Safety and efficacy of an additive consisting of potassium diformate (Formi™ LHS) for piglets (weaned) and pigs for fattening (Addcon GmbH)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of potassium diformate (Formi™ LHS) as a technological feed additive for piglets (weaned) and pigs for fattening. The FEEDAP Panel concluded that potassium diformate is safe for weaned piglets and for pigs for fattening at the level of 6,000 mg/kg complete feed, with no margin of safety. The use of potassium diformate in weaned piglets and pigs for fattening nutrition under the conditions of use proposed is of no concern for consumer safety. Potassium diformate does not raise concern regarding the effects on respiratory system and the skin but is an eye irritant. The use of potassium diformate as a feed additive is considered safe for the environment. The additive is considered to be efficacious as acidity regulator in feedingstuffs for weaned piglets and pigs for fattening at the minimum proposed concentration of 6,000 mg/kg complete feed.

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Keywords: Potassium diformate, technological additive, acidity regulator, piglets (weaned), pigs for fattening, safety, efficacy

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

The European Commission received a request from Addcon GmbH\(^2\) for authorisation of the product potassium diformate, when used as a feed additive for piglets (weaned) and pigs for fattening (category: technological additive; functional group: acidity regulators).

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). The particulars and documents in support of the application were considered valid by EFSA as of 8 July 2019.

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 product potassium diformate, when used under the proposed conditions of use (see Section 3.1.3).

1.2. **Additional information**

The subject of the assessment is the feed additive consisting of potassium diformate, intended for use as a technological additive (functional group: acidity regulators) for weaned piglets and pigs for fattening.

The EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued five opinions on Formi\(^{TM}\) LHS (potassium diformate): one on the efficacy and safety for sows, safety for consumers, users and the environment (EFSA, 2004), one on its safety and efficacy for weaned piglets and pigs for fattening (EFSA, 2006), one on its re-evaluation as feed additive for sows (EFSA FEEDAP Panel, 2009) and two on the renewal of the authorisation as feed additive for sows (EFSA FEEDAP Panel, 2020a,b).

Potassium diformate was authorised by Commission Regulation (EC) No 184/2007 as a feed additive for piglets (weaned) and pigs for fattening; this authorisation expired in 2017.\(^3\) Potassium diformate is currently authorised by Commission Regulation (EU) No 333/2012 as a preservative feed additive for all animal species.\(^4\) The additive is also authorised by Commission Regulation (EU) No 104/2010 as feed additive for sows.\(^5\)

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\(^6\) in support of the authorisation request for the use of potassium diformate as a feed additive.

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

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\(^1\) 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.

\(^2\) Addcon GmbH, Parsevalstrasse 6, 06749 Bitterfeld-Wolfen, Germany.

\(^3\) Commission Regulation (EC) No 184/2007 of 20 February 2007 concerning the authorisation of potassium diformate (Formi LHS) as a feed additive, OJ L 291, 5.11.2005, p. 8.

\(^4\) Commission Regulation (EU) No 333/2012 of 19 April 2012 concerning the authorisation of a preparation of potassium diformate as a feed additive for all animal species and amending Regulation (EC) No 492/2006, OJ L 89, 28.3.2006, p.6.

\(^5\) Commission Regulation (EU) No 104/2010 of 5 February 2010 concerning the authorisation of potassium diformate as a feed additive for sows (holder of authorization BASF SE) and amending Regulation (EC) No 1200/2005, OJ L 35, 6.2.2010, p. 4, amended by Commission Implementing Regulation (EU) 2017/410 of 8 March 2017, OJ L 63, 5.3.2017, p. 98.

\(^6\) FEED dossier reference: FAD-2019-0025.
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 active substance in animal feed are valid and applicable for the current application.7

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of potassium diformate is in line with the principles laid down in Regulation (EC) No 429/20088 and the relevant guidance documents: Guidance for the preparation of dossiers for technological additives (EFSA FEEDAP Panel, 2012a), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

Potassium diformate is intended to be used as a technological additive (functional group: acidity regulators) in feed for weaned piglets and pigs for fattening.

3.1. Characterisation

3.1.1. Characterisation of the additive

The active substance of the additive is potassium diformate (KCOOH+HCOOH) which is an association of potassium formate and formic acid. It has the chemical formula C$_2$H$_3$O$_4$K, molecular weight is 130.1 Da, the CAS number is 20642-05-1 and the EINECS number 243-934-6. Potassium diformate is produced by mixing formic acid and potassium hydroxide in a reactor at atmospheric pressure at a temperature of 50–60°C. The crystal mass and the saturated solution of potassium diformate are separated by centrifugation. Solid potassium diformate is obtained by drying and is mixed with silicon dioxide as an anticaking agent.

The additive is specified to contain minimum 98% potassium diformate, with a maximum of 1.5% silicon dioxide (as an anticaking agent) and a maximum of 0.5% water.9 The analysis of ten batches of the additive, showed that the additive meets those specifications: potassium diformate 98.3% (range 98.2–98.5%), anticaking agent 1.5% (range 1.4–1.5%), water 0.2% (range 0.1–0.3%).10 Analytical data of heavy metals (cadmium, lead and mercury) and arsenic, content in three independent batches was provided.11 Values reported were below the limits of detection (LODs) or limits of quantification (LOQs)12 and are considered of no concern. Dioxins (polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/F)) measured in three batches13 amounted to $< 0.09$ ng Bioanalytical Equivalents (BEQ)/kg (LOQ), and the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) was $< 0.2$ ng BEQ/kg (LOQ). Non-DL-PCBs were 1.2 ng/g. The values are of no concern.

Due to its chemical nature, it is not expected that the additive supports microbiological growth. The additive is described as a dry, white and free flowing crystalline product, with a bulk density of 900–1,000 kg/m$^3$.14 The dusting potential of the additive was measured in three independent batches showing an average of 348 mg/m$^3$ (range: 254–415 mg/m$^3$).15

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7 The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FormateGroup.pdf
8 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.
9 Commission Regulation (EU) No 104/2010 of 5 February 2010 concerning the authorization of potassium diformate as a feed additive for sows (holder of authorization BASF SE) and amending Regulation (EC) No 1200/2005, OJ L 35, 6.2.2010, p. 4.
10 Technical dossier/Section II/Annex_II_2.
11 Technical dossier/Supplementary information_Nov19/Annex_1.
12 Lead: 0.06 mg/kg (LOQ); Cadmium: 0.02 mg/kg (LOD); Mercury: 0.01 mg/kg (LOD); Arsenic: 0.03 mg/kg (LOD).
13 Technical dossier/Supplementary information_Nov19/Annex_2.
14 Technical dossier/Section II/Annex_II_5.
15 Technical dossier/Supplementary information_Nov19/Annex_3.
3.1.2. Stability and homogeneity

The shelf-life of the product was tested in two studies, in which three batches each of the additive were stored in polyethylene bags at 25°C and 55–60% relative humidity (RH) or at 40°C and 75–90% RH for 6 months, or at room temperature for 24 months.16 No substantial losses in the content of potassium diformate were observed during storage.

The stability of the additive (three batches) in pre-starter and starter piglet mash feeds was studied for eight months storage at room temperature.17 Recovery at the end of the storage was 95.0–98.3 (pre-starter feed) and 98.9% (starter feed). Although the applicant claims that potassium diformate is stable to feed processing temperatures up to 110°C, no data to support this claim was provided.

The capacity of potassium diformate to homogeneously distribute was studied in mash and pelleted pig feed at two different inclusion levels (0.5% and 1.8%).18 The coefficients of variation (n = 10) in mash feed were 6.1% and 10.4% for the 0.5% and 1.8% inclusion levels, respectively. The coefficients of variation (n = 10) in pelleted feed were 7.7% and 15.5% for the 0.5% and 1.8% inclusion levels, respectively.

3.1.3. Conditions of use

Potassium diformate is intended to be used in feed for weaned piglets and pigs for fattening at a minimum inclusion level of 6,000 and a maximum level of 18,000 mg/kg complete feed (0.6–1.8%). The use in premixtures is not foreseen for this product.

3.2. Safety

The safety of use of potassium diformate in feed for weaned piglets (up to 18,000 mg/kg) and pigs for fattening (up to 12,000 mg/kg feed) was first considered by the FEEDAP Panel in 2006 (EFSA, 2006), following a previous assessment by the Scientific Committee for Animal Nutrition (SCAN) (European Commission, 2002). In 2009, in the framework of the re-evaluation of the additive Formi™ LHS for sows, the Panel re-assessed the safety for the consumer, user and the environment (EFSA FEEDAP Panel, 2009).

In the present application, the applicant has submitted a new tolerance study in weaned piglets, and the same studies already assessed in 2009 by the FEEDAP Panel for the safety for the consumer, user and environment. The FEEDAP Panel has re-assessed all the data submitted in the present dossier, which is summarised in the following sections.

3.2.1. Safety for the target species

To support the safety for the target species, the applicant submitted three old studies (two in pigs for fattening and one in piglets) previously assessed by SCAN (European Commission, 2001; European Commission, 2002 respectively) and by the FEEDAP Panel (EFSA, 2006).

Considering the current standards and the limitations in the three studies (poor trial set up, poor reporting, and no statistical report), these studies cannot further be considered to assess the safety of the additive for pigs for fattening and piglets (weaned), at the maximum proposed inclusion level of 1.8%.

The applicant also submitted one recent tolerance study in piglets (weaned).

3.2.1.1. Tolerance study in piglets (weaned)

A total of 128 piglets (Topigs Stambo HBI Dalland 40, 28 days of age, mean body weight 7.8 kg; equal number of males and females) distributed in four treatments with eight replicate pens of four piglets each were fed with diets (based on barley, wheat, maize and soy protein concentrate; pre-starter, from day 0 to 14; starter, from day 15 to 42) supplemented with 0, 6,000 (0.3 × the maximum content), 18,000 (1 ×), or 72,000 (4 ×) mg potassium diformate/kg feed (confirmed by analysis).19 Feed in mash form and water were offered ad libitum. Health status and mortality were monitored daily. Feed intake and body weight were recorded at the beginning (day 1), and at days 14, 28 and 42 of the experiment. Average daily body weight gain and feed to gain ratio were calculated. At day 1

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16 Technical dossier/Section II/Annex II_11.
17 Technical dossier/Section II/Annex II_12.
18 Technical dossier/Section II/Annex II_13.
19 Technical dossier/Supplementary information_Nov19/Annex_4 and Supplementary information February 2020/annex 5.
and at the end of the experiment (day 42), 32 piglets (1 per replicate pen) were selected and blood samples were taken for haematology\(^{20}\) and blood biochemistry.\(^{21}\) The data were analysed by repeated measurements ANOVA with treatment and time and their interaction, and a Tukey test was used for the comparison of the group means. The pen was considered as the experimental unit. Significance level was set at 0.05.

No mortality or culling occurred. The main results are reported in Table 1. No differences in the zootechnical parameters were observed between the groups fed 0.3\(^{9}\) or 1\(^{9}\) the maximum content compared to the control group. The group fed 4\(^{9}\) potassium diformate showed a statistically lower feed intake and body weight gain compared to the control group. Feed to gain ration was similar among all four groups. Haematocrit, haemoglobin and red blood cells (RBC) at day 42 were lower in a dose dependent manner in the groups receiving potassium diformate compared to the control group; the values were significantly different compared to control from the level 1\(^{9}\) of the additive for haematocrit and haemoglobin and at 4\(^{9}\) for RBC. Also, serum chloride was lower compared to the control group at 4\(^{9}\). No other relevant effects were observed for any other haematological and biochemical parameters.

Table 1: Main effects of the supplementation of feeds for weaned piglets with potassium diformate on the performance and on blood related parameters

| Groups (mg potassium diformate/kg feed) | 0     | 6,000 | 18,000 | 72,000 |
|----------------------------------------|-------|-------|--------|--------|
| Feed intake (g)                        | 683\(^{b}\) | 681\(^{b}\) | 679\(^{b}\) | 505\(^{a}\) |
| Final body weight (kg)                 | 25.53\(^{b}\) | 26.45\(^{b}\) | 25.60\(^{b}\) | 20.03\(^{a}\) |
| Average daily gain (g)                 | 436\(^{b}\)  | 437\(^{b}\)  | 438\(^{b}\)  | 291\(^{a}\)  |
| Feed to gain ratio                     | 1.56 | 1.46 | 1.57 | 1.78 |
| Haematocrit (%)                        | 31.6\(^{a}\) | 27.2\(^{ab}\) | 24.0\(^{b}\) | 23.1\(^{b}\) |
| Haemoglobin (g/dL)                     | 9.95\(^{a}\) | 8.80\(^{ab}\) | 7.95\(^{b}\) | 8.16\(^{b}\) |
| Red blood cells (\(\times 10^{6}/\mu L\)) | 6.01\(^{a}\) | 5.47\(^{ab}\) | 5.23\(^{ab}\) | 5.14\(^{b}\) |
| Serum chloride (mmol/L)                | 98.4\(^{a}\) | 97.8\(^{ab}\) | 96.5\(^{ab}\) | 95.1\(^{b}\) |

\(^{a,b,c}\): Mean values with a different superscript within a row are significantly different \(p < 0.05\).

The results of this study showed a lower performance of the piglets in the group that received 72,000 mg potassium diformate/kg feed with decreases in RBC counts and haematocrit, and lower haemoglobin content. The effects on haematocrit and haemoglobin content were also seen at the level of 18,000 mg/kg complete feed. These effects are considered as adverse effects and consequently the FEEDAP Panel concludes that the additive is not safe at the level of 18,000 mg/kg complete feed or above in piglets.

Based on the data from this tolerance trial in piglets, the FEEDAP Panel concludes that the additive is safe for weaned piglets at the level of 6,000 mg/kg complete feed with no margin of safety and the same conclusion is extended to pigs for fattening.

3.2.2. Safety for the consumer

3.2.2.1. Absorption, distribution, metabolism and excretion

Potassium diformate remains in the diformate form under acidic conditions and dissociates into formate and potassium ions under neutral or alkaline conditions. Therefore, diformate, present as the salt in the stomach, is likely to dissociate in the neutral conditions prevailing in the intestine and after eventual absorption, in plasma and tissues. Formate is a normal endogenous metabolite (EFSA FEEDAP Panel, 2009).

Formic acid partially enters the one-carbon pool of the body or is further oxidised to carbon dioxide and water in the liver and in the erythrocytes. The residual unmetabolised formic acid and other minor metabolites are excreted via urine, faeces or expired air. No significant increase in the presence of

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\(^{20}\) Red blood cells (RBC), haemoglobin, haematocrit, platelets, mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), mean corpuscular volume (MCV), red cell distribution width (RCDW), white blood cells (WBC), neutrophils, lymphocytes, monocytes, eosinophils, basophils.

\(^{21}\) Glucose, cholesterol, total protein, urea, albumin, bilirubin tot., creatinine, alkaline phosphatase (ALP), aspartate aminotransferase (AST), alanine aminotransferase (ALT), calcium, phosphorus, chloride, potassium, sodium, magnesium.
formate per se is expected in the animal products, although carbon derived from formate may be incorporated into tissues as a consequence of normal anabolism (Hanzlik et al., 2005). This assumption was confirmed by the residue studies provided by the applicant (see Section 3.2.2.2).

### 3.2.2.2. Residue studies

The applicant submitted data on residues of potassium diformate in tissues in pigs for fattening from a study already assessed by the SCAN (European Commission, 2001, 2002, respectively) and by the FEEDAP Panel (EFSA, 2006) (see Section 3.2.1), and data from the tolerance study in piglets (see Section 3.2.1.1).

In the study with pigs for fattening, the animals were fed with diets supplemented with potassium diformate at concentrations of 0, 12,000, 24,000 or 60,000 mg/kg. Two animals were killed at the beginning of the study (day 0) and at days 30, 60 and 90 and samples of muscle, liver, kidney, heart, lung and plasma were analysed for formate concentration. Notwithstanding the low number of samples, no increase in tissues’ concentrations of formate as observed in the animals fed up to 24,000 mg potassium diformate/kg feed compared with the control animals in any of the sampling points, nor overall.

In the study with piglets (weaned), eight animals from each group (0, 18,000 and 72,000 mg potassium diformate/kg feed) were killed at the end of the study and samples of muscle, skin, fat, spleen, lung, liver and kidney were analysed for formate concentration. In none of the tissues analysed an increase of formate was observed in the animals fed 18,000 mg potassium diformate compared to the control animals.

### 3.2.2.3. Toxicological studies

The applicant provided a series of toxicological studies that were already evaluated by the FEEDAP Panel in 2009 (EFSA FEEDAP Panel, 2009). This included studies on genotoxicity (bacterial mutagenicity tests (Salmonella Typhimurium, Escherichia coli), in vitro mouse lymphoma assay and chromosome aberration test in human peripheral blood lymphocytes, and an in vivo bone marrow micronucleus test in rats). The FEEDAP Panel concluded that no potential genotoxicity was observed.

Regarding laboratory animal toxicity studies, the following data were available:

- A subchronic toxicity study in mice, which did not cause adverse effects even in the highest dose tested (3,000 mg/kg diet).
- Chronic studies in mice and rats, in which no treatment-related increase in tumours was seen in either species. NOAELs of 400 and 50 mg/kg body weight (bw) per day in mice and rats, respectively, were identified.

The FEEDAP Panel concluded that the additive is not genotoxic and of low toxicity (EFSA FEEDAP Panel, 2009).

The Panel is not aware of any new information that would lead to reconsider the previous conclusions, in line with the recent opinion on the same product for use in sows (EFSA FEEDAP Panel, 2020b).

### 3.2.2.4. Conclusions on the safety for the consumer

Considering the negative outcome of the genotoxicity testing, the low toxicity of potassium diformate and the lack of an increased consumer exposure to formate, the FEEDAP Panel considers that the use of potassium diformate as a feed additive in piglets and pigs for fattening at the maximum inclusion level of 1.8% is safe for the consumer.

### 3.2.3. Safety for the user

All the data presented in this dossier were previously evaluated by SCAN (European Commission, 2001, 2002) and by the FEEDAP Panel (EFSA, 2006; EFSA FEEDAP Panel, 2009). Based on skin23 and eye irritation studies (rabbit),24 skin sensitisation test (Magnusson–Kligman test with Guinea pigs)25

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22 Ion-chromatography, limit of quantification: 1 mg/kg.
23 Technical dossier/Section III/Annex III_21.
24 Technical dossier/Section III/Annex III_22.
25 Technical dossier/Section III/Annex III_23.
and an acute inhalation toxicity test (rats)\textsuperscript{26} the Panel concludes that the additive does not raise concern regarding the effects on respiratory system and the skin, but is an eye irritant.

### 3.2.4. Safety for the environment

Since the excretion products, formic acid and formate, are naturally occurring metabolites, the use of potassium diformate is not expected to increase the natural concentrations of formate (and potassium ions) in the environment. The FEEDAP Panel concludes that the use of potassium diformate as feed additive in piglets (weaned) and pigs for fattening under the proposed conditions of use is safe for the environment.

### 3.3. Efficacy

To support the efficacy of potassium diformate as an acidity regulator, four \textit{in vitro} studies were provided; these studies included three trials with complete feed for piglets (weaned) and three with complete feed for pigs for fattening. The four studies shared the same methodology, only potassium diformate inclusion levels varied in the studies. In all the studies, three 10 g subsamples of the feedingstuffs treated with each of concentration of potassium diformate were taken, grounded and added to 100 mL of distilled deionized water. The solution was mixed with a magnetic stirrer for 15 minutes and the pH was measured. The results were statistically analysed by an ANOVA and a Tukey test for group comparison.

The first study included two trials in which one commercial feed for pigs for fattening and one for piglets (weaned) were supplemented with potassium diformate at concentrations of 0, 2,000, 4,000, 6,000, 8,000, 10,000 or 12,000 mg/kg.\textsuperscript{27,28} In the second study, two commercial feeds for weaned piglets (pre-starter and starter) were supplemented with potassium diformate at concentrations of 0, 6,000 or 18,000 mg/kg.\textsuperscript{29} In the third study, one commercial feed for pigs for fattening was supplemented with potassium diformate at concentrations of 0, 5,000, 6,000 or 18,000 mg/kg.\textsuperscript{30} In the fourth study, one commercial feed for pigs for fattening was supplemented with potassium diformate at concentrations of 0, 6,000 or 18,000 mg/kg.\textsuperscript{31}

In the four studies, the supplementation of feeds with potassium diformate reduced the pH in a dose dependent manner, starting from the lowest supplementation applied. The lowest concentration common in the four studies was 6,000 mg/kg feed. The results of the studies are summarised in Table 2.

#### Table 2: Effects of potassium diformate on the pH of commercial feedingstuffs for piglets weaned and pigs for fattening

| Trial | Potassium diformate inclusion level (mg/kg feed) | pH |
|-------|--------------------------------------------------|----|
|       | 0 | 2,000 | 4,000 | 5,000 | 6,000 | 8,000 | 10,000 | 12,000 | 18,000 |
| Trial 1 |
| Piglets | 5.50\textsuperscript{a} | 5.28\textsuperscript{b} | 5.22\textsuperscript{c} | – | 5.17\textsuperscript{d} | 5.12\textsuperscript{e} | 5.06\textsuperscript{f} | 5.01\textsuperscript{g} | – |
| Pigs for fattening | 5.84\textsuperscript{a} | 5.59\textsuperscript{b} | 5.51\textsuperscript{c} | – | 5.42\textsuperscript{d} | 5.32\textsuperscript{e} | 5.23\textsuperscript{f} | 5.15\textsuperscript{g} | – |
| Trial 2 |
| Piglets (pre-starter) | 6.19\textsuperscript{a} | – | – | – | 5.82\textsuperscript{b} | – | – | – | 5.25\textsuperscript{c} |
| Piglets (starter) | 6.06\textsuperscript{a} | – | – | – | 5.64\textsuperscript{b} | – | – | – | 5.12\textsuperscript{c} |
| Trial 3 |
| Pigs for fattening | 5.82\textsuperscript{a} | – | – | 5.46\textsuperscript{b} | 5.36\textsuperscript{c} | – | – | – | 5.08\textsuperscript{d} |
| Trial 4 |
| Pigs for fattening | 6.10\textsuperscript{a} | – | – | – | 5.70\textsuperscript{b} | – | – | – | 5.31\textsuperscript{c} |

\textsuperscript{a,b,c,d,e,f,g: Mean values with a different superscript within a row are significantly different \(p < 0.05\).}

\textsuperscript{26} Technical dossier/Section III/Annex_III_19.
\textsuperscript{27} Technical dossier/Section IV/Annex_IV_1a.
\textsuperscript{28} Technical dossier/Section IV/Annex_IV_1b.
\textsuperscript{29} Technical dossier/Section IV/Annex_IV_2a.
\textsuperscript{30} Technical dossier/Section IV/Annex_IV_3a.
\textsuperscript{31} Technical dossier/Section IV/Annex_IV_4a.
3.3.1. Conclusions on efficacy

Based on the four studies, the FEEDAP Panel concludes that potassium diformate is an effective acidity regulator in feedingstuffs for piglets (weaned) and pigs for fattening at the minimum proposed concentration of 6,000 mg/kg complete feed.

4. Conclusions

Potassium diformate is safe for weaned piglets and for pigs for fattening at the level of 6,000 mg/kg complete feed, with no margin of safety.

The use of potassium diformate in feed for weaned piglets and pigs for fattening under the conditions of use proposed is of no concern for consumer safety.

Potassium diformate does not raise concern regarding the effects on respiratory system and the skin but is an eye irritant.

The use of potassium diformate as a feed additive is considered safe for the environment.

The additive is considered to be efficacious as acidity regulator in feedingstuffs for weaned piglets and pigs for fattening at the minimum proposed concentration of 6,000 mg/kg complete feed.

5. Documentation provided to EFSA/Chronology

| Date       | Event                                                                 |
|------------|------------------------------------------------------------------------|
| 02/04/2019 | Reception mandate from the European Commission                          |
| 12/04/2019 | Dossier received by EFSA. Formi LHS (potassium diformate) submitted by Addcon GmbH |
| 08/07/2019 | Application validated by EFSA – Start of the scientific assessment     |
| 10/10/2019 | Comments received from Member States                                   |
| 17/09/2019 | 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 and safety for the target species, consumers, users and environment |
| 22/11/2019 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 20/12/2019 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: Safety for the target species and consumers |
| 06/02/2020 | 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**

| Abbreviation | Description |
|--------------|-------------|
| BEQ | Bioanalytical Equivalents |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CFU | colony forming unit |
| DL-PCB | dioxin-like polychlorinated biphenyl |
| EINECS | European Inventory of Existing Chemical Substances |
| EURL | European Union Reference Laboratory |
| FCR | feed conversion ratio |
| FEEDAP | EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed |
| LOQ | limit of quantification |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular volume |
| MIC | minimum inhibitory concentration |
| PCDD/F | polychlorinated dibenzo-p-dioxins and dibenzofurans |
| SCAN | Scientific Committee on Animal Nutrition |