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Safety and efficacy of Levucell SC® (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive for calves and minor ruminant species and camelids at the same developmental stage

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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 was asked to deliver a scientific opinion on the safety and efficacy of Levucell® SC when used in feed for calves and minor ruminant species and camelids at the same developmental stage. The additive consists of viable cells of *Saccharomyces cerevisiae*. This species is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment. This approach requires the identity of the strain to be conclusively established. 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, Levucell® SC is presumed safe for all target species, consumers of products derived from animals fed the additive and for the environment. The Panel considers these conclusions to apply also in the current assessment. In a previous opinion, the Panel also concluded that the additive is considered an eye irritant but not a dermal irritant or sensitiser and that inhalation exposure is unlikely. Since the use of the additive in calves and minor ruminant species and camelids at the same developmental stage is considered unlikely to introduce hazards for users of the product not already considered as part of the first assessment, these conclusions are still considered valid. Levucell SC® has the potential to be efficacious in calves at the minimum inclusion level of 1×10^9 CFU/kg complete feed. The conclusion on efficacy for calves can be extrapolated to minor ruminant species and camelids at the same developmental stage.

Keywords: zootechnical additive, gut flora stabiliser, digestibility enhancers, Levucell® SC, *Saccharomyces cerevisiae* CNCM I-1077, calves, minor ruminant species and camelids

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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 Lallemand SAS[2] for renewal of the authorisation of the product Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077), when used as a feed for calves and minor (pseudo)ruminants species (category: zootechnical additive; functional group: gut flora stabiliser and digestibility enhancers). In the course of the assessment the applicant clarified that the target species are calves and minor species and camelids at the same developmental stage.[3]

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). The particulars and documents in support of the application were considered valid by EFSA as of 25 September 2018.

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 Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The additive Levucell® SC is a preparation of *S. cerevisiae* CNCM I-1077. EFSA issued several opinions on the safety and efficacy of this product for the following species: dairy goats and dairy ewes (EFSA, 2006a; EFSA FEEDAP Panel, 2018), leisure horses (EFSA, 2006b, 2009), lambs for fattening (EFSA, 2008), dairy cows, cattle for fattening, minor ruminant species and camelids (EFSA FEEDAP Panel, 2017) and lambs and horses (EFSA FEEDAP Panel, 2019).

The product is currently authorised for use in horses,[4] lambs,[5] dairy goats and dairy sheep,[6] dairy cows and cattle for fattening.[7]

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[8] in support of the authorisation request for the use of Levucell® SC as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active agent in animal feed are valid and applicable for the current application.[9]

[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] Lallemand SAS. 137, 19 Rue des Briquetiers, BP 31702. 59700 Blagnac, France.
[3] Technical dossier/Supplementary information April 19.
[4] Commission Regulation (EC) No 910/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation *of Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for horses (holder of authorisation Lallemand SAS). OJ L 257, 30.9.2009, p. 7.
[5] Commission Regulation (EC) No 1293/2008 of 18 December 2008 concerning the authorisation of a new use of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive. OJ L 340, 19.12.2008, p. 38 plus.
[6] Commission Regulation (EC) No 226/2007 of 1 March 2007 concerning the authorisation of *Saccharomyces cerevisiae* CNCM I 1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive. OJ L 64, 2.3.2007, p. 26 plus amendments.
[7] Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs. OJ L 195, 27.7.2005, p. 6 plus amendments.
[8] FEED dossier reference: FAD-2018-0049.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0120-levucell.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Levucell® SC is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

Levucell® SC[11] is a preparation consisting of viable cells of *S. cerevisiae* (CNCM I-1077) intended for use as a zootechnical additive (gut flora stabiliser and digestibility enhancer) in feed for calves and minor ruminant species and camelids at the same developmental stage (i.e. calves of the species *Bos taurus* (reared for reproduction, veal production or beef production) from birth until weaning/full development of the rumen, buffalo calves, goat kids, lambs, calves/kids of species in the family Cervidae and other species of ruminants, from birth until weaning/full development of the rumen and calves of *Camelus* spp. from birth until weaning/full development of the rumen).[3]

3.1. Characterisation

The product is marketed in two forms, a granulated free-flowing powder, Levucell® SC20, with a minimum concentration of viable yeast cells of 2×10^{10} colony forming units (CFU)/g of additive and [redacted] Levucell® SC10 ME/Titan, with a minimum concentration of viable yeast cells of 1×10^{10} colony forming units (CFU)/g of additive. The active agent and additive were fully characterised in a previous opinion; therefore, all data pertaining to composition, purity, physico-chemical properties and stability described thereof are considered valid also for this application (EFSA FEEDAP Panel, 2017).

The additive is intended for use in complete feed for calves and minor ruminant species and camelids at the same developmental stage at the minimum inclusion level of 1×10^9 CFU/kg complete feed.[3]

3.2. Safety

The species *S. cerevisiae* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007, EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established. In a previous opinion (EFSA FEEDAP Panel, 2017), the identity of the Levucell® active agent was confirmed to be a *S. cerevisiae* strain. Accordingly, this strain is considered by EFSA to be suitable for the QPS approach to safety and is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since no concerns are expected from other components of the additive, Levucell® SC was also considered safe for the target species, consumers of products from animals fed the additive and the environment. The Panel considers these conclusions to apply also in the current assessment.

In the same opinion, Levucell® SC was considered not a skin irritant or sensitiser but, an eye irritant. Inhalation exposure was found to be unlikely. The use of the additive with the additional target species 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.

3.3. Efficacy

3.3.1. Efficacy for calves

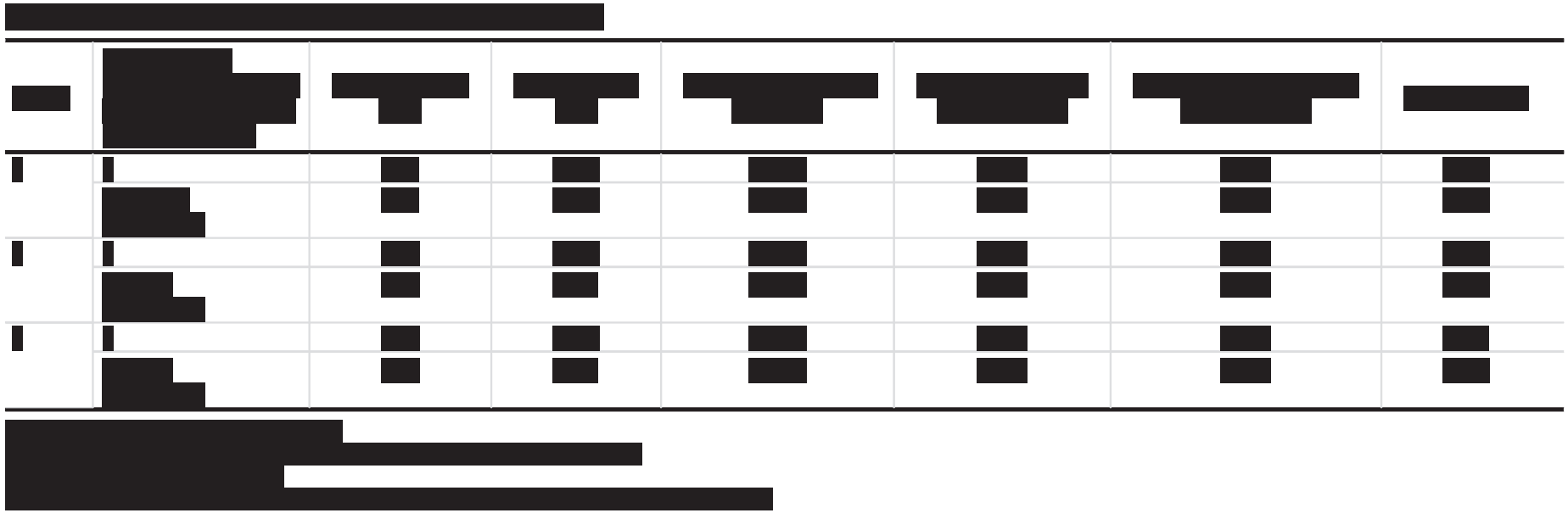
The dossier contains three studies, two of which carried out in the same location but in different periods. In the three studies Levucell® SC20 was used. The two forms are considered equivalent when used to deliver the same dose.

[10] 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.

[11] Levucell® SC Titan may be marketed with other tradenames: Levupro® SC20/SC10 ME Titan, Proficell® SC20/SC10 ME Titan, Lallemand® SC20/SC10 ME Titan.

[redacted]

[redacted]



No mortality occurred in any of the studies. Inclusion of Levucell SC® in feed led to a significantly greater weight gain and improved feed to gain ratio in the three studies. This was reached at an inclusion level of approximately 1×10^9 CFU/kg complete feed.

3.3.1.1. Conclusions on efficacy for calves

Levucell SC® has the potential to be efficacious in calves at the minimum inclusion level of 1×10^9 CFU/kg complete feed.

3.3.2. Efficacy for minor ruminant species and camelids

The efficacy of Levucell SC® for calves has been established at 1×10^9 CFU/kg complete feed. Considering the physiological similarity of the developmental stage and since the dose proposed for use with minor species is the same as that demonstrated to be effective in a physiologically similar major species, and it can be reasonably assumed that the mode of action is the same, the conclusion on efficacy for calves can be extrapolated to minor ruminant species and camelids at the same developmental stage.

3.4. 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[15] and Good Manufacturing Practice.

4. Conclusions

Levucell SC® is considered safe for the target animals, consumers of products derived from treated animals and the environment.

Levucell® SC is considered an eye irritant but not a dermal irritant or sensitiser. Inhalation exposure is unlikely.

Levucell SC® has the potential to be efficacious in calves at the minimum inclusion level of 1×10^9 CFU/kg complete feed. The conclusion on efficacy for calves can be extrapolated to minor ruminant species and camelids at the same developmental stage.

Documentation provided to EFSA/Chronology

Date	Event
27/07/2018	Dossier received by EFSA. Saccharomyces cerevisiae CNCM I-1077. July 2018. Submitted by Lallemand SAS
13/08/2018	Reception mandate from the European Commission
25/09/2018	Application validated by EFSA – Start of the scientific assessment
10/04/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
25/12/2018	Comments received from Member States
26/04/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
14/05/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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[15] 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

CFU	colony forming unit
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	Qualified Presumption of Safety