SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 7 May 2020

doi: 10.2903/j.efsa.2020.6138

Statement on the safety and efficacy of perlite for ruminants and poultry

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Abstract

The additive perlite (sodium potassium aluminium silicate) is intended to be used as a technological additive (functional group: anticaking agents) for ruminants and poultry. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assessed the data provided by the applicant in the technical dossier. During the course of the assessment, the need for additional information in order to be able to deliver an opinion on the safety and efficacy of this additive was identified and notified to the applicant. The information requested covered the characterisation and identification, the safety for the target species and user, and the efficacy of the additive. The applicant has failed to provide the additional information. Therefore, considering the data provided in the original dossier and the absence of response from the applicant to the requests from EFSA, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive perlite as a technological additive for ruminants and poultry.

Keywords: Technological additive, anticaking agent, perlite, safety, efficacy, ruminants, poultry

Requestor: European Commission

Question number: EFSA-Q-2014-00457

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Acknowledgments: The Panel wishes to acknowledge the contribution of Davide Guerra to this opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kos Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brozzi R, Galobart J, Gregoretti L, López-Gálvez G, Innocenti ML, Vettori M-V and Sofianidis K, 2020. Scientific Opinion on the statement on the safety and efficacy of perlite for ruminants and poultry. EFSA Journal 2020;18(5):6138, 5 pp. https://doi.org/10.2903/j.efsa.2020.6138

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

Regulation (EC) No 1831/2003[1] 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 1 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 7 years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Nordisk Perlite Aps on behalf of European Perlite Association[2] for re-evaluation of the authorisation of the product perlite (sodium potassium aluminum silicate), when used as a feed additive (category: technological additive; functional group: anticaking agents) for ruminants and poultry.

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) (re-evaluation of an authorised 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 18 December 2014.

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 perlite for ruminants and poultry.

2. The application dossier

The present application concerns the product perlite to be used as a technological additive (functional group: anticaking agents) in feed for ruminants and poultry.

The European Commission received an application for the use of this product in feed for ruminants and poultry on 15 February 2010. This application was received by the EFSA on 1 March 2010. EFSA immediately started the verification of the dossier to check whether all the documents and particulars requested in Article 7(3) of Regulation (EC) No 1831/2003 were provided. The dossier was considered valid for the start of the assessment on 18 December 2014. The scientific evaluation of the technical dossier started immediately. During the course of the assessment, the working group of technological additives of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) identified the need for additional information in order to be able to deliver an opinion on the safety and efficacy of this additive. The information requests were sent to the applicant on 18 June 2015 and 13 July 2015, and covered the characterisation and identification, the safety for the target species and the user, and the efficacy of the additive. The deadline to provide the information was set to 18 November 2015. The applicant had been asked on 23 May 2019 to answer EFSA's request but the data were never provided. Therefore, on 30 June 2019, EFSA notified the applicant its intention to finalise the assessment regarding the dossier of reference.

The European Union Reference Laboratory (EURL) delivered its report on the methods of analysis for this dossier.[3]

3. Conclusions

Considering the limited data provided in the original dossier and the absence of response from the applicant to the requests from EFSA for additional information, the FEEDAP Panel is not in a position to deliver an opinion on the safety and efficacy of the additive perlite as a technological additive for ruminants and poultry.

[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] Nordisk Perlite Aps, Hammersholt Erhvervspark 1-5, 3400 Hillerød, Denmark.
[3] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad%202010-0012-perlite.pdf

4. Documentation as provided to EFSA/Chronology

Date	Event
01/03/2010	Dossier received by EFSA. Perlite for ruminants and poultry. Submitted by Nordisk Perlite Aps on behalf of European Perlite Association.
23/06/2014	Reception mandate from the European Commission
18/12/2014	Application validated by EFSA – Start of the scientific assessment
24/02/2015	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
18/03/2015	Comments received from Member States
18/06/2015	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 and identification, safety for target species, safety for user, efficacy.*
13/07/2015	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for target species.*
30/06/2019	Scientific assessment restarted
07/05/2020	Statement adopted by the FEEDAP Panel. End of the Scientific assessment

Abbreviations

EURL European Union Reference Laboratory
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed