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Safety and efficacy of Coxiril® (diclazuril) for chickens reared for laying

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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® (diclazuril) for chickens reared for laying. Coxiril®, containing 0.5% diclazuril, is intended for the prevention of coccidiosis in chickens reared for laying at a dose range of 0.8–1.2 mg diclazuril/kg of complete feed up to a maximum age of 12 weeks. Derived from data already assessed for chickens and turkeys for fattening, diclazuril from Coxiril® is safe for chickens reared for laying up to 1.2 mg/kg complete feed when applied until 12 weeks of age. The FEEDAP Panel extended its previous assessment of consumer safety for the use of diclazuril from Coxiril® in chickens for fattening to chickens reared for laying. 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 until 12 weeks of age. Coxiril® was 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 chickens reared for laying at the highest proposed feed concentration would 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. Derived from data already assessed for chickens for fattening, diclazuril from Coxiril® has the potential to control coccidiosis in chickens reared for laying at a minimum concentration of 0.8 mg/kg complete feed.

Keywords: Coxiril®, diclazuril, coccidiostats, chickens reared for laying, 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 Huvepharma N.V.[2] for authorisation of the product Coxiril® (diclazuril), when used as a feed additive for chickens reared for laying (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 7 December 2015.

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 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 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).

The additive Coxiril® is authorised in chickens for fattening, turkeys for fattening, guinea fowl for fattening and breeding by Regulation (EU) 2015/46[3] 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 115/2013[4] 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 dossier[6] 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 429/2008[7] 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 or other expert bodies or other scientific reports to deliver the present output.

[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-2015-0036.
[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[7] 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) 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 chickens reared for laying up to a maximum age of 12 weeks.

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 already reviewed by the FEEDAP Panel (EFSA FEEDAP Panel, 2014a).

Coxiril®, containing 0.5% diclazuril, is intended for the prevention of coccidiosis in chickens reared for laying at a dose range of 0.8–1.2 mg diclazuril/kg of complete feed up to a maximum age of 12 weeks. 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). Although a margin of safety could not be established with accuracy, feeding the threefold and the 12-fold concentration of diclazuril to chickens for fattening and to turkeys for fattening, respectively, did not result in adverse effects.

In the view of the FEEDAP Panel, the safety established in chickens for fattening applies also to chickens reared for laying since the same species (only a different category) in the same physiological stage (growing) is considered. Tolerance studies with two major species (chickens and turkeys for fattening) identified a sufficiently large range of safe levels for the intended diclazuril concentration in feed. The FEEDAP Panel considers that they cover the longer administration time of diclazuril to chickens reared for laying (12 weeks) compared to chickens for fattening.

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

The FEEDAP Panel concludes that diclazuril from Coxiril® at a level of 1.2 mg/kg is safe for chickens reared for laying when applied until 12 weeks of age.

3.2.2. Safety for the consumer

The FEEDAP Panel concluded in 2014 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) and for turkeys for fattening (EFSA FEEDAP Panel, 2014b) does not raise concerns for the consumer safety.

[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2012-0017.pdf

MRLs for Coxiril® for chickens for fattening, turkeys for fattening and guinea fowl were put into force by Regulation (EU) 2015/46[9] (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 115/2013[4] for the use of diclazuril as veterinary medicine in poultry.

There are no MRLs for eggs. Regulation (EC) No 124/2009[10] on setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed established a maximum content of 2 μg/kg wet weight in eggs for diclazuril.

3.2.2.1. Diclazuril carry-over into eggs of laying hens

In order to investigate the potential presence of diclazuril residues in the first eggs (after onset of laying), a study was submitted.[11] A total of 22 chickens reared for laying (6 weeks of age) received complete feeds supplemented with 1.2 mg diclazuril/kg (analytically confirmed) for 6 weeks (until 12 weeks of age). The birds were then fed control feed until the end of the experiment (20 weeks of age). The animals were kept together until the 16th week of age, and then placed in individual cages for egg collection. Two additional birds were fed control feeds all along the experiment.

The first five eggs from the ten experimental hens with earliest onsets of laying (first egg laid at approximately 18th week of age) were collected. The yolk and white of each egg were combined and diclazuril measured using a validated liquid chromatography with tandem mass spectrometry (LC–MS/MS) method with a limit of quantification (LOQ) of 0.5 μg/kg. Residue concentrations in all eggs were below the LOQ.

3.2.2.2. Conclusions on safety for the consumer

Chickens reared for laying are at a similar physiological stage (growth) as chickens for fattening. The use level proposed for diclazuril in feed is the same for both categories of birds. Consequently, the metabolic fate and residue status of this additive described for chickens for fattening (EFSA FEEDAP Panel, 2014a) can be extrapolated to chickens reared for laying.

The FEEDAP Panel confirms its previous assessment of consumer safety for the use of diclazuril from Coxiril® in chickens for fattening and extends it to chickens reared for laying. The same MRLs for tissues as already established by Regulation (EU) 2015/46[9] can be applied.

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 until 12 weeks of age. Therefore, no MRLs for eggs are proposed.

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

The FEEDAP Panel assessed the safety of Coxiril® for the environment when fed to 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).

The former assessments have been reviewed and updated based on more recent information submitted and considering the use of the additive in chickens reared for laying.

[9] OJ L 9, 15.1.2015, p. 5.
[10] Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed. OJ L 40, 11.2.2019, p. 7.
[11] Technical dossier/Supplementary information April 2017/Reference 2.

3.2.4.1. Phase I

Physicochemical properties

The physicochemical properties of diclazuril are summarised in Table 1.

Table 1: Physicochemical properties of diclazuril

Property	Value	Unit
Octanol/water partition coefficient (log K_{ow})[(a)]	3.6	–
Water solubility (20°C)[(b)]	2.638×10^{-3} (pH 5) 2.334×10^{-2} (pH 7) 1.437 (pH 9)	mg/L
Vapour pressure[(b)]	1.21×10^{-22} (20°C) 7.94×10^{-22} (25°C)	Pa
Dissociation constant pKa[(c)]	5.89	–

(a): Technical dossier/Section II.
(b): EFSA FEEDAP Panel, 2015.
(c): https://www.ebi.ac.uk/chembldb/index.php/compound/inspect/CHEMBL284733

The FEEDAP Panel noted that diclazuril is a triazine which can probably be deprotonated to a soluble anionic form at a pH above the pKa value of 5.89. At pH lower than 5.89, diclazuril is present in its neutral form.

Fate and behaviour

Fate in manure

No new data have been provided.

Fate in soil

Adsorption

In its opinion on the use of diclazuril from Coxiril® for rabbits. the FEEDAP Panel noted that values of K_{oc} measured at pH not higher than 7.2 were available (EFSA FEEDAP Panel, 2015). The K_{oc} lowest value used was 4,986.4 mL/g, obtained in five soil types (sand, loamy sand, sandy loam, loam and clay) at different pH values (5.1, 5.5, 6.8, 7.2 and 7.1); the geometric mean of five measurements was 8,822 mL/g.

For the current assessment, the applicant provided a new sorption study performed in soils at higher pH.[12] The Freundlich adsorption of ^{14}C-labelled diclazuril was studied in four soils with pH values ranging from 7.8 till 8.3. At these pH values, the soil with the highest organic carbon content showed the highest K_{oc} and the anionic form of diclazuril is predominant. The geometric mean of the K_{oc} values is 5,962 mL/g organic carbon for the anionic form of diclazuril.

Degradation

The biodegradation of diclazuril was determined in a study performed according to OECD 307 (EFSA FEEDAP Panel, 2015). This study indicated that the biodegradation of diclazuril in soil shows marked pH dependence (EFSA FEEDAP Panel, 2015). At high pH, the anionic form of diclazuril is transformed with a DT_{50} of 70 and 97 days (giving a mean value of 84 days). At low pH, no degradation or transformation was observed at pH 5.1 during 120 days, whereas a slow transformation was observed at pH 5.5 with a half-life of 119 days. This slow transformation might be attributed to the presence of a low percentage of the anionic form since the pH 5.5 is not too far from the pKa. In soil with low pH, the DT_{50} was > 2,120 days at 12°C (1,000 days at 20°C).

Conclusion on fate and behaviour

In high pH soils (well above the pKa of 5.89), diclazuril is present in an anionic form whereas it is present in a neutral form in acid soils. Based on the data available, the FEEDAP Panel noted that the two forms exhibit a different behaviour and should be considered separately. In particular, the neutral form of diclazuril exhibits very low water solubility, high sorption and high persistence in soil; the anionic form on the other hand has much higher solubility and much lower sorption and persistence.

[12] Technical dossier/Supplementary information April 2017/Reference 4.

A DT_{50} of 84 days (corresponding to 178 days at 12°C) and K_{oc} 5,962 mL/g was used for the calculation of the predicted environmental concentration (PEC) for high pH soils; for acid soil the PECs were calculated using a DT_{50} > 2,120 days at 12°C (corresponding to > 1,000 days at 20°C) and a K_{oc} of 8,822 mL/g.

Predicted environmental concentrations

The methodology for the calculation of the maximum PECs in soil, groundwater, surface water and sediment are described in the technical guidance for assessing the safety of feed additives for the environment (EFSA, 2008a). For a highly persistent compound like diclazuril, a refined PEC in soil should be used according to the guidance, giving a $PEC_{plateau}$ in soil, groundwater, surface water and sediment. The input values used for high pH soils (anionic form of diclazuril) were: 1.2 mg/kg feed, molecular weight 407.64, vapour pressure 1.21×10^{-22} Pa, solubility 1.4 mg/L, DT_{50} of 178 days at 12°C (corresponding to 84 days at 20°C) and K_{oc} of 5,962 mL/g. For acid soils (neutral from of diclazuril), the following values were used for the calculations: DT_{50} of > 2,120 days at 12°C (corresponding to > 1,000 days at 20°C), the solubility of 2.638×10^{-3} at pH 5 and the geometric mean K_{oc} of 8,822 mL/g (EFSA FEEDAP Panel, 2015) (Table 2).

Table 2: Initial plateau predicted environmental concentration of diclazuril in soil, sediment (μg/kg), groundwater and surface water (μg/L) for high pH and acid soils

Compartment	$PEC_{plateau}$	
	High pH soils	Acid soils
Soil	8	> 55
Ground water	0.08	> 0.36
Surface water	0.02	> 0.12
Sediment	6	> 6

PEC: predicted environmental concentration.

The Phase I PEC trigger values are not exceeded for high pH soils; therefore, a Phase II assessment is not considered necessary for these soils.

The FEEDAP Panel estimated the $PEC_{plateau}$ acid soil to be above 55 μg/kg. The Panel noted that it is very difficult to estimate a PEC in acid soils since accumulation over the years might occur in soil, while a single liming event might lead to a sudden leaching of diclazuril. The uncertainty of the $PEC_{plateau}$ acid soil estimation is too high to allow for a further comparison with ecotoxicity data for the terrestrial compartment (EFSA FEEDAP Panel, 2015). The same uncertainty applies to the PECs for the aquatic compartment.

3.2.4.2. Conclusions on safety for the environment

The use of diclazuril from Coxiril® in chickens reared for laying at the highest proposed feed concentration 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.

3.3. Efficacy

The efficacy of diclazuril from Coxiril® in preventing coccidiosis in chickens for fattening was assessed in the previous opinion (EFSA FEEDAP Panel, 2014a). The Panel concluded that 'diclazuril from Coxiril® has the potential to control coccidiosis in chickens for fattening at a minimum concentration of 0.8 mg/kg complete feed'. The Panel considers that these conclusions reached in chickens for fattening can be extended to chickens reared for laying.

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[13] and Good Manufacturing Practice.

[13] 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.

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

4. Conclusions

Derived from data already assessed for chickens and turkeys for fattening, diclazuril from Coxiril® is safe for chickens reared for laying up to 1.2 mg/kg complete feed when applied until 12 weeks of age.

The FEEDAP Panel extends its previous assessment of consumer safety for the use of diclazuril from Coxiril® in chickens for fattening to chickens reared for laying. 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 until 12 weeks of age.

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 chickens reared for laying at 1.2 mg/kg complete feed would 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.

Derived from data already assessed for chickens for fattening, diclazuril from Coxiril® has the potential to control coccidiosis in chickens reared for laying at a minimum concentration of 0.8 mg/kg complete feed.

5. Recommendations

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 chickens reared for laying. October 2015. Huvepharma N.V.
2) Coxiril® for chickens reared for laying. Supplementary information April 2017. Huvepharma N.V.
3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Coxiril®.
4) Comments from Member States.

References

EFSA (European Food Safety Authority), 2008a. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. EFSA Journal 2008,6(10):842, 28 pp. https://doi.org/10.2903/j.efsa.2008.842

EFSA (European Food Safety Authority), 2008b. Technical Guidance: microbial studies. EFSA Journal 2008;6 (10):836, 3 pp. https://doi.org/10.2903/j.efsa.2008.836

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011a. Guidance for the preparation of dossiers for coccidiostats and histomonostats. EFSA Journal 2011;9(5):2174, 12 pp. https://doi.org/10.2903/j.efsa.2011.2174

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011b. Technical guidance: tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. https://doi.org/10.2903/j.efsa.2011.2175

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for establishing the safety of additives for the consumer. EFSA Journal 2012;10(1):2537, 12 pp. https://doi.org/10.2903/j.efsa.2012.2537

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance. EFSA Journal 2012;10(6):2740, 10 pp. https://doi.org/10.2903/j.efsa.2012.2740

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014a. Scientific Opinion on the safety and efficacy of Coxiril® (diclazuril) as a feed additive for chickens for fattening. EFSA Journal 2014;12(6):3728, 23 pp. https://doi.org/10.2903/j.efsa.2014.3728

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014b. Scientific Opinion on the safety and efficacy of Coxiril® (diclazuril) as a feed additive for turkeys for fattening. EFSA Journal 2014;12(6):3729, 16 pp. https://doi.org/10.2903/j.efsa.2014.3729

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014c. Scientific Opinion on the safety and efficacy of Coxiril® (diclazuril) as a feed additive for guinea fowl. EFSA Journal 2014;12(6):3730, 13 pp. https://doi.org/10.2903/j.efsa.2014.3730

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

Abbreviations

DT_{50}	period required for 50% dissipation
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LC–MS/MS	liquid chromatography with tandem mass spectrometry
log K_{ow}	octanol/water partition coefficient
LOQ	limit of quantification
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration