SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 26 September 2023

doi: 10.2903/j.efsa.2023.8358

Efficacy of a feed additive consisting of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) for cats (Prosol S.p.A)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the efficacy of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) as a zootechnical additive for cats. The additive is already authorised for use in sows, dairy cows, horses, weaned piglets, dogs, cattle and minor ruminants for fattening and minor ruminants for dairy production. In a previous opinion, the FEEDAP Panel concluded that Biosprint® is safe when used in feeds for cats and dogs. However, based on the data available, the FEEDAP Panel was unable to conclude on the efficacy of the additive when administered to cats. In the current application, the applicant provided an additional efficacy trial in cats. Based on the previously and newly submitted data, the FEEDAP Panel concluded that Biosprint® has the potential to be efficacious as a zootechnical additive for cats under the proposed conditions of use.

Keywords: zootechnical additives, digestibility enhancers, Biosprint®, *Saccharomyces cerevisiae*, cats, efficacy, follow-up

Requestor: European Commission

Question number: EFSA-Q-2022-00587

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output to Daniel Pagés Plaza.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., & Casanova, J. O. (2023). Efficacy of a feed additive consisting of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) for cats (Prosol S.p.A). *EFSA Journal*, *21*(10), 1–7. https://doi.org/10.2903/j.efsa.2023.8358

ISSN: 1831-4732

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

Table of contents

1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Prosol, is seeking a Community authorisation of *S. cerevisiae* MUCL 39885 as a feed additive to be used as gut flora stabilisers for cats. (Table 1).

Table 1: Description of the additive

Category of additive	Zootechnical additives
Functional group of additive	Gut flora stabilisers
Description	*Saccharomyces cerevisiae* MUCL 39885
Target animal category	Cats
Applicant	Prosol
Type of request	New Opinion

On 23 June 2021, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of the additive when administered to cats.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 12 April 2022 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks EFSA to deliver a new opinion on *S. cerevisiae* MUCL 39885 as a feed additive for cats based on the supplementary data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

Biosprint® contains viable cells of the strain *S. cerevisiae* MUCL 39885. The additive is currently authorised for use in sows, dairy cows, horses, weaned piglets, dogs, cattle for fattening, minor ruminants for fattening and minor ruminants for dairy production as a zootechnical additive (4b1710).

The EFSA FEEDAP Panel issued several opinions on the safety and efficacy of Biosprint® (*S. cerevisiae* MUCL 39885) in different target species (EFSA, 2004, 2009; EFSA FEEDAP Panel, 2010a, b,c, 2013, 2015, 2019a,b, 2020, 2021).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[2] to a previous application on the same product.[3]

In accordance with Article 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] a non-confidential version of the supplementary information has been published on Open.EFSA.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Dossier reference: EFSA-Q-2022-00587.
[3] Dossier reference: FAD-2020-0054.
[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.
[5] Decision available online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive under assessment contains viable cells of *S. cerevisiae* MUCL 39885 (tradename: Biosprint®) with a minimum concentration of 1×10^9 colony forming unit (CFU)/g additive.

The additive is intended to be used as a zootechnical additive (functional group: gut flora stabiliser) in feed for cats at a minimum inclusion level of 7×10^{10} CFU/kg of complete feed.

In a previous opinion on the safety and efficacy of the additive in cats and dogs, the FEEDAP Panel concluded that the additive is safe for the target species, it is considered a potential skin and eye irritant and a skin and respiratory sensitiser and has the potential to be efficacious in dogs at the proposed level of inclusion (EFSA FEEDAP Panel, 2021). The Panel could not conclude on the efficacy of the additive when administered to cats.

The applicant has provided additional information to address the gaps identified in the assessment of the efficacy of the additive in cats, which are the subject of this assessment.

3.1. Efficacy

In the previous assessment, one trial was submitted to support the efficacy in cats, but no significant and positive differences were found on faecal dry matter content between the cats receiving the additive and the control group.

The applicant has now submitted a new efficacy trial[7] in cats to complement the previous assessment.

Ten cats (3–5 years old, European shorthair, sex not indicated) were individually housed and randomly allocated into two groups (representing five cats per treatment), balanced by initial body weight. A wet commercial diet (dry matter [DM] 21%; 838 kcal [metabolisable energy]/kg feed, as is) based on meat, animal-derived ingredients and vegetable protein was either not supplemented (control) or top-dressed with Biosprint® to provide 7.45×10^{10} CFU/kg complete feed.[8] The experimental feeds were offered to the cats twice a day on a restricted basis[9] for 36 days.

Health status was monitored daily. The cats were individually weighed, and faecal samples were collected at the start of the study and on days 6, 12, 18, 24, 30 and 36. Feed intake was recorded daily. Faecal samples were analysed for dry matter content as an indicator of the faecal consistency.

The experimental data were analysed using a mixed model including the treatment, time and the interaction treatment × time as fixed effects and faecal DM content at the start of the study was used as covariate. The individual animal was the experimental unit. Group means were compared with Tukey's test. Significance level was set at 0.1.

Animals were healthy during the whole experiment. No differences were observed in the body weight and feed intake of the animals throughout the trial. Supplementation of the cats' feed with Biosprint® significantly increased DM content of faeces as compared with the control group (47.88% vs. 51.35%).

Conclusions on efficacy

Based on the efficacy data in dogs evaluated by the Panel in the previous opinion (EFSA FEEDAP Panel, 2021) and the new study in cats, the Panel concludes that the additive has the potential to be efficacious as a zootechnical additive when added to cats feed at 7×10^{10} CFU/kg complete feed (88% DM).

[6] 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.

[7] 'Annex_IV_2 Efficacy Report Trial Prosol.Cat.01.21'.

[8] Annex_IV_06 CoA; Level calculated in feed 5.1×10^{10} CFU/kg feed.

[9] Animals up to 3.5 kg of BW were fed with 300 g/day; animals with a BW greater than 3.5 kg were fed 400 g/day.

4. Conclusions

The FEEDAP Panel concludes that Biosprint® is considered to be efficacious as a zootechnical additive for cats when added to feed at 7×10^{10} CFU/kg complete feed (88% DM).

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Abbreviations

CFU	colony forming unit
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
MUCL	Mycothéque de l'Université Catholique de Louvain