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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-2008-0045  
CRL/080024

Product name: Sodium Carbonate

Active Substance(s): *sodium carbonate*

Rapporteur Laboratory: Community Reference Laboratory for  
Feed Additive (CRL-FA)

Report prepared by: Sulhattin Yasar (CRL-FA)

Report checked by: Piotr Robouch (CRL-FA)

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Report approved by: Giuseppe Simone (CRL-FA)

Date: 05/10/2009

## EXECUTIVE SUMMARY

In the current application authorisation is sought for *Sodium Carbonate* under the category technological additives, functional group 1(j) as an acidity regulator for all animal species, according to Annex I of Regulation (EC) No 1831/2003.

The active agent is *sodium carbonate* of technical grade with a minimum purity of 99.5%. It is intended to be marketed as a white odourless powder to be incorporated into *premixtures* and/or complete *feedingstuffs* to obtain a maximum recommended dosage of *sodium carbonate* of 400 mg/kg of *feedingstuffs* for all animal species.

For the determination of *sodium carbonate* in *feed additives* the applicant proposes the international standard method ISO 740:1976. The method is based on a titrimetric assay for the determination of total soluble alkalinity of sodium carbonate for industrial use. The CRL recommends this ISO method for official controls for the determination of *sodium carbonate* in *feed additives*.

The unambiguous determination of the content of exogenous sodium carbonate added to the *premixtures* and the *feedingstuffs* is not achievable by analysis. Nevertheless, several analytical methods are available for the determination of total sodium and total carbonates in *premixtures* and in *feedingstuffs*. Among them, the CRL recommends two international standard methods for official controls:

- CEN method EN 15510:2008 for the determination of total *sodium*

and

- Community method (Regulation (EC) No 152/2009) for the determination of total *carbonates*.

Further testing or validation is not considered necessary.

## KEYWORDS

*Sodium Carbonate*, Acidity Regulator, Technological Additives

## 1. BACKGROUND

Sodium Carbonate is a technological additive, belonging to the functional group 1(j) “acidity regulators”, according to Annex I of Regulation (EC) No 1831/2003 [1].

The active agent is *sodium carbonate* of technical grade (CAS-No 497-19-8) with a minimum purity of 99.5%. The additive is intended to be marketed as a white odourless powder form to be incorporated into *premixtures* and/or complete *feedingstuffs* to obtain a maximum recommended dosage of *sodium carbonate* of 400 mg/kg of *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-2008-0045), the methods of analysis submitted in connection with the *Sodium Carbonate* were evaluated for their suitability for official controls.

## 3. EVALUATION

### *Identification/Characterisation of the feed additive*

#### *Quantitative and qualitative composition of impurities in the additive*

For the determination of sodium chloride, sodium sulphate, calcium oxide, magnesium oxide and total iron the applicant refers to internationally recognised ISO and CEN standards [3]. The CRL considers these methods suitable for official controls of the above mentioned impurities in the *feed additive*.

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

For the determination of *sodium carbonate* in the *feed additive* the applicant proposes the international standard method ISO 740:1976 [4]. The method is based on a titrimetric assay for the determination of total soluble alkalinity of sodium carbonate for industrial use.

The assay requires a solution of test portion which is filtered and titrated for total soluble alkalinity against a standard volumetric solution of hydrochloric acid, using methyl orange as indicator. The total alkalinity is expressed as a percentage of sodium carbonate. The CRL recommends the above mentioned ISO standard method for official controls for the determination of *sodium carbonate* in *feed additives*.

The applicant did not submit any analytical methods for the determination of *sodium carbonate* in *premixtures* and in *feedingstuffs*.

Several methods are available for the determination of total sodium and total carbonates in *premixtures* and in *feedingstuffs*. Among them, the CRL recommends for official controls two international standard methods:

- CEN method EN 15510:2008 for the determination of total *sodium* [5]

and

- Community method (Regulation (EC) No 152/2009) for the determination of total *carbonates* [6].

However, since these methods do not allow for the determination of the origin of sodium and carbonate, nor provide information on the content of exogenous *sodium carbonate* added to the *premixtures* and *feedingstuffs*, monitoring the proposed maximum dose (400 mg/kg) of *sodium carbonate* in *feedingstuffs* [2] for the purpose of official controls is technically not possible.

Further testing or validation is not considered necessary.

#### 4. CONCLUSIONS AND RECOMMENDATIONS

For the determination of *sodium carbonate* in *feed additives* the CRL recommends the ISO standard method ISO 740:1976 for official controls.

Since the unambiguous determination of the origin of sodium carbonate in *premixtures* and *feedingstuffs* is not achievable by analysis, the CRL recommends the CEN method EN 15510:2008 for the determination of total *sodium* and the Community method (Regulation (EC) No 152/2009) for the determination of total *carbonate*.

Further testing or validation is not considered necessary.

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

For sodium carbonate in the *feed additives*: titrimetric method based on the determination of total soluble alkalinity of sodium carbonate against a standard hydrochloric acid solution.

For total sodium in *premixtures* and *feedingstuffs*: CEN EN 15510:2008

For total carbonates in *premixtures* and *feedingstuffs*: Community method “Determination of carbonates”, Annex III Section O. of Commission Regulation (EC) 152/2009.

## **5. DOCUMENTATION AND SAMPLES PROVIDED TO CRL**

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of 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] \* Reference SANCO/D/2: Forw. Appl. 1831/029-2008.
- [2] \* Annex A, Proposal for Register Entry.
- [3] \* Section II: Annex\_II.2\_Method of analysis
- [4] \*Supplementary Information: ISO\_740 \_Sodium Carbonate.....pdf
- [5] CEN/TC 327 – Animal feeding stuffs – Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, arsenic, lead and cadmium by ICP-AES. EN 15510:2008.
- [6] COMMISSION REGULATION (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed. Annex III, Section O. Determination of carbonates. Official Journal of the European Commission, L54/52, 26.2.2009.

\*Refers to Dossier No: FAD-2008-0045.

## **7 RAPPORTEUR LABORATORY**

The Rapporteur Laboratory for this evaluation was the Community Reference Laboratory for Feed Additive (CRL-FA), IRMM, Geel, Belgium. This report is in accordance

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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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