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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

Sorbitan Monolaurate
(FAD-2010-0333; CRL/100238)

European Union Reference Laboratory
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

Dossier related to:	**FAD-2010-0333 - CRL/100238**
Name of Product:	**Sorbitan monolaurate**
Active Agent (s):	**Sorbitan monolaurate**
Rapporteur Laboratory:	**European Union Reference Laboratory for Feed Additives (EURL-FA)** **Geel, Belgium**
Report prepared by:	**Rebeca Fernández Orozco**
Report checked by: Date:	**Zigmas Ezerskis and Piotr Robouch (EURL-FA)** **23/07/2014**
Report approved by: Date:	**Christoph von Holst** **23/07/2014**

EXECUTIVE SUMMARY

In the current application authorisation is sought under article 10(2) for *Sorbitan monolaurate* under the category/ functional group 1(c) "technological additives"/"emulsifiers" according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the *feed additive* for all animal species and categories.

Sorbitan monolaurate is an yellow-to-amber oily liquid, consisting of a minimum of 95 % of a mixture of partial esters of sorbitol, sorbitan and isosorbide with edible commercial lauric acid; the later comprises mainly lauric acid (ca. 40-60 %), myristic acid (ca. 14-25 %) and palmitic acid (ca. 7-15 %). The Applicant states that the specific purity criteria set in the Commission Directive 2008/84/EC for the food additive are applicable for the *feed additive*.

Sorbitan monolaurate is intended to be added to other feed additives (mainly antioxidants) in order to assist their uniform distribution when added to other feed ingredients. No recommended minimum or maximum concentration levels were proposed by the Applicant. However, the typical maximum inclusion level is equivalent to 5 g of the *feed additive* /kg complete *feedingstuffs*.

For the characterisation of *Sorbitan monolaurate* in the *feed additive* the Applicant submitted the internationally recognised FAO JECFA monographs dedicated for *Sorbitan monolaurate*, based on the determination of - saponification-, - acid-, - hydroxyl- values; and - the assay of polyols and fatty acids, as recommended by Commission Directive 2008/84/EC.

Even though no performance characteristics were provided, the EURL recommends for official control the methods described in the above mentioned FAO JECFA monographs to characterise *Sorbitan monolaurate* in the *feed additive*.

For the characterisation of fatty acids in the *feed additive* the gas chromatography (GC) method described in the European Pharmacopoeia monographs (Eur. Ph. 6.0, 1040 and 20422) may be applied.

The accurate determination of *Sorbitan monolaurate* in *premixtures* and *feedingstuffs* is not achievable experimentally. Therefore the EURL is not able to evaluate nor recommend any method for official control to determine *Sorbitan monolaurate* 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.

KEYWORDS

Sorbitan monolaurate, technological additives, emulsifiers, all animal species and categories

1. BACKGROUND

In the current application authorisation is sought under article 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Sorbitan monolaurate* under the category / functional group 1(c) "technological additives"/"emulsifiers" according to the classification system of Annex I of Regulation (EC) No 1831/2003 [1]. Specifically, the authorisation is sought for the use of the *feed additive* for all animal species and categories [1,2].

Sorbitan monolaurate is an yellow-to-amber oily liquid, consisting of a minimum of 95 % of a mixture of partial esters of sorbitol, sorbitan and isosorbide with edible commercial lauric acid; the later comprises mainly lauric acid (ca. 40-60 %), myristic acid (ca. 14-25 %) and palmitic acid (ca. 7-15 %) [3].

The Applicant states that the specific purity criteria set in the Commission Directive 2008/84/EC for the food additive are applicable for the *feed additive* [3].

Sorbitan monolaurate is intended to be added to other feed additives (mainly antioxidants) in order to assist their uniform distribution when added to other feed ingredients. No recommended minimum or maximum concentration levels were proposed by the Applicant [2]. However, the typical maximum inclusion level is equivalent to 5 g of the *feed additive* /kg complete *feedingstuffs* [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 *Sorbitan monolaurate* 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 [4]

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

For the characterisation of *Sorbitan monolaurate* in the *feed additive* the Applicant submitted the internationally recognised FAO JECFA monographs dedicated for *Sorbitan monolaurate* [5, 6], based on the determination of - saponification-, - acid-, - hydroxyl- values; and - the assay of polyols and fatty acids, as recommended by Commission Directive 2008/84/EC.

Even though no performance characteristics were provided, the EURL recommends for official control the methods described in the above mentioned FAO JECFA monographs to characterise *Sorbitan monolaurate* in the *feed additive*.

For the characterisation of the fatty acids in the *feed additive* the EURL identified the gas chromatography (GC) method, described in the European Pharmacopoeia monographs [7,8], which may be applied.

The accurate determination of *Sorbitan monolaurate* in *premixtures* and *feedingstuffs* is not achievable experimentally. Therefore the EURL is not able to evaluate nor recommend any method for official control to determine *Sorbitan monolaurate* 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 this authorisation the EURL recommends for official control the methods described in FAO JECFA *Sorbitan monolaurate* monograph No. 1 (2006), Combined Compendium for Food Additive Specifications. The following methods are included: determination of - saponification-, - acid-, - hydroxyl- values; and - the assay of polyols and fatty acids.

For the characterisation of fatty acids in the *feed additive* the gas chromatography (GC) method described in the European Pharmacopoeia monographs (Eur. Ph. 6.0, 1040 and 20422) may be applied.

The accurate determination of *Sorbitan monolaurate* in *premixtures* and *feedingstuffs* is not achievable experimentally. Therefore the EURL is not able to evaluate nor recommend any method for official control to determine *Sorbitan monolaurate* in *premixtures* and *feedingstuffs*.

Recommended text for the register entry (analytical method)

For the characterisation of *Sorbitan monolaurate* in the *feed additive*:

– FAO JECFA Monograph *'Sorbitan Monolaurate'*

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Sorbitan monolaurate* 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. 1831/0056-2013

[2] *Application, Proposal for Registry Entry – Annex A

[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] 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 (last visited on 02/07/2014)

[6] FAO JECFA Combined Compendium of Food Additive Specifications, *Sorbitan monolaurate*, Monograph No. 1 (2006)
http://www.fao.org/ag/agn/jecfa-additives/details.html?id=822 (last visited on 02/07/2014)

[7] European Pharmacopoeia monograph - Ph. Eur. 6.0, 01/2008:1040

[8] European Pharmacopoeia monograph - Ph. Eur.6.0, 01/2008:20422

*Refers to Dossier no: FAD-2010-0333

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:

- Fødevarestyrelsen, Ringsted (DK)[1]
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, En ota za patologijo prehrane in higieno okolja, Ljubljana (SI)
- Państwowy Instytut Weterynaryjny, Puławy (PL)
- Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)[2]
- Thüringer Landesanstalt für Landwirtschaft (TLL), Jena (DE)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 - Labore Landwirtschaft, Nossen (DE)[3]

[1] Official name and address according to Regulation (EC) No 885/2009: Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby

[2] Name and address according to Regulation (EC) No 885/2009: Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim

[3] Name and address according to Regulation (EC) No 885/2009: Sächsische Landesanstalt für Landwirtschaft. Fachbereich 8 – Landwirtschaftliches Untersuchungswesen, Leipzig