



**EUROPEAN COMMISSION**  
JOINT RESEARCH CENTRE

Directorate F - Health, Consumers & Reference Materials (Geel/Ispra)  
**European Union Reference Laboratory for Feed Additives**

JRC F.5/CvH/SB/AS/Ares

**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**

**Lignosulphonate of magnesium**  
*(FAD-2010-0017; CRL/090047)*





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in connection with the Application for Authorisation of a  
Feed Additive according to Regulation (EC) No 1831/2003**

Dossier related to: **FAD-2010-0017 - CRL/090047**

Name of Feed Additive: ***Lignosulphonate of magnesium***

Active Agent (s): **-**

Rapporteur Laboratory: **European Union Reference Laboratory for  
Feed Additives (EURL-FA)  
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Date: **13/03/2020**

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Date: **13/03/2020**

## EXECUTIVE SUMMARY

In the current application authorisation is sought under Article 10(2) for *lignosulphonate of magnesium* (E565) as a *feed additive* under the category "technological feed additives", functional group 1(g) "binders" according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought to use the *feed additive* for all animal species and categories.

The Applicant did not include in the dossier any activity definition, purity criteria or minimum content. The Applicant did not specify any conditions of use.

The Applicant did not provide experimental data or an analytical method for the determination of *lignosulphonate of magnesium* in the *feed additive*, *premixtures*, *feedingstuffs* and *water*. Furthermore, an unambiguous determination of *lignosulphonate of magnesium* 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 *lignosulphonate of magnesium* in the *feed additive*, *premixtures*, *feedingstuffs* and *water*.

## KEYWORDS

*Lignosulphonate of magnesium*, technological feed additives, binders, all animal species and categories

## 1. BACKGROUND

In the current application authorisation is sought under Article 10(2) for *lignosulphonate of magnesium* (E565) as a *feed additive* under the category "technological feed additives", functional group 1(g) "binders" according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1,2]. The authorisation is sought to use the *feed additive* for all animal species and categories [1,2].

The *lignosulphonates* are lignosulphonic acid salts manufactured as by-product by cellulose industry [3]. The *lignosulphonate of magnesium* presented in the current application is a brown aqueous solution produced from eucalyptus derivative [3]. The Applicant did not include in the dossier any activity definition, purity criteria or minimum content. The Applicant did not specify any conditions of use [3].

The *feed additive* is already authorised by Commission Directive 70/524/EEC under number E 565 [3].

Note: The EURL previously evaluated the analytical methods for the determination of *lignosulphonates* in the frame of dossier FAD-2010-0209 [4].

## **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 *lignosulphonate of magnesium* 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, feedingstuffs and when appropriate water (section 2.6.1 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)***

The Applicant did not provide experimental data or an analytical method for the determination of *lignosulphonate of magnesium* in the *feed additive, premixtures, feedingstuffs* and *water* [3].

In the frame of dossier FAD-2010-0209, the EURL recommended for the determination of *lignosulphonate* in the *feed additive* an indirect method, described in the JECFA monograph for calcium *lignosulphonate*, based on the determination of reducing sugars and total ash [4,5]. The conclusions of the above mentioned report could have been also considered for the present application. However, due to the lack of a precise description of the *feed additive* the EURL cannot evaluate nor recommend any method for official control for the determination of *lignosulphonate of magnesium* in the *feed additive*.

Furthermore, an unambiguous determination of *lignosulphonate of magnesium* 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 *lignosulphonate of magnesium* in *premixtures* and *feedingstuffs*.

***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.

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

An evaluation of corresponding methods of analysis is not considered necessary by the EURL.

**4. CONCLUSIONS AND RECOMMENDATIONS**

The Applicant did not provide experimental data or analytical method for the determination of *lignosulphonate of magnesium* in the *feed additive, premixtures, feedingstuffs* and *water*. Furthermore, an unambiguous determination of *lignosulphonate of magnesium* 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 *lignosulphonate of magnesium* in the *feed additive, premixtures, feedingstuffs* and *water*.

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

None

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

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *lignosulphonate of magnesium* 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.1831/0036-2014
- [2] \*Application, Annex 1 – submission number 1267014584577-412
- [3] \*Technical dossier, sumario científico 3.doc
- [4] FAD-2010-0209, Lignosulphonate, Ref. Ares(2011)439690 – 19/04/2011  
<https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0209.pdf>
- [5] FAO JECFA Monographs 5 (2008), Calcium Lignosulfonate (40-65)  
[http://www.fao.org/fileadmin/user\\_upload/jecfa\\_additives/docs/monograph5/additive-505-m5.pdf](http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph5/additive-505-m5.pdf)

\*Refers to Dossier no: FAD-2010-0017

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## **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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- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 — Labore Landwirtschaft, Nossen (DE)
- <sup>1</sup> Wageningen Food Safety Research (WFSR) (NL)
- Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia, PESCA, Alimentació i Medi Natural. Generalitat de Catalunya, Cabrils (ES)

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