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SCIENTIFIC OPINION

Safety of a feed additive consisting of vitamin B_2/riboflavin produced with *Eremothecium ashbyi* CCTCCM 2019833 for all animal species (Hubei Guangji Pharmaceutical Co., Ltd)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch

Abstract

Following a request from the 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 of a feed additive consisting of vitamin B_2/riboflavin produced with *Eremothecium ashbyi* CCTCCM 2019833 intended for use as a nutritional additive (functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effects) for all animal species. The characterisation, safety and efficacy of the additive have been already assessed previously; however, the FEEDAP Panel could not conclude on the safety of the additive for the target species, consumers and the users due to lack of reliable toxicological data. In the present assessment, the applicant submitted new genotoxicity and repeated dose oral toxicity studies. After the assessment of the data newly submitted, the FEEDAP Panel concluded that the use of the feed additive in animal nutrition under the conditions of use proposed is of no safety concern for the target species and the consumer. The additive is not a skin/eye irritant nor a skin sensitiser, but it is considered a respiratory sensitiser.

KEYWORDS

Eremothecium ashbyi, nutritional additives, riboflavin, safety, vitamin B_2, vitamins

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 and, in particular, Article 9 defines the terms of the authorisation of the Commission.

The applicant, Hubei Guangji Pharmaceutical Co., Ltd., represented in the EU by Nutreco Procurement B.V., is seeking a Community authorisation of Vitamin B_2/Riboflavin produced with *Eremothecium ashbyi* CCTCCM 2019833 as a feed additive (Table 1).

TABLE 1 Description of the additive.

Category of additive	Nutritional additives
Functional group of additive	Vitamins, pro-vitamins and chemically well-defined substances having similar effects
Description	Vitamin B_2/Riboflavin produced with *Eremothecium ashbyi* CCTCCM 2019833
Target animal category	All animal species
Applicant	Hubei Guangji Pharmaceutical Co., Ltd
Type of request	New opinion

On 10.02.2021, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on safety and efficacy of the additive Vitamin B_2/Riboflavin produced with *Eremothecium ashbyi* CCTCCM 2019833 for all animal species, could not conclude on the safety of the additive.

The Commission gave the possibility to the applicant to submit supplementary information and data to complete the assessment and allow a revision of the EFSA's opinion, the new data have been transmitted by the applicant using the e-submission food chain platform (application number FEED-2023-18430).

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety of Vitamin B2/Riboflavin produced with *E. ashbyi* CCTCCM 2019833 as a feed additive for all animal species based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2 | Additional information

The product Vitamin B_2 (5%) consisting of vitamin B_2/riboflavin produced with *E. ashbyi* CCTCCM 2019833 is not currently authorised in the European Union.

The FEEDAP Panel adopted an opinion on the safety and efficacy of the additive under assessment (EFSA FEEDAP Panel, 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] The dossier was received on 23 October 2023 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00693.

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.

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 and experts' knowledge, to deliver the present output.

[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-2023-00693.
[3]Dossier reference: FAD-2020-0027.
[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, pp. 1–48.
[5]Decision available at: 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 vitamin B_2/riboflavin produced with *E. ashbyi* CCTCCM 2019833 is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data (EFSA SC, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

3 | ASSESSMENT

The additive under assessment is produced with a non-genetically modified strain of *E. ashbyi* CCTCCM 2019833 and it is a dried microbial biomass which contains the remnants of the strain and fermentation broth as well as the products from the fermentation by the production strain, with a riboflavin content of at least 5%. The additive under assessment will be hereafter referred to as Vitamin B_2 (5%).

Vitamin B_2 (5%) is intended to be used as a nutritional additive (functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effects) for all animal species.

The characterisation of the additive and the production strain, the safety and the efficacy were evaluated in the previous opinion of the Panel (EFSA FEEDAP Panel, 2021). However, the FEEDAP Panel could not conclude on the safety of the additive for the target species, the consumers and the users, due to the lack of reliable toxicological data.

In the current dossier, the applicant submitted additional data to address the gaps identified in the previous assessment regarding the toxicological profile of the additive. Moreover, data on particle size were submitted.

3.1 | Characterisation

The applicant has provided additional data on particle size of the additive measured on three batches by centrifugal liquid sedimentation. No particles below 0.5 μm were found in any of the samples analysed.[7] No further characterisation of the fraction of small/nanoparticles is needed.[8]

3.1.1 | Conditions of use

The additive is intended to be used in feed for all animal species to provide riboflavin at the recommended levels as in Table 2.

The FEEDAP Panel calculated that the proposed riboflavin uses levels, assuming a minimum content of 5% of riboflavin in the additive, would correspond to levels of Vitamin B_2 (5%) ranging from 60 to 1600 mg/kg complete feed (Table 2).

TABLE 2 Recommended use levels of riboflavin and of the additive Vitamin B_2 (5%) for the target species.

Target species	Riboflavin (mg/kg complete feed)	Vitamin B_2 (5%) (mg/kg complete feed)
Poultry		
Chickens, starter	8–10	160–200
Chickens, grower-finisher	7–9; 6–8	140–180; 120–200
Chickens, breeders	12–16	240–320
Laying hens	5–7	100–140
Turkey, starter	15–20	300–400
Turkey, grower	10–15	200–300
Turkey, finisher	8–10	160–200
Turkey, breeder	15–20	300–400
Ducks/geese	7–9	140–180
Partridges/Quails	5–7	100–140

[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_II_01.

[8]https://www.efsa.europa.eu/sites/default/files/2024-07/-minutes_2.pdf.

TABLE 2 (Continued)

Target species	Riboflavin (mg/kg complete feed)	Vitamin B_2 (5%) (mg/kg complete feed)
Pigs		
Piglets pre-starter	10–15	200–300
Piglets starter	10–15	200–300
Grower phase	7–10	140–200
Finisher phase, gilts, sows and boars	6–10	120–200
Other species		
Dogs	13–22	260–440
Cats	22–27	440–540
Rabbits	3–6	60–120
Minks and Foxes	10–20	200–400
Trout and salmon	20–30	400–600
Warm-water fish	15–20	300–400
Sea bream and sea bass	20–30	400–600
Shrimp	40–80	800–1600
	Riboflavin (mg/head per day)	**Vitamin B_2 (5%) (mg/kg head per day)**
Horses		
Foals	20–30	400–600
Leisure horses	30–40	600–800
Race and breeding horses	70–85	1400–1700

3.2 | Safety

In the previous assessment (EFSA FEEDAP Panel, 2021), no studies addressing the potential of the additive to induce gene mutation were submitted. An in vivo chromosomal aberration test was provided; however, the FEEDAP Panel identified some limitations which did not allow to consider conclusive the results of the study. Due to the lack of data on the potential of the additive to induce gene mutations and the limitations identified in the in vivo chromosomal aberration test, the FEEDAP Panel could not conclude on the genotoxic potential of the additive under assessment. The applicant also provided a subchronic oral toxicity study and a prenatal developmental toxicity study; however, the FEEDAP Panel noted some limitations and deviations to the relevant OECD Testing Guideline (TG) and did not consider them further in the assessment (EFSA FEEDAP Panel, 2021).

Regarding the safety for the target species, the Panel concluded that the additive under assessment would not represent a concern for the target species considering the levels of riboflavin proposed to be added to the feeds. However, owing to the characteristics/nature of the additive and the lack of studies supporting the safety of the additive under assessment for the target species, the FEEDAP Panel could not conclude on the safety of the additive for the target species (EFSA FEEDAP Panel, 2021).

Regarding the safety for the consumers, the FEEDAP Panel concluded in 2021 that the supplementation of feed with riboflavin could not be of concern for the consumers (EFSA FEEDAP Panel, 2014, 2016, 2018). However, apart from riboflavin, the toxicological profile of the other components of the additive, which is a fermentation product, was not established, and therefore, uncertainties remained as regards to the safety for the consumers of food products obtained from animals receiving the additive under assessment.

Regarding the safety for the users, the FEEDAP Panel concluded that 'The additive is not a skin/eye irritant nor a skin sensitiser, but it is considered to be a respiratory sensitiser'. The lack of data regarding the toxicological profile of the additive does not allow the Panel to conclude on the safety of the additive for the users.

Therefore, in the absence of appropriate safety data on the additive, the FEEDAP Panel could not conclude on the safety of Vitamin B_2 (5%) produced with *E. ashbyi* CCTCCM 2019833 for the target animals, the consumers and the users. The FEEDAP Panel concluded that the use of the product as a feed additive poses no concerns for the environment (EFSA FEEDAP Panel, 2021).

For the current assessment, the applicant provided an in vitro mammalian cell micronucleus test, a mammalian alkaline comet assay combined with an in vivo mammalian micronucleus test and repeated oral dose toxicity studies, which are described below.

3.2.1 | Toxicological studies

3.2.1.1 | *Genotoxicity*

In vitro mammalian cell micronucleus test

To evaluate the potential of Vitamin B_2 (5%) produced with *Eremothecium ashbyi* CCTCCM 2019833 to induce chromosome damage, an in vitro micronucleus test was carried out in Chinese hamster lung cells (CHL) according to OECD Test Guideline (TG) 487 (2016), in a study claimed to be compliant with the good laboratory practice (GLP) principles.[9] Based on the results obtained in a preliminary cytotoxicity test, three concentrations (i.e. 6.67, 20, 60 and 180 μg/mL) were selected for the analysis of the frequency of micronuclei in binucleated cells applying a short treatment in the absence and presence of metabolic activation (3 + 21 h of recovery) and a continuous treatment in the absence of metabolic activation (24 + 0 h of recovery). Precipitation was observed at the two highest concentrations tested and limited the analysis of micronuclei to 6.67 and 20 μg/mL of the test item. No cytotoxicity was recorded at any of the tested concentrations. No increase in the frequency of micronuclei was induced in treated cells compared to vehicle control cultures at any concentration and in any experimental condition. The FEEDAP Panel noted that no precipitate or cytotoxicity was observed at the highest concentration chosen for the analysis of micronuclei and thus, considered the results obtained in the present study of limited relevance.

Combined in vivo mammalian alkaline comet assay and erythrocyte micronucleus test

A combined in vivo study was performed applying the mammalian alkaline comet assay with the erythrocyte micronucleus test to evaluate the potential of Vitamin B_2 (5%) to induce DNA damage. The test item was orally administered by gavage to male and female Wistar rats Crl: WI(Han) at 1500, 3000 and 6000 mg/kg body weight (bw) per day for three consecutive days. Due to low solubility, the dose of 6000 mg/kg bw per day was applied as split dose of 2 × 3000 mg/kg bw per day. Rats were sacrificed within 4 h from the last treatment.

To evaluate the potential of the test item to induce primary damage to DNA, the alkaline comet assay was performed following OECD TG 489, in a study claimed to be compliant with GLP. The level of primary DNA damage, as measured by the percentage of tail intensity (%TI), was analysed in liver, duodenum and ileum. In liver and duodenum, %TI was comparable between treated and vehicle control groups; all the observed values fell within the historical control values. In ileum, a statistically significant increase in %TI was observed both in males and females only at the mid dose (3000 mg/kg bw of Vitamin B_2 (5%)). In males, this increase was associated with high frequency of hedgehog cells, suggesting that local cytotoxicity could trigger primary damage to DNA. Since histopathological analysis of ileum did not show morphological degenerative changes indicative of cellular toxicity, the observed increase in %TI could not be due to cytotoxicity. However, the FEEDAP Panel concluded that these findings were not biologically relevant since the increase of %TI was not dose-related and not reproducible in tissues other than ileum. In addition, it was considered not biologically plausible that a positive result was only observed in ileum but not in duodenum and liver. Therefore, the FEEDAP Panel concluded that Vitamin B_2 (5%) did not induce primary DNA damage in vivo under the experimental conditions applied in this study.[10]

The in vivo mammalian erythrocyte micronucleus test was carried out in peripheral blood cells to evaluate the potential of Vitamin B_2 (5%) to induce chromosomal damage. The study was performed in rats according to OECD TG 474 and claimed to be GLP compliant. Cytotoxicity was observed at the highest dose tested of 6000 mg/kg bw/day, as shown by a reduction of the ratio immature/mature erythrocytes of 25% and 27% in males and females, respectively. Based on the OECD TG 474 principles, a 20% reduction in the ratio immature/mature erythrocytes compared to concurrent vehicle controls should be considered sufficient to indicate bone marrow toxicity and, thus, target tissue exposure. The analysis of the frequency of micronuclei was performed by flow cytometry in 10,000 immature erythrocytes/rat. No increase in the frequency of micronucleated immature erythrocytes was observed in treated rats compared to the vehicle negative control group. Therefore, the FEEDAP Panel concluded Vitamin B_2 (5%) did not induce clastogenic nor aneugenic effects in the experimental conditions applied in this study.

3.2.1.2 | *Repeated dose toxicity studies*

28-day toxicity study

Wistar rats (3/sex/group) were administered with the additive under assessment (Vitamin B_2 5%) in the feed at concentrations of 0 (control), 16,000, 80,000, 160,000 and 240,000 mg/kg feed (corresponding to 0, 1920, 9600, 19,200 and 28,800 mg/kg bw per day)[11] for 28 days (dose-range finding study).[12]

[9]Annex_III_3c.

[10]Annex_III_3a conf STUGC21AA2306-2_Amendment_Rep.pdf.

[11]Calculated applying a default value of 0.12 for subacute studies, as indicated in the 'Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data' (EFSA SC, 2012).

[12]Annex_III_1b.

The study was claimed to be conducted according with OECD TG 408 and not GLP compliant. The FEEDAP Panel noted that 28-day study should follow the OECD TG 407. However, the current study was not fully conducted in compliance with the OECD TG 407. No adverse effects related to the test item were observed during the study. Based on these findings, dose levels of 80,000, 160,000 and 240,000 mg/kg diet were selected for the subsequent 90-day study (described below).

90-day toxicity study

A subchronic dietary toxicity study in Wistar rats (10/sex/group) was performed with the additive under assessment Vitamin B_2 (5%) administered in the feed at concentrations of 0, 80,000, 160,000 and 240,000 mg/kg feed (corresponding to 0, 7200, 14,400 and 21,600 mg/kg bw per day)[13] for 90 days. The study was conducted in agreement with OECD TG 408 and claimed to be GLP compliant.[14]

No adverse effects related to the administration of the additive were observed during the study.

Some statistically significant differences were recorded (serum ALT, AST, creatinine, total bile acids, total bilirubin and potassium for males and on ALT, AST, AP, creatine, cholesterol, HDL, total protein and total albumin for females, kidney and liver weights for males, and on spleen, thyroid/parathyroid and liver weights for females) between control and treated animals, but these were not dose-related and/or inconsistent between sexes and/or within the physiological ranges and not correlated to any other findings (e.g. histopathology); therefore, they were considered by the FEEDAP Panel to be unrelated to treatment.

Based on this study, the FEEDAP Panel identified a No Observed Adverse Effects Level (NOAEL) for the additive Vitamin B_2 (5%) of 240,000 mg/kg feed (corresponding to 21,600 mg/kg bw per day), the highest dose tested.

3.2.1.3 | *Conclusion on toxicological studies*

Based on the negative results obtained in the in vivo studies, it can be concluded that the additive does not raise concern for genotoxicity. From the 90-day study submitted, the additive does not cause adverse effects, and the NOAEL identified is 21,600 mg/kg bw per day, the highest dose tested.

3.2.2 | Safety for the target species

No tolerance studies in the target species were provided by the applicant. A valid 90-day study performed in rats has been submitted (see Section 3.2.1.2), and from this study, a NOAEL of 21,600 mg/kg bw per day for Vitamin B_2 (5%) has been identified. Applying an uncertainty factor (UF) of 100 to the NOAEL, the safe daily dose for the target species was derived following the EFSA Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), and thus, the maximum safe feed concentration of the additive was calculated (Table 3).

TABLE 3 Maximum safe concentration (mg/kg feed) of the additive Vitamin B_2 (5%) in complete feed for the different target species.

Animal category	Daily feed intake (g DM/kg bw)	Maximum safe use level (mg/kg complete feed)
Chickens for fattening	79	2406
Laying hens	53	3586
Turkeys for fattening	59	3240
Piglets	44	4320
Pigs for fattening	37	5184
Sows lactating	30	6300
Veal calves (milk replacer)	19	10,800
Cattle for fattening	20	9504
Dairy cows	31	6178
Sheep/goat	20	9504
Horses	20	9504*
Rabbits	50	3802
Salmons	18	10,862
Dogs	17	11,405
Cats	20	9504
Ornamental fish	5	42,240

*Based on the proposed conditions of use (70–85 mg/head/day) and considering a feed intake of 8 kg DM per day per adult horse, the highest proposed use level would be approximately 187 mg/kg complete feed.

[13]Calculated applying a default value of 0.09 for subchronic studies, as indicated in the 'Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data' (EFSA SC, 2012).

[14]Annex_III_1a.

The calculated maximum safe concentrations of the additive in complete feed (88% dry matter, DM) ranged from 2406 to 42,240 mg/kg. These levels are above the highest inclusion levels of the additive recommended for the corresponding target species (60–1700 mg/kg complete feed).

For other target species, the lowest calculated safe concentration of 2406 mg/kg complete feed would apply. Therefore, the FEEDAP Panel concludes that the additive Vitamin B_2 (5%) is safe for all animal species under the proposed conditions of use.

3.2.2.1 | *Conclusion on the safety for the target species*

The additive is safe for all animal species at the proposed conditions of use.

3.2.3 | Safety for the consumer

Based on the new toxicological information provided and the fact that riboflavin is not expected to significantly accumulate in animal tissues/products, the FEEDAP Panel concludes that the product under assessment does not pose a safety concern for the consumers.

3.2.4 | Safety for the users

For the current assessment, the applicant provided toxicological studies which did not give rise to any specific concern for the safety for the users. Therefore, the FEEDAP Panel concludes that the additive is not a skin/eye irritant nor a skin sensitiser, but it is considered a respiratory sensitiser.

4 | CONCLUSIONS

The use of the Vitamin B_2 (5%) in animal nutrition under the proposed conditions of use is safe for the target species and consumers.

The additive is not a skin/eye irritant nor a skin sensitiser, but it is considered a respiratory sensitiser.

ABBREVIATIONS

BW	body weight
DM	dry matter
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
UF	uncertainty factor

REQUESTOR

European Commission

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