SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 21 March 2017

doi: 10.2903/j.efsa.2017.4761

Safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) for sows and suckling piglets

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Abstract

Following a request from the European Commission, the EFSA 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 Calsporin® when used in feed for sows and piglets. The additive contains viable spores of a single strain of *Bacillus subtilis*. This species is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment, which requires the identity of the strain to be conclusively established, evidence that the strain is not toxigenic and that it does not show resistance to antibiotics of human and veterinary importance. The strain was found to meet the criteria for the QPS approach in the context of previous opinions and since concerns are not expected from other components of the additive, Calsporin® is presumed safe for all target species, consumers and the environment. In a previous opinion, the FEEDAP Panel concluded that Calsporin® is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser. Use of the additive in feed for sows and suckling piglets will not introduce hazards for users not already considered. Three trials performed with sows over a complete reproductive cycle and their offspring showed positive effects on zootechnical parameters of sows and piglets. Therefore, Calsporin® has the potential to improve one or more performance parameters of sows and suckling piglets when supplemented to both sows and suckling piglets at 3×10^8 CFU/kg of complete feedingstuffs. In the view of the FEEDAP Panel, the effects observed can predominantly be traced back to the administration of the additive to pregnant/lactating sows. The proportion of effects which could be related to feeding supplemented creep feed to suckling piglets cannot be quantified.

Keywords: zootechnical additive, Calsporin, *Bacillus subtilis*, piglets, sows, safety, efficacy

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Question number: EFSA-Q-2015-00296

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Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, De Lourdes Bastos M, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez Puente S, Lopez-Alonso M, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2017. Scientific Opinion on the safety and efficacy of Calsporin® (*Bacillus subtilis* DSM 15544) for sows and suckling piglets. EFSA Journal 2017;15(4):4761, 9 pp. doi:10.2903/j.efsa.2017.4761

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] 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.

The European Commission received a request from Calpis Co. Ltd.[2] for authorisation of the product Calsporin® (*Bacillus subtilis* DSM 15544), when used as a feed additive for sows and suckling piglets (category: Zootechnical additives; functional group: gut flora stabilisers).

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). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 7 July 2015.

According to Article 8 of Regulation (EC) No 1831/2003, 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. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Calsporin® (*Bacillus subtilis* DSM 15544), when used under the proposed conditions of use (see Section 3.2).

1.2. Additional information

The additive Calsporin® is a preparation containing viable spores of a single strain of *Bacillus subtilis*. EFSA has issued several opinions on the safety and efficacy of this product when used with chickens for fattening (EFSA, 2006, 2007a), with weaned piglets (EFSA FEEDAP Panel, 2010a), with turkeys for fattening, ducks, geese, pigeons and other game birds for meat production, ducks, geese, pigeons, game birds, ornamental and sporting birds for rearing to point of lay, turkeys reared for breeding and chickens reared for laying (EFSA FEEDAP Panel 2010b), with laying hens and minor avian species for laying (EFSA FEEDAP Panel, 2015a) and with ornamental fish (EFSA FEEDAP Panel, 2015b).

The additive is currently authorised for use with chickens for fattening,[3] weaned piglets,[4] chickens reared for laying, turkeys, minor avian species and other ornamental and game birds,[5] and laying hens and ornamental fish.[5]

The species *B. subtilis* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to establishing safety for the target species, consumers and the environment (EFSA, 2007b; EFSA BIOHAZ Panel, 2013). This approach requires the identity of the active agent to be established and the absence of toxigenic potential and susceptibility to a selected range of antibiotics to be demonstrated.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[6] in support of the authorisation request for the use of Calsporin® (*Bacillus subtilis* DSM 15544) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of

[1] 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.

[2] On 26 January 2016, the applicant communicated the change from Calpis Co. Ltd. to Asahi Calpis Wellness Co. Ltd., represented in the European Union by Asahi Calpis Wellness Co. Ltd. Europe Representative Office. 46 rue Paul Valery, 75116, Paris, France.

[3] Commission Regulation (EC) No 1444/2006 of 29 September 2006 concerning the authorisation of *Bacillus subtilis* C-3102 (Calsporin) as a feed additive. OJ L 271, 30.9.2006, p. 19 plus amendments.

[4] Commission Regulation (EU) No 333/2010 of 22 April 2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Calpis Co. Ltd. Japan, represented in the European Union by Calpis Co. Ltd. Europe Representative Office). OJ L 102, 23.4.2010, p. 19.

[5] Commission Regulation (EU) No 184/2011 of 25 February 2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office). OJ L 53, 26.2.2011, p. 33.

[6] FEED dossier reference: FAD-2015-0018.

Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[7] and the applicable EFSA guidance documents.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Calsporin® is in line with the principles laid down in Regulation (EC) No 429/2008, the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012) and Technical guidance on tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011a).

3. Assessment

Calsporin® is a preparation of viable spores of a single strain of *Bacillus subtilis* intended for use as a zootechnical additive (gut flora stabiliser) in feeds for sows, in order to have benefit in piglets, and for suckling piglets.

3.1. Characterisation

The additive is a preparation of viable spores of *Bacillus subtilis* DSM 15544[9] at a minimum declared concentration of 1×10^{10} colony-forming units (CFU)/g additive. It has the same formulation and method of manufacture as that considered in previous applications (EFSA, 2006, EFSA FEEDAP Panel, 2010a,b, 2015a,b). Thus, the data pertaining to composition, impurities, physical properties and shelf life still apply.

Although no specific data on stability in feed for the target species or ability to mix in such feed was provided, the data on mixing and stability in premixes, mash and pelleted feeds variously produced for chickens for fattening, turkeys and piglets is considered sufficient given the similarity in feed formulation.

3.2. Conditions of use

Calsporin® is proposed to be used simultaneously in feeds for sows during the whole reproductive cycle and for suckling piglets at a minimum recommended dose of 3×10^8 CFU/kg of complete feedingstuffs.

3.3. Safety

The species *B. subtilis* is considered by EFSA to be suitable for the QPS approach to establishing safety for the target species, consumers and the environment (EFSA, 2007b; EFSA BIOHAZ Panel, 2013). In a previous opinion (EFSA FEEDAP Panel, 2015a), the identification of the strain and compliance with the QPS qualifications were confirmed. Therefore, the Panel concluded that *Bacillus subtilis* DSM 15544 can be presumed safe for target animals, consumers of products derived from animals fed the additive and the environment. The Panel considers these conclusions to apply also in the current assessment. No concerns are expected from other excipients present in the product, so Calsporin® is also considered safe for target animals, consumers and the environment.

In a previous opinion on the use of Calsporin® in feed for chickens for fattening, the Panel concluded that the additive is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser (EFSA, 2006). The use of the additive in sows and suckling piglets is considered unlikely to introduce hazards for users of the product not already considered as part of the first assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2009-0013.pdf

[9] C-3102 is an in-house identifier; the active agent is *Bacillus subtilis* DSM 15544 and is referred to like this throughout this opinion.

3.4. Efficacy

Three efficacy studies, conducted in three Member States in which Calsporin® was added simultaneously to feed for sows and suckling piglets, were submitted.

The detailed designs of the studies are presented in Table 1 and the results in Table 2. The studies considered sows homogeneously distributed (based on parity) into two treatments: a control group receiving a basal diet with no supplementation and a group receiving the same basal diet with Calsporin® from insemination until weaning of the offspring. The exception was study 2 which was developed in two consecutive cycles from weaning/service until weaning/service (cycle 1: duration of 170 days including 30 days before insemination, gestation and lactation; and cycle 2: duration of 140 days). The first cycle involved 55 sows and the second the 44 sows that remained after the exclusion of nine sows culled (four from the control group and five from the treated group) and two sows removed (from the control group) due to a late return to oestrus. In all cases, the offspring was maintained in the same groups and cross-fostering within treatments was done within 1–2 days to equalise litters. Piglets were fed mash creep *ad libitum* from 7 to 10 days of age until weaning. The additive was administered as top-dressing in a dose corresponding to 30 mg/kg based on total daily feed intake; to reach the intended dose of 3×10^8 CFU/kg of complete feed. Controls received the same amount of top-dressing but without added Calsporin®. Concentration in the top-dressing and/or feeds was confirmed by analysis. The parameters measured on the sows were: back fat, body weight, body score (only in study 3), daily feed intake, number of piglets born alive/dead and number of piglets weaned. Those on the litters were: weight of piglets at birth, after cross-fostering and at weaning, feed intake, morbidity and mortality. In addition, faecal samples were collected on a daily basis from piglets in all studies and from sows in studies 2 and 3 to monitor faecal consistency. In study 1, faecal sows' samples were collected from 10 sows/treatment at day 0, at 10 days after moving to farrowing unit (115 days) and at weaning. Faecal scores were determined using a 5-scale basis with 1 denoting no incidence of diarrhoea and higher values indicating increasing incidence/severity). Data on sows' health and performance, feed intake and piglets' mortality were analysed using an analysis of variance (ANOVA). Since study 1 involved sows of two consecutive batches, the model also included the fixed effects of the batches. In trial 2, data from the two cycles were analysed independently. Tukey's test was used to compare means for treatments. Each sow with her litter represented an experimental unit.

In the first study, weight loss of sows during the farrowing/suckling period was significantly lower in the Calsporin® group when compared to control (Calsporin® = 40.2 vs control = 46.1 kg, respectively; $p = 0.034$).[10] Back fat thickness and faecal consistency were not affected by treatment. Piglets mortality to weaning was significantly reduced when Calsporin® was supplemented simultaneously in lactating sows' and piglets' feed. Piglet birth weights, weight at weaning, weight gain (birth-weaning) and the other parameters measured, such as diarrhoea incidence, were not affected by treatment.

At the end of the first cycle of study 2, feed consumption of sows in the farrowing/suckling period was significantly higher for Calsporin® sows than for control (Calsporin®: 247.8 kg vs control: 219.1 kg, $p < 0.005$).[11] Calsporin® sows weighed more than control sows (Calsporin®: 207.0 kg vs control: 191.8 kg, $p = 0.077$), which was confirmed by a significantly lower weight loss during the farrowing/suckling period (Calsporin®: 35.0 kg vs control: 46.9 kg; $p < 0.005$). Moreover, Calsporin® sows tended to have more back fat at study end compared to control sows (Calsporin®: 10.59 vs control: 9.41 mm, respectively; $p = 0.071$). The weaning–oestrus interval (period between weaning and mating) was significantly shorter for Calsporin® sows compared with control sows (Calsporin®: 5.3 vs control: 6.5 days; $p = 0.004$). Piglet mortality did not significantly differ between groups (Table 2). Piglets of the Calsporin® group showed a significantly greater daily weight gain and weight at weaning than piglets in the control group. None of the other parameters measured was influenced by treatment. In the second cycle, study parity (control = 4.2 vs Calsporin® = 4.2) and the initial weight of the sows (control = 238.1 kg vs Calsporin® = 236.9 kg) were similar among groups, some significant differences in sows' feed intake, bodyweight and back fat losses and in litter weight at birth and weaning and number of piglets weaned were observed between control and Calsporin® groups. The statistical analysis of the two cycles was done independently. However, the results of the second

[10] Technical dossier/Section IV/Annex IV.3.1.
[11] Technical dossier/Section IV/Annexes IV.3.2 and IV.3.3.

cycle are not considered to be independent from the first, and thus, can only be used as supportive evidence.

In study 3, weight loss during the lactation period was significantly lower in the Calsporin® sows group when compared to control sows (Calsporin® = 7.8 kg vs control = 17.7 kg; $p < 0.01$).[12] Back fat thickness (Calsporin® = 14.4 mm vs control = 12.8 mm, respectively; $p = 0.05$), body condition score at weaning (Calsporin® = 3.24 vs control = 3.12, respectively; $p = 0.01$) and back fat loss during lactation (Calsporin® = 0.86 mm vs control = 1.98 mm, respectively; $p < 0.001$) were also positively and significantly affected by treatment. No other parameters for sows were affected. The Calsporin® group showed slightly heavier litters at birth (Calsporin®: 21.1 kg vs control: 20.3 kg; $p = 0.458$) and after cross-fostering (Calsporin®: 20.1 kg vs control: 19.7 kg; $p = 0.553$) than the control group, but these differences did not reach significance until weaning. No other litter parameters measured were influenced by treatment except for faecal score (Calsporin = 3.6 vs control = 3.5, $p = 0.06$), but this difference is not considered to be of biological relevance.

Table 1: Details on the study design for the studies performed in sows

Study	Breed (parity)	Sows per treatment(a)	Calsporin® (CFU/kg feed)	Duration (days)	Sows' basal diets (main ingredients)	Creep feed (main ingredients)(time, from day to day)
1	Hybrid (1–5)	24	0 3×10^8	136	Wheat/barley/ maize/ beat pulp	Whey powder/oat flakes/wheat bran (10–20)
2A 2B	Large White x Landrace (1–10, av. 3.3–3.6) (2–11, av. 4.2–4.2)	27/28 21/23	0 3×10^8	170 140	Wheat/maize/ soybean meal	Maize/barley/whey powder/wheat bran (8–28/30)
3	Danbred (2–5)	25	0 3×10^8	140	Barley/wheat/ soybean meal	Wheat/soybean meal/ skimmed milk powder/rolled oats (7–25)

CFU: colony-forming unit.
(a): Control/treatment in each cycle of study 2.

Table 2: Summary of the overall performance results on suckling piglets of the three trials

Trial no	Treatment (CFU/kg feed)	No of piglets born alive	No of piglet after cross-fostering	No of piglets weaned	Piglet body weight at birth (kg)	Piglet body weight at weaning (kg)	Piglet weight gain (g/day)	Mortality from cross-fostering to weaning (%)
1	0	16.3	14.5	13.5	1.34	5.28	207	7.3^b
	3×10^8	15.3	14.0	13.5	1.35	5.15	195	3.4^a
2A	0	12.3	12.2	11.2	1.58	7.46^a	195.0^a	8.4
	3×10^8	12.3	12.0	11.2	1.55	8.09^b	217.0^b	6.3
2B	0	12.2		11.1^a	1.37^a	7.64^a	236.1	9.1
	3×10^8	12.6		11.9^b	1.50^b	8.08^b	244.0	5.7
3	0	14.8	14.1	13.7	1.38	6.65^a	208.0	3.0
	3×10^8	15.1	14.1	13.7	1.39	6.99^b	220.8	2.9

CFU: colony-forming unit.
a,b: Means with different superscript differ significantly at $p < 0.05$.

In the three studies, the simultaneous supplementation of Calsporin® at the recommended dose to sows and piglets positively and significantly affected at least one parameter in sows (reduction in weight loss in three studies, greater back fat thickness in two studies) and in piglets (reduced mortality in one study and increased weight at weaning in the other two studies).

[12] Technical dossier/Supplementary information October 2016/Annex IV.3.4

3.5. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[13] and Good Manufacturing Practice.

4. Conclusions

The active agent fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Calsporin® can be presumed safe for the target animals, consumers of products from treated animals and the environment.

The additive is not a dermal/eye irritant or a skin sensitiser but should be considered a potential respiratory sensitiser. Use of the additive in feed for sows and suckling piglets will not introduce hazards for users not already considered.

Three trials performed with sows over a complete reproductive cycle and with their offspring showed positive effects on zootechnical parameters of sows and piglets. Therefore, Calsporin® has the potential to improve one or more performance parameters of sows and of suckling piglets when supplemented to both sows and suckling piglets at 3×10^8 CFU/kg of complete feedingstuffs.

In the view of the FEEDAP Panel, the effects observed can predominantly be traced back to the administration of the additive to pregnant/lactating sows. The proportion of effects which could be related to feeding supplemented creep feed to suckling piglets cannot be quantified.

Documentation provided to EFSA

1) CALSPORIN®. *Bacillus subtilis* C-3102, DSM 15544. 2/2015. Submitted by Calpis Co. Ltd.
2) CALSPORIN®. *Bacillus subtilis* C-3102, DSM 15544. Supplementary information October 2016. Submitted by Asahi Calpis Wellness Co. Ltd.
3) Comments from Member States.

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[13] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

ANOVA	analysis of variance
CFU	colony-forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety