

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of sodium hydroxide for dogs, cats and ornamental fish¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The additive consists, by specification, of a minimum of 98.0 % sodium hydroxide or alkali in the solid form, the content of solutions scaled accordingly, based on the stated or labelled concentration. No data have been provided that would support the specification of the solid form, only a 50.0 % w/w solution of sodium hydroxide in water, which is the final product of the production process described in the dossier. Sodium hydroxide is considered safe for the target animals, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance. Sodium hydroxide in solid form and in aqueous solution at concentrations > 8.0 % is corrosive. At lower concentrations it is irritant to skin and eyes (0.5 % and 0.2 %, respectively) and the respiratory tract (0.5 %). Exposure via inhalation is likely to be minimal. Sodium hydroxide is not considered to be a skin sensitiser. As sodium hydroxide is used in food as an acidity regulator, and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

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KEY WORDS

Sodium hydroxide, technological additives, acidity regulator, safety, efficacy

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SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on sodium hydroxide as an acidity regulator in feed for dogs, cats and ornamental fish.

The additive consists, by specification, of a minimum 98.0 % of sodium hydroxide or alkali in the solid form, the content of solutions scaled accordingly, based on the stated or labelled concentration. No data have been provided that would support the specification of the solid form, only a 50.0 % w/w solution of sodium hydroxide in water, which is the final product of the production process described in the dossier.

Sodium hydroxide is considered safe for the target animals, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance.

Sodium hydroxide in solid form and in aqueous solution at concentrations > 8.0 % is corrosive. At lower concentrations it is irritant to skin and eyes (0.5 % and 0.2 %, respectively) and the respiratory tract (0.5 %). Exposure via inhalation is likely to be minimal. Sodium hydroxide is not considered to be a skin sensitiser.

As sodium hydroxide is used in food as an acidity regulator and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

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BACKGROUND

Regulation (EC) No 1831/2003⁴ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7 and article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company Additifs pour Aliments pour Animaux de Compagnie G.E.I.E.⁵ for authorisation/re-evaluation of the product sodium hydroxide, when used as a feed additive for cats, dogs and ornamental fish (category: technological additive; functional group: acidity regulator) under the conditions mentioned in Table 1.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application.⁶ According to Article 8 of that Regulation, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. The particulars and documents in support of the application were considered valid by EFSA as of 08 May 2012.

Sodium hydroxide is currently authorised for use as technological additive (acidity regulator) in feed for dogs and cats.

The Scientific Committee for Food (EC, 1991) issued an opinion on the safety of sodium hydroxide.

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, and the users and the efficacy of the product sodium hydroxide, when used under the conditions described in Table 1.

⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

⁵ Additifs pour Aliments pour Animaux de Compagnie G.E.I.E., Avenue Louise 89, 1050 Brussels, Belgium.

⁶ EFSA Dossier reference: FAD-2011-0006.

Table 1: Description and conditions of use of the additive as proposed by the applicant

Additive		Sodium hydroxide		
Registration number/EC No/No (if appropriate)		E 524		
Category(ies) of additive		Technological		
Functional group(s) of additive		Acidity regulator		
Description				
Composition, description		Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Sodium Hydroxide		NaOH	Not less than 98% total alkali (calculated as NaOH)	
Trade name (if appropriate)		–		
Name of the holder of authorisation (if appropriate)		–		
Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg or Units of activity or CFU/kg of complete feedingstuffs (select what applicable)		
Cats, dogs, and ornamental fish	–	none specified	none specified	–
Other provisions and additional requirements for the labelling				
Specific conditions or restrictions for use (if appropriate)		–		
Specific conditions or restrictions for handling (if appropriate)		–		
Post-market monitoring (if appropriate)		–		
Specific conditions for use in complementary feedingstuffs (if appropriate)		–		
Maximum Residue Limit (MRL) (if appropriate)				
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues	
–	–	–	–	

ASSESSMENT

This opinion is based in part on data provided by a company involved in the production/distribution of sodium hydroxide. It should be recognised that these data cover only a fraction of the existing additives containing sodium hydroxide. The FEEDAP Panel has sought to use the data provided, together with data from other sources, to deliver an opinion.

1. Introduction

Sodium hydroxide is currently listed in the European Union Register of Feed Additives as a technological additive (functional group (j), acidity regulator) for dogs and cats, without restrictions on age and levels in feed.⁷

Sodium hydroxide is approved as a food additive⁸ for use as an acidity regulator without limitation (*quantum satis*) in jams, jellies, marmalades, sweetened chestnut purée, other similar fruit and vegetable spreads, processed cereal-based foods and baby foods, other foods for young children, dietary foods for infants for special medical purposes and special formulas for infants. Sodium hydroxide is also approved for use in food additives, food enzymes, food flavourings and nutrients with no limitation (*quantum satis*).⁹

Sodium hydroxide was assessed by the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Committee on Food Additives (JECFA, 1966) and by the Scientific Committee for Food (EC, 1991), and both set an acceptable daily intake (ADI) of “not specified”. Sodium hydroxide has also been assessed under the framework of the OECD (Organization for Economic Cooperation and Development) HPV (High Production Volume) Chemicals Programme (OECD, 2002) and by the Scientific Committee on Health and Environmental Risks (SCHER, 2006).

The applicant is seeking the re-evaluation of sodium hydroxide as a technological additive (functional group: acidity regulator) for cats and dogs and an authorisation for use in feed for ornamental fish.

2. Characterisation

2.1. Characterisation of the active substance

The active substance sodium hydroxide (synonyms: lye and caustic soda; Chemical Abstracts Service (CAS) No 1310-73-2, molecular weight 39.99, molecular formula NaOH, density 2.13 g/cm³, solubility in water (at 20 °C) 111 g/100 mL) is produced via electrolysis of sodium chloride.

The Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners¹⁰ sets as specifications for sodium hydroxide a “minimum of 98.0 % of sodium hydroxide or alkali in the solid form, content of solutions accordingly, based on the stated or labelled”. The applicant states that the specification of the additive is the same as the one for food use. No data have been provided that would support the specification of the solid form (i.e. minimum 98.0 % sodium hydroxide), but only for a 50 % w/w solution of sodium hydroxide in water, as the manufacturing process gives as the final product a solution of 50 % sodium hydroxide in water, and a further concentration step is not foreseen.

⁷ European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. Available at: http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

⁸ Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p. 178.

⁹ Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.

¹⁰ Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners OJ L 253/1, 20.9.2008, p. 1.

The analysis of 125 production batches of this commercial product showed an average sodium hydroxide concentration of 50 %.¹¹

The analysis of 28 batches of the sodium hydroxide water solution (50 % w/w) for water-insoluble and organic matter, carbonate (expressed as Na₂CO₃), arsenic and lead comply with the purity criteria set in the Commission Directive 2008/84/EC for food additives.¹² Mercury was not analysed because no potential mercury source is involved in the production process described in the dossier.

2.2. Stability and homogeneity

No data on the shelf-life of the additive and on the stability of the additive in feedingstuffs and premixtures were provided. Stability studies are normally not required for mineral-based products. Similar considerations can be applied to sodium hydroxide. According to the applicant, sodium hydroxide is added to feed only in the form of a water solution. Considering the high solubility of sodium hydroxide, no further information on the homogeneous distribution of the aqueous solution of the additive in feedingstuffs is considered necessary.

2.3. Conditions of use

Sodium hydroxide is intended to be used as an acidity regulator in feed for dogs, cats and ornamental fish without restrictions on age or levels in feed. The applicant mentions “typical levels of inclusion” in feed of 50–1 000 mg/kg complete feed (expressed as sodium, corresponding to a maximum of 1 740 mg sodium hydroxide/kg feed).

2.4. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

EFSA has verified the EURL report as it relates to the methods used for the control of sodium hydroxide in animal feed. The executive summary of the EURL report can be found in the Appendix.

3. Safety

3.1. Safety for the target species

Sodium hydroxide is authorised as an additive for a selected variety of foodstuffs without limitation (*quantum satis*).

The Scientific Committee for Food (EC, 1991) assessed the safety of the use of sodium hydroxide as a food additive in an opinion on different acids and bases and their salts (i.e. ammonium, sodium, potassium, calcium and magnesium). The safety assessment was based on the corresponding anions and cations. The Committee concluded that “these cations are natural constituents of man, animals and plants, and therefore occur in foodstuffs. They, together with certain anions, constitute the major electrolytes present in all biological materials. The Committee therefore established a group ADI not specified for these cations, although exhaustive systematic toxicological studies have not been carried out with the individual ions. No safety problems are likely to arise, provided that the contributions from food intake do not disturb the homeostatic mechanisms controlling the electrolyte balance of the body.”

In assessing the safety of sodium hydroxide as a feed additive for dogs, cats and ornamental fish, the same approach has been applied by the FEEDAP Panel. Sodium hydroxide is therefore considered to be safe for the target animals, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance.

¹¹ Technical dossier/Section II/Annex II-1 Analytical Data.

¹² Technical dossier/Section II/Annex II-1 Analytical Data.

3.2. Safety for the user

In 2002, an initial health and environmental risk assessment of sodium hydroxide was performed under the framework of the OECD HPV Chemicals Programme (OECD, 2002). The OECD concluded that sodium hydroxide in solid form and in aqueous solution at concentrations > 8.0 % is corrosive. At lower concentrations it is irritant to skin and eyes (0.5 % and 0.2 %, respectively) and to the respiratory tract (0.5 %). The OECD also concluded that exposure via inhalation is likely to be minimal and that sodium hydroxide is not considered to be a skin sensitiser. These hazards are reflected in the material safety data sheet, and proper protective measures are recommended.

4. Efficacy

As sodium hydroxide is used in food as an acidity regulator and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Sodium hydroxide is considered safe for the target animals, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance.

Sodium hydroxide in solid form and in aqueous solution at concentrations > 8.0 % is corrosive. At lower concentrations it is irritant to skin and eyes (0.5 % and 0.2 %, respectively) and the respiratory tract (0.5 %). Exposure via inhalation is likely to be minimal. Sodium hydroxide is not considered to be a skin sensitiser.

As sodium hydroxide is used in food as an acidity regulator and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

RECOMMENDATIONS

Specifications set for sodium hydroxide (including mercury) should follow those set in the Commission Directive 2008/84/EC for food additives.

DOCUMENTATION PROVIDED TO EFSA

1. Sodium hydroxide for cats, dogs and ornamental fish. November 2010. Submitted by Additifs pour Aliments pour Animaux de Compagnie G.E.I.E.
2. Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Sodium Hydroxide.
3. Comments from Member States received through the ScienceNet.

REFERENCES

- EC (European Commission), 1991, online. Opinion of the Scientific Committee for Food: First Series of Food Additives of Various Technological Functions. Available from: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf
- Joint FAO/WHO Expert Committee On Food Additives (JECFA), 1966. Specifications for the identity and purity of food additives and their toxicological evaluation: some antimicrobials, antioxidants, emulsifiers, stabilisers, flour-treatment agents, acids, and bases. Ninth Report of the Joint FAO/WHO Expert Committee On Food Additives. Rome, 13–20 December 1966. Available from: http://whqlibdoc.who.int/trs/WHO_TRS_339.pdf

OECD (Organization for Economic Cooperation and Development), 2002. SIDS Initial Assessment Report. Sodium hydroxide CAS No 1310-73-2. SIAM 14 (Paris, 26–28 March 2002). Available from: <http://www.inchem.org/documents/sids/sids/NAHYDROX.pdf>

SCHER (Scientific Committee on Health and Environmental Risks), 2006. Targeted Risk Assessment Report on Sodium Hydroxide (NaOH). Human Health Part. CAS No.: 1310-73-2; EINECS No.: 215-185-5. Available from:

http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_o_045.pdf

APPENDIX

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Sodium Hydroxide¹³

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 feedingstuffs¹, 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.

¹³ The full report is available on the EURL website:
http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx