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## Assessment of a feed additive consisting of vitamin B<sub>6</sub> (pyridoxine hydrochloride) for all animal species for the renewal of its authorisation (Kaesler Nutrition GmbH)

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### Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of vitamin B<sub>6</sub> (pyridoxine hydrochloride) produced by chemical synthesis as a feed additive for all animal species. The applicant has provided data demonstrating that the additive in the market complies with the conditions of the authorisation. The FEEDAP Panel confirms that the use of pyridoxine hydrochloride under the current authorised conditions of use is safe for the target species, the consumers and the environment. Pyridoxine hydrochloride is non-irritant to skin and eyes. In the absence of data, no conclusion can be drawn on skin sensitisation potential. Pyridoxine hydrochloride may cause photosensitisation. Despite the lack of data on inhalation toxicity, the additive is not dusty and exposure through inhalation is unlikely. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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**Keywords:** nutritional additive, vitamins and pro-vitamins, vitamin B<sub>6</sub>, pyridoxine hydrochloride, renewal, safety

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## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Kaesler Nutrition GmbH<sup>2</sup> for the renewal of the authorisation of vitamin B<sub>6</sub> (pyridoxine hydrochloride), when used as a feed additive for all animal species (category: nutritional additives; functional group: vitamins, provitamins and chemically well-defined substances having a similar effect).

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 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 27 August 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 vitamin B<sub>6</sub> in the form of pyridoxine hydrochloride, when used under the proposed conditions of use (see Section 3.1.3).

### 1.2. Additional information

The EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued two opinions on the safety and efficacy of vitamin B<sub>6</sub>, in the form of pyridoxine hydrochloride, when used as a feed additive for all animal species (EFSA FEEDAP Panel, 2010, 2011). In 2020, the FEEDAP Panel issued an opinion on the renewal of authorisation of vitamin B<sub>6</sub> as a feed additive for all animal species (EFSA FEEDAP Panel, 2020).

Vitamin B<sub>6</sub> (3a831) in the form of pyridoxine hydrochloride, is currently authorised as a nutritional additive for all animal species.<sup>3</sup>

Pyridoxine hydrochloride is described in the European Pharmacopoeia 10.0 (PhEur), monograph 0245 (PhEur, 2020).<sup>4</sup>

The Scientific Committee for Food (SCF) established a tolerable upper intake level (UL) for vitamin B<sub>6</sub> of 25 mg/day for adults (SCF, 2000). The EFSA Panel on Dietetic Products, Nutrition and Allergy issued an opinion on dietary reference values for vitamin B<sub>6</sub> (EFSA NDA Panel, 2016).

Pyridoxine hydrochloride is authorised for use as a food additive,<sup>5</sup> for use in food nutritional purposes,<sup>6</sup> in the manufacture of food supplements,<sup>7</sup> for use in cosmetics as antistatic, hair conditioning and skin conditioning ingredient<sup>8</sup> and as a veterinary medicinal product.<sup>9,10</sup>

<sup>1</sup> 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.

<sup>2</sup> Kaesler Nutrition GmbH, Zeppelinstrasse 3, 27472, Cuxhaven, Germany.

<sup>3</sup> Commission Regulation (EU) No 515/2011 of 25 May 2011 concerning the authorisation of vitamin B<sub>6</sub> as a feed additive for all animal species. OJ L 138, 26.5.2011, p. 40–42.

<sup>4</sup> Technical dossier/Section II/Annex II\_3\_PhEur\_0245.

<sup>5</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, OJ L 404, 30.12.2006.

<sup>6</sup> 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.

<sup>7</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2001 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51.

<sup>8</sup> Commission Decision of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (2006/257/EC). OJ L 97, 5.4.2006, p. 1.

<sup>9</sup> 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.

<sup>10</sup> Commission Regulation (EC) No 997/1999 of 11 May 1999 amending Annexes I, II and III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 122, 12.5.1999, p. 24.

## 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<sup>11</sup> in support of the authorisation request for the use of the vitamin B<sub>6</sub> (pyridoxine hydrochloride) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.<sup>12</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of vitamin B<sub>6</sub> (pyridoxine hydrochloride) is in line with the principles laid down in Regulation (EC) No 429/2008<sup>13</sup> and the relevant guidance document: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012).

## 3. Assessment

Vitamin B<sub>6</sub> in the form of pyridoxine hydrochloride (purity > 98.5%) is currently authorised as a nutritional additive (functional group: vitamins, provitamins and chemically well-defined substances having a similar effect) for use in feed and water for drinking in all animal species. This assessment regards the renewal of the authorisation.

### 3.1. Characterisation

#### 3.1.1. Characterisation of the additive

Pyridoxine hydrochloride is a white or almost white, crystalline powder. It is practically odourless and freely soluble in water (1 g dissolves in about 4.5 mL), sparingly soluble in anhydrous ethanol and acetone, practically insoluble in fats and oils. The bulk density is 500–600 kg/m<sup>3</sup>, the pH of a 5% solution is 2.65–2.70.

Pyridoxine hydrochloride [International Union of Pure and Applied Chemistry (IUPAC) name: (5-hydroxy-6-methylpyridine-3,4-diyl) dimethanol hydrochloride] is identified with the Chemical Abstracts service (CAS) number 58-56-0 and the European Inventory of Existing Chemical Substances (EINECS) number 200-386-2. It has a molecular formula C<sub>8</sub>H<sub>11</sub>NO<sub>3</sub>·HCl and a molecular mass of 205.64 g/mol.

The product under assessment is obtained by chemical synthesis. The applicant stated that the manufacturing process and the composition of the additive have not been modified since the previous authorisation and provided data from recent batches on the composition of the additive to support this statement.

The applicant provided data on the batch-to-batch variation of three recent batches of the active substance analysed in accredited laboratories using two different methods (described in Regulation (EU) No 515/2011).<sup>14</sup> The concentration of pyridoxine hydrochloride in the dried substance was on average 100.2% (range: 100.1–100.3%) and demonstrated compliance with the existing specifications and as foreseen in the authorising Regulation (purity ≥ 98.5%).<sup>3</sup>

Substance-related impurities listed in the European Pharmacopoeia were also measured in three batches, namely 6-methyl-1,3-dihydrofuro[3,4-c]pyridine-7-olacetate (impurity A, < 0.05%) and 5-(hydroxymethyl)-2,4-dimethylpyridin-3-ol (impurity B, < 0.05%). The detected amounts of impurities

<sup>11</sup> FEED dossier reference: FAD-2020-0041.

<sup>12</sup> The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0047.pdf>

<sup>13</sup> 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.

<sup>14</sup> Technical dossier/Section II\_Annexes 2.14-2.16 and 2.17-2.19.

were below the limits specified in the European Pharmacopoeia monograph (unspecified impurities < 0.10, impurity B < 0.15% and total impurities < 0.2%) (European Pharmacopoeia (PhEur), 2020).<sup>15</sup>

In the same batches, heavy metals and arsenic were below the corresponding limit of quantification (LOQ).<sup>16</sup> Polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs were below the LOQs in one batch of the additive.<sup>17</sup> The levels of dioxins and the sum of dioxins and dioxin-like-PCBs (upper bond) were calculated to be 0.33 ng WHO-PCDD/F-TEQ/kg and 0.58 ng WHO-PCDD/F-PCB-TEQ/kg, respectively. Non-dioxin-like PCBs were 1.7 µg/kg. The concentrations of the undesirable substances analysed do not represent a concern.

Particle size distribution was analysed in three recent batches of the additive. The results showed that the 10%, the 50% and the 90% of particles have a diameter of 118–129 µm, 236–264 and 436–505 µm, respectively.<sup>18</sup> The applicant provided the dusting potential of three recent batches, which confirmed that the additive is not dusty (equal to zero).<sup>19</sup>

### 3.1.2. Stability and homogeneity

Stability and homogeneity of the additive have been evaluated by EFSA during previous assessment (EFSA FEEDAP Panel, 2010). Stability data on batches manufactured in 2012 were provided and confirmed that no reduction in the concentration occurred when pyridoxine hydrochloride is stored up to 48 months at 25°C or up to 6 months at 40°C.<sup>20</sup>

### 3.1.3. Conditions of use

Vitamin B<sub>6</sub> in the form of pyridoxine hydrochloride (purity > 98.5%) is currently authorised for use in feed for all animal species without a maximum content.

The authorisation, under other provisions, foresees:

- 1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting and in water.
- 2) Vitamin B<sub>6</sub>/pyridoxine hydrochloride may be used also via water for drinking.
- 3) For user safety: breathing protection, safety glasses and gloves shall be worn during handling.

The applicant proposes to keep the same conditions of use as authorised.

## 3.2. Safety

The safety of pyridoxine hydrochloride for the target species, consumers, users and the environment has been evaluated in previous opinions (EFSA FEEDAP Panel, 2010, 2011). The FEEDAP Panel concluded that pyridoxine hydrochloride is considered to be safe for all animal species at the commercial use levels and that the use of pyridoxine hydrochloride as a nutritional additive does not raise safety concerns for consumers and the environment. Concerning the safety for the user, in the absence of data the FEEDAP Panel could not conclude on skin and eye irritation and skin sensitisation but noted that pyridoxine hydrochloride may cause photosensitisation. The FEEDAP Panel concluded that data on physical properties of the specific formulation considered in the previous opinion would indicate that the risk of inhalation exposure was low. The Panel noted that this conclusion could only apply to other formulations with similar physical properties.

The applicant carried out a structured literature search<sup>21</sup> using several databases: American Chemical Society (ACS) publications, Science Direct, Springer, Wiley online library, PubMed and Web of Science. The search was limited to information available since the last authorisation in 2011 until January 2020. The main strings used were: 'pyridoxine OR vitamin B<sub>6</sub>' with filters safety/safe. A detailed description of the iterations used and the inclusion/exclusion criteria for the selection was provided.<sup>17</sup>

<sup>15</sup> Technical dossier/Section II\_Annexes 2.14-2.16.

<sup>16</sup> Technical dossier/Section II\_Annexes 2.17-2.19. LOQs: lead < 0.5 mg/kg, cadmium < 0.2 mg/kg, mercury < 0.02 mg/kg and arsenic < 0.5 mg/kg.

<sup>17</sup> Technical dossier/Section II\_Annex 2.18.

<sup>18</sup> Technical dossier/Section II/Annex 2.20.

<sup>19</sup> Technical dossier/Supplementary information December 2020/Annex 2.25\_Dusting potential test.

<sup>20</sup> Technical dossier/Section II/Annex 2.11 Long term stability and Annex 2.12 Accelerated stability.

<sup>21</sup> Technical dossier/Section III/Annex\_3.2 Database Research.

The search identified five publications which were considered relevant for the safety of vitamin B<sub>6</sub> for humans. None of these papers identified a safety concern for the consumers. No publications related to target animals, user/worker safety, environmental safety, or residue levels in edible tissues were identified.

### 3.2.1. Reassessment of consumer exposure

In the previous assessments of the FEEDAP Panel, the overall vitamin B<sub>6</sub> intake was estimated to range between 1.2 and 2.8 mg/day, with food of animal origin contributing to about 50% of the total intake from food sources. The FEEDAP Panel concluded that there was no risk to exceed the UL of 25 mg/day from food sources and that the use of vitamin B<sub>6</sub> as nutritional additive in feed for food producing animals is safe for the consumer (EFSA FEEDAP Panel, 2010, 2011).

According to the EFSA opinion on dietary reference values for vitamin B<sub>6</sub> (EFSA NDA Panel, 2016), 'based on data from 13 surveys in nine countries in the EU, average total vitamin B<sub>6</sub> intake ranges across countries from 0.4 to 0.8 mg/day in infants, from 0.9 to 1.3 mg/day in children aged 1 to < 3 years, from 1 to 1.6 mg/day in children aged 3 to < 10 years, and from 1.5 to 2.3 mg/day in children aged 10 to < 18 years. Average total vitamin B<sub>6</sub> intake ranges between 1.4 and 3.1 mg/day in adults (≥ 18 years old)', showing no risk to exceed the UL (SCF, 2000) from food sources.

The NDA Panel opinion also estimated the minimum and maximum percentage contribution of different food groups to vitamin B<sub>6</sub> intake in males and females. Meat (up to 30% in males and 26% in females) and milk and dairy products (up to 22% in males and 27% in females) were the main food groups contributing to vitamin B<sub>6</sub> intake in all age groups > 3 years of age. The analysis of the 13 dietary surveys in the EFSA Comprehensive European Food Consumption Database (EFSA NDA Panel, 2016) confirmed the conclusions of the previous assessment of the FEEDAP Panel, which showed that food of animal origin represents approximately 50% of total vitamin B<sub>6</sub> intake from food sources (EFSA FEEDAP Panel, 2011).

Therefore, even in the absence of new data on residue levels in edible tissues, there is no reason to reconsider the conclusion that the use of vitamin B<sub>6</sub> in animal nutrition would not lead to an increase in human consumption above the UL established by the SCF (2000) and considered still valid by EFSA (EFSA NDA Panel, 2016; EFSA, 2018).

### 3.2.2. User safety

No data were submitted on inhalation toxicity. However, considering that the product was shown to be not dusty, the exposure through inhalation is unlikely.

The applicant provided new studies on skin and eye irritation with pyridoxine hydrochloride.

The skin irritation potential of pyridoxine hydrochloride was tested in a valid study performed according to OECD guideline 404, which showed that it is not a skin irritant.<sup>22</sup>

The eye irritation potential of pyridoxine hydrochloride was tested in a valid study performed according to OECD guideline 405, which showed that it is not an eye irritant.<sup>23</sup>

No specific studies investigating the skin sensitisation potential of the additive were submitted. The FEEDAP Panel notes that pyridoxine hydrochloride may cause photosensitisation.

### 3.2.3. Conclusions on safety

Based on the above and the fact that the manufacturing process, the composition of the additive and the conditions of use for the species/categories of animals for which the additive is authorised have not been modified, the Panel considers that there is no evidence to reconsider the conclusions reached in previous assessment for the target animals, consumers and the environment. The FEEDAP Panel concludes that vitamin B<sub>6</sub> in the form of pyridoxine hydrochloride remains safe for the target species, the consumer and the environment under the conditions of use currently authorised.

Despite the lack of data on inhalation toxicity, the additive is not dusty and exposure through inhalation is unlikely. Pyridoxine hydrochloride is non-irritant to skin and eyes. In the absence of data, no conclusion can be drawn on skin sensitisation potential. It may cause photosensitisation.

<sup>22</sup> Technical dossier/Supplementary information December 2020/Annex 3.09\_Eurofins Irritation Test Report-VB6.

<sup>23</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

### 3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

### 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<sup>23</sup> and Good Manufacturing Practice.

## 4. Conclusions

The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation.

The FEEDAP Panel concludes that vitamin B<sub>6</sub> in the form of pyridoxine hydrochloride remains safe for all animal species, for the consumers and the environment under the conditions of use currently authorised. Pyridoxine hydrochloride is non-irritant to skin and eyes. In the absence of data, no conclusion can be drawn on skin sensitisation potential. Pyridoxine hydrochloride may cause photosensitisation. Despite the lack of data on inhalation toxicity, the additive is not dusty and exposure through inhalation is unlikely.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

## 5. Documentation as provided to EFSA/Chronology

Date	Event
05/06/2020	Dossier received by EFSA. Pyridoxine hydrochloride for all animal species. Submitted by Kaesler Nutrition GmbH.
18/06/2020	Reception mandate from the European Commission
27/08/2020	Application validated by EFSA – Start of the scientific assessment
22/10/2020	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, safety</i>
30/11/2020	Comments received from Member States
18/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
05/05/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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## Abbreviations

CAS	Chemical Abstracts Service
CD	Commission Decision
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification
MW	molecular weight
NDA Panel	EFSA Panel on Dietetic Products, Nutrition and Allergy
PCBs	polychlorinated biphenyls
PCDD/F	polychlorinated dibenzo- <i>p</i> -dioxins and dibenzofurans
SCF	Scientific Committee for Food
TEQ	Toxic equivalency factor
UL	Upper intake level
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization