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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of L-valine produced with *Corynebacterium glutamicum* KCCM 80365 for all animal species (CJ Europe GmbH)

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

Abstract

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of L-valine produced with a genetically modified strain of *Corynebacterium glutamicum* (KCCM 80365) when used as a nutritional additive in feed and water for drinking for all animal species and categories. L-Valine manufactured by fermentation using *C. glutamicum* KCCM 80365 does not give rise to any safety concern regarding the genetic modifications of the production strain. No viable cells or DNA of the production strain were detected in the final product. The use of L-valine produced with *C. glutamicum* KCCM 80365 in feed is safe for the target species when supplemented in appropriate amounts to the diet according to the nutritional needs of the species. The FEEDAP Panel has concerns on the use of L-valine in water for drinking. The use of L-valine produced by fermentation with *C. glutamicum* KCCM 80365 in animal nutrition is considered safe for the consumers and for the environment. L-Valine produced with *C. glutamicum* KCCM 80365 is not irritant to skin and eyes, nor considered a skin sensitiser. The additive L-valine is regarded as an effective source of the amino acid L-valine for all non-ruminant species. To be as efficacious in ruminants as in non-ruminants, it should be protected from ruminal degradation.

KEYWORDS

amino acids, *Corynebacterium glutamicum* KCCM 80365, efficacy, L-valine, nutritional additives, safety

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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 feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from CJ Europe GmbH[2] for the authorisation of L-valine produced with *Corynebacterium glutamicum* KCCM 80365, when used as a feed additive for target species (category: nutritional additive; functional group: amino acids, their salts and analogues).

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 dossier was received on 28 January 2024 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00032. The particulars and documents in support of the application were considered valid by EFSA as of 22 April 2024.

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 L-valine produced with a genetically modified strain of *C. glutamicum* KCCM 80365, when used under the proposed conditions of use (see **Section 3.1.6**).

1.2 | Additional information

The additive L-valine produced by fermentation with *C. glutamicum* KCCM 80365 has not been previously authorised as a feed additive in the European Union. L-Valine produced by fermentation using different production strains is currently authorised for its use in all animal species as a nutritional and sensory additive.[3,4]

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued a series of scientific opinions on the safety and efficacy of L-valine produced by fermentation using different production strains, when used in feed for all animal species as a nutritional additive (functional group: amino acids, their salts and analogues).

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[5] in support of the authorisation request for the use of L-valine produced with *C. glutamicum* KCCM 80365 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[6] 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,[7] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 14 October to 4 November 2024. Two entries were registered but the comments submitted were deemed as not relevant to the scope of the public consultation, and therefore, were not considered further.

[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]CJ Europe GmbH, Unterschweinsteige 2–14, 60549, Frankfurt and Main (Germany).

[3]Commission Implementing Regulation (EU) No 2015/1114 of 9 July 2015 OJ L 182, 10.7.2015, p. 18 and Commission Implementing Regulation (EU) 2020/1797 of 30 November 2020 OJ L 402, 1.12.2020, p. 36 (3c370); Commission Implementing Regulation (EU) 2019/1289 of 31 July 2019 OJ L 203, 1.8.2019, p. 2 (3c371); Commission Implementing Regulation (EU) 2021/719 of 30 April 2021 OJ L 151, 3.5.2021, p. 12 (3c371i); Commission Implementing Regulation (EU)2021/2077 of 26 November 2021/ Corrigendum in OJ L 83 10.3.2022 p. 65. OJ L 426, 29.11.2021, p. 5/Corrigendum in OJ L 8310.3.2022 p. 65 and Commission Implementing Regulation (EU) 2022/1492 of 8 September 2022 OJ L 234, 9.9.2022, p. 14 (3c371ii); Commission Implementing Regulation (EU) 2024/997 of 3 April 2024 OJ L, 4.4.2024 (3c373).

[4]Commission Implementing Regulation (EU) 2018/249 of 15 February 2018. OJ L 53, 23.2.2018, p. 134.

[5]FEED-2023-20791.

[6]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.

[7]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 24 April to 24 July 2024 for which the received comments were considered for the assessment.

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.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the L-valine produced by *C. glutamicum* KCCM 80365 in animal feed.[8]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of L-valine is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: 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 FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024).

3 | ASSESSMENT

L-Valine (≥ 98.0% L-valine on a dry matter [DM] basis) produced by fermentation with a genetically modified strain of *C. glutamicum* KCCM 80365 is intended to be used as nutritional additive (functional group: amino acids, their salts and analogues) in feed and water for drinking for all animal species and categories.

3.1 | Characterisation

3.1.1 | Characterisation of the production microorganism

L-Valine is produced with a genetically modified strain of *C. glutamicum*, which is deposited in the Korean Culture Collection of Microorganisms (KCCM) with accession number KCCM 80365.[10]

Taxonomic identification of the production strain, KCCM 80365, was confirmed [redacted]

The antimicrobial susceptibility of the production strain was tested against the battery of antibiotics described for '*Corynebacterium* and other Gram-positive' recommended by EFSA (EFSA FEEDAP Panel, 2018).[12] All the measured minimum inhibitory concentration values were equal to or fell below the cut-off values, and therefore, the strain is considered susceptible to the relevant antibiotics.

The WGS data of the production strain were screened for the presence of plasmids [redacted] The strain has shown to harbour no plasmids.

The WGS data of the production strain were searched for the presence of antimicrobial resistance (AMR) genes [redacted][13] [redacted][14] [redacted], it can be concluded that no acquired AMR genes were identified and the strain raises no concerns.

[8]Evaluation report received on 9/7/2024 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

[9]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.

[10]Annex 2.2.2. Certificate of strain deposition.

[11]Annex 2.2.3. WGS data.

[12]Annex 2.2.4. Antimicrobial susceptibility.

[13]Annex 2.2.3. WGS data.

[14]Annex_Q1 AMR gene_VAL, Annex_Q2 ARM gene.

3.1.1.1 | *Information related to the genetically modified microorganism*[15]

Characterisation of the recipient or parental microorganism

[redacted]

Description of the genetic modification

[redacted]

[redacted][16] [redacted] All the genetic modifications, including the intended and unintended ones, were reported and no concerns were identified.[17] [redacted][18].

3.1.2 | Manufacturing process

L-Valine is produced by fermentation with *C. glutamicum* KCCM 80365.[19] [redacted]

The applicant declared that no antimicrobial substances are used in the manufacturing process.[20]

[15]Annex 2.2.1. Strain information.
[16]Annex 2.2.1. Strain information.
[17]Annex_Q1 Genetic modification.
[18]Annex 2.2.3. WGS data.
[19]Annex 2.3.1. Manufacturing process.
[20]Annex 2.3.2. Declaration letter on antibiotic free production.

3.1.3 | Characterisation of the active substance/additive

L-Valine (International Union of Pure and Applied Chemistry (IUPAC) name: ((2S)-2-amino-3-methylbutanoic acid; synonyms: α-amino isovaleric acid, 2-amino-3-methylbutyric acid), a compound identified by Chemical Abstracts Service (CAS) No 72-18-4 and European Inventory of Existing Commercial Chemical Substances (EINECS) No 200-773-6, has a molecular weight of 117.15 g/mol; the molecular formula is $C_5H_{11}NO_2$ and its structural formula is given in Figure 1.

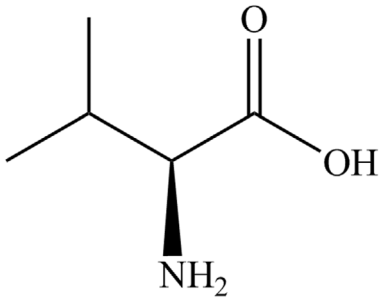

FIGURE 1 Molecular structure of L-valine.

The additive is specified to contain ≥ 98.0% L-valine on a DM basis and moisture ≤ 1.5%.

Compliance with the specification was shown in five batches in which L-valine was on average 99.0% on DM basis (range 98.5%–99.7%).[21] Moisture and crude ash were < 0.2% and < 0.4%, respectively.[22]

The total amount of identified material on a DM basis was at least 99.0%.

The specific optical rotation ranged from +27.07 to +28.15°. These values are within the reference range specified in the European Pharmacopoeia monograph (2025) for this substance (+26.6 to +29.0°) and confirm the L-enantiomer of L-valine.[23]

Three batches of the additive were analysed for cadmium, lead, mercury and arsenic showing values below the limit of quantification (LOQ) of the corresponding methods.[24]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in three batches and found to be below the corresponding LOQ. The calculated upper bound (UB) for the sum of PCDD/Fs was 0.05683 ng WHO 2005 TEQ/kg, and the sum of PCDD/Fs and DL-PCBs was 0.1161 ng WHO 2005-TEQ/kg. The UB for the sum of non-DL-PCBs was 0.53 ug/kg (all expressed in 88% DM).[25]

The analysis of mycotoxins, including aflatoxins (B1, G1, B2, G2), ochratoxin A, deoxynivalenol, zearalenone, T-2 toxin, HT-2 toxin and fumonisins (B1, B2, B3) was carried out in three batches and all values were below the corresponding LOQ.[26]

Microbiological contamination was analysed in three batches by determination of yeasts (including osmophilic yeasts), moulds (including xerophilic moulds), *Enterobacteriaceae*, *Escherichia coli* and *Salmonella* spp. Yeasts and moulds were < 10 colony forming units (CFU)/g, *Enterobacteriaceae* and *E. coli* were not detected in 10 g, and *Salmonella* spp. was not detected in 25 g.[27]

The FEEDAP Panel considers that the results of the microbial analyses and the amounts of the detected impurities do not raise safety concerns.

The presence of viable cells of the production strain was investigated in three batches of the final product, [redacted].[28] [redacted]. No viable cells were detected.

The presence of DNA of the production strain in the final product was investigated in three batches of the final product, [redacted].[29] [redacted]

[21]2.6. Methods of Analysis l-val; Amino acid analyser, ref. Commission Regulation (EC) No 152/2009 Annex III section F.

[22]Annex 2.1.3. Batch to batch variation.

[23]Annex 2.1.2. Optical rotation.

[24]Annex 2.1.4b Purity (contaminants). LOQ in mg/kg were 0.015 for lead, 0.010 for cadmium and mercury, and 0.04 for arsenic.

[25]Annex 2.1.4b Purity (contaminants): Upper bound concentrations are calculated on the assumption that all valuer of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for PCDD/Fs and DL-PCBs established by WHO in 2005 (van der Berg et al., 2005).

[26]Annex 2.1.4b. Purity (contaminants). LOQ (μg/kg) were 0.2 for Aflatoxins B1, B2, G1 and G2, 0.5 for Ochratoxin A, 10 for Deoxynivalenol, 5.0 for zearalenone, 2.0 for T-2 Toxin and HT-2 Toxin, and 50 for Fumonisins B1, B2 and B3.

[27]Annex 2.1.4a. Purity (microbiology).

[28]Annex 2.2.5. Absence of viable cells.

[29]Annex 2.2.6. DNA absence.

[redacted]. No DNA from the production strain was detected in any of the samples tested.

3.1.4 | Physical properties of the additive

L-Valine is a white crystalline powder. The bulk density of the three batches ranged from 385 to 490 kg/m^3. The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values ranging 55–195 mg/m^3. The particle size distribution of the additive was analysed by laser-diffraction method; the results showed that on average (v/v) the fractions of particles having a diameter < 100 μm, < 50 μm, < 10 μm ranged 67.0%–80.1%, 48.4%–65.9% and 4.5%–5.2%, respectively.[30]

3.1.5 | Stability and homogeneity

The shelf life of the additive (three batches) was studied when stored at 25°C and 40°C in kraft paper bags with plastic liner for 6 months. Losses at the end of the storage period were below 0.25% at 25°C, and below 0.35% at 40°C.[31]

The stability of the additive (three batches) was studied in a premixture for chickens for fattening when supplemented with 10% L-valine and stored at 25°C in aluminium bags for 6 months. Losses at the end of storage were below 0.10%.[32]

The stability of the additive (three batches) in a complete feed (mash and pelleted forms) for chickens for fattening was studied when supplemented at 0.3%. The pelleting process did not cause any losses of L-valine. After pelleting, the mash and pelleted feed were stored at 25°C in aluminium bags for 3 months. At the end of the storage the losses in the mash feed were below 0.91%, and no losses were detected in pelleted feed.[33]

The stability of the additive (three batches) in water for drinking was studied when supplemented at 1 g/L. Samples were stored in aluminium bags at room temperature for 48 h. No losses were detected.[34]

The capacity for homogeneous distribution of the additive in premixtures was studied in 10 subsamples of one batch. The coefficient of variation was 1.89%.[35]

The capacity for homogeneous distribution of the additive in mash and pelleted feeds was studied in 10 subsamples of one batch. The coefficients of variation were 1.59% and 1.11%, respectively (total analysed free valine content).[36]

3.1.6 | Conditions of use

L-Valine is intended to be used in complete feed for all animal species, directly or through complementary feed, premixtures or in water. No inclusion levels have been proposed as the requirements, in quantitative terms, depend on the nutrient composition, in particular the amino acid composition of the un-supplemented diet, the species, the age of the animal, the physiological state of the animal, the performance level and the environmental conditions.

3.2 | Safety

3.2.1 | Safety of the production microorganism

The production organism *C. glutamicum* KCCM 80365 is a genetically modified strain developed to increase the production of L-valine. The production strain belongs to a species, *C. glutamicum,* that qualifies for the qualified presumption of safety (QPS) when used for production purposes (EFSA BIOHAZ Panel, 2023). The taxonomic identification of the production strain was unequivocally established, it does not carry acquired antimicrobial resistance genes and the genetic modification does not raise safety concerns. No viable cells nor DNA of the production strain were detected in the final product. Therefore, the FEEDAP Panel concludes that the additive does not pose any safety concern regarding the genetically modified *C. glutamicum* strain (KCCM 80365).

[30] Annex 2.1.5. Physical state.
[31] Annex 2.1.5. Physical state.
[32] Annex 2.4.2. stability in feed.
[33] Annex 2.4.2. stability in feed.
[34] Annex 2.4.3. Stability in water.
[35] Annex 2.4.2. stability in feed.
[36] Annex 2.4.2. stability in feed.

3.2.2 | Safety for the target species, consumers and the environment

The L-valine requirements of the target animal species and the safety of this essential amino acid in non-ruminant and ruminant nutrition are well-known by feed formulators and available in general publications on animal nutrition.

The additive is produced by fermentation with a genetically modified *C. glutamicum* strain (KCCM 80365), and no safety concerns were identified for the production strain (see **Section 3.2.1**), the fermentation process and its residues/metabolites. Moreover, the resulting product is highly purified (≥ 98% L-valine and 1% unidentified material on a DM basis). L-Valine produced with *C. glutamicum* KCCM 80365 is safe for the target species when used to supplement the diet in appropriate amounts to satisfy the animal requirements. However, due to the risk of nutritional imbalances and hygienic reasons associated to the use of amino acids via water for drinking (EFSA FEEDAP Panel, 2010), the FEEDAP Panel reiterates its statement on the safety of the simultaneous oral administration of amino acid-containing additives via feed and water for drinking.

The absorption and metabolic fate of L-valine in the organism is well-known. The amino acid L-valine, supplemented to feed, will be incorporated into proteins of tissues and/or products of animal origin and any of its potential excess will be metabolised and excreted. Therefore, the protein composition of tissues and products of animal origin will not be affected using L-valine in animal nutrition. Therefore, the Panel considers that the use of the additive in animal nutrition is safe for the consumer.

The amino acid L-valine is a physiological and natural component of animals and plants. When consumed, it will be absorbed and the non-absorbed fraction will be incorporated into the intestinal microbial mass and excreted as such. The use of amino acids in water for drinking, when given in addition to complete diets with a well-balanced amino acid profile, would disturb the nitrogen balance and increase nitrogen excretion via urine. The use of the product L-valine in animal nutrition would not lead to any localised increase in the concentration in the environment. The use of L-valine produced by fermentation with *C. glutamicum* KCCM 80365 as a feed additive does not represent a risk to the environment.

3.2.3 | Safety for the user

Based on the highest dusting potential measured value (195 mg/m^3), the FEEDAP Panel considers that the exposure of users through inhalation is likely.

An acute inhalation study (nose only exposure) was performed following the OECD Guideline (TG) 403.[37] The lethal concentration 50 (LC50) is more than 4.9 mg/L.

The skin irritation potential of the additive was tested in an in vitro skin irritation assay performed according to OECD TG 439, which showed that the additive is not a skin irritant (UN GHS No Category).[38]

The eye irritation potential of the additive was tested in bovine corneal opacity and permeability (BCOP) test performed according to OECD TG 437, which showed that the additive is not an eye irritant (UN GHS No Category).[39]

The skin sensitisation potential of the additive was tested in a local lymph node assay performed according to OECD TG 429, which showed that the additive is not a skin sensitiser.[40]

3.2.3.1 | *Conclusions on the safety for the user*

The additive is not irritant to skin and eyes, nor a skin sensitiser.

3.3 | Efficacy

Efficacy studies are not required for amino acids that occur naturally in plant and animal proteins. The nutritional role of the amino acid L-valine is well established in the scientific literature. The additive L-valine is regarded as an efficacious source of the essential amino acid L-valine for non-ruminant animal species. For the supplemental L-valine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

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[41] and Good Manufacturing Practice.

[37] Annex 3.3.1 Acute inhalation toxicity.

[38] Annex 3.3.2 Skin irritation.

[39] Annex 3.3.3 Eye irritation.

[40] Annex 3.3.4 Skin sensitisation.

[41] 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.

4 | CONCLUSIONS

The production strain *C. glutamicum* KCCM 80365 does not raise safety concerns regarding the genetic modification. No viable cells or DNA of the production strain were detected in the final product. Therefore, the FEEDAP Panel concludes that the additive does not pose any safety concern regarding the production strain.

The use of L-valine produced with *C. glutamicum* KCCM 80365 in feed is safe for the target species when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species. The FEEDAP Panel has concerns on the of use L-valine in water for drinking.

The use of L-valine produced by fermentation with *C. glutamicum* KCCM 80365 in animal nutrition is considered safe for the consumers and for the environment.

Regarding user safety, L-valine produced with *C. glutamicum* KCCM 80365 is not irritant to the eyes and skin, and is not considered a skin sensitiser.

The feed additive consisting of L-valine produced by fermentation with *C. glutamicum* KCCM 80365 is regarded as an effective source of the amino acid L-valine for all non-ruminant species. In order to be as efficacious in ruminants as in non-ruminants, it should be protected from ruminal degradation.

ABBREVIATIONS

[redacted]	[redacted]
AMR	antimicrobial resistance
ATCC	American Type Culture Collection
BCOP	bovine corneal opacity and permeability
CAS	Chemical Abstracts Service
[redacted]	[redacted]
CFU	colony forming unit
DM	dry matter
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
KCCM	Korean Culture Collection of Microorganisms
LOD	limit of detection
LOQ	limit of quantification
[redacted]	[redacted]
MIC	minimum inhibitory concentration
[redacted]	[redacted]
OECD	Organisation for Economic Co-operation and Development
[redacted]	[redacted]
QPS	qualified presumption of safety
UB	upper bond
WGS	whole genome sequence

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