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European Union Reference Laboratory for Feed Additives

**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**

Polyethyleneglycol ester of fatty acids from soya oil (E487)
(FAD-2010-0359; CRL/100195)
(FAD-2012-0014; CRL/120002)



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Dossier related to: **FAD-2010-0359 - CRL/100195
FAD-2012-0014 - CRL/120002**

Feed Additive Name: **Polyethyleneglycol ester of fatty acids
from soya oil (E487)**

Active Agent (s): **Polyethyleneglycol ester of fatty acids
from soya oil**

Rapporteur Laboratory: **European Union Reference Laboratory for
Feed Additives (EURL-FA)
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Date: **10/10/2013**

Report approved by: **Christoph von Holst**
Date: **28/10/2013**

EXECUTIVE SUMMARY

In the current applications authorisations is sought under articles 4(1)¹ and 10(2)² for *Polyethyleneglycol ester of fatty acids from soya oil (E 487)* under the category/functional group 1(c) "technological additives"/"emulsifiers" 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 categories¹ and calves².

Polyethyleneglycol ester of fatty acids from soya oil (PEGEFA) is a mixture of the mono- and diesters of mixed polyoxyethylene diols with the fatty acids and corresponding free polyol. The average number of moles of ethylene oxide used in production process per mole of fatty acids varies from 20 to 65. Soya oil itself is a triglyceride extracted from the soybean *Glycine max. L*, comprising mainly linoleic acid (ca. 48-55 %), oleic acid (ca. 17-30 %) and palmitic acid (ca. 9-13 %). The Applicant in both applications suggested the following technical specification ranges to characterise the *feed additive*: 45 to 95 mg KOH/g for the saponification value; 5.0 to 7.5 for pH; less than 2 mg KOH/g for the acid value; and less than 2 % w/w for the water content.

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*, with recommended maximum *PEGEFA* concentration levels for calves of 6 g /kg *feedingstuffs*. However, a typical *PEGEFA* inclusion level in the milk replacers varies from 3 to 5 g /kg.

For the characterisation of *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive* the Applicant in both applications proposed several official methods developed by the American Oil Chemists' Society (AOCS) and the standard of American Society for Testing and Materials (ASTM) for the determination of the: - saponification value (AOCS Cd 3-25); - acid value (AOCS 3d-63); - pH value (ASTM Standard D1172-95:2007); and - water content (AOCS Ca 2e-84). Even though no performance characteristics are provided, the EURL recommends for official control the official AOCS methods and the ASTM standard to characterise *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive*. The accurate determination of *Polyethyleneglycol ester of fatty acids from soya oil* in *premixtures* and *feedingstuffs* is not achievable experimentally. Furthermore, the Applicant did not provide any analytical method or data for determination of the active substance in the mentioned matrices. Therefore, the EURL cannot evaluate nor recommend any method for official control to determine *Polyethyleneglycol ester of fatty acids from soya oil* in *premixtures* and *feedingstuffs*.

¹ FAD-2012-0014; ² FAD-2010-0359

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

Polyethyleneglycol ester of fatty acids from soya oil (E 487), technological additives, emulsifiers, calves, all animal species and categories

1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use of the *feed additive* for FAD-2012-0014) [1] and 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC for FAD-2010-0359) [2] for *Polyethyleneglycol ester of fatty acids from soya oil (E 487)* under the category/functional group 1(c) "technological additives"/"emulsifiers" 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] and calves [2].

Polyethyleneglycol ester of fatty acids from soya oil (PEGEFA) is a mixture of the mono- and diesters of mixed polyoxyethylene diols with the fatty acids and corresponding free polyol. The average number of moles of ethylene oxide used in production process per mole of fatty acids varies from 20 to 65 [3]. Soya oil itself is a triglyceride extracted from the soybean *Glycine max. L.*, comprising mainly linoleic acid (ca. 48-55 %), oleic acid (ca. 17-30 %) and palmitic acid (ca. 9-13 %) with minor amounts of linolenic, stearic and arachidic acids [4].

The Applicant suggested the following technical specifications to characterise the *feed additive* [3]:

<i>parameter</i>	<i>Range</i>
Saponification value:	from 45 to 95 mg KOH/g
pH:	from 5.0 to 7.0
acid value:	< 2 mg KOH/g
water content:	< 2 % w/w

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures* [4], with recommended maximum *PEGEFA* concentration levels for calves of 6 g /kg complete *feedingstuffs* [3]. However, a typical *PEGEFA* inclusion level in the milk replacers varies from 3 to 5 g /kg [4].

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 *Polyethyleneglycol ester of fatty acids from soya oil (E 487)* 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, aflatoxin B1 and dioxins) are available from the respective European Union Reference Laboratories [5].

The Applicant indicated the maximum levels in the *feed additive* for ethylene oxide and 1,4-dioxane impurities of 1 and 5 mg/kg, respectively. Both can be determined by gas chromatography with flame ionization detection (GC-FID) [6].

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

For the characterisation of *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive* the Applicant proposed several official methods developed by the American Oil Chemists' Society (AOCS) and the standard of American Society for Testing and Materials (ASTM) for the determination of the saponification- [7], acid- [8], pH- [9] and water content [10]. In addition, the EURL identified equivalent generic methods described in the internationally recognised FAO JECFA monograph for food additives [11] and/or in the European Pharmacopoeia monographs [12-16].

Even though no performance characteristics are provided, the EURL recommends for official control the AOCS methods and the ASTM standard to characterise *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive*. However, the methods described in the FAO JECFA and the European Pharmacopoeia monographs mentioned above can be considered for the characterisation of *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive*. If further characterisation of the product is required, methods for fatty acids analysis described for instance in FAO JECFA monograph for food additives [11] and/or in the European Pharmacopoeia monograph [17] may be applied. However the Applicant did not provide any experimental proof that these methods work for this specific product.

The accurate determination of *Polyethyleneglycol ester of fatty acids from soya oil* in *premixtures* and *feedingstuffs* is not achievable experimentally. Furthermore, the Applicant did not provide any analytical method or data for determination of the active substance in the mentioned matrices. Therefore, the EURL cannot evaluate nor recommend any method for

official control to determine *Polyethyleneglycol ester of fatty acids from soya oil* 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

In the frame of current authorisation the EURL recommends for official control of *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive*:

- the official methods of the American Oil Chemists' Society (AOCS) for the determination of the saponification value; the acid value; and the water content by Karl Fischer titration, together with
- the standard of the American Society for Testing and Materials (ASTM) for the determination of the pH value.

The accurate determination of *Polyethyleneglycol ester of fatty acids from soya oil* in *premixtures* and *feedingstuffs* is not achievable experimentally. Furthermore, the Applicant did not provide any analytical method or data for determination of the active substance in the mentioned matrices. Therefore, the EURL cannot evaluate nor recommend any method for official control to determine *Polyethyleneglycol ester of fatty acids from soya oil* in *premixtures* and *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the characterisation of *Polyethyleneglycol ester of fatty acids from soya oil* in the *feed additive*:

- determination of the saponification value - AOCS Official Method Cd 3-25;
- determination of the acid value - AOCS Official Method 3d-63;
- determination of the water content by Karl Fischer titration - AOCS Official Method Ca 2e-84; and
- determination of the pH value - ASTM Standard D1172-95 (2007)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Polyethyleneglycol ester of fatty acids from soya oil* 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] ^a Application, Reference SANCO/G/1 Forw. Appl. 1831/0061-2012
- [2] ^b Application, Reference SANCO/G/1 Forw. Appl. 1831/0064-2012
- [3] ^{a,b} Supplementary information, Proposal for Register Entry – updated Annex A
- [4] ^{a,b} Technical dossier, Section II – Identity, characterisation and conditions of use of the additive; Methods of analysis
- [5] 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
- [6] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20425)
- [7] ^{a,b} Supplementary information – American Oil Chemists' Society (AOCS) Official Method Cd 3-25 – Saponification value
- [8] ^{a,b} Supplementary information – American Oil Chemists' Society (AOCS) Official Method Cd 3d-63 – Acid value
- [9] ^{a,b} Supplementary information – American Society for Testing and Materials (ASTM), D1172-95:2007 – Standard guide for pH of aqueous solutions of soaps and detergents
- [10] ^{a,b} Supplementary information – American Oil Chemists' Society (AOCS) Official Method Ca 2e-84 – Moisture Karl Fischer Reagent
- [11] FAO JECFA Combined Compendium for Food Additive Specifications - *Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications*, Monographs No. 1, Vol. 4
<http://www.fao.org/docrep/009/a0691e/a0691e00.htm>
- [12] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20506)
- [13] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20501)
- [14] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20203)
- [15] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20504)
- [16] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20512)
- [17] European Pharmacopoeia monograph (Ph. Eur. 6.0, 01/2008:20422)

^a Refers to Dossier No. FAD-2012-0014

^b Refers to Dossier No. FAD-2010-0359

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:

- Centro di Referenza Nazionale per la Sorveglianza e il Controllo degli Alimenti per gli Animali (CReAA) (IT)
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft (BfUL), Geschäftsbereich 6 – Labore Landwirtschaft, Nossen (DE)
- Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen, Jena (DE)
- Fødevarestyrelsen, Ringsted (DK)
- Instituut voor Voedselveiligheid (RIKILT), Wageningen (NL)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
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