

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of potassium sorbate for dogs and cats¹

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The feed additive consists of pure potassium sorbate and it is intended to be used as a preservative in semi-moist feed for dogs and cats at a proposed concentration of 5 000 mg/kg feed. Potassium sorbate is considered safe for both dogs and cats at a maximum content of 5 000 mg/kg semi-moist complete feed, based on the limited data available in public literature. Potassium sorbate is a skin and eye irritant and a potential irritant of the respiratory tract. Potassium sorbate is added to food with a wide range of moisture content as preservative. Similar preservative effects can be expected in semi-moist feed for dogs and cats.

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KEY WORDS

Potassium sorbate, technological additive, preservative, semi-moist feed, dogs, cats

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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 the safety and efficacy of potassium sorbate when used as preservative in semi-moist feed for dogs and cats at a proposed concentration of 5 000 mg/kg feed.

Potassium sorbate is considered safe for both dogs and cats at a maximum content of 5 000 mg/kg semi-moist complete feed, based on the limited data available in the public literature.

Potassium sorbate is a skin and eye irritant and a potential irritant of the respiratory tract.

Potassium sorbate is added to food with a wide range of moisture content as preservative. Similar preservative effects can be expected in semi-moist feed for dogs and cats.

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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 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 time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company Cornelius Group plc⁵ for re-evaluation of the product potassium sorbate, when used as a feed additive for dogs and cats (category: technological additive; functional group: preservative) 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 10(2)/(7) (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 30 November 2011.

The additive consists of potassium sorbate. This product is permanently authorised for use all animal species and categories (E 202).

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 animal(s), user and the environment and the efficacy of the product potassium sorbate, 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 Cornelius Group Plc, Cornelius House, Woodside, Bishop's Stortford CM23 5RG, UK.

⁶ EFSA dossier reference: FAD-2010-0114.

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

Additive		Potassium sorbate		
Registration number/EC No/No (if appropriate)		E202		
Category(ies) of additive		Technological		
Functional group(s) of additive		Preservatives		
Description				
Composition, description		Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
White or off-white granules		C6H7KO2	99% (anhydrous basis)	Titration vs perchloric acid
Trade name (if appropriate)		N/A		
Name of the holder of authorisation (if appropriate)		N/A		
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)		
Dogs & cats	None	None	None	N/A
Other provisions and additional requirements for the labelling				
Specific conditions or restrictions for use (if appropriate)		N/A		
Specific conditions or restrictions for handling (if appropriate)		N/A		
Post-market monitoring (if appropriate)		N/A		
Specific conditions for use in complementary feedingstuffs (if appropriate)		N/A		
Maximum Residue Limit (MRL) (if appropriate)				
Marker residue		Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
N/A		N/A	N/A	N/A

ASSESSMENT

This opinion is based on data provided by a company involved in the production of potassium sorbate. The application is for the active substance, and the composition of an additive formulation is not the subject of the application. The Panel has sought to use the data provided, together with data from other sources, to deliver an opinion and to produce recommendations for the authorisation, which would secure the safety of future uses of potassium sorbate as a feed additive.

As the additive is used only in non food-producing animals, the assessment of safety is limited to the target species and the user.

1. Introduction

Potassium sorbate is currently listed in the European Union Register of Feed Additives as a feed additive (technological additive, preservative) for all animal species with no limits on age and level in feed.⁷ The applicant is now seeking the re-evaluation of potassium sorbate for use as preservative of semi-moist feed for cats and dogs.

Potassium sorbate is approved (E202) as a food additive⁸ for use as a preservative and antioxidant in a wide range of commonly consumed foods up to 2 000 mg/kg. The additive has been assessed by the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA, 1973).

2. Characterisation

2.1. Characterisation of the additive

The active substance is potassium sorbate (potassium 2,4-hexadienoate; CAS (Chemical Abstracts Service) no 24634-61-5, European Inventory of Existing Commercial Chemical Substances (EINECS) no 246-367-1, molecular weight 150.22, molecular formula $C_6H_7KO_2$), in the form of white or off-white granules showing no change in colour after heating for 90 minutes at 105 °C. The manufacturing process is fully described in the dossier.

The additive consists only of potassium sorbate (99 % on an anhydrous basis by specification) with no carrier materials. Product consistency is confirmed by analyses of five batches showing a mean value of 100 % potassium sorbate.⁹

The analytical data from five batches¹⁰ for loss on drying, acidity (as sorbic acid), arsenic, lead, mercury and heavy metals (as Pb)¹¹ comply with the requirements set by Commission Directive 2008/84/EC for food additives.¹²

2.2. Stability and homogeneity

A study on five batches of potassium sorbate stored in the original carton package under ambient temperature showed a shelf-life of two years.¹³

No specific data on the stability of potassium sorbate have been provided considering the wide range of moisture contents typical of pet diets. As an alternative, stability in feed can be demonstrated by the

⁷ http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

⁸ European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ No L 61, 18. 3. 1995, p. 1.

⁹ Technical dossier/Section II/Annex_II_COA-K sorbate.

¹⁰ Technical dossier/Section II/Annex_II_COA-K sorbate.

¹¹ Technical dossier/Section II/Annex_II_COA-K sorbate.

¹² 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.

¹³ Technical dossier/Section II/Annex_II_COA-K sorbate.

maintenance of the effect. As potassium sorbate is considered to be an effective preservative in food with a wide range of moisture content,¹⁴ it is expected that the additive would show the same persistence of effect required to demonstrate stability in moist and semi-moist diets for dogs and cats.

No specific studies are required to demonstrate the homogeneous distribution of the additive in moist and semi-moist diets for dogs and cats, owing to the high solubility of the active substance in water.

2.3. Conditions of use

Potassium sorbate is intended to be used as a preservative in semi-moist feedingstuffs for dogs and cats (without limitation on age) at the recommended dose of 5 000 mg/kg complete feed (0.5 %). Minimum or maximum contents are not specified.

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

The EFSA has verified the EURL report as it relates to the methods used for the control of potassium sorbate 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

Since no specific studies with the additive under application were performed and no typical tolerance studies were provided, findings in the available literature with potassium sorbate (or sorbic acid) are described in this section.

3.1.1. Dogs

In a study on dogs, potassium sorbate administered for three months at a dietary concentration of 2 % produced no adverse effects, including no variation in weight gain (Mellon Institute, 1954, cited in Walker, 1990).

From a 90-day study of puppies (three in each group) fed a control diet containing 50 % Cheddar cheese, supplemented with 0 % or 4 % sorbic acid (analytically confirmed, corresponding to 5 % on a moisture-free basis) or 4 % caproic acid, the authors concluded that 4 % sorbic acid added to the diet was harmless to dogs (Deuel et al., 1954). This conclusion was based on the fact that the dogs remained in excellent condition throughout the study, the lack of changes in haemoglobin concentration and the absence of any specific abnormalities that could be detected on gross examination and on histological examination (liver, kidney, heart, lung, pancreas, stomach, small intestine, spleen, adrenal glands, thyroid gland, parathyroid gland, gonad, striated muscle and skin).

In another study, potassium sorbate was administered in the diet for 3 months at concentrations of 1 % and 2 % to two groups of eight dogs each. Weight gains were comparable to those of the control group. No adverse effects attributable to potassium sorbate were found upon gross examination at necropsy (Federation of American Scientists for Experimental Biology, 1975).

3.1.2. Cats

Bedford and Clarke (1973) pair-fed five groups of two young (1–2 years old) male cats of similar weight. The basis of all diets was a proprietary brand of meat, supplemented with 0 %, 0.1 %, 0.2 %, 0.5 % or 1 % sorbic acid. During the 28-day observation period, no influence of any of the sorbic acid concentrations tested on the appearance and behaviour of the animals or on feed intake was seen. In the same study, a sixth pair of male cats was fed the same diet supplemented with 2 % sorbic acid for 1 week. No toxic effects were observed by the authors.

¹⁴ European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners, OJ No L 61, 18. 3. 1995, p. 1.

3.2. Conclusions on safety for the target species

Based on findings in the literature, and taking into account the deficiencies in the available studies, potassium sorbate can be considered safe (i) for dogs at a concentration of 1 %, calculated from the levels of administration of 2–4 % for a limited number of animals, and (ii) for cats at a concentration of 0.5 %, calculated from the level of administration of 1 % for a limited numbers of animals.

The maximum potassium sorbate concentration considered safe in feed for both dogs and cats is 5 000 mg/kg semi-moist complete feed (0.5 %).

3.3. Safety for the user

Potassium sorbate is a skin (Commission Directive EEC 84/449, B.4)¹⁵ and eye (Commission Directive EEC 84/449, B.5) irritant, and a potential irritant for the respiratory tract. These hazards are reflected in the material safety data sheet. No information on inhalation toxicity of the additive is available in the literature.

4. Efficacy

Potassium sorbate is added as preservative to food with a wide range of moisture content. Consequently, no studies are required to demonstrate its efficacy as a preservative in semi-moist feed for dogs and cats.

CONCLUSIONS

The FEEDAP Panel concluded that potassium sorbate is safe for both dogs and cats at a maximum level of 5 000 mg/kg semi-moist complete feed, based on the limited data available in the public literature.

Potassium sorbate is a skin and eye irritant and a potential irritant for the respiratory tract.

Potassium sorbate has the potential to act as preservative in semi-moist feed for dogs and cats.

DOCUMENTATION PROVIDED TO EFSA

1. Potassium sorbate for dogs and cats. September 2010. Submitted by Cornelius Group plc.
2. Potassium sorbate for dogs and cats. Supplementary Information. April 2012. Submitted by Cornelius Group plc.
3. Evaluation report of the European Union Reference Laboratory for Feed Additives on the methods(s) of analysis for potassium sorbate.
4. Comments from Member States received through ScienceNet.

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¹⁵ Commission Directive 84/449/EEC of 25 April 1984 adapting to technical progress for the sixth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ L 251, 19.9.1984, pp. 1–223.

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APPENDIX

Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Potassium Sorbate^{16, 17}

In the current application authorisation is sought under articles 4(1) and 10(2) for *sorbic acid* (Applicant (I), FAD 2010-0193) and *potassium sorbate* (Applicant (I) and Applicant (II), FAD 2010-0145) under the category of "technological additives" functional group 1(a) "preservatives" (I, II) and 1(k) "silage additives" (I), according to the classification system of Annex I of Regulation (EC) No 1831/2003. According to the Applicants, the active substances in the *feed additives* are *sorbic acid* and its *potassium sorbate* salt respectively, both with a minimum purity of 99 %. Specifically, authorisation is sought for the use of the *feed additive* for all animal species and categories. The *feed additive* is intended to be used in *premixtures*, *feedingstuffs* and *water*, as well in *silage* (I). The Applicant does not propose any minimum or maximum concentration, similarly to what was set in previous regulation. However, the recommended levels are ranging between 0.1 to 1.5 g/kg for *water* and 0.1 to 2.5 g/kg for *feed* and *silage*.

For the determination of *sorbic acid* in the *feed additive*, the Applicant (I) proposed the JECFA monograph method, based on European Pharmacopoeia method. Therefore the EURL recommends for official control the internationally recognised European Pharmacopoeia method - Ph. Eur. 6.0, method 01/2008:0592, to determine *sorbic acid* in the *feed additive*.

For the determination of *potassium sorbate* in the *feed additive*, both Applicants proposed the JECFA monograph method, based on European Pharmacopoeia method. Therefore, the EURL recommends for official control the internationally recognised European Pharmacopoeia method - Ph. Eur. 6.0, method 01/2008:0618, to determine *potassium sorbate* in the *feed additive*.

For the determination of *sorbic acid* and *potassium sorbate* in *premixtures*, *feedingstuffs* and *water*, the Applicant (I) proposed a ring-trial validated method, based on ion exclusion High Performance Liquid Chromatography (HPLC) with UV detection. The following performance characteristics were reported:

- a relative standard deviation for *repeatability* (RSD_r) ranging from 6 % to 7.3 % for concentrations ranging from 0.1 to 100 g/kg;
- a relative standard deviation for *reproducibility* (RSD_R) ranging from 4.5 % to 10 % for concentrations ranging from 8 to 60 g/kg;
- a *recovery* rate (R_{rec}) ranging from 99 % to 105 %; and
- a limit of detection (LOD) and quantification (LOQ) of 5 and 10 mg/kg *feedingstuffs*, respectively.

Based on the acceptable performance characteristics presented, the EURL recommends for official control the ring-trial validated ion-exclusion HPLC-UV method to determine *sorbic acid* and *potassium sorbate* in *premixtures*, *feedingstuffs* and *water*, within the concentration range covered by the experimental data.

For the determination of *sorbic acid* and *potassium sorbate* in *silage*, the Applicant (I) did not provide any analytical method or experimental data. Therefore, the EURL cannot evaluate nor recommend any method for official control to determine *sorbic acid* and *potassium sorbate* in *silage*.

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.

¹⁶ The EURL produced a combined report for the additives sorbic acid and potassium sorbate.

¹⁷ The full report is available on the EURL website: <http://irmm.jrc.ec.europa.eu/SiteCollectionDocuments/FinRep-FAD-2010-0145+0193.pdf>