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Safety and efficacy of a feed additive consisting of cashew nutshell liquid for all animal species (Oligobasic Europe)

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Abstract

Following a request from European Commission, the 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 the additive cashew nutshell liquid as a technological additive (antioxidant) in feedingstuffs for all animal species. The additive cashew nutshell liquid consists of an artificial mixture of two components, the oil extracted from the cashew nutshell, called CNSL and castor oil. In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the characterisation of the additive nor to conclude on the safety of cashew nutshell liquid for the target species, the consumer and the environment. The additive is considered skin and eye irritant and a skin sensitiser. Exposure via inhalation is unlikely. The additive is an effective antioxidant in feedingstuffs and feed material for all animal species at the proposed conditions of use.

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1. Introduction

1.1. Background and Terms of Reference

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.

The European Commission received a request from Oligobasic Europe² for the authorisation of the additive consisting of cashew nutshell liquid, when used as a feed additive for all animal species (category: technological additives; functional group: antioxidants).

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 8 May 2017.

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 feed additive consisting of cashew nutshell liquid, when used under the proposed conditions of use (see **Section 3.1.5**).

1.2. Additional information

Cashew nutshell liquid is not authorised as a feed or a food additive in Europe. The safety and efficacy of the product when used as a feed additive has not been assessed before.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier³ in support of the authorisation request for the use of cashew nutshell liquid as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports, to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.⁴

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of cashew nutshell liquid is in line with the principles laid down in Regulation (EC) No 429/2008⁵ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

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 Oligobasic Europe, Avenida València 32, oficina 4, 25001, Lleida, Spain.

³ FEED dossier reference: FAD-2016-0027.

⁴ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/finrep-fad-2016-0027-cashew-nutshell-liquid.pdf>

⁵ 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.

3. Assessment

The additive under assessment consists of two components, cashew nutshell liquid (further named CSNL) and castor oil. It is intended to be used as a technological additive (functional group: antioxidant) in feed for all animal species.

3.1. Characterisation

3.1.1. Manufacturing process

The additive results from mixing the two components CSNL (77%) and castor oil (23%). The manufacturing process of the additive is described in a generic way and no further details are given.

CNSL is derived from the nutshell of the cashew fruit. CNSL is the oil extracted from the nutshell with a roasting process. In this process, the nuts are immersed in CSNL oil at high temperature (185–190°C) for ~ 1.5 min, releasing the oil contained in the nuts into the CSNL oil used for immersion.

Castor oil is extracted from the castor bean by either solvent extraction or mechanical crushing, grinding and pressing. After pressing, the oil is further refined by steaming, filtration and bleaching.

No further details on the manufacturing of the components of the additive were available.

3.1.2. Characterisation of the components

CSNL (Chemical Abstract System (CAS) number 8007-24-7) is specified to contain cardol (10–20%), cardanol (50–60%), methyl cardol (1–5%), polymers (20–40%) and ashes (0.5%). According to the applicant, the 'polymer' is the result of the polymerisation at high temperatures (reached during the oil extraction) of cardol and cardanol. The polymers are mainly dimers, trimers, tetramers and higher oligomers of cardol and/or cardanol. The results of the analysis of 19 batches of CSNL (analytical reports not available) showed average concentrations of cardol of 13.58% (10.97–15.25%), in compliance with the specifications, the concentration of cardanol in the same batches was above the specified maximum content in 15 batches (average 63.10%, range 57.60–68.62%).⁶ Three additional batches were analysed (analytical reports not available), showing concentrations of 12.1% cardol (11.2–14.0%), 59.4% cardanol (58.8–60.7%), 2.99% methyl cardol (1.74–4.7%), 25.7% polymers (20.8–28.3%) and 0.36% ashes (0.16–0.51%).⁶

CNSL is liquid at ambient temperature and polymerises before its boiling point (220°C). It is soluble in alcohol and not miscible in water. No analytical data to support the purity of CNSL (e.g. heavy metals, microbial contamination, mycotoxins, dioxins and pesticides) were provided.

Castor oil (CAS number 8001-79-4) is described as a mixture containing 85–95% ricinoleic acid, oleic acid (2–6%), linoleic acid (1–5%), α -linolenic acid (0.5–1%), stearic acid (0.5–1%) and palmitic acid (0.5–1%). Castor oil is declared to comply with the specifications of the Food Chemical Codex (FCC),^{7,8} however, no analytical data to support the composition of castor oil and the compliance of the oil with FCC specifications were provided. Castor oil is a liquid with a boiling point of 313°C, insoluble in water and soluble in alcohol.

3.1.3. Characterisation of the additive

The additive is a dark brown liquid, which is declared to contain CSNL (77%) and castor oil (23%). No analytical data to support compliance with this specification and no information related to the purity of the additive were made available. In absence of these data, the FEEDAP Panel is not in the position to conclude on the characterisation of the additive cashew nutshell liquid.

3.1.4. Stability and homogeneity

Three batches of the additive were stored at 55°C for 2 weeks, showing limited loss in the concentration of cardol (3–11%) and an increase in the concentration of cardanol (5–7%). In another test, three batches of the additive were stored at ambient temperature for 16 months. The analysis of cardol and cardanol showed a loss of less than 5% for cardol and an increase of less than 6% of cardanol.⁹

⁶ Technical dossier/Supplementary Information October 2020/Section II.

⁷ <https://www.foodchemicalscodex.org/>

⁸ Acid value: < 7 mL of 0.10 N NaOH for 10 g sample; specific gravity at 25°C: 0.952–0.966; iodine value: 83–88; saponification value: 176–185; hydroxyl number: 160–168, lead: < 0.1 mg/kg.

⁹ Technical dossier/Section II/Annex II Appendix 2-Stability and Supplementary information October 2020/Appendix 2-Stability.

Two samples of three batches of pelleted turkey feed supplemented with the additive at unknown concentration (< 1%) were analysed in triplicate (six samples total for each batch) for cardol and cardanol.¹⁰ The results of the analyses showed average concentrations of 75 mg cardol/kg feed and 324 mg cardanol/kg feed. However, without the analysis of the initial concentration, the study is considered of no value.

3.1.5. Conditions of use

The additive is intended to be used as an antioxidant in premixtures and feedingstuffs for all animal species. The applicant proposed a minimum and a maximum inclusion level of 100 and 1,000 mg additive/kg complete feed, respectively (corresponding to 8–100 mg cardol/kg, 40–400 mg cardanol/kg and 23–230 mg ricinoleic acid/kg). The Panel noted that, considering the composition of CNSL and the description of the additive, the concentrations of cardol, cardanol, and ricinoleic acid would be in the range of: cardol from ~ 8 to ~ 156 mg/kg; cardanol from ~ 40 to ~ 460 mg/kg and ricinoleic acid from ~ 20 to ~ 220 mg/kg.

3.2. Safety

3.2.1. Safety for the target species

No information on the safety of the additive for the target species was available. A tolerance study in which chickens for fattening were fed diets supplemented with CSNL was made available.¹¹ Since the study was not done with the additive under assessment, but only with one of its two components, it could not be used to assess the safety of cashew nutshell liquid for the target species, and it was not further considered.

In addition, a series of publications were made available, in which chickens for fattening (seven studies), quails (one study), turkeys (two studies), piglets (two studies), cattle for fattening (six studies), dairy cows (four studies), sheep (two studies), goats (one study), piglets (three studies), fish (one study) and dogs (one study) were fed diets supplemented with the additive or the component CSNL. All these publications had limitations (e.g. only one concentration tested, no multi-fold concentration tested, absence of appropriate statistical replicates, no relevant parameters analysed), which would preclude their assessment to support the safety for the target species.

In the absence of adequate data, the FEEDAP Panel is not in the position to conclude on the safety of the additive for the target species.

3.2.2. Safety for the consumer

No specific information has been provided on the safety of castor oil, one of the two components of the additive. The applicant made instead reference to a previous evaluation (EFSA ANS Panel, 2017) of an additive containing ricinoleic acid (polyglycerol polyricinoleate). However, in the absence of a proper identification and characterisation of the castor oil used to manufacture the additive, it is not possible to assess the correspondence of the test item used in the studies described in that Opinion and to evaluate the relevance of the conclusions for the current assessment.

No specific information on the absorption, distribution, metabolism and excretion (ADME) of CSNL was made available. Only some information on the metabolic fate of alkylresorcinols (the chemical group to which cardol belongs) and of phenols (the chemical group to which cardanol belongs) naturally present in cereals was provided. No residues studies were available.

Regarding the toxicological profile of CSNL, two publications describing genotoxic and (co)carcinogenic activity (George and Kuttan, 1997; Leite et al., 2019) of an extract of cashew nutshell (extraction process not corresponding to the one described for the additive under assessment) were provided. In addition, partial summaries of a 14-day study (dose range finding study) and a 49-day study (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test studies done with an uncharacterised CNSL) were submitted. In the absence of the original reports and of the evidence of correspondence of the test item with the additive under assessment, these studies could not be further considered.

¹⁰ Technical dossier/Supplementary Information October 2020/Appendix 8-Turkey data.

¹¹ Technical dossier/Supplementary Information October 2020/Appendix 6A Chicken Safety.

Overall, in the absence of an adequate dataset to define the toxicological profile of the two components of the additive, and in the absence of data on consumer exposure, the FEEDAP Panel is not in the position to conclude on the safety of the additive for the consumer.

3.2.3. Safety for the user

The additive is an oily liquid; therefore, exposure via inhalation is not expected.

The skin irritation potential of the additive was tested in a valid study performed according to OECD testing guideline (TG) 404, which showed that it is a skin irritant (category 2 GHS), therefore it is also considered an irritant to the eye.

No specific studies investigating the skin sensitisation potential of the additive was submitted. However, the applicant referred to an evaluation from the United States Environmental Protection Agency (EPA, 2007), which considered CNSL as a 'strong sensitiser'.

The additive is considered a skin and eye irritant and a skin sensitiser.

3.2.4. Safety for the environment

No specific information on the safety of the additive, of CNSL and of castor oil for the environment were made available.

Cashew trees are not typical of Europe; therefore, it cannot be excluded that the use of cashew nutshell liquid in animal nutrition could significantly alter the concentration and or distribution of its components (i.e. cardol, cardanol, their polymers and methylcardol) in the receiving environment.

In the absence of data, the FEEDAP Panel cannot conclude on the safety of the additive for the environment.

3.3. Efficacy

The efficacy of the additive as antioxidant was tested in three *in vitro* studies. The three studies shared the same design. Two complete feedingstuffs for turkeys (developer phase I and II),¹² two complete feedingstuffs for laying hens (same basal diet formulated with 2% of fish oil or poultry fat)¹³ and two feed materials (poultry and pork fat)¹⁴ were supplemented with the additive (composition of the additive and analytical confirmation of the inclusion level not provided), then the oxidative status of the feeds was measured. The feedingstuffs for turkeys were supplemented with 0 or 750 mg additive/kg and oxidative status was measured in three subsamples with the active oxygen method (AOM) at 6 and 10 h after preparation. The AOM (AOCS Cd 12-57) measures the time (in hours) required for a sample of fat or oil to attain a predetermined peroxide value under the specific conditions of the test. The feeds for laying hens were supplemented with 0, 375 or 750 mg additive/kg feed and three subsamples were analysed with the AOM at 6 and 10 h and with the oxidative status index (OSI) method. The OSI (AOCS Cd 12b-92) is a method that determines the relative resistance of fats or oils to oxidation, measuring the time needed to change the conductivity of water in which ions of the fats are dissociated after oxidation. The two feed materials (fats) were supplemented with 0, 2,600 or 7,800 mg additive/kg. A positive control supplemented with an authorised antioxidant at 50 mg/kg feed was also included. The oxidative status was measured in three subsamples with OSI method. The results were statistically analysed with an analysis of variance (ANOVA) and group comparisons with Tukey test (third study).

The results of the study in feeds for turkeys showed a significant reduction ($p = 0.008$) of oxidation rate in both the treated feedingstuffs compared to the respective control either at 6 and 10 h (Developer I: 8.7 vs. 13.7 mEq/kg at 6 h and 15.3 vs. 17.3 mEq/kg at 10 h; Developer II: 9.0 vs. 12.3 mEq/kg at 6 h and 21.0 vs. 25.7 mEq/kg at 10 h).

The results of the study with feeds for laying hens showed a significant reduction of the oxidation of the fats in both the treated feed compared to the control (dose-related effect), measured either by the OSI ($p = 0.008$) and the AOM methods ($p < 0.0001$). The results are summarised in Table 1.

¹² Technical dossier/Supplementary Information October 2020/Appendix_8.

¹³ Technical dossier/Supplementary Information October 2020/Appendix_9.

¹⁴ Technical dossier/Supplementary Information October 2020/Appendix_10.

Table 1: Effects of the supplementation with cashew nutshell liquid on the oxidative status of feedingstuffs for laying hens manufactured with different fat sources

	Additive concentration in feed (mg/kg feed)	Active oxygen method (AOM) (mEq/kg)		Oxidative stability index (OSI) (h)
		6 h	10 h	
Feed with poultry fat	0	18.00	26.00	6.14
	750	16.00	22.67	6.66
	1,500	10.67	17.00	7.65
Feed with fish oil	0	14.00	15.33	6.97
	750	10.33	8.67	6.00
	1,500	6.00	11.33	11.33

The results of the study with feed materials showed that both treated fats were significantly less oxidised (dose related effect) than the feed materials not treated (control) or treated with an authorised antioxidant (positive control). The results are summarised in Table 2.

Table 2: Effects of the supplementation with cashew nutshell liquid on the oxidative status of poultry of pork fat

Additive concentration in feed material (mg/kg fat)	Oxidative stability index (OSI) (h)	
	Poultry fat	Pork fat
0 (control)	2.75 ^c	2.86 ^d
50 (positive control)	4.77 ^b	4.97 ^c
2,600	4.94 ^b	7.36 ^b
7,800	7.97 ^a	12.06 ^a

a,b,c,d: Means within a column with different superscript letters are significantly different ($p \leq 0.05$).

3.3.1. Conclusions on efficacy

The additive is an effective antioxidant in feedingstuffs and feed materials for all animal species at the proposed conditions of use.

4. Conclusions

The FEEDAP Panel is not in the position to conclude on the characterisation of the additive cashew nutshell liquid.

In the absence of an adequate data, the FEEDAP Panel is not in the position to conclude on the safety of the additive for the target species, the consumer and the environment.

The additive is considered a skin and eye irritant and a skin sensitiser. Exposure via inhalation is unlikely.

The additive is an effective antioxidant in feedingstuffs and feed material for all animal species at the proposed conditions of use.

5. Documentation provided to EFSA/Chronology

Date	Event
20/04/2016	Dossier received by EFSA. Cashew nutshell liquid. Submitted by Oligo Basic Europa SL
28/04/2016	Reception mandate from the European Commission
08/05/2017	Application validated by EFSA – Start of the scientific assessment
23/05/2017	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: Methods of analysis</i>
08/08/2017	Comments received from Member States
03/12/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
16/12/2019	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives

Date	Event
19/05/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: Characterisation of the additive, safety for the target species, safety for the consumer, safety for the environment</i>
02/10/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
29/09/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

- ADME absorption, distribution, metabolism and excretion
ANOVA analysis of variance

ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
AOCS	American Oil Chemists's Society
AOM	active oxygen method
CAS	Chemical Abstracts Service
CSNL	CASHEW nutshell liquid
EURL	European Union Reference Laboratory
EPA	United States Environmental Protection Agency
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FCC	Food Chemical Codex
GHS	Globally Harmonized System
OSI	oxidative stability index

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of the Analysis for cashew nutshell liquid

In the current application authorisation is sought under Article 4(1) for cashew nutshell liquid under the category/functional group 1(b) “technological additives”/“antioxidants”, according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the feed additive for all animal species. The feed additive is to be marketed as a preparation containing a minimum of 4% (w/w) of cardol and a minimum of 10% (w/w) of cardanol as active substances. The feed additive is intended to be incorporated into premixtures and feedingstuffs. The Applicant proposed levels of the preparation of the feed additive ranging from 200 to 2000 mg/kg feedingstuffs, which correspond to cardol and cardanol levels in feedingstuffs ranging from 8 to 100 mg/kg and 40 to 400 mg/kg, respectively. For the quantification of cardol and cardanol in the feed additive the Applicant proposed a single-laboratory validated and further verified method based on [REDACTED]. The following performance characteristics were reported by the Applicant in the frame of the validation and verification studies for the quantification of cardol and cardanol in the feed additive: [REDACTED]

[REDACTED] Based on the experimental evidence available the EURL recommends for the official control the above mentioned single-laboratory validated and further verified [REDACTED] method for the quantification of cardol and cardanol in the feed additive. Since the determination of the content of cashew nutshell liquid added to premixtures and feedingstuffs is not achievable experimentally, the EURL cannot evaluate nor recommend any method for official control to determine cashew nutshell liquid in feedingstuffs. Furthermore, the EURL cannot recommend the above mentioned [REDACTED] method for official control for the quantification of cardol and cardanol in feedingstuffs at the proposed conditions of use. However, the EURL considers as fit-for-purpose above mentioned single-laboratory validated and further verified [REDACTED] method for the quantification of cardol and cardanol (expressed as a sum) in premixtures at the validated and verified mass fraction ranges of the analytes.

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, as last amended by Regulation (EU) 2015/1761) is not considered necessary.