EUROPEAN COMMISSION
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JRC.D.5/SFB/CvH/JK/msd/Ares

European Union Reference Laboratory

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

Natural mixture of dolomite plus magnesite and magnesiumphyllosilicates

(FAD-2012-0043; CRL/120031)

European Union Reference Laboratory
Feed Additives

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

Dossier related to:	**FAD-2012-0043 - CRL/120043**
Name of Product	**Fluidol**
Active Substance(s):	**Natural mixture of dolomite plus magnesite and magnesiumphyllosilicates**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA) Geel, Belgium**
Report prepared by:	**Johanna Keltti**
Report revised by: Date:	**Piotr Robouch (EURL-FA)** **1/10/2013**
Report approved by: Date:	**CvH** **22/10/2013**

EXECUTIVE SUMMARY

In the current application authorisation is sought under article 4(1) *Fluidol*, natural mixture of *dolomite* plus *magnesite* and *magnesiumphyllosilicates* (later referred as *DMM*), under the category/functional group and 1(i) 'technological additives'/'binders' and '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. *DMM* is an odourless grey powder obtained by crushing and milling natural rocks. The *feed additive* consists mainly of *dolomite*, *magnesite* and *magnesiumphyllosilicates* and other minerals such as hydrated silicates. According to the Applicant, the *feed additive* contains a minimum of 40% of *dolomite* and *magnesite*. The *feed additive* is intended to be used in *premixtures* and *feedingstuffs*. The Applicant did not specify any maximum or minimum concentration of *DMM* in *feedingstuffs* but recommends a dosage of 0.5 - 2% for all animal species.

For the determination of mineralogical composition of the *feed additive* the Applicant submitted experimental data obtained using X-ray diffraction (XRD) method. Furthermore, the chemical composition of the *feed additive* was characterised by the Applicant using atomic absorption spectrophotometry (AAS). Based on the experimental evidence provided, the EURL recommends for official control the two methods (XRD and AAS) for the characterisation of *Fluidol.*

As the quantification of *DMM* in *premixtures* and *feedingstuffs* is not achievable experimentally, the EURL cannot recommend any method for official control in these matrices.

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

Fluidol, dolomite, *magnesite*, *magnesiumphyllosilicates*, technological additives, anticaking agents, all animal species.

1. BACKGROUND

In the current application authorisation is sought under article 4(1) *Fluidol*, natural mixture of d*olomite* plus n*agnesite* and n*agnesiumphyllosilicates* (later referred as *DMM*), under the category/functional group and 1(i) 'technological additives'/'binders' and 'anticaking agents', according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1]. The authorisation is sought for the use of the *feed additive* for all animal species [2].

DMM is an odourless grey powder obtained by crushing and milling natural rocks. The *feed additive* consists mainly of *dolomite*, *magnesite* and *magnesiumphyllosilicates* and other minerals such as hydrated silicates. According to the Applicant, the *feed additive* contains a minimum of 40% of *dolomite* and *magnesite* [2].

The *feed additive* is intended to be used in *premixtures* and *feedingstuffs*. The Applicant did not specify any maximum or minimum concentration of *DMM* in *feedingstuffs* but recommends a dosage of 0.5 - 2% for all animal species [3].

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 *Fluidol,* and their suitability to be used for official controls in the frame of the authorisation, were evaluated.

3. EVALUATION

Qualitative and quantitative composition of impurities in the feed additive

When required by EU legislation, analytical methods for official control of undesirable substances in the additive such as heavy metals (arsenic, cadmium, lead and mercury), dioxins, microbiological agents and mycotoxins are available from the respective European Union Reference Laboratories [4].

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

For the determination of mineralogical composition of the *feed additive* the Applicant submitted experimental data obtained using X-ray diffraction (XRD) method. The following results are derived from the analyses of 3 samples [3, 5]:

dolomite:	29.7 ± 3.5%
magnesite:	17.3 ± 3.5%
hydrated silicates of magnesium:	35.7 ± 1.1%
hydrated silicates of aluminium-magnesium:	17.3 ± 1.1%

Furthermore, the *feed additive* was characterised by the Applicant using atomic absorption spectrophotometry (AAS) and the following chemical composition was derived from the analysis of elements in 5 samples [3, 6]:

SiO_2	28.4 ± 0.4 %
MgO	27.8 ± 0.7 %
Fe_2O_3	8.1 ± 0.2 %
CaO	5.1 ± 0.2 %
Al_2O_3	2.5 ± 0.2 %

Based on the experimental evidence provided, the EURL recommends for official control the crystallographic characterisation by X-ray diffraction (XRD) together with the chemical analysis by atomic absorption spectrophotometry (AAS) for the characterisation of *Fluidol.*

The Applicant provided no experimental data or any analytical method for the determination of the *DMM* in *premixtures* or *feedingstuffs* as the unambiguous determination of *Fluidol* content added to these matrices is not achievable experimentally. Therefore, the EURL cannot evaluate nor recommend any method for official control for the direct determination of *DMM* in *premixtures* or *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 X-ray diffraction (XRD) together atomic absorption spectrophotometry (AAS) for the characterisation of *Fluidol* (*feed additive).*

As the quantification of *DMM* in premixtures and feedingstuffs is not achievable experimentally, the EURL cannot recommend any method for official control in these matrices.

Recommended text for the register entry (analytical method)

Characterisation of *the feed additive*:

- X-ray diffraction (XRD) together with
- Atomic absorption spectrophotometry (AAS)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference sample of *Fluidol* 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] Reference SANCO/D/2 Forw. Appl. 1831/0008-2013

[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] Technical dossier, Section II – Annex 2-1-1

[6] Technical dossier, Section II – Annex 2-1-2

7. RAPPORTEUR LABORATORY

The Rapporteur Laboratory for this evaluation was the 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:

- Fødevarestyrelsen, Ringsted (DK)
- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)
- Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin (PL)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)
- RIKILT - Instituut voor Voedselveiligheid, Wageningen (NL)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana (SL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Labore Landwirtschaft, Leipzig (DE)