in animal nutrition
[5] EURL report: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0128_en
[6] *Technical dossier, Sect_2.6_Methods_II.6 Method of analysis and reference samples
[7] *Technical dossier, Sect_II_Annexes_2.6.1 Method of analysis
[8] EN ISO 12677:2011 – Chemical analysis of refractory products by X-ray fluorescence (XRF) – fused cast-bead method
[9] EURL reports: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0282_en
[10] *Technical dossier, Sect_II _Annexes_2.1.3 BtB 22-00375- 220126 CONFID

*Refers to Dossier no: FEED-2023-16782

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation is the European Union Reference Laboratory for Feed Additives, JRC, 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 (EU) 2015/1761.

8. ACKNOWLEDGEMENTS

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- Państwowy Instytut Weterynaryjny, Pulawy (PL)
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- Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana (SI)
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- Centro di referenza nazionale per la sorveglienza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)