



JRC.DG.D.5/CvH/ZE/AG/ARES(2012)197882

**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-2011-0022 - CRL/100341

Product Name: Shellac

Active Substance(s): Shellac

Rapporteur Laboratory: European Union Reference Laboratory
for Feed Additives (EURL-FA)
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Date: 21/02/2012

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Date: 21/02/2012

EXECUTIVE SUMMARY

In the current application authorisation is sought under article 4(1) for *Shellac* as *feed additive* under the category/functional group 1(d) 'technological additives'/ 'stabilisers' according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of *Shellac* for all animal species and categories. *Shellac* is a purified and bleached natural biopolymer resulting from the resinous secretion of the *Laccifer Tachardia lacca Kerr* insect. Furthermore, the purity criteria set in the Commission Directive 2008/84/EC for *Shellac* as food additive are applicable also for the same product as a *feed additive*. The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures*, with no recommended minimum or maximum concentration levels.

For the identification of *Shellac* in the *feed additive* the Applicant proposed the internationally recognised FAO JECFA monographs for food additives, recommended by Commission Directive 2008/84/EC, and based on: - colour reaction with ammonium molybdate; - test for solubility; and - determination of acid value.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods recommended by Commission Directive 2008/84/EC and described in the FAO JECFA monographs (No. 1, Vol. 4) and "*Shellac Bleached*" monograph No. 1 (2006), Combined Compendium for Food Additive Specifications, to identify *Shellac* in the *feed additive*.

The Applicant provided no experimental data or any analytical methods for the determination of *Shellac* in *premixtures* and *feedingstuffs*, as the accurate determination of the active substance in these matrices is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Shellac* 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

Shellac, technological additives, stabilisers, all animal species and categories

1. BACKGROUND

In the current application authorisation is sought under article 4(1) (new authorisation) for *Shellac* as *feed additive* under the category/functional group 1(d) 'technological additives/'stabilisers' [1] according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of *Shellac* for all animal species and categories [2].

Shellac is a purified and bleached natural biopolymer resulting from the resinous secretion of the *Laccifer (Tachardia) lacca Kerr* insect [3]. The Applicant states that the purity criteria set in the Commission Directive 2008/84/EC for *Shellac* as food additive are applicable also for the same product as a *feed additive* [2].

The *feed additive* is intended to be incorporated directly into *feedingstuffs* or through *premixtures* [3], with no recommended minimum or maximum concentration levels [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 *Shellac* 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 determination of the active substance in feed additive, premixtures, feedingstuffs and water

For the identification of *Shellac* in the *feed additive* the Applicant proposed the internationally recognised FAO JECFA monographs for food additives [5, 6] (recommended by Commission Directive 2008/84/EC) which are based on:

- colour reaction with ammonium molybdate;
- test for solubility;
- determination of acid value; and
- the following purity tests: - loss on drying; - test for absence of rosin by colour reaction with phenol after hexane extraction; and - gravimetric quantification of wax.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods recommended by Commission Directive 2008/84/EC and described in the FAO JECFA monographs to identify *Shellac* in the *feed additive*.

The Applicant provided no experimental data or any analytical methods for the determination of *Shellac* in *premixtures* and *feedingstuffs*, as the accurate determination of the active substance in these matrices is not achievable experimentally. Therefore the EURL cannot evaluate nor recommend any method for official control to determine *Shellac* 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 *Shellac* in the *feed additive*, the identification methods recommended by Commission Directive 2008/84/EC and described in FAO JECFA monographs (No. 1, Vol. 4) and "*Shellac Bleached*" monograph No. 1 (2006), Combined Compendium for Food Additive Specifications:

- colour reaction with ammonium molybdate;
- test for solubility; and
- determination of acid value.

Recommended text for the register entry (analytical method)

For the identification of *Shellac* in the *feed additive*: (a) colour reaction with ammonium molybdate; b) test for solubility; c) determination of acid value as described in:

- Commission Directive 2008/84/EC referring to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4); and the Monograph No. 1 (2006) "*Shellac Bleached*".

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of *Shellac* 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/(00174) (10165)-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] 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 21/02/2012)
- [6] FAO JECFA Combined Compendium of Food Additive Specifications, *Shellac Bleached*, Monograph No. 1 (2006)
<http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-384.pdf>
(last visited on 21/02/2012)

*Refers to Dossier No. FAD-2011-0022

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:

- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Plantedirektoratet, Laboratorium for Foder og Gødning, Lyngby (DK)
- Skúšobné laboratórium – Oddelenie analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava (SK)
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)