
Dossier related to: FAD-2011-0006 - CRL/100297
Feed additive: Sodium hydroxide (E524)
Active Substance(s): Sodium hydroxide
Rapporteur Laboratory: National Veterinary Research Institute (NVRI), Poland (PL)
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Date: 13/08/2012
Report approved by: Christoph von Holst
Date: 13/08/2012
EXECUTIVE SUMMARY

In the current application authorisation is sought under articles 4(1) and 10(2) for sodium hydroxide (E524) under the category/functional group 1(j) 'technological additives' / 'acidity regulators: substances which adjust the pH of feedingstuffs', 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 cats, dogs and ornamental fish.

The feed additive is a white solid substance, containing a minimum of 98% of sodium hydroxide. The Applicant states that the purity criteria set in Commission Directive 2008/84/EC and in Commission Regulation EU/231/2012 for the food additive are applicable for the feed additive.

The feed additive is intended to be incorporated to feedingstuffs through premixtures, with no recommended minimum or maximum concentration levels. However, the Applicant suggested a typical inclusion level varying from 50 to 1000 mg sodium /kg feedingstuffs.

For the determination of sodium hydroxide in the feed additive, the Applicant proposed the internationally recognised FAO JECFA monographs for food additives, where: identification is based on the following tests: alkalinity, sodium and solubility in water/ethanol, while quantification is based on a titrimetric method. Even though no performance characteristics are provided, the EURL recommends for official control the methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC and by Commission Regulation EU/231/2012 - to determine sodium hydroxide in the feed additive.

The Applicant did not provide any analytical method for the determination of sodium hydroxide in premixtures and feedingstuffs as the unambiguous determination of sodium hydroxide in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine sodium hydroxide 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

Sodium hydroxide, E524, technological additives, acidity regulators, cats, dogs, ornamental fish
1. BACKGROUND

In the current application authorisation is sought under articles 4(1) (new use in ornamental fish) and 10(2) (re-evaluation of the already authorised additives under provisions of Council Directive 70/524/EEC) for sodium hydroxide (E524) under the category/functional group 1(j) 'technological additives' / 'acidity regulators: substances which adjust the pH of feedingstuffs', 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 cats, dogs and ornamental fish [2].

The feed additive is a white solid substance, containing a minimum of 98% of sodium hydroxide [2]. The Applicant states that the purity criteria set in Commission Directive 2008/84/EC and in Commission Regulation EU/231/2012 for the food additive are applicable for the feed additive [3].

The feed additive is intended to be incorporated to feedingstuffs through premixtures [3], with no recommended minimum or maximum concentration levels [2]. However, the Applicant suggested a typical inclusion level ranging from 50 to 1000 mg sodium /kg feedingstuffs.

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 (EFSA) for each application or group of applications. For this dossier, the method of analysis submitted in connection with the sodium hydroxide (E524) and its 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) are available from the respective European Union Reference Laboratories [4].
Description of the analytical methods for the determination of the active substances in feed additive, premixtures and feedingstuffs.

For the determination of sodium hydroxide in the feed additive, the Applicant proposed the internationally recognised FAO JECFA monographs for food additives [5, 6], where:

- **identification** is based on tests for alkalinity, sodium and solubility in water and ethanol, while

- **quantification** is based on titrimetric method. The aliquot of 1.5 g is dissolved in 40 ml of water and phenolphthalein is added. Solution is titrated with 1 N sulphuric acid. At the point of disappearance of the pink colour the volume of the acid is recorded, then methyl orange is added and solution is titrated to a persistent pink colour. Total volume of the acid required for the titration is recorded. One ml of 1 N sulphuric acid is equivalent to 40.00 mg of total alkali, calculated as sodium hydroxide.

Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods described in the FAO JECFA monographs - as recommended by Commission Directive 2008/84/EC and by Commission Regulation EU/231/2012 - to determine sodium hydroxide in the feed additive.

The Applicant did not provide any analytical method for the determination of sodium hydroxide in premixtures and feedingstuffs as the unambiguous determination of sodium hydroxide in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine sodium hydroxide 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 Applicant did not provide any analytical method for the determination of sodium hydroxide in premixtures and feedingstuffs as the unambiguous determination of sodium hydroxide in these matrices is not achievable experimentally. Therefore, the EURL could not evaluate nor recommend any method for official control to determine sodium hydroxide in premixtures and feedingstuffs.

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

For the determination of sodium hydroxide in the feed additive:


**5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL**

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of sodium hydroxide 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**

[2] *Application, Proposal for Register Entry – Annex A
[3] *Technical dossier, Section II: Identity, characterisation and conditions of use; methods of analysis
   http://www.fao.org/docrep/009/a0691e/a0691e00.htm
   (last visited on 13/08/2012)
   (last visited on 13/08/2012)

*Refers to Dossier No. FAD-2011-0006*
7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation was National Veterinary Research Institute (NVRI), Poland. 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)
- Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin (PL)
- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim (DE)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)