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Safety and efficacy of Coxiril[®] (diclazuril) for pheasants

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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 and efficacy of Coxiril[®] for pheasants. Coxiril[®], containing 0.5% diclazuril, is intended for the prevention of coccidiosis in pheasants at a dose range of 1.0–1.2 mg/kg of complete feed. Diclazuril from Coxiril[®] is considered safe for pheasants at a level of 1.2 mg/kg complete feed. The conclusion was made by extrapolating the results of a tolerance study with turkeys for fattening. The FEEDAP Panel considered that the residues in pheasant tissues and eggs would be of the same magnitude as those measured in the physiologically similar major species chickens and turkeys for fattening. The use of diclazuril at a maximum concentration of 1.2 mg/kg complete feed for pheasants would be safe for the consumer, provided that the maximum residue limits (MRLs) established for poultry would not be exceeded. The conclusions on the safety of the additive for the target species and the consumer are made under the provision that Coxiril[®] is not fed to laying birds. Coxiril[®] is considered as a non-irritant to eyes and skin. It is not a potential skin sensitiser. User inhalation exposure to Coxiril[®], as a result of normal handling, is unlikely to cause respiratory or systemic toxicity. The use of diclazuril from Coxiril[®] in pheasants does not pose a risk to the environment for neutral/alkaline soils (pH \geq 7). A final conclusion on the risk resulting from the use of the additive in acid soil cannot be done due to the high uncertainties related to potential accumulation of diclazuril over time. The FEEDAP Panel concluded that diclazuril from Coxiril[®] at a minimum dose of 1 mg/kg complete feed has the potential to control coccidiosis in pheasants.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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 Huvepharma N.V.² for authorisation of the product Coxiril® (diclazuril), when used as a feed additive for pheasants (category: coccidiostats and histomonostats).

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 18 July 2017.

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 animal, consumer, user and the environment and on the efficacy of the product Coxiril® (diclazuril), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted in 2014 four opinions on the safety and efficacy of Coxiril® when used as a feed additive in chickens for fattening (EFSA FEEDAP Panel, 2014a), turkeys for fattening (EFSA FEEDAP Panel, 2014b), guinea fowl (EFSA FEEDAP Panel, 2014c) and rabbits for fattening and rabbits for breeding (EFSA FEEDAP Panel, 2015). In 2018, the FEEDAP Panel adopted an opinion on the safety and efficacy of Coxiril® for chickens reared for laying (EFSA FEEDAP Panel, 2018).

The additive Coxiril® is authorised in chickens for fattening, turkeys for fattening, guinea fowl for fattening and breeding by Regulation (EU) 2015/46³ with maximum residue limits (MRLs) of diclazuril of 1,500 µg/kg wet liver, 1,000 µg/kg wet kidney, 500 µg/kg wet muscle and skin/fat. The same MRLs are reported in Regulation (EU) No 115/2013⁴ for the use of diclazuril as veterinary medicine in poultry. Coxiril® is also authorised in rabbits by Regulation (EU) 2015/1417.⁵

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁶ in support of the authorisation request for the use of Coxiril® (diclazuril) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008⁷ and the applicable EFSA guidance documents.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA.

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 Huvepharma N.V. Uitbreidingstraat 80, 2600 Antwerp, Belgium.

³ Commission Implementing Regulation (EU) 2015/46 of 14 January 2015 concerning the authorisation of diclazuril as a feed additive for chickens for fattening, for turkeys for fattening and for guinea fowl for fattening and breeding (holder of authorisation Huvepharma NV). OJ L 9, 15.1.2015, p. 5.

⁴ Commission Implementing Regulation (EU) No 115/2013 of 8 February 2013 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance diclazuril. OJ L 38, 9.2.2013, p. 11.

⁵ Commission Implementing Regulation (EU) 2015/1417 of 20 August 2015 concerning the authorisation of diclazuril as a feed additive for rabbits for fattening and for breeding (holder of the authorisation Huvepharma NV). OJ L 220, 21.8.2015, p. 15.

⁶ FEED dossier reference: FAD-2017-00030.

⁷ 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.

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.⁸

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Coxiril® is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance for the preparation of dossiers for coccidiostats and histomonostats (EFSA FEEDAP Panel, 2011a), Technical guidance: tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011b), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008a), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012a), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Technical Guidance: microbial studies (EFSA, 2008b), Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008c) and Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012b).

3. Assessment

The current opinion assesses safety and efficacy of Coxiril® (diclazuril) when used as a feed additive for pheasants.

3.1. Characterisation

The identity of the additive, the characterisation of the active substance, the manufacturing process, the identity of diclazuril impurities and stability of the additive have been previously reviewed by the FEEDAP Panel (EFSA FEEDAP Panel, 2014a).

Coxiril®, containing 0.5% diclazuril, is intended for the prevention of coccidiosis in pheasants at a dose range of 1.0–1.2 mg diclazuril/kg of complete feed. A withdrawal period of zero days is proposed, in line with that for chickens and turkeys for fattening.

3.2. Safety

3.2.1. Safety for the target species

The safety of diclazuril at a dose of 0.8–1.2 mg/kg complete feed was assessed and diclazuril was considered safe by the FEEDAP Panel for chickens for fattening (EFSA FEEDAP Panel, 2014a) and for turkeys for fattening (EFSA FEEDAP Panel, 2014b). A margin of safety could not be established with accuracy. Feeding the twelve-fold concentration of diclazuril to turkeys for fattening did not result in adverse effects.

No tolerance study with Coxiril® in pheasants was submitted. However, an extrapolation of the safety data from major species to a relevant physiologically similar minor species is acceptable if the additive shows a wide margin of safety (at least 10) in the major species (EFSA, 2008c).

Diclazuril has no substantial antibacterial activity, and consequently, no microbial risk for the target species or induction of cross-resistance to clinically relevant antibiotics is expected (EFSA FEEDAP Panel, 2014a,b).

The FEEDAP Panel considers Coxiril® at the maximum concentration of 1.2 mg/kg complete feed, as safe for pheasants.

3.2.2. Safety for the consumer

In previous opinions, the FEEDAP Panel concluded that the use of diclazuril from Coxiril® at the maximum concentration of 1.2 mg diclazuril/kg feed for chickens for fattening (EFSA FEEDAP Panel, 2014a), for turkeys for fattening (EFSA FEEDAP Panel, 2014b) and for chickens reared for laying (EFSA FEEDAP Panel, 2018) does not raise concerns for the consumer safety. MRLs for Coxiril for chickens for fattening, turkeys for fattening and guinea fowl are established by Regulation (EU) No 2015/46⁹

⁸ The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2013-0014-Coxiril_0.pdf

⁹ OJ L 9, 15.1.2015, p. 5.

(1,500 µg/kg wet liver, 1,000 µg/kg wet kidney, 500 µg/kg wet muscle and skin/fat). The same MRLs are set in Regulation (EU) No 115/2013⁴ for the use of diclazuril as veterinary medicine in poultry.

No residue data for pheasants have been submitted. Since the dose of the additive in the feed of pheasants and the major species, in accordance with the FEEDAP Guidance on the Extrapolation of data from major species to minor species (EFSA, 2008c), the FEEDAP Panel considers that the residues in pheasant tissues would be of the same magnitude as those measured in the physiologically similar major species chickens and turkeys for fattening. Based on the same guidance, the same MRLs can be extrapolated. In conclusion, the use of diclazuril at a maximum concentration of 1.2 mg/kg complete feed for pheasants would be safe for the consumer, provided the MRLs would not be exceeded.

In its opinion on the safety and efficacy of Coxiril® for chickens reared for laying, (EFSA FEEDAP Panel, 2018), it was concluded that 'no measurable diclazuril residues were found in the first eggs laid from chickens reared for laying fed diclazuril from Coxiril® at 1.2 mg/kg complete feed for the first 12 weeks of life'. This conclusion can be extended to birds reared for laying.

3.2.3. Safety for the user

Safety for the user was already assessed in the previous opinion on diclazuril from Coxiril® for chickens for fattening (EFSA FEEDAP Panel, 2014a). The Panel reiterates its previous conclusions that 'Coxiril® is considered as non-irritant to eyes and skin. It is not a potential skin sensitiser. User inhalation exposure to Coxiril®, as a result of normal handling, is unlikely to cause respiratory or systemic toxicity'.

3.2.4. Safety for the environment

In accordance with the technical guidance on the extrapolation from major species to minor species regarding the assessment of feed additives for use in animal nutrition (EFSA, 2008c), the environmental risk assessment for pheasants can be extrapolated from the assessment done for the use of diclazuril in the major species. Recently, the FEEDAP Panel concluded that the use of diclazuril from Coxiril® in chickens reared for laying at 1.2 mg/kg complete feed would not pose a risk to the environment for neutral/alkaline soils (pH ≥ 7). A final conclusion on the risk resulting from the use of diclazuril in acid soil from Coxiril® cannot be done due to the high uncertainties related to potential accumulation of diclazuril over time (EFSA FEEDAP Panel, 2018). As the conditions of use among poultry species are similar, the same conclusion applies to the use of the additive in pheasants.

3.3. Efficacy

The efficacy of diclazuril from Coxiril® in controlling coccidiosis in chickens for fattening (EFSA FEEDAP Panel, 2014a) and turkeys for fattening (EFSA FEEDAP Panel, 2014b) has been demonstrated at a minimum dose of 0.8 mg/kg complete feed. Considering that the principal efficacy of diclazuril against *Eimeria* spp. has been demonstrated but no data are available on *Eimeria* spp. typically occurring in pheasants, in accordance with the FEEDAP Guidance on the Extrapolation of data from major species to minor species (EFSA, 2008c), one study is required to demonstrate the efficacy of the additive in pheasants.¹⁰

A floor pen study in pheasants was submitted. Five hundred birds of both sexes (four pens per treatment and 25 birds per pen) were penned and distributed into five treatment groups: one uninfected untreated group (UUC), one infected untreated group (IUC) and three infected treated groups (IT). The IT groups received feed containing 1 mg (analysed 0.89–0.98 mg), 2 mg (1.78–2.12 mg) and 4 mg (3.56–3.68 mg) diclazuril/kg. The experimental diets were fed from study day 8 until the end of the study (day 70).

On study day 0, all birds except those in UUC were inoculated orally (via feed) with 7,500 oocysts/bird of a mixed field strain (recently isolated) containing *Eimeria colchici* and *Eimeria duodenalis*. The inoculation dose necessary to provoke adverse effects has been evaluated in preliminary tests. Animal health and mortality were monitored daily. Feed intake and body weight of the animals were measured throughout the study, feed to gain ratio was calculated. On days 0, 6, 14, 22, 30, 40, 49, 64 and 70, five fresh faecal samples were collected from each pen, pooled on a pen basis and analysed for oocyst concentration. On days 6 and 7, one animal per pen per day was randomly selected for necropsy. Intestinal lesions were scored.

¹⁰ Technical dossier/Section IV/Annex 15.

Data were statistically analysed (body weight using a mixed effects linear model, numbers of oocysts and lesions scores using Wilcoxon's rank sum test; for both methods two sided 5% significance level).

Oocyst excretion was not reduced in the IT groups compared to the IUC group at the different time points. Lesion scores were assessed in the proximal and distal small intestine and caecum of 10 birds each per group on day 6/7 after inoculation. The main differences occurred in the caeca, values of IUC were significantly higher than those of UUC and the three IT. In the caeca, no lesions (score 0) were observed in 90% of the UUC birds and in 55%, 95% and 85% of the IT birds with 1, 2 and 3 mg diclazuril/kg, respectively. No bird with score 0 was found in the IUC group. The highest lesion scores 3 and 4 were not observed in the UUC and the IT groups but in 30% of the IUC birds. In the distal small intestine, lesion score 0 was found in only 65% of the IUC birds but in 95% of the UUC birds. The values for the IT birds with 1, 2 and 3 mg diclazuril/kg were 80, 90 and 80%, respectively.

No comparable significant differences were seen in the small intestine, the only significant difference was found for higher lesion scores of IUC compared to UUC in the proximal small intestine.

Table 1 summarises the results concerning mortality and zootechnical endpoints. Mortality after *Eimeria* inoculation was low in all groups. Body weight gain and feed intake were significantly depressed in the first 9 days of the study by the oocyst inoculation. Feeding diclazuril in the infected groups restored feed intake and body weight gain up to the level of the UUC group. Feed to gain ratio followed the pattern described above for feed intake and body weight gain. Final body weight as well as feed to gain ratios after day 9 did not show significant differences between the groups.

Table 1: Performance parameters in the first 9 days of the study and mortality of pheasants

	Feed Intake (g/day)	Weight Gain (g)	Feed to gain ratio	Mortality (%)
UUC	45.6	137.3 ^a	3.00 ^b	5
IUC	42.4	80.2 ^b	4.91 ^a	4
IT, 1 mg/kg	44.6	137.8 ^a	2.93 ^b	3
IT, 2 mg/kg	44.3	137.0 ^a	2.93 ^b	5
IT, 3 mg/kg	45.3	132.9 ^a	3.09 ^b	4

UUC: uninfected untreated; IUC: infected untreated; IT: infected treated.

a,b: Means in a column within a study with different superscript are significantly different ($p \leq 0.05$).

3.3.1. Conclusion on efficacy

Treatment of pheasants with diclazuril from Coxiril® at a minimum dose of 1 mg/kg reduced the intestinal lesion scores (predominantly in the caeca) provoked by inoculation with pheasant specific *Eimeria* species, measured at 6/7 days after inoculation. A further consequence of this anticoccidial effect was the restoring of feed intake, body weight gain and feed to gain ratio, which were negatively affected by the inoculation challenge, to the level of the UUC group.

The FEEDAP Panel concludes that diclazuril from Coxiril® at a minimum dose of 1 mg/kg complete feed has the potential to control coccidiosis in pheasants.

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 Regulation¹¹ and Good Manufacturing Practice.

Field monitoring of *Eimeria* spp. resistance to diclazuril should be undertaken, preferably during the latter part of the period of authorisation.

4. Conclusions

Diclazuril from Coxiril® is considered safe for pheasants at a level of 1.2 mg/kg complete feed.

The FEEDAP Panel considers that the residues in pheasant tissues and eggs would be of the same magnitude as those measured in the physiologically similar major species chickens and turkeys for fattening. The use of diclazuril at a maximum concentration of 1.2 mg/kg complete feed for pheasants would be safe for the consumer, provided the MRLs established for poultry would not be exceeded.

¹¹ 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.

The conclusions on the safety of the additive for the target species and the consumer are made under the provision that Coxiril® is not fed to laying birds.

Coxiril® is considered as a non-irritant to eyes and skin. It is not a potential skin sensitiser. User inhalation exposure to Coxiril®, as a result of normal handling, is unlikely to cause respiratory or systemic toxicity.

The use of diclazuril from Coxiril® in pheasants does not pose a risk to the environment for neutral/alkaline soils (pH \geq 7). A final conclusion on the risk resulting from the use of diclazuril in acid soil from Coxiril® cannot be done due to the high uncertainties related to potential accumulation of diclazuril over time.

The FEEDAP Panel concludes that diclazuril from Coxiril® at a minimum dose of 1 mg/kg complete feed has the potential to control coccidiosis in pheasants.

5. Remark

The FEEDAP Panel noted that the following recommendation was made in its previous assessment on the use of Coxiril® for chickens reared for laying (EFSA FEEDAP Panel, 2018): 'The potential of diclazuril to accumulate in acid soils over the years should be investigated by monitoring and in a field study'.

Documentation provided to EFSA

- 1) Coxiril® for pheasants. May 2017. Submitted by Huvepharma NV.
- 2) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Coxiril®.
- 3) Comments from Member States.

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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Coxiril® (diclazuril) for rabbits for fattening and breeding. EFSA Journal 2015;13(1):3968, 20 pp. <https://doi.org/10.2903/j.efsa.2015.3968>
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Abbreviations

FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
IT	infected treated
IUC	infected untreated
MRL	maximum residue limit
UUC	uninfected untreated