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

Dossier related to: FAD-2010-0136 - CRL/100034

Feed Additive Name: Polyoxyethylene (20)-sorbitan monooleate

Active Substance(s): Polyoxyethylene (20)-sorbitan monooleate

Rapporteur Laboratory: European Union Reference Laboratory for Feed Additives (EURL-FA)  
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## EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for *Polyoxyethylene (20)-sorbitan monooleate (E 433)* 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.

*Polyoxyethylene (20)-sorbitan monooleate (E 433)* contains a minimum of 96.5 % of *Polyoxyethylene (20)-sorbitan monooleate* by weight calculated on anhydrous basis; a maximum of 3 % of water; the rest being ethylene oxide, 1,4-dioxane, mono- and di-ethylene glycols. The main constituent contains a minimum of 65 % of polyoxyethylene groups.

The *feed additive* is intended to be incorporated in *feedingstuffs* through *premixtures*. The Applicant proposes a maximum *E 433* concentration in *feedingstuffs* of 5 g/kg.

For the identification of *Polyoxyethylene (20)-sorbitan monooleate* in the *feed additive* the Applicant proposed the European Pharmacopoeia (Eur. Ph. 6.0 01/2008:0428) and the internationally recognised FAO JECFA monographs for food additives, based on - infrared absorption spectrophotometry; - the determination of saponification value; - the tests for the identity and composition of fatty acids; - the colour reaction with ammonium cobalthiocyanate; and - the assay of oxyethylene groups as recommended by Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned European Pharmacopoeia and FAO JECFA methods to identify *Polyoxyethylene (20)-sorbitan monooleate* in the *feed additive*.

The accurate determination of *Polyoxyethylene (20)-sorbitan monooleate* in *premixtures* and *feedingstuffs* is not achievable experimentally. The Applicant presented some Nuclear Magnetic Resonance (NMR) spectra, however no satisfactory validation and verification data were provided. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Polyoxyethylene (20)-sorbitan monooleate* 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

Polyoxyethylene (20)-sorbitan monooleate, technological additives, emulsifiers, all animal species and categories

## 1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use in all *feedingstuffs*) and 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for *Polyoxyethylene (20)-sorbitan monooleate (E 433)* under the category/functional group 1(c) "technological additives"/"emulsifiers" according to Annex I of Regulation (EC) No 1831/2003 [1]. The authorisation is sought for the use of the *feed additive* for all animal species and categories [2].

*Polyoxyethylene (20)-sorbitan monooleate (E 433)* contains a minimum of 96.5 % of Polyoxyethylene (20)-sorbitan monooleate by weight calculated on anhydrous basis; a maximum of 3 % of water; the rest being ethylene oxide, 1,4-dioxane, mono- and di-ethylene glycols [2]. The main constituent contains a minimum of 65 % of polyoxyethylene groups [2]. The Applicant states that the purity criteria set in the Commission Directive 2008/84/EC for the food additive apply to the requirement for the *feed additive* [3].

The *feed additive* is intended to be incorporated in *feedingstuffs* through *premixtures* [3]. The Applicant proposes a maximum concentration of 5 g *E 433* /kg *feedingstuffs* [2, 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 *Polyoxyethylene (20)-sorbitan monooleate* 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].

Ethylene oxide, 1,4-dioxane, mono- and di-ethylene glycols do not exceed 1, 5 and 0.25 mg/kg in *feed additive*, respectively. They can be determined by gas chromatography with flame ionization detection [5, 6].

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

For the identification of *Polyoxyethylene (20)-sorbitan monooleate (E 433)* in the *feed additive* the Applicant proposed the tests described in European Pharmacopoeia [7] and the internationally recognised FAO JECFA monographs for food additives [8, 9], which are based on:

- infrared absorption spectrophotometry;
- the determination of saponification value;
- the tests for the identity and composition of fatty acids;
- the colour reaction with ammonium cobalthiocyanate; and
- the assay of oxyethylene groups as recommended by Commission Directive 2008/84/EC.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned European Pharmacopoeia and FAO JECFA methods to identify *Polyoxyethylene (20)-sorbitan monooleate* in the *feed additive*.

The accurate determination of *Polyoxyethylene (20)-sorbitan monooleate* in *premixtures* and *feedingstuffs* is not achievable experimentally. The Applicant presented some Nuclear Magnetic Resonance (NMR) spectra, however no satisfactory validation and verification data were provided [10, 11]. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Polyoxyethylene (20)-sorbitan monooleate* 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 of *Polyoxyethylene (20)-sorbitan monooleate* in the *feed additive*, the identification tests described in European Pharmacopoeia (Ph. Eur. 6.0, 01/2008:0428), the JECFA monographs (No. 1, Vol. 4) and Polyoxyethylene (20)-sorbitan monooleate monograph No. 1 (2006), Combined Compendium for Food Additive Specifications:

- infrared absorption spectrophotometry;
- determination of saponification value;
- identity and composition of fatty acids;
- colour reaction with ammonium cobalthiocyanate; and
- the assay for oxyethylene groups recommended by Commission Directive 2008/84/EC.

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

For the identification of *Polyoxyethylene (20)-sorbitan monooleate* in the *feed additive*:  
(a) infrared absorption spectrophotometry; (b) determination of saponification value;  
(c) identity and composition of fatty acids; (d) colour reaction with ammonium cobalthiocyanate; and the assay for oxyethylene groups as described in:

- Commission Directive 2008/84/EC referring to FAO JECFA Combined Compendium for Food Additive Specifications - Analytical methods Vol. 4; and/or
- The Polyoxyethylene (20)-sorbitan monooleate monograph, FAO JECFA Combined Compendium for Food Additive Specifications - Monograph No. 1 (2006); and/or
- European Pharmacopoeia (Ph. Eur. 6.0, 01/2008:0428).

## 5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Polyoxyethylene (20)-sorbitan monooleate* 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/D/2 Forw. Appl. 1831/0086-2010
  - [2] \*Application, Proposal for Register 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] European Pharmacopoeia method - Ph. Eur. 5.0, 2.4.25
  - [6] European Pharmacopoeia method - Ph. Eur. 5.0, 2.4.30
  - [7] European Pharmacopoeia method - Ph. Eur. 6.0, 01/2008:0428
  - [8] 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 06/01/2012)
  - [9] FAO JECFA Combined Compendium of Food Additive Specifications, *Polyoxyethylene (20)-sorbitan monooleate*, Monograph No. 1 (2006)  
<http://www.fao.org/ag/agn/jecfa-additives/details.html?id=317> (last visited on 06/01/2012)
  - [10] \*Technical dossier, Section II –Annex II\_7 – Validation report
  - [11] \*Technical dossier, Section II –Annex II\_8 – Verification report
- \*Refers to Dossier No. FAD-2010-0136

## 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 (DK)
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)