
Ethyl cellulose
(FAD-2011-0023; CRL/100339)

Dossier related to: FAD-2011-0023 - CRL/100339

Name of Product / Feed Additive: Ethyl Cellulose

Active Agent (s): -

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

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Date: 12/08/2015

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Date: 12/08/2015
EXECUTIVE SUMMARY

In the current application authorisation is sought under article 10 for Ethyl cellulose under the 'category' / 'functional groups' 1(g) 'technological additives' / 'binders' according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additive for all animal species. Ethyl cellulose presents white granular or powder appearance. The Applicant stated that the purity criteria/technical specification set in Commission Regulation (EU) 231/2012 for the food additive apply also to the feed additive. The feed additive is intended to be included through premixtures or added directly into feedingstuffs quantum satis.

For the characterisation of the feed additives, the Applicant referred to the Commission Regulation (EU) 231/2012 and submitted the FAO JECFA 'Ethyl cellulose' monograph of compendium for food additives, and the dedicated European Pharmacopoeia monograph (01/2008:0822). According to the Commission Regulation (EU) 231/2012 two qualitative tests are required for the characterisation of ethyl cellulose: - solubility test; - film forming test, together with three quantitative assays: - loss on drying; - sulphated ash; and – determination of the ethoxyl groups content. Two additional qualitative tests are prescribed by the European Pharmacopoeia: - acidity or alkalinity; and - viscosity. Even though no performance characteristics are provided, the EURL recommends for official control the methods required by Commission Regulation (EU) 231/2012 and described in the FAO JECFA and in the European Pharmacopoeia monographs for the characterisation of the feed additives.

Since the accurate quantification of Ethyl cellulose added to premixtures or feedingstuffs is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify Ethyl cellulose 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.

KEYWORDS

Ethyl cellulose, E 462, technological additives, binders, all animal species
1. BACKGROUND

In the current application authorisation is sought under article 10 (authorisation of an existing product) for Ethyl cellulose under the 'category' / 'functional groups' 1(g) 'technological additives' / 'binders' according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1]. Specifically, authorisation is sought for the use of the feed additive for all animal species [1,2].

Ethyl cellulose is a derivative of wood cellulose and presents white granular or powder appearance. The Applicant states that the specific purity criteria set in the Commission Regulation (EU) 231/2012 for the food additive are applicable for the feed additive [3,4].

The feed additive is intended to be included through premixtures or added directly into feedingstuffs quantum satis [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 "ethyl cellulose" 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) are available from the respective European Union Reference Laboratories [5].

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

For the characterisation of the feed additives, the Applicant referred to the Commission Regulation (EU) 231/2012 [4,6] and submitted the FAO JECFA 'Ethyl cellulose' monograph of compendium for food additives [7], and the dedicated European Pharmacopoeia monograph (01/2008:0822) [8].
According to the Commission Regulation (EU) 231/2012 [4] two qualitative tests are required for the characterisation of ethyl cellulose: - solubility test; - film forming test, together with three quantitative assays: - loss on drying; - sulphated ash; and – determination of the ethoxyl groups content. All these tests are described in the FAO JECFA monograph [7]. Two additional qualitative tests are prescribed by the European Pharmacopoeia [8]: - acidity or alkalinity; and - viscosity.

Insoluble in water, glycerol or propane-1,2-diol, ethyl cellulose containing more than 46 % ethoxyl groups is soluble in methanol, ethanol, toluene, chlorophorm and ethyl acetate [4,7,8].

A flammable film is formed when ethyl cellulose dissolved in a toluene/ethanol solution is deposited on a glass plate [4,7].

For the determination of loss on drying, the sample is placed in the oven at 105°C for 2h. The sample is weighed again after cooling to room temperature, and the difference of the weights is calculated [4,7,8]

Sufficient diluted sulphuric acid is added to the sample to moisten the entire sample. The sample is then gently heated most of/all the sample is volatilised. The insoluble matter is ignited at 800 °C for 15 min. The residues are weighed after cooling [4,7,8] to determine the amount of sulphate ash.

The sample is added to water and shaken for 15 min. The slurry is then filtered. The supernatant turns red in basic media, or red in acidic media in the presence phenolphtalein or methyl red indicators, respectively [8].

The sample is added to an ethanol/toluene mixture and shaken till complete dissolution. The viscosity is then determined using a suitable capillary viscometer at a room temperature by measuring the time required for the level of the liquid to drop from one mark to the other [8].

For the quantification of the content of ethoxy groups in ethyl cellulose the Applicant submitted the gas chromatography (GC) assay described in the European Pharmacopoeia monograph [8]. The sample (50 mg) is added to adipic acid and to the toluene/o-xylene internal standard in a pressure tight closed vial. Hydriodic acid is then added and the mixture is shaken and heated to 125 °C for 10 min (this step is repeated three times). 1 mL is sampled from the upper layer and injected into the GC. The content of the ethoxy groups is derived from the ratio of normalised iodoethane peak areas in the sample and the iodoethane reference solution [8].

Even though no performance characteristics are provided, the EURL recommends for official control the methods required by Commission Regulation (EU) 231/2012 and described in the FAO JECFA and in the European Pharmacopoeia monographs for the characterisation of the feed additives.
Since the accurate quantification of Ethyl cellulose added to premixtures or feedingstuffs is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify Ethyl cellulose 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 the methods required in Commission Regulation (EU) 231/2012 and described in the FAO JECFA ‘Ethyl cellulose’ monograph and in the European Pharmacopoeia monograph (01/2008:0822), for the characterisation of the feed additive.

Since the accurate quantification of Ethyl cellulose added to premixtures or feedingstuffs is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to quantify Ethyl cellulose in premixtures or feedingstuffs.

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

For the characterisation of Ethyl cellulose in the feed additive:


5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of Ethyl cellulose 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 – Annex A

[3] Technical dossier, Section II: Identify, characterisation and conditions of use of the additive; methods of analysis


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 (DK)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Laboratorio Arbitral Agroalimentario, Ministerio de Agricultura, Alimentación y Medio Ambiente, Madrid (ES)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Labore Landwirtschaft, Nossen (DE)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarni inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Laboratoire de Rennes, SCL L35, Service Commun des Laboratoires, Rennes (FR)