EUROPEAN COMMISSION
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Institute for Reference Materials and Measurements
Community Reference Laboratory for Feed Additives

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CRL Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation as a Feed Additive according to Regulation (EC) No 1831/2003

Dossier related to:	**FAD-2009-0049** **CRL/090006**
Name of Additive:	**Sodium Bisulphate**
Active Substance(s):	***sodium bisulphate***
Rapporteur Laboratory:	**Centro di Referenza Nazionale per la Sorveglianza ed il Controllo degli Alimenti per Animali (C.Re.A.A), Torino, Italy**
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Date:	**03/05/2010**
Report approved by:	**Christoph von Holst**
Date:	**04/05/2010**

EXECUTIVE SUMMARY

In the current application authorisation is sought for *Sodium Bisulphate* under the category technological additives and sensory additives, functional group 1(a) preservatives (all species), 1(j) acidity regulators (pet & non-food fur animals), 1(k) silage additive (all species), 2(b) flavouring compounds(pets:dogs & cats), according to Annex I of Regulation (EC) No 1831/2003.

The active agent is *sodium bisulphate* of technical grade with a minimum purity of 95.2%. It is intended to be marketed as a dry (anhydrous), non-dusting (>100 μm diameter spheres) granular crystals to be incorporated into *premixtures* and/or complete *feedingstuff* at *quantum satis* concentration. For the determination of *sodium bisulphate* in *feed additive* the applicant proposes the Food Chemicals Codex IV (FCC IV) monograph. The method is based on a titrimetric assay for the determination of sodium bisulphate for industrial use. The CRL recommends this FCC IV monograph method for official controls for the determination of *sodium bisulphate* in *feed additives*.

The unambiguous determination of the content of exogenous *sodium bisulfate* added to *premixtures* or *feedingstuffs* is not achievable by analysis. The Applicant did not provide any experimental method or data on this matter. Furthermore, no international standard methods of analysis could be identified. Therefore the CRL cannot evaluate nor recommend any method for official control to determine *sodium bisulfate* in *premixtures* or *feedingstuffs*.

Further testing or validation is not considered necessary.

KEYWORDS

Sodium bisulphate, preservative, acidity regulator, silage additive, flavouring compound, technological additive, sensory additive, all species

1. BACKGROUND

Sodium Bisulphate is already authorised by Regulation (EC) No 1831/2003 as a technological/silage additive, group (1k), for which the re-evaluation of authorisation is sought (Article 10). The authorisation under Article 4 of Regulation (EC) No 1831/2003 refers to the requested authorisation as "technological additive" for all species as "preservative" (group 1a), pets and other non food producing animals as "acidity regulator" (group 1j) and pets as "flavouring" (group 2b), according to Annex I of Regulation (EC) No 1831/2003 [1].

The active agent is *sodium bisulphate* of technical grade (CAS-No-7681-38-1) with a minimum purity of 95.2%. The additive is intended to be marketed as a dry (anhydrous), granular, odourless to slightly fresh/pungent odour, free-flowing crystalline product with a large particle size and low dusting potential. *Sodium bisulphate (SBS)* consists of homogeneous, spherical white beads to be incorporated into *premixtures* and/or *complete feedingstuffs* to obtain at *quantum satis* (as much as needed) dosage of *SBS* in *feedingstuffs* for all animal species [2].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003, the CRL is requested to submit a full evaluation report to the European Food Safety Authority for each application. For this particular dossier (FAD-2009-0049), the methods of analysis submitted in connection with the *Sodium Bisulphate* were evaluated for their suitability to be used for official controls.

3. EVALUATION

Identification/Characterisation of the feed additive

Quantitative and qualitative composition of impurities in the additive

For undesirable substances (i.e. arsenic, cadmium, mercury, lead and selenium) internationally recognised standard methods are available at the respective Community Reference Laboratories, in accordance with COMMISSION REGULATION (EC) No 776/2006.

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

For the determination of *sodium bisulphate* in the *feed additive* the applicant proposes the FCC IV Monograph [3]. The method is based on a titrimetric assay for the determination of total acidity of sodium bisulphate for industrial use. The assay requires a solution of test portion titrated for total soluble acidity against a standard volumetric solution of sodium hydroxide, using phenophthalein as indicator. The CRL recommends the above mentioned FCC standard method for official controls for the determination of *sodium bisulphate* in *feed additive*.

The unambiguous determination of the content of exogenous *sodium bisulfate* added to *premixtures* or *feedingstuffs* is not achievable by analysis. The Applicant did not provide any experimental method or data on this matter. Furthermore, no international standard methods of analysis could be identified. Therefore the CRL cannot evaluate nor recommend any method for official control to determine *sodium bisulphate* in *premixtures* or *feedingstuffs*.

Further testing or validation is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

For the determination of *sodium bisulphate* in the *feed additive*, the CRL recommends the FCC IV Monograph for official controls.

Further testing or validation is not considered necessary.

Recommended text for the register entry, fourth column (Composition, chemical formula, description, analytical method)

For *sodium bisulphate* in the *feed additive*:

titrimetric method based on the determination of total soluble acidity of sodium bisulphate against a standard sodium hydroxide solution.

5. DOCUMENTATION AND SAMPLES PROVIDED TO CRL

In accordance with the requirements of Regulation (EC) No 1831/2003, samples have been sent to the Community Reference Laboratory for Feed Additives. The dossier has been made available to the CRL by EFSA.

6. REFERENCES

[1] * Application, Reference SANCO/D/2 Forw. Appl. 1831/038-2009
[2] * FAD-2009-0049_RegEntry.
[3] * Technical Dossier, section II: Annex_II_6_1.pdf
* Refers to Dossier No: FAD-2007-0049

7. RAPPORTEUR LABORATORY

The Rapporteur Laboratory for this evaluation was the Centro di Referenza Nazionale per la Sorveglianza ed il Controllo degli Alimenti per Animali (C.Re.A.A), Torino, Italy. 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.

8. ACKNOWLEDGEMENTS

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- Plantedirektoratet, Laboratorium for Foder og Gødning, Denmark
- Service Commun des Laboratoires Laboratoire de Rennes, France
- Skúšobné laboratórium –Slovakia