

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of sorbic acid and potassium sorbate when used as technological additives for all animal species based on two dossiers from Nutrinova Nutrition Specialties & Food Ingredients GmbH¹

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Sorbic acid and potassium sorbate are already authorised for use in food and feed as preservatives. Sorbic acid and potassium sorbate are safe when used at the maximum proposed dose in feed for pigs, poultry, dogs and cats (2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed) and young ruminants (6 700 (sorbic acid) and 9 000 (potassium sorbate) mg/kg complete feed). This conclusion is extended to all other animal species at maximum concentrations of 2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed. Both additives are considered safe for target animals when used in water for drinking, provided that the same maximum exposure is respected. No residues of sorbic acid or potassium ions are expected in edible products of food-producing animals when fed sorbic acid or potassium sorbate at the maximum proposed concentrations. Therefore, their use in feed up to the maximum proposed level is considered safe for the consumer. Sorbic acid and potassium sorbate are skin, eye and respiratory tract irritants. The use of sorbic acid and its potassium salt in animal nutrition would not pose a risk to the environment. As sorbic acid and potassium sorbate are food additives authorised within the EU for use as preservatives, it is reasonable to expect that the effect in food will be observed in feed when used at comparable concentrations and under similar conditions. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has reservations about the effectiveness of sorbic acid and its potassium salt as preservatives in complete feedingstuffs with a moisture content of $\leq 12\%$.

© European Food Safety Authority, 2015

KEY WORDS

technological additive, preservative, sorbic acid, potassium sorbate, safety, efficacy

¹ On request from the European Commission, Questions No EFSA-Q-2011-00838 and EFSA-Q-2011-00839, adopted on 8 September 2015.

² Panel members: Gabriele Aquilina, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli, Maria Luisa Fernandez-Cruz, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino Lopez Puente, Marta Lopez-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester. Correspondence: feedap@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Organic acids: Noel Dierick for the preparatory work on this scientific opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014. Scientific Opinion on the safety and efficacy of sorbic acid and potassium sorbate when used as technological additives for all animal species based on two dossiers from Nutrinova Nutrition Specialties & Food Ingredients GmbH. EFSA Journal 2015;13(9):4239, 15 pp. doi:10.2903/j.efsa.2015.4239

Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2015

SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of sorbic acid and potassium sorbate when used as preservatives in feed and water for drinking for all animal species.

Sorbic acid and its potassium salt are antimicrobial agents commonly used as preservatives in feed, food, wine and personal care products to prevent the growth of filamentous fungi and yeast. Sorbic acid and potassium sorbate are approved as food additives for use as preservatives in a wide range of commonly consumed foods and are authorised as preservatives in feed for all animal species without restrictions.

Sorbic acid and potassium sorbate are safe when used at the maximum proposed dose in feed for pigs, poultry, dogs and cats (2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed) and young ruminants (6 700 (sorbic acid) and 9 000 (potassium sorbate) mg/kg complete feed). This conclusion is extended to all other animal species at a maximum concentration of 2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed. The FEEDAP Panel extends the conclusion to include the use in water for drinking, provided that the same maximum total exposure is respected.

The contribution of potassium sorbate to the potassium supply of animals should be considered when formulating diets or when it is included in water for drinking.

No residues of sorbic acid or potassium ions are expected in edible products of food-producing animals when fed sorbic acid or potassium sorbate at the maximum proposed concentrations. Therefore, their use in feed up to the maximum proposed level is considered safe for the consumer.

Sorbic acid and potassium sorbate are skin, eye and respiratory tract irritants.

The use of sorbic acid and its potassium salt in animal nutrition would not pose a risk to the environment.

Sorbic acid and potassium sorbate are authorised food additives within the EU for use as preservatives. It is reasonable to expect that the effect in food will be observed in feed when they are used at comparable concentrations and under similar conditions. However, the FEEDAP Panel has reservations about the effectiveness of sorbic acid and potassium sorbate as preservatives in complete feedingstuffs with a moisture content of $\leq 12\%$.

The FEEDAP Panel made a recommendation regarding the specification of the equivalent concentration for sorbic acid and potassium sorbate when used as preservatives in water for drinking.

TABLE OF CONTENTS

Abstract	1
Summary	2
Background	4
Terms of reference.....	4
Assessment	8
1. Introduction.....	8
2. Characterisation.....	8
2.1. Characterisation of the additives	8
2.1.1. Sorbic acid	8
2.1.2. Potassium sorbate	9
2.2. Stability and homogeneity	9
2.2.1. Shelf life	9
2.2.2. Stability in vitamin–mineral premixtures	10
2.2.3. Stability in feedingstuffs.....	10
2.2.4. Stability in water.....	10
2.2.5. Homogeneity	10
2.3. Conditions of use.....	10
2.4. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL).	10
3. Safety.....	11
3.1. Safety for the target species.....	11
3.2. Safety for the consumer.....	11
3.3. Safety for the user.....	11
3.4. Safety for the environment	12
4. Efficacy	12
Conclusions and recommendations	12
Documentation provided to EFSA	13
References	13

BACKGROUND

Regulation (EC) No 1831/2003¹ 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 time limit or pursuant to Directive 82/471/EEC.

The European Commission received two requests from the company Nutrinova² for the re-evaluation of the products sorbic acid and potassium sorbate, when used as feed additives for all animal species (category: technological additives; functional group: preservative) under the conditions mentioned in Table 1 and Table 2.

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 dossiers in support of this application.³ 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 September 2011.

Sorbic acid (E 200) and potassium sorbate (E 202) are presently listed in the EU Register of Feed Additives,⁴ as preservatives in feed for all animal species, without restrictions. Both substances are also approved as food additives⁵ for use as preservatives in a wide range of commonly consumed foods, up to 2000 mg/kg.

Sorbic acid and potassium sorbate have been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974). The Scientific Committee for Food (SCF) issued an opinion on sorbic acid and its calcium and potassium salts in 1996 (EC, 1996). The European Chemicals Agency (ECHA) reported a proposal for harmonised classification and labelling of potassium sorbate (ECHA, 2011). The European Food Safety Authority (EFSA) issued two opinions on the safety and efficacy of potassium sorbate for use in dogs and cats (EFSA FEEDAP Panel, 2012) and as a silage additive for all animals except dogs and cats (EFSA FEEDAP Panel, 2013), and an opinion on the safety and efficacy of sorbic acid and potassium sorbate when used as technological additives for all animal species (EFSA FEEDAP Panel, 2014). An opinion on the re-evaluation of sorbic acid, potassium sorbate and calcium sorbate as food additives, has been recently adopted (EFSA ANS Panel, 2015).

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additives comply with the conditions laid down in Article 5. EFSA shall deliver an opinion on the

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives used for animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Nutrinova Nutrition Specialties & Food Ingredients GmbH, Am Unisys Park 1, 6584 Sulzbach, German.

³ EFSA Dossier references: FAD-2010-0163 and FAD-2010-0164.

⁴ Available online: http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

⁵ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

safety for the target animals, consumer, user and the environment and the efficacy of sorbic acid and potassium sorbate, when used under the conditions described in Tables 1 and 2.

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

Additive		Sorbic Acid		
Registration number/EC No/No (if appropriate)		E 200		
Category(ies) of additive		Technological Additive		
Functional group(s) of additive		(a) preservatives		
Description				
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)	
Sorbic acid Other component: Water	C ₆ H ₈ O ₂	not less than 99 % on the anhydrous basis	HPLC method L00.00.9 out of the German official collection of methods according to §64 of the German Food and Feed law	
Trade name (if appropriate)		Nutrinova® Sorbic Acid		
Name of the holder of authorisation (if appropriate)		not applicable		
Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg/kg of complete feedingstuffs		
All animal species except young ruminants for rearing or fattening Young ruminants for rearing or fattening	No restrictions-during all life cycle	Not applicable	feed: 2500 mg/kg of complete feedingstuffs, supplementary feed (based on end feed) and in water for drinking water for drinking: *	not applicable
		Not applicable	feed: 6700 mg/kg of complete feedingstuffs, supplementary feed (based on end feed) and in water for drinking water for drinking: * * Maximum content in water for drinking can be derived from conditions for use in feedingstuffs on basis of the feed–water ratios per species as applied by EFSA.	

Other provisions and additional requirements for the labelling

Specific conditions or restrictions for use (if appropriate)	Not applicable
Specific conditions or restrictions for handling (if appropriate)	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. First aid: Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician if irritation continues. Skin contact: Immediately remove contaminated clothing and wash affected area with soap and water. Inhalation: Consult a physician, if irritation of respiratory passages occurs.
Post-market monitoring (if appropriate)	Not applicable
Specific conditions for use in complementary feedingstuffs (if appropriate)	Not applicable

Maximum Residue Limit (MRL) (if appropriate)

Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues

Table 2: Description and conditions of use of the additive as proposed by the applicant

Additive	Potassium Sorbate
Registration number/EC No/No (if appropriate)	E 202
Category(ies) of additive	Technological Additive
Functional group(s) of additive	(a) preservatives

Description

Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Potassium sorbate Other component: Water	C ₆ H ₇ KO ₂	not less than 99 % on a dry weight basis	HPLC method L00.00.9 out of the German official collection of methods according to §64 of the German Food and Feed law

Trade name (if appropriate)	Nutrinova [®] Potassium Sorbate Powder Nutrinova [®] Potassium Sorbate Granules
Name of the holder of authorisation (if appropriate)	not applicable

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg/kg of complete feedingstuffs		
All animal species except young ruminants for rearing or fattening	No restrictions - during all life cycle	Not applicable	feed: 3400 mg/kg of complete feedingstuffs, supplementary feed (based on end feed) and in water for drinking water for drinking: *	not applicable
Young ruminants for rearing or fattening		Not applicable	feed: 9000 mg/kg of complete feedingstuffs, supplementary feed (based on end feed) and in water for drinking water for drinking: *	
* Maximum content in water for drinking can be derived from conditions for use in feedingstuffs on basis of the feed–water ratios per species as applied by EFSA.				

Other provisions and additional requirements for the labelling

Specific conditions or restrictions for use (if appropriate)	Not applicable
Specific conditions or restrictions for handling (if appropriate)	Causes serious eye irritation. Do not get in eyes, on skin, or on clothing. First aid: Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician if irritation continues.
Post-market monitoring (if appropriate)	Not applicable
Specific conditions for use in complementary feedingstuffs (if appropriate)	Not applicable

Maximum Residue Limit (MRL) (if appropriate)

Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues

ASSESSMENT

1. Introduction

Sorbic acid and its potassium salt are antimicrobial agents commonly used as preservatives in feed, food, wine and personal care products to prevent the growth of filamentous fungi and yeasts. Sorbic acid is a naturally occurring compound found, for example, in some berries. For commercial purposes, sorbic acid and potassium sorbate are produced synthetically.

Sorbic acid (E 200) and potassium sorbate (E 202) are presently listed in the European Union (EU) Register of Feed Additives⁶ as preservatives in feed for all animal species, but subject to re-evaluation. Both substances are also approved as food additives⁷ for use as preservatives in a wide range of commonly consumed foods, up to 2 000 mg/kg.

Sorbic acid and potassium sorbate have been assessed by the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA, 1974). The Committee allocated an acceptable daily intake (ADI) of 25 mg/kg body weight (bw). The Scientific Committee on Food endorsed the ADI set by JECFA (EC, 1996).

The application is for the re-evaluation of sorbic acid and potassium sorbate as technological additives when used as preservatives in feed for all animal species. The applicant is also seeking a new authorisation for the use of sorbic acid and potassium sorbate in water for drinking.

2. Characterisation

2.1. Characterisation of the additives

2.1.1. Sorbic acid

Sorbic acid (2,4-hexadienoic acid, Chemical Abstracts Service (CAS) No 110-44-1) is an odourless white crystalline powder with a molecular weight of 112.12 and the molecular formula $\text{CH}_3\text{CH}=\text{CHCH}=\text{CHCOOH}$. It is produced by chemical synthesis, with crotonaldehyde, a ketene and acetic acid used as starting materials. It is soluble in water at about 1.6 g/L at 20 °C. The structural formula of sorbic acid is shown in Figure 1.

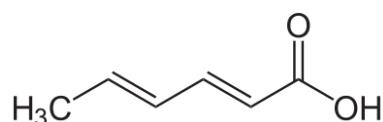


Figure 1: Structural formula of sorbic acid

Sorbic acid is manufactured to meet the specification set by Commission Directive 2008/84/EC⁸ for use as a food additive. This requires a purity of not less than 99.0 % (w/w) sorbic acid, and impurities that do not to exceed 0.5 % loss on drying, 0.2 % sulphated ash/residues on ignition, 0.1 % aldehydes on a w/w basis (calculated as formaldehyde), 3 mg arsenic/kg, 5 mg lead/kg and 1 mg mercury/kg. Analysis of 10 batches of the additive showed compliance with this specification.⁹

⁶ http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm

⁷ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

⁸ 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, 20.9.2008, p. 1.

⁹ Technical dossier/Section II/Annex II_3.

The particle size distribution of one commercial batch of sorbic acid was determined by laser diffraction. Approximately 17 % of particles (v/v) were of inhalable size (< 100 µm diameter), 6 % had diameters of < 50 µm and 1 % of particles were respirable (< 10 µm diameter).¹⁰ Dusting potential determined in one commercial batch by the Stauber–Heubach test was 0.04 g/m³.¹¹

2.1.2. Potassium sorbate

Potassium sorbate (potassium 2,4-hexadienoate, CAS No 24634-61-5) is a white solid with a molecular weight of 150.22 and the molecular formula CH₃CH=CHCH=CHCOOK. It is soluble in water at about 582 g/L at 20 °C. The structural formula of potassium sorbate is shown in Figure 2.

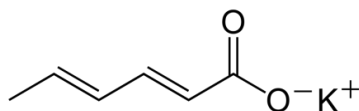


Figure 2: Structural formula of potassium sorbate

Potassium sorbate is produced by neutralising sorbic acid with potassium hydroxide and is manufactured by this applicant in powder and granular forms. Potassium sorbate is manufactured to meet the specification set by Commission Directive 2008/84/EC¹² for use as a food additive. This requires a purity of no less than 99.0 % (w/w) potassium sorbate¹³ and impurities that do not exceed 1 % loss on drying, 1 % alkalinity, 0.1 % aldehydes (calculated as formaldehyde), 3 mg arsenic/kg, 5 mg lead/kg and 1 mg mercury/kg. Analysis of 10 batches of the additive showed compliance with this specification.¹⁴

Dusting potential and particle size distributions were determined in two commercial batches of potassium sorbate (powder and granules) by the Stauber–Heubach test and laser diffraction method (v/v), respectively. Dusting potential was 0.68 g/m³ in the case of powder and 0.12 g/m³ in the case of the granulated form.¹⁵ In the potassium sorbate powder, approximately 48 % of particles were respirable (< 10 µm diameter) and 80 % were of inhalable size (< 100 µm diameter). Approximately 1 % of the granulated product was < 500 µm diameter.¹⁶

2.2. Stability and homogeneity

The FEEDAP Panel considers that stability data provided for sorbic acid in premixtures, feedingstuffs and water for drinking also apply to its potassium salt.

2.2.1. Shelf life

The proposed shelf life of sorbic acid is at least three years. This proposal was supported by the analysis of one commercial batch of sorbic acid stored for three years at ambient temperature (up to 30 °C) and in a dry environment (up to 65 % relative humidity). After the storage period, no loss of sorbic acid was observed.¹⁷

The proposed shelf life of potassium sorbate is at least three years when stored at ambient temperature and in a dry environment in the original closed packaging protected from direct sunlight. This proposal

¹⁰ Technical dossier/Section II/Annex II_9.

¹¹ Technical dossier/Section II/Annex II_8.

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, 20.9.2008, p. 1.

¹³ Technical dossier/Section II/Annex II_5.

¹⁴ Technical dossier/Section II/Annex II_4.

¹⁵ Technical dossier/Section II/Annex II_9.

¹⁶ Technical dossier/Section II/Annex II_10.

¹⁷ Technical dossier/Section II/ Annex II_16.

was supported by the analysis of one commercial batch of each form (powder and granule) of potassium sorbate stored for three years at ambient temperature (up to 30 °C) and in a dry environment (up to 65 % relative humidity). After the storage period, no loss of potassium sorbate was observed.¹⁸

2.2.2. Stability in vitamin–mineral premixtures

Typical layer, piglet and ruminant vitamin–mineral premixtures were formulated with sorbic acid at inclusion rates of 20 %, 20 % and 16.7 %, respectively, designed to deliver 1 %, 1 % and 1.5%, respectively, on a final feed basis.¹⁹ All samples were stored at ambient temperature and analysed at the start of the study and after six months. No losses were observed over the test period.

2.2.3. Stability in feedingstuffs

Single batches of chicken, piglet and ruminant feeds were supplemented with 1 % sorbic acid.²⁰ Feed for chicken and piglets were studied in mash and pelleted forms, the ruminant feed only in pelleted form. Feed processing by pelleting did not affect the sorbic acid content in feed. Losses after three months of storage were between 15 and 22 %, not influenced by feed type and form.

2.2.4. Stability in water

Sorbic acid was added to water at a concentration of 0.25 %. No loss of sorbic acid was detected after 48 hours at ambient temperature.²¹

2.2.5. Homogeneity

Ten sub-samples were collected from each of the five feeds used in the stability studies. Sorbic acid content was measured in each sub-sample and the coefficient of variation (CV) was calculated. The individually calculated CVs did not exceed 5 % and, when averaged across the five feeds, a value of 3.6 % was obtained.²²

2.3. Conditions of use

Sorbic acid is intended to be used as a preservative in feedingstuffs for all animal species. A maximum content of 6 700 mg/kg complete feedingstuffs is proposed for young ruminants for rearing or fattening and 2 500 mg/kg complete feedingstuffs for all other species and categories.

Potassium sorbate (powder and granules) is intended to be used as a preservative in feedingstuffs for all animal species. A maximum content of 9 000 mg/kg complete feedingstuffs is proposed for young ruminants for rearing or fattening and 3 400 mg/kg complete feedingstuffs for all other species and categories.

The applicant proposes that maximum concentrations for sorbic acid and potassium sorbate in water for drinking should be derived from the maximum concentrations in feedingstuffs according to European Food Safety Authority (EFSA) recommendations (EFSA FEEDAP Panel, 2010).

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 sorbic acid and potassium sorbate in animal feed and in water. The Executive Summary of the EURL report can be found in the Appendix.

¹⁸ Technical dossier/Section II/ Annex II_19 & 20.

¹⁹ Supplementary information June 2015/Annex_SIn_1_QA_006_AC_4.pdf

²⁰ Supplementary information June 2015/Annex_SIn_1_QA_006_AC_4.pdf

²¹ Supplementary information June 2015/Annex_SIn_1_QA_006_AC_4.pdf

²² Supplementary information June 2015/Annex_SIn_1_QA_006_AC_4.pdf

3. Safety

3.1. Safety for the target species

Since animals are exposed to sorbate, studies using either sorbic acid or its potassium salt are considered equivalent when supplemented on an equimolar basis.

The FEEDAP Panel delivered an opinion on the safety and efficacy of sorbic acid and potassium sorbate in 2014 (EFSA FEEDAP Panel, 2014). In this opinion, the safety for the target species was established based on published papers and reports in which sorbic acid/potassium sorbate was fed to target species at concentrations greater than the maximum proposed. From these data, the FEEDAP Panel concluded that sorbic acid and potassium sorbate are safe when used at the maximum proposed level in complete feed for pigs, poultry, dogs and cats (2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed) and young ruminants (6 700 (sorbic acid) and 9 000 (potassium sorbate) mg/kg complete feed). The FEEDAP Panel extended this conclusion to all animal species at a maximum concentration of 2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed.

In the current application, the applicant did not submit any information that was not already considered in the previous opinion regarding the safety for the target species. The FEEDAP Panel is not aware of any new information that would lead to a revision of its previous conclusions on the safety of sorbic acid and potassium sorbate for all animal species.

The FEEDAP Panel extends the conclusion to include the use in water for drinking, provided that the same maximum dose is respected. Maximum concentrations of sorbic acid in water for drinking should be calculated according to the “Statement on the use of feed additives authorised/applied for use in feed when supplied via water” (EFSA FEEDAP Panel, 2010).

The contribution of potassium sorbate to the potassium supply of animals should be considered when formulating diets or when it is included in water for drinking.

3.2. Safety for the consumer

Sorbic acid and potassium sorbate are permitted food additives that may be added directly to food intended for human consumption. JECFA (1974) has set a group ADI for sorbic acid of 25 mg/kg bw, based on a No Observed Adverse Effect Level (NOAEL) of 5 % in the diet (highest dose tested equivalent to 2 500 mg/kg bw per day) of rats from a two-generation study. The Scientific Committee on Food (EC, 1996) endorsed this ADI.

Sorbic acid and potassium sorbate dissociate into sorbate in the gastrointestinal tract. Sorbate is readily metabolised like other short-chain fatty acids with almost complete oxidation of sorbic acid to carbon dioxide and water (FDA, 1975; EC, 1996). No sorbate residues are expected in edible products of food producing animals when fed sorbic acid or its potassium salt. Therefore, the FEEDAP Panel considers that the use of sorbic acid or potassium sorbate up to the maximum proposed levels in feed is safe for the consumer.

3.3. Safety for the user

No studies on user safety of sorbic acid and potassium sorbate were provided by the applicant.

Sorbic acid is considered to be a skin and eye irritant but not a skin sensitiser by the European Chemicals Agency (ECHA, 2011). It is also considered a potential irritant to mucous membranes. Although 6 % of particles (v/v) were <50 µm, the dusting potential would suggest a low probability of exposure by inhalation.

Potassium sorbate is classified as a skin and eye irritant, and is regarded as a potential irritant for the respiratory tract (ECHA, 2011). The high proportion of inhalable and respirable particles in potassium sorbate powder (80 % of < 100 µm diameter and 48 % of < 10 µm diameter, respectively) indicates

that any dust produced would be respirable and does constitute a risk to the user. The granular form of potassium sorbate described in this application does not contain respirable particles.

The FEEDAP Panel notes that the conclusions on inhalation exposure are applicable only to the formulations presented in this dossier.

3.4. Safety for the environment

Sorbates, when ingested, are rapidly and completely metabolised to carbon dioxide. The contribution of potassium, arising from the use of the salt of sorbic acid, to the background levels of this element in the environment would be negligible. Consequently, the FEEDAP Panel concludes that the use of sorbic acid in animal nutrition would not pose a risk to the environment.

4. Efficacy

Sorbic acid and potassium sorbate are authorised as food additives within the EU and are used for a number of technical functions, including that of preservatives in a wide range of foodstuffs. It is reasonable to expect that the effect seen in food will be observed in feed when they are used at comparable concentrations and under similar conditions.

The FEEDAP Panel has reservations about the effectiveness of sorbic acid and potassium sorbate as preservatives in complete feedingstuffs with a moisture content of $\leq 12\%$. However, it is recognised that, under practical conditions of storage, the moisture content of all or part of the feed may rise above this level. Under these circumstances, the additive could be effective in preventing or reducing deterioration.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Sorbic acid and potassium sorbate are safe when used at the maximum proposed dose in feed for pigs, poultry, dogs and cats (2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed) and young ruminants (6 700 (sorbic acid) and 9 000 (potassium sorbate) mg/kg complete feed). This conclusion is extended to all other animal species at a maximum dose of 2 500 (sorbic acid) and 3 400 (potassium sorbate) mg/kg complete feed. The FEEDAP Panel extends the conclusion to include the use in water for drinking, provided that the same maximum total exposure is respected.

The contribution of potassium sorbate to the potassium supply of animals should be considered when formulating diets or when it is included in water for drinking.

No residues of sorbic acid or potassium ions are expected in edible products of food-producing animals when fed sorbic acid or potassium sorbate at the maximum proposed concentrations. Therefore, their use in feed up to the maximum proposed level is considered safe for the consumer.

Sorbic acid and potassium sorbate are skin, eye and respiratory tract irritants.

The use of sorbic acid and its potassium salt in animal nutrition would not pose a risk to the environment.

Sorbic acid and potassium sorbate are authorised food additives within the EU for use as preservatives. It is reasonable to expect that the effect in food will be observed in feed when they are used at comparable concentrations and under similar conditions. However, the FEEDAP Panel has reservations about the effectiveness of sorbic acid and potassium sorbate as preservatives in complete feedingstuffs with a moisture content of $\leq 12\%$.

RECOMMENDATIONS

Equivalent concentrations for sorbic acid and potassium sorbate when used as preservatives in water for drinking should be specified, in agreement to the “Statement on the use of feed additives authorised/applied for use in feed when supplied via water” (EFSA FEEDAP Panel, 2010).

DOCUMENTATION PROVIDED TO EFSA

Sorbic Acid:

1. Sorbic acid for all animal species. October 2010. Submitted by Nutrinova Nutrition Specialties & Food Ingredients GmbH.
2. Sorbic acid for all animal species. Supplementary information. June 2014. Submitted Nutrinova Nutrition Specialties & Food Ingredients GmbH.
3. Sorbic acid for all animal species. Supplementary information. June 2015. Submitted Nutrinova Nutrition Specialties & Food Ingredients GmbH.
4. Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for sorbic acid and potassium sorbate.
5. Comments from Member States received through the ScienceNet.

Potassium sorbate:

1. Potassium sorbate for all animal species. July 2011. Submitted by Nutrinova Nutrition Specialties & Food Ingredients GmbH.
2. Potassium sorbate for all animal species. Supplementary information. June 2014. Submitted by Nutrinova Nutrition Specialties & Food Ingredients GmbH.
3. Potassium sorbate for all animal species. Supplementary information. June 2015. Submitted Nutrinova Nutrition Specialties & Food Ingredients GmbH.
4. Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for sorbic acid and potassium sorbate.
5. Comments from Member States received through the ScienceNet.

REFERENCES

- EC (European Commission), 1996. Scientific Committee for Food (SCF). Opinion on sorbic acid and its calcium and potassium salts. Reports of the Scientific Committee for Food, Thirty-fifth series, 19–22. Available online: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_35.pdf
- ECHA (European Chemicals Agency), 2011. CLH-Report. Proposal for harmonised classification and labelling. Potassium sorbate. Available online: http://echa.europa.eu/documents/10162/13626/clh_potassium_sorbate_en.pdf
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal 2015;13(6):4144, 91 pp. doi:10.2903/j.efsa.2015.4144
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Scientific Opinion on the safety and efficacy of potassium sorbate as a silage additive for all animals except dogs and cats. EFSA Journal 2013;11(7):3283, 12 pp. doi:10.2903/j.efsa.2013.3283

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014. Scientific Opinion on the safety and efficacy of sorbic acid and potassium sorbate when used as technological additives for all animal species. EFSA Journal 2014;12(7):3792, 18 pp. doi:10.2903/j.efsa.2014.3792
- EFSA Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP), 2010. Statement on the use of feed additives authorised/applied for use in feed when supplied via water. EFSA Journal 2010;8(12):1956, 9 pp. doi:10.2903/j.efsa.2010.1956
- EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2012. Scientific Opinion on the safety and efficacy of potassium sorbate for dogs and cats. EFSA Journal 2012;10(6):2735, 10 pp. doi:10.2903/j.efsa.2012.2735
- FDA (Food and Drug Administration), 1975. Select Committee on GRAS Substances (SCOGS). SCOGS Opinion: Potassium sorbate. Report number, 57; ID code 24634-61-5.
- JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1974. Toxicological evaluation of some food additives including anti-caking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organisation Technical report series, 1974, No 539; FAO Nutrition Meetings Report Series, 1974, No 53. Available online: <http://www.inchem.org/documents/jecfa/jecmono/v05je18.htm>

Annex A. Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for sorbic acid and potassium sorbate¹

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 *sorbic acid* 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 *sorbic acid* 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.

¹ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0145%2B0193.pdf>