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Safety and efficacy of L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation with *Corynebacterium glutamicum* KCTC 12307BP as feed additives for all animal species

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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 for the target animals, consumer, user and the environment and on the efficacy of a concentrated liquid L-lysine (base, minimum 50%) and a L-lysine monohydrochloride (HCl, minimum 99%) produced by fermentation with a genetically modified strain of *Corynebacterium glutamicum* (KCTC 12307BP). Both forms of L-lysine are intended to be used in feed for all animal species and categories. Neither the production strain nor its recombinant DNA were detected in the final products. The additives do not pose any safety concern associated with the genetic modification of the production strain. Concentrated liquid L-lysine (base) and L-lysine HCl produced by the strain *C. glutamicum* KCTC 12307BP do not represent a risk for the target species, for the consumer, for the user and for the environment. L-Lysine HCl and concentrated liquid L-lysine (base) are considered to be efficacious sources of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

Keywords: L-lysine monohydrochloride, concentrated liquid L-lysine (base), feed additive, *Corynebacterium glutamicum* KCTC 12307BP, recombinant DNA, viable cells

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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. 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 Daesang Europe BV[2] for authorisation of the products L-lysine monohydrochloride (HCl) and concentrated liquid L-lysine (base) produced by fermentation with *Corynebacterium glutamicum* KCTC 12307BP, when used as a feed additive for all animal species (category: nutritional additives; 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 particulars and documents in support of the application were considered valid by EFSA as of 10 June 2020.

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 products L-lysine HCl and concentrated liquid L-lysine (base) produced by fermentation with *C. glutamicum* KCTC 12307BP, when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

L-Lysine produced using different microbial strains is currently authorised for its use in all animal species as a nutritional additive.[3]

L-Lysine is authorised for use in food,[4] cosmetics[5] and as a veterinary medicinal product.[6,7]

L-Lysine hydrochloride is described in a monograph of the European Pharmacopoeia (European Pharmacopeia, 2017) monograph 01/2008:0930.

The Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has published several opinions on the safety and efficacy of L-lysine and/or its salts produced by fermentation using different strains of *C. glutamicum* for all animal species (EFSA, 2007a; EFSA FEEDAP Panel, 2015b, 2016b, 2017a, 2019a–e, 2020a–c); one opinion on the safety and efficacy of concentrated liquid L-lysine (base) and L-lysine HCl produced by fermentation with *C. casei* KCCM 80190 for all animal species (EFSA FEEDAP Panel, 2020d); and others on the safety and efficacy of L-lysine and/or its salts produced by fermentation using different strains of *Escherichia coli* (EFSA FEEDAP Panel, 2013, 2014, 2015a, 2015b, 2015c, 2016a, 2017a).

L-Lysine HCl and concentrated liquid L-lysine (base) produced by fermentation with *C. glutamicum* KCTC 12307BP has been re-evaluated in two previous opinions (EFSA FEEDAP Panel, 2016a,b, 2019a). The applicant, however, decided to withdraw the application for authorisation of the additive (both forms) after the adoption of the opinion in 2019.

[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] Daesang Europe BV, Van Heuven Goedhartlaan 935, 1181 LD, Amsterdam, The Netherlands.
[3] Commission Directive 88/485/EEC of 26 July 1988 amending the Annex to Council Directive 82/471/EEC concerning certain products used in animal nutrition. OJ L 239, 30.8.1988, pp. 36–39.
[4] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35.
[5] Commission Decision of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products. OJ L 97, 5.4.2006, pp. 1–528.
[6] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1.
[7] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OL L 152, 16.6.2009, p. 11.

In the 2019 opinion, the Panel concluded that there were uncertainties concerning the presence of the production strain and/or its recombinant DNA in the final products. Nevertheless, as the recipient strain of *C. glutamicum* KCTC 12307BP qualified for the qualified presumption of safety (QPS) approach for safety assessment, the genetic modification did not introduce any safety concern and no introduced antibiotic resistance genes remained in the genome of the production strain, the presence of viable cells and/or its recombinant DNA in the products did not raise safety concerns.

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 L-lysine monohydrochloride (HCl) and concentrated liquid L-lysine (base) as feed additives.

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, to deliver the present output.

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 L-lysine in animal feed are valid and applicable for the current application.[9]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of L-lysine HCl and concentrated liquid L-lysine (base) produced by fermentation with *C. glutamicum* KCTC 12307BP is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), 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 target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017d, Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012) and Guidance for assessing the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019f).

3. Assessment

The product subject of this application is L-lysine in the forms of L-lysine HCl and concentrated liquid L-lysine (base) produced by fermentation with a genetically modified strain of *C. glutamicum* (KCTC 12307BP). The applicant is requesting the authorisation of these products as nutritional additives, under the functional group 'amino acids, their salts and analogues' for use in feed for all animal species and categories.

3.1. Characterisation

3.1.1. Characterisation of the production microorganism

The production strain is a *C. glutamicum* deposited in the Korean Collection for Type Cultures (KCTC) with the accession number 12307BP.[11]

The full genome of the production strain was sequenced and used for identification purposes. A bioinformatic analysis of the whole genome sequence (WGS) of the production strain confirmed its identity as belonging to the species *C. glutamicum*.[12] [redacted]

[8] FEED dossier reference: FAD-2020-0024.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0067.pdf
[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] Technical dossier/Section II/Annex 2.2.1.2a.
[12] Technical dossier/Section II/Annexes 2.2.1.2c to e CONFID.

Plasmids were searched [redacted] No plasmids were found.[13]

The susceptibility of the production strain to the antibiotics listed in the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018) for '*Corynebacterium* and other Gram positive' was tested [redacted].[14] All the minimum inhibitory concentration (MIC) values determined were equal or fell below the corresponding cut-off values. Therefore, the strain is susceptible to those antibiotics.

The WGS of the production strain was interrogated for the presence of antimicrobial resistance (AMR) genes,[15] [redacted] Therefore, no genes of concern were identified.

3.1.1.1. Information related to the genetically modified microorganism

Characterisation of the parental or recipient microorganism

[redacted][16]

Characteristics of the introduced sequences

[redacted]

Description of the genetic modification

[redacted][17]

[redacted]

[13] Technical dossier/Section II/Annex 2.2.1.2c.
[14] Technical dossier/Section II/Annex 2.2.2.2.
[15] Technical dossier/Section II/Annexes Section II/Annex 2.2.1.2.c.
[16] Technical dossier/Section II/Annex 2.2.1.2b Confid.
[17] Technical dossier/Section II/Annexes Section II/Annex 2.2.1.2.c.

[redacted]

3.1.2. Manufacturing process

L-Lysine is produced by fermentation with the production strain. [redacted][18]

The applicant declared that no antimicrobials are used in the manufacturing process.[19]

3.1.3. Characterisation of concentrated liquid L-lysine (base)

L-Lysine (International Union of Pure and Applied Chemistry (IUPAC) name: (2*S*)-2,6 diaminohexanoic acid; synonym: (*S*)-2,6-diaminocaproic acid), a compound identified with the Chemical Abstracts Service (CAS) No 56-87-1 and the European Inventory of Existing Commercial chemical Substances (EINECS) No 200-294-2, has a molecular weight of 146.2 g/mol. The molecular formula is $C_6H_{14}N_2O_2$ and the molecular structure is given in Figure 1.

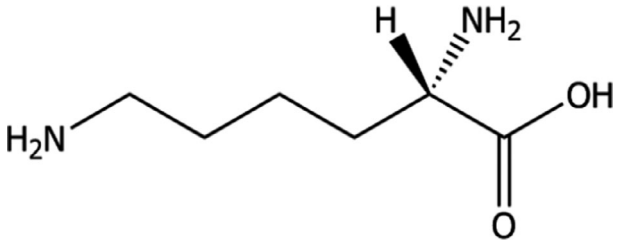

Figure 1: Molecular structure of L-lysine

The product is specified to contain ≥ 50% L-lysine and ≤ 48% water. Compliance with the specification was shown in eight batches in which lysine was on average 52.1% on 'as is' basis (range 51.4–53.1%). Water content was 46.7% (range 45.3–47.6%).[20] Total identified material on 'as is' basis was 98.8%.

3.1.3.1. Impurities

Three batches were analysed for undesirable substances. Cadmium and mercury were not detected whilst the lead concentration was 0.3 mg/kg in the three batches. Arsenic was also below the limit of detection (LOD).[21] Polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F) and dioxin-like polychlorinated biphenyls (PCBs) were below the corresponding limits of quantification (LOQ) in six batches of the additive.[22] The levels of dioxins and the sum of dioxins and dioxin-like-PCBs (upper bond) were calculated to be 0.14 ng WHO-PCDD/F-TEQ/kg (88% DM) and 0.27 ng WHO-PCDD/F-PCB-TEQ/kg (88% DM), respectively. As per mycotoxins contents, the analysis of those batches showed aflatoxins (not specified) ranging from 1 to 2 μg/kg and citrinin ranging from 86 to 98 μg/kg. The rest

[18] Technical dossier/Section II.3 and Annex 2.2.1.2b CONFID.
[19] Technical dossier/Section II/Annex 2.3.1a.
[20] Technical dossier/Section II/Annex 2.1.4a CoA and supplementary information August 2020/Annexes 1a to 1e. Lysine analysed following the method described in section 2.2.56 (method I) of the European Pharmacopoeia 9th edition.
[21] Technical dossier/Section II/Annex 2.1.4a CoA and supplementary information August 2020/Sin 220720 Answers/Answer to question 2. LOD was 0.005 mg/kg for lead, cadmium, mercury and arsenic.
[22] Technical dossier/Section II/Annexes 2.1.4g to h and supplementary information August 2020/Sin 220720 Answers/Answer to question 2. LOD was 1 CFU/g for *E. coli*, yeasts and moulds.

of mycotoxins analysed (ochratoxin A, zearalenone, fumonisins B1+B2+B3 and deoxynivalenol) were below the LOD.[23]

Microbiological analysis indicated that *Salmonella* spp. was not detected in 25 g sample and *E. coli* was not detected in 1 g sample. Yeasts and filamentous fungi were not detected.[24]

The presence of viable cells of the production strain in the final additive was investigated in three batches of concentrated liquid L-lysine (base).[25] No cells of the production strain were found.

The presence of DNA of the production strain in concentrated liquid L-lysine (base) was tested in three batches of the additive.[26] No DNA of the production strain was detected.

3.1.3.2. Physical characteristics

The additive is a dark brown odourless liquid.[27] The specific gravity (at 20°C) was measured in eight batches of the additive and was 1.149 g/mL (range 1.147–1.151 g/mL).[28] The pH (measured in five batches) was on average 10.4 (range 10.3–10.5).[29]

3.1.3.3. Stability and homogeneity

No data were provided on the shelf life or on the stability in feedingstuffs of the concentrated liquid L-lysine (base) under assessment. The technical dossier contains data on the shelf life of nine batches of other concentrated liquid L-lysine (base) (production strains are unknown) when stored in closed containers at 20 and 25°C. The recovery after 12 months was nearly complete.[30]

The capacity of the additive to homogeneously distribute in a compound feed for chickens for fattening was investigated in a study made with the concentrated liquid L-lysine (base) under assessment.[31] The compound feed was based on wheat, soybean meal and maize with a total lysine content of 9.8%.[32] The supplemental level of lysine was not described. Ten subsamples were analysed for supplemental lysine and the coefficient of variation (CV) calculated was 8%.

3.1.4. Characterisation of the L-lysine monohydrochloride

L-Lysine HCl (IUPAC name: (2*S*)-2,6-diaminohexanoic acid monohydrochloride; synonym: L-(+)-2,6-diamino-*N*-caproic acid monohydrochloride, a compound identified with the CAS No 657-27-2 and the EINECS No 211-519-9), has a molecular weight of 182.65 g/mol. The theoretical content of lysine in lysine monohydrochloride is 80%. The molecular formula is $C_6H_{15}ClN_2O_2$ and the molecular structure is given in Figure 2.

[23] Technical dossier/Section II/Annex 2.1.4b. LOD in µg/kg was 5 for ochratoxin A, 17 for zearalenone, 25 for fumonisine B1+B2+B3, and 134 for deoxynivalenol.
[24] Technical dossier/Section II/Annex 2.1.4a CoA.
[25] Technical dossier/Supplementary information September 2020/Annex_1.
[26] Technical dossier/Section II/Annex II.2.1.4l.
[27] Technical dossier/Section II/Annex 2.5.2b.
[28] LTechnical dossier/Section II/Annex 2.1.4a CoA and supplementary information August 2020/Annexes 1a to 1e.
[29] Technical dossier/Supplementary information August 2020/Annexes 1a to 1e.
[30] Technical dossier/Supplementary information August 2020/Sin 220720 Answers/Answer to question 3; letter of access AMAC FEFANA 200812 and Section II Identity L-lysine AMAC dossier.
[31] Technical dossier/Section II/Annex 2.4.2b.
[32] Technical dossier/Section II/Annex 2.4.2c.

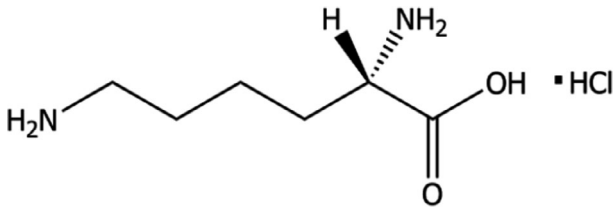

Figure 2: Molecular structure of L-lysine HCl

The specifications are for an additive containing ≥ 99% L-lysine HCl on dry matter basis, ≤ 1% water.

Lysine was analysed in five batches and the average was 79.5% on a dry matter (DM) basis (range from 79.4% to 79.5%) and a moisture content of 0.3%.[33] The analysis of eight batches showed an average lysine HCl content of 99.3% (range 99.2–99.4%) on a DM basis and a moisture content of 0.3% (range 0.2–0.3%).[34] Residue on ignition was 0.1% in all eight batches. On a dry matter basis, the amount of unidentified material was < 1%.

The specific optical rotation of those batches was analysed by the Food Chemical Codex method and it was on average +21.0° (range +20.9° +21.1°) (reference values +18 to +21.5°).[35] The analytical data confirm the presence of the L-enantiomer of lysine in the additive.

3.1.4.1. Impurities

Three batches were analysed for undesirable substances. Cadmium and mercury could not be detected whilst lead concentration was 0.3 mg/kg in the three batches. Values for arsenic were also below the LOD.[36] PCDD/F and dioxin-like-PCBs were below the corresponding LOQ in two batches of the additive. The levels of dioxins and the sum of dioxins and dioxin-like-PCBs (upper bond) were calculated to be 0.12 ng WHO-PCDD/F-TEQ/kg (88% DM) and 0.24 ng WHO-PCDD/F-PCB-TEQ/kg (88% DM), respectively.[37] As per mycotoxins contents, the analysis of those batches showed aflatoxins (not specified) ranging from < 0.05 to 0.18 μg/kg and citrinin ranging from 31 to 46 μg/kg. The rest of mycotoxins analysed (ochratoxin A, zearalenone, fumonisins B1+B2+B3 and deoxynivalenol) were below the LOD.[38]

Microbiological analysis indicated that *Salmonella* spp. was not detected in 25 g sample and *E. coli* was not detected in 1 g sample. Yeast and filamentous fungi were not detected.[39]

The presence of viable cells of the production strain in the final additive was investigated in three independent batches of L-lysine HCl.[40] [redacted] In conclusion, cells of the production strain were not found.

The presence of DNA of the production strain in L-lysine HCl was tested in three batches of the additive.[41] [redacted]

[33] Technical dossier/Supplementary information November 2020/Annexes 2a to 2e. Lysine was analysed by method I of section 2.2.56 of the European pharmacopoeia 9th edition.
[34] Technical dossier/Section II/Annex 2.1.4a CoA. Lysine was analysed by method I of section 2.2.56 of the European pharmacopoeia 9th edition and Lysine HCl was calculated by stoichiometry.
[35] Technical dossier/Section II/Annex 2.1.4a CoA.
[36] Technical dossier/Section II/Annex 2.1.4a CoA and supplementary information August 2020/Sin 220720 Answers/Answer to question 6. LOD was 0.005 mg/kg for cadmium, mercury and arsenic.
[37] Technical dossier/Section II/Annexes 2.1.4c1 and d1.
[38] Technical dossier/Section II/Annex 2.1.4b. LOD in μg/kg was 0.05 for aflatoxins, 5 for ochratoxin A, 17 for zearalenone, 25 for fumonisine B1+B2+B3 and 134 for deoxynivalenol.
[39] Technical dossier/Section II/Annex 2.1.4a CoA and supplementary information August 2020/Sin 220720 Answers/Answer to question 6. LOD was 1 CFU/g for *E. coli*, yeasts and filamentous fungi.
[40] Technical dossier/Section II/Annex 2.1.4i.
[41] Technical dossier/Section II/Annex 2.1.4k.

[redacted] No DNA of the production strain was detected.

3.1.4.2. Physical characteristics

The additive is a crystalline powder of beige to brown colour, with a solubility in water of about 600 g/L (at 20°C).[42] The average bulk density analysed in eight batches was 635 kg/m^3 (range from 616 to 653 kg/m^3).[43]

The dusting potential of three batches tested with the Stauber–Heubach method ranged 4.9–7.5 g/m^3.[44] The particle size distribution was analysed by laser diffraction in three batches. The average diameter of the particles of the additive was about 540 μm and the percentage of particles with diameter < 18, < 50 and < 100 μm were < 1, 2 and 4% (w/v), respectively.[45]

3.1.4.3. Stability and homogeneity

No data were submitted on the shelf-life of L-lysine HCl under assessment. The technical dossier contains data on 10 batches of another L-lysine HCl (origin not described) showing that, when stored in the original package under ambient conditions (20–25°C) for 24 months, 0.6% of its initial lysine content is lost.[46]

The applicant submitted a study to investigate the stability of L-lysine HCl (one batch) produced with a different *C. glutamicum* strain in a premixture and in a compound feed for pigs.[47] A vitamin premixture was supplemented with 10% L-lysine HCl, packed in sewed lined paper bags and stored at ambient temperature (18–35°C) for 3 months. At the end of the storage period the L-lysine loss observed was of 2.5%. The FEEDAP Panel notes that the storage period tested is only half of the one requested in the corresponding guidance.

The premixture described above was used to produce a mash and pelleted compound feed for pigs. A basal diet consisting of maize and dehulled soya beans after oil extraction was supplemented up to a level of 0.4% L-lysine HCl. Pelleting was performed at 83°C and it represented a loss of 2% lysine. Samples of mash and pelleted feed were packed in paper bags and stored at 18–35°C for 3 months. At the end of the storage period, no loss was detected in mash feed and a loss of 4% was observed in the pelleted feed. As for the manufacturing process, the composition and characteristics of the L-lysine HCl tested were similar to the L-lysine HCl under assessment, the FEEDAP Panel considers that the results of the stability study in the vitamin premixture and in the compound feed for pigs can be used to support the stability of the L-lysine HCl under assessment.

The capacity of the additive to homogeneously distribute in a compound feed for chickens for fattening was investigated in a study made with the L-lysine HCl under assessment.[48] The compound feed was based on wheat (with xylanase), soybean meal and maize with a total lysine content of 9.8%.[49] The supplemental lysine was not described. Ten subsamples were analysed for supplemental lysine and the CV calculated was 9%.

3.1.5. Conditions of use

The concentrated liquid L-lysine (base) and L-lysine HCl under assessment are intended to be used in feed for all animal species. Both forms of the additive can be added directly to complete or complementary feed. The liquid form is not foreseen for addition via premixtures. No inclusion levels are provided, as the optimal daily allowance in quantitative terms depends on the species, the physiological state of the animal, the performance level and the environmental conditions, as well as the amino acid composition of the unsupplemented diet.

[42] Technical dossier/Section II/Annex 2.5.2a.
[43] Technical dossier/Section II/Annex 2.1.4a and supplementary information August 2020/Annexes 2a to 2e.
[44] Technical dossier/Section II/Annex 2.1.5a to c.
[45] Technical dossier/Section II/Annex 2.1.4c2 to e2.
[46] Technical dossier/Section II/Supplementary information August 2020/Sin 220720 Answers/Reply to question 9; letter of access AMAC FEFANA 200812 and Section II identity L-lysine AMAC dossier.
[47] Technical dossier/Section II/Annex 2.4.1b.
[48] Technical dossier/Section II/Annex 2.4.2a.
[49] Technical dossier/Section II/Annex 2.4.2c.

3.2. Safety of L-lysine HCl and concentrated liquid L-lysine (base)

3.2.1. Safety of the production microorganism

The production organism *C. glutamicum* KCTC 12307BP was developed to increase the production of L-lysine. The production strain belongs to a species, *C. glutamicum*, considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment when used for production purposes (EFSA, 2007b; EFSA FEEDAP Panel, 2020a–d). The genes inserted during the genetic modification [redacted] do not raise safety concerns, and the production strain does not carry acquired antimicrobial resistance genes. The production strain and its DNA were not detected in the additives. Therefore, the additives do not pose any safety concern regarding the genetic modification of the production strain.

3.2.2. Safety for the target species, consumer and environment

Both forms of the additive are highly purified. The use of the amino acid L-lysine 'per se' will not raise safety concerns for the target animals provided that it is supplemented in appropriate amounts to the diets. Concerns from the use of the additive may arise from residues of the fermentation process/ production strain remaining in the final product. The production strain (KCTC 12307BP) belongs to species *C. glutamicum*, that is considered suitable for the QPS approach to safety assessment when used for production purposes. Consequently, no safety concerns for target animals, consumers of products derived from animals fed the additive and the environment would arise from the fermentation residues that may be present in the final additives.

The amino acid L-lysine, supplemented to feed, will be incorporated into proteins of tissues and/or products of animal origin and any of their potential excess will be metabolised and excreted as urea/ uric acid and carbon dioxide. Therefore, the composition of tissues and products of animal origin will not be affected by the use of L-lysine in animal nutrition.

The additives under assessment do not give rise to any concern for the environment associated with the production strain. The amino acid L-lysine is a physiological and natural component of the proteins of living organisms. 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 these additives in animal nutrition would not lead to any localised increase in its concentration in the environment and do not represent a risk to the environment.

The FEEDAP Panel concludes that both forms of L-lysine produced with *C. glutamicum* KCTC 12307BP are safe for the target species, for the consumer and for the environment.

3.2.3. Safety for the user

The applicant has submitted studies on the safety for the user performed with concentrated liquid L-lysine (base) and L-lysine HCl originating from the strain under assessment *C. glutamicum* KCTC 12307BP. These studies were already assessed in a previous opinion (EFSA FEEDAP Panel, 2019a).

3.2.3.1. Concentrated liquid L-lysine (base)

Effects on skin and eyes

The skin irritation potential of the additive was tested in a study performed according to the Organisation for Economic Co-operation and Development (OECD) guideline 404 and compliant with good laboratory practice (GLP), which showed that it is not a skin irritant and has no corrosive effect on skin.[50]

The eye irritation potential of the additive was tested in a study performed according to OECD Guideline 405 and GLP compliant, which showed that it is not an eye irritant.[51]

In a skin sensitisation in accordance with OECD Guideline 406 (Guinea pig maximisation test) and GLP compliant, the additive was found not to be a skin sensitiser.[52]

[50] Technical dossier/Section III/Annex 3.3.1.2b.
[51] Technical dossier/Section III/Annex 3.3.1.2d.
[52] Technical dossier/Section III/Annex 3.3.1.2f.

3.2.3.2. L-Lysine HCl

Effects on the respiratory system

Although the additive has very small fraction of particles below 100 μm (up to 4%), its dusting potential is high (up to 7.5 g/m^3), indicating that exposure of the user by inhalation is possible.

In an acute inhalation toxicity study according to OECD Guideline 436 and GLP compliant, the additive showed an inhalation median lethal dose > 5.1 mg/L air and the test item required no classification.[53]

Effects on skin and eyes

The skin irritation/corrosion potential of the additive was tested in a study performed according to OECD Guideline 404 and GLP compliant, which showed that it has no irritant effect on the skin.[54]

The eye irritation/corrosion potential of the additive was tested in a study performed according to OECD Guideline 405 and GLP compliant, which showed that it is not an eye irritant.[55]

In a skin sensitisation in accordance with OECD Guideline 406 and GLP compliant, the additive was found not to be a skin sensitiser.[56]

3.2.3.3. Conclusions on the safety for the user

Concentrated liquid L-lysine (base) and L-lysine HCl produced by *C. glutamicum* KCTC 12307BP are not irritant to skin or eyes and they are not skin sensitisers. L-Lysine HCl is not hazardous by inhalation.

3.3. Efficacy of L-lysine HCl and concentrated liquid L-lysine (base)

Efficacy studies are not required for amino acids naturally occurring in proteins of plants and animals. The nutritional role of the amino acid L-lysine is well established in the scientific literature. The efficacy of L-lysine for both non-ruminant and ruminant species was described in two previous opinions (EFSA FEEDAP Panel, 2013; 2014). In general, the products concentrated liquid L-lysine (base) and L-lysine HCl are considered as efficacious sources of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine 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[57] and Good Manufacturing Practice.

4. Conclusions

Both forms of L-lysine, concentrated liquid L-lysine (base) and L-lysine HCl, are produced by the genetically modified strain *C. glutamicum* KCTC 12307BP. Neither the production strain nor its recombinant DNA were detected in the final products. The additives do not pose any safety concern associated with the genetic modification of the production strain.

Concentrated liquid L-lysine (base) and L-lysine HCl produced by the strain *C. glutamicum* KCTC 12307BP do not represent a risk for the target species, for the consumer, for the user and for the environment.

L-lysine HCl and concentrated liquid L-lysine (base) are considered to be efficacious sources of the essential amino acid L-lysine for non-ruminant animal species. For the supplemental L-lysine to be as efficacious in ruminants as in non-ruminant species, it would require protection against degradation in the rumen.

[53] Technical dossier/Section III/Annex 3.3.1.1.
[54] Technical dossier/Section III/Annex 3.3.1.2a.
[55] Technical dossier/Section III/Annex 3.3.1.2c.
[56] Technical dossier/Section III/Annex 3.3.1.2e.
[57] 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.

5. Documentation as provided to EFSA/Chronology

Date	Event
25/03/2020	Dossier received by EFSA. L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation with Corynebacterium glutamicum KCTC 12307BP for all animal species. Submitted by Daesang Europe BV
23/05/2020	Reception mandate from the European Commission
10/06/2020	Application validated by EFSA – Start of the scientific assessment
22/07/2020	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 of the additive*
18/08/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
03/09/2020	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 of the additive*
11/09/2020	Comments received from Member States
06/10/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
18/11/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

AMR	Antimicrobial resistance
CAS	Chemical Abstracts Service
CFU	colony forming unit
CV	coefficient of variation
DM	dry matter
EINECS	European Inventory of Existing Commercial chemical Substances
EURL	European Union Reference Laboratory
FCC	Food chemical codex
FEEDAP	Panel on additives and products or substances used in animal feed
GLP	Good Laboratory Practice
IEC-VIS/FLD	ion exchange chromatography coupled to visible or fluorescence detection
IUPAC	International Union of Pure and Applied Chemistry
KCTC	Korean Collection for Type Cultures
LOD	limit of detection
LOQ	limit of quantification
MCE	mixed cellulose esters

MIC	minimum inhibitory concentration
PCB	polychlorinated biphenyls
PCDD/F	polychlorinated dibenzodioxins/dibenzofurans
PCR	polymerase chain reaction
PVDF	polyvinylidene fluoride
QPS	Qualified presumption of safety
OECD	Organisation for Economic Co-operation and Development
TEQ	Toxic equivalents
VDLUFA	Association of German agricultural analytic and research institutes
WGS	Whole genome sequence
WHO	World Health Organization