CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance acequinocyl[1]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the Netherlands, for the pesticide active substance acequinocyl are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses as an acaricide on ornamentals, apples and pears. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified for all the outdoor uses assessed.

KEY WORDS

Acequinocyl, peer review, risk assessment, pesticide, acaricide

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SUMMARY

Acequinocyl is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC the Netherlands (hereinafter referred to as the 'RMS') received an application from Agro Kanesho Co. Ltd for approval. Complying with Article 6(3) of Directive 91/414/EEC the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2003/636/EC.

The RMS provided its initial evaluation of the dossier on acequinocyl in the Draft Assessment Report (DAR), which was received by the EFSA on 8 March 2005. The peer review was initiated on 15 March 2005 by dispatching the DAR for consultation of the Member States and the applicant Agro Kanesho Co. Ltd. Subsequently the comments received on the DAR were evaluated by the RMS and the need for additional data was agreed in an evaluation meeting in November 2005. Remaining issues, as well as further data made available by the applicant upon request, were evaluated in a series of scientific meetings with Member State experts in November and December 2006. A final discussion of the outcome of the expert consultation took place with representatives from the Member States in November 2007, leading to the conclusion laid down in EFSA Scientific Report (2007) 125, which was finalised on 17 December 2007.

Following the submission of additional information from the applicant, the RMS provided an updated evaluation of the dossier on acequinocyl in the form of Addenda to the DAR, which were received by the EFSA on 15 November 2011. The European Commission requested EFSA to organise a peer review of the updated evaluation and revise its conclusion on acequinocyl. The peer review was initiated on 30 November 2011 by dispatching the Addenda to the DAR for consultation of the Member States and the applicant Agro Kanesho Co. Ltd.

Following consideration of the comments received on the Addenda to the DAR, it was concluded that the EFSA should conduct an expert consultation in the area of ecotoxicology and EFSA should adopt a conclusion on whether acequinocyl can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of acequinocyl as an acaricide on ornamentals, apples and pears, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

A data gaps was set for the section analytical methods. No concerns were identified.

A data gap on the toxicological relevance of the impurities present in the technical material was set in the mammalian toxicology section, but no area of concern was identified.

Based on the available data, the plant residue definition for monitoring and risk assessment, limited to the fruit crop group only, was proposed as acequinocyl. Considering the uses on apple and pear, no chronic or acute risk was identified for the consumers.

The information available on environmental fate and behaviour is sufficient to carry out the necessary environmental exposure assessments for the representative uses at the EU level. For the representative uses assessed, the potential for groundwater exposure by acequinocyl and its major metabolites R1 and AKM-18 above the parametric drinking water limit of 0.1 µg/L, is concluded to be low.

For the representative use on apple and pear orchards a high long-term risk to small granivorous birds, small herbivorous mammals and frugivorous mammals was concluded. In addition, a high risk to aquatic invertebrates was concluded for all FOCUS scenarios even with a 20 m no-spray buffer zone combined with a 20 m vegetative buffer strip (for run-off scenarios) used to mitigate the risk. A high risk to small omnivorous and small herbivorous mammals and aquatic invertebrates was also concluded for the use on outdoor ornamentals. All other areas of the ecotoxicological risk assessment the risk was concluded as low.

For the representative use to outdoor ornamentals a high long-term risk to small omnivorous mammals and small herbivorous mammals was concluded. In addition a high risk to aquatic invertebrates was concluded even with a 15 m no-spray buffer zone as risk mitigation. For all other areas of the ecotoxicological risk assessment the risk as considered low.

A low risk to non-target organisms was concluded for the representative glasshouse use to ornamentals.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC (hereinafter referred to as the 'RMS') received an application from Agro Kanesho Co. Ltd. for approval of the active substance acequinocyl. Complying with Article 6(3) of Directive 91/414/, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2003/636/EC.[6]

The RMS provided its initial evaluation of the dossier on acequinocyl in the DAR, which was received by the EFSA on 8 March 2005 (Netherlands, 2005). The peer review was initiated on 15 March 2005 by dispatching the DAR to Member States and the applicant Agro Kanesho Co. Ltd. for consultation and comments. Subsequently the comments received on the DAR were evaluated by the RMS and the need for additional data was agreed in an evaluation meeting in November 2005. Remaining issues, as well as further data made available by the applicant upon request, were evaluated in a series of scientific meetings with Member State experts in November and December 2006. A final discussion of the outcome of the expert consultation took place with representatives from the Member States in November 2007, leading to the conclusion laid down in EFSA Scientific Report (2007) 125 (EFSA, 2007a), which was finalised on 17 December 2007.

Following the submission of additional information from the applicant, the RMS provided an updated evaluation of the dossier on acequinocyl in the form of Addenda to the DAR, which were received by the EFSA on 15 November 2011. The European Commission requested EFSA to organise a peer review of the updated evaluation and revise its conclusion on acequinocyl. The peer review was

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.

[6] Commission Decision 2003/636/EC of 2 September 2003, recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of potassium phosphite, acequinocyl and cyflufenamid in Annex I of Council Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No L221, 4.9.2003, p. 42-43

initiated on 30 November 2011 by dispatching the Addenda to the DAR for consultation of the Member States and the applicant Agro Kanesho Co. Ltd.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 16 March 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and the EFSA should organise an expert consultation in the area of ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in March/April 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an acaricide on ornamentals, apples and pears, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the Addenda to the DAR,
- the Reporting Table (30 March 2013)
- the Evaluation Table (25 March 2013),
- the report(s) of the scientific consultation with Member State experts (where relevant)
- the comments received on the assessment of the additional information (where relevant)
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of March 2013 containing all individually submitted addenda (Netherlands, 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion. The back ground documents of the Peer Review Report (EFSA, 2007b) and the Final Addendum (Netherlands, 2007) developed and prepared during the course of the initial peer review are made publicly available as part of the documentation to the original conclusion, finalised on 17 December 2007 (EFSA, 2007).

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Acequinocyl is the ISO common name for 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate (IUPAC).

The representative formulated product for the evaluation was "Kanemite", a suspension concentrate (SC) containing 164 g/L acequinocyl.

The representative uses evaluated comprise field and greenhouse foliar spraying to control *Tetranychus urticae* in ornamentals, and foliar spray applications to control *Panonychus ulmi* in apples and pears. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

Acequinocyl was discussed at the PRAPeR Experts' Meeting on physical chemical properties in November 2006 (PRAPeR 06).

The minimum purity of the active substance is 960 g/kg. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of acequinocyl or the representative formulation. The main data regarding the identity of acequinocyl and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of acequinocyl in technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. Appropriate HPLC-MS/MS methods are available for the post-registration monitoring of acequinocyl and its metabolite R1 in apples, oranges, egg-plants and grapes with LOQs of 0.01 mg/kg for both compounds. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Validated analytical methods based on HPLC-MS/MS exist for the determination of acequinocyl, and metabolites R1 and AKM-18 in soil with LOQs of 0.01 mg/kg for each substance. Residues of acequinocyl and metabolite R1 in ground water and surface water can be monitored by HPLC-MS/MS method with LOQs of 0.1 µg/L for each. A HPLC-MS/MS method is available for the determination of acequinocyl and metabolite R1 in air with LOQs of 0.075 mg/m^3 individually. A data gap has been identified for a method for residues in body fluids and tissues as the active substance was classified as toxic (see Section 2).

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Acequinocyl was discussed at the PRAPeR Experts' Meeting on mammalian toxicology (PRAPeR 9) in November - December 2006.

The batches used in the toxicological studies support the technical specification as presented in the revised addendum to Volume 4 of the DAR. However, the toxicological relevance of the individual impurities present in the technical specification has not been addressed.

Acequinocyl and most of its identified metabolites are structure analogues of vitamin K. Therefore, its mechanism of toxicity is probably competitive inhibition of the vitamin K dependent prothrombin synthesis.

Regarding the mammalian metabolism, there are distinct indications of sizeable biliary first pass elimination. However, based on the critical effect of acequinocyl, the extent of oral absorption was considered to represent 28% of the administered dose. Twenty-four hours after dosing, the highest concentrations of radioactivity were found in the gastro-intestinal tract and its contents; excretion occurs predominantly via faeces and no potential for accumulation was observed. Acequinocyl is extensively metabolized with 0-2.5 % parent compound found in urine, bile or faeces.

Low acute toxicity was observed when acequinocyl was administered by the oral and dermal routes. Severe inflammatory reactions were observed in the lungs upon acute exposure through inhalation (aggregates of alveolar macrophages, thickening of alveolar walls, apparent alveolar collapse, bronchiolar epithelial erosion or necrosis, hyperplasia/metaplasia and bronchiolar obliteration/obstruction). Based on these effects (ECHA, 2010), the substance is classified as T; R39/23 in accordance with Directive 67/548/EEC[7], and as STOT SE 1– H370 'Causes damage to organs (lung) after inhalatory exposure' in accordance with the CLP Regulation[8] (3rd ATP[9]). Acequinocyl is not a skin or eye irritant; however classification is required regarding skin sensitisation based on a Maximisation test: Xi; R43 according to Directive 67/548/EEC and Skin Sens. 1 - H317 'may cause an allergic reaction' according to the CLP Regulation.

In repeated dose studies, acequinocyl caused haematological effects (increased platelet levels and blood clotting time) in rats, mice and dogs; in addition, haemorrhagic ocular effects were observed in rats and hepatotoxicity in mice. Based on mortality, liver effects, haemorrhages and haematological effects observed in several species, classification as STOT RE 2 - H373 'May cause damage to organs (blood) through prolonged or repeated exposure' was concluded (ECHA, 2010). The relevant short-term NOAEL was the dose level of 5 mg/kg bw per day derived from the 52-week dog study, and the relevant long-term NOAEL was the dose level of 2.3 mg/kg bw per day derived from the 2-year rat study. No genotoxic or carcinogenic potential was observed.

Acequinocyl showed no effect on fertility parameters up to the highest tested dose of 107 mg/kg bw per day in a 2-generation reproduction toxicity study in rats. The parental and offspring NOAEL were set at 6.9 mg/kg bw per day based on treatment-related haemorrhages and protruding eyes in the adult animals, and haemorrhagic effects and delayed physical and functional development before weaning in pups. In a developmental study in rat, an increased incidence of major abnormalities was observed at the highest dose in the presence of severe maternal toxicity (haemorrhagic effects, thin blood clinical signs and deaths), the maternal NOAEL was 150 mg/kg bw per day and the developmental NOAEL 500 mg/kg bw per day. In rabbits, both the developmental and maternal NOAEL were set at 60 mg/kg bw per day based on clinical signs and pathological findings including intra-uterine haemorrhage, pale liver and lungs, blood in the urine and resorption of foetuses at the top dose level of 120 mg/kg bw per day.

No potential for neurotoxicity was evidenced. Four acute studies in rats and monkey were submitted to investigate the effects of acequinocyl on the blood clotting system resulting in an overall NOAEL of 8 mg/kg bw for prolongation of blood clotting time in rats.

[7] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196, 16.8.1967, p. 1–98.
[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
[9] Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 179, 11.7.2012, p. 3-10.

Toxicological studies were provided on two metabolites, that were found as main faecal metabolites in rats, and were identified in plants, livestock (see section 3) and groundwater (see section 4):

Metabolite AKM-18 presented an acute oral LD_{50} higher than 5000 mg/kg bw in mice; no genotoxic potential was observed in three *in vitro* genotoxicity/clastogenicity studies (point mutation in *S. typhimurium* and *E. coli*, and chromosome aberrations in Chinese hamster lung cells).

Metabolite R1 presented an acute oral LD_{50} higher than 5000 mg/kg bw and an acute dermal LD_{50} higher than 2000 mg/kg bw in rats. No conclusion could be drawn from the *in vitro* genotoxicity studies (point mutation in *S. typhimurium* and *E. coli*, and chromosome aberrations in Chinese hamster lung cells) as the range of concentration used exceeded the precipitation level of the test substance; but an *in vivo* mouse bone marrow micronucleus assay gave negative results.

The acceptable daily intake (ADI) for acequinocyl is 0.023 mg/kg bw per day, based on the NOAEL of 2.3 mg/kg bw per day from the combined chronic toxicity/carcinogenicity study in rats, 100 uncertainty factor (UF) applied. The acute reference dose (ARfD) is 0.08 mg/kg bw based on the overall NOAEL for blood clotting effects of 8 mg/kg bw from the mechanistic studies in rat upon single oral exposure, and a 100 UF. The acceptable operator exposure level (AOEL) is 0.014 mg/kg bw per day, based on the NOAEL of 5 mg/kg bw per day from the one-year dog study, which is supported by the two-generation study in rats, considering an UF of 100 and a correction factor for limited oral absorption of 28 % (overall assessment factor of 357).

Dermal absorption is 3.6 % when handling the concentrate formulation and 16.7 % when handling the spray dilution. Considering the representative outdoor uses of Kanemite SC, the estimated worst case operator exposure is below the AOEL according to the German model, when personal protective equipment (PPE) is worn, such as protective gloves during mixing/loading and gloves, protective coverall, sturdy footwear and broad brimmed headgear during application. Regarding greenhouse applications (on ornamentals), according to a German approach to operator exposure in greenhouse applications (upward spraying) using data by Mich, G. (1996), operator exposure is estimated to be below the AOEL when PPE of gloves during mixing/loading and application and coverall during application are worn. Considering a pre harvest interval (PHI) of 30 days for apples and pears applications, worker exposure for inspection activities is estimated to be lower than the AOEL without considering the use of PPE. Estimated worker exposure after application on ornamentals is below the AOEL when PPE is used (gloves, assuming that arms, body and legs are covered). Exposure of bystanders is estimated to be lower than the AOEL.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports. Acequinocyl was discussed at the PRAPeR Experts' Meeting for residues in November 2006 (PRAPeR 09).

The metabolism of acequinocyl was investigated in the fruit crop group only, on apple, egg plant and orange. In these plants, the metabolic pathway was seen to be similar and proceeds through the hydrolysis of the acetic acid ester to the metabolite R1, followed by the opening of the naphthalenedione ring leading to the metabolite AKM-18 and further hydrolysis of the dodecyl aliphatic chain, resulting in the formation of phthalic acid. Acequinocyl was by far the major component of the radioactive residues, accounting for 28% to 41% TRR in fruits 30 days after application, the other identified metabolites representing less than 10% TRR. Based on these studies, the residue definition for monitoring and risk assessment was proposed as acequinocyl. Although considered as structural analogues of vitamin K, and therefore of a similar toxicity as the parent acequinocyl, metabolites R1 and AKM-18 were not included in the residue definition for risk assessment, having regard to their low relative amounts and considering that they are not expected to increase significantly the toxicological burden of the parent compound. In addition, phthalic acid was not included, due to its lack of specificity and its presence in the environment from other sources.

Supervised residue trials conducted in northern and southern Europe over two growing seasons were provided, where samples were analysed for acequinocyl and its metabolite R1, respectively. Except one location, all trials were performed with a total of two applications, while only one treatment is recommended under the cGAP. These trials were however considered appropriate to derive a MRL for apple as the contribution of the first application to the final residue levels was seen to be negligible. Metabolite R1 was only detected in some rare samples and at levels close to the LOQ of 0.01 mg/kg. These results can be considered as reliable as storage stability studies demonstrated that residues of acequinocyl and metabolite R1 are stable in high water content matrices for at least 18 months when stored at -18°C. Considering the low residue levels in raw commodities and the low consumer exposure, processing studies were not submitted and are not required.

Studies on the residues in rotational crops were not submitted, as pome fruits are perennial crops and since it was accepted that fields used for ornamental crops are not normally planted as part of a rotation with food/feed crops. However, residues in rotational crops have to be considered (at least for the soil metabolite R1), in local situations where certain ornamental crops are commonly rotated with edible crops.

A metabolism study in lactating goat was submitted, although the potential exposure of livestock to acequinocyl residues through consumption of apple pomace was calculated to be below the trigger value of 0.1 mg/kg DM. The metabolic pattern was investigated in liver, kidney and fat, but not in muscle and milk, having regard to the low TRRs observed in these matrices. Parent compound and metabolites R1, AKM-18 and AKM-15 were identified in proportions ranging from 10% to 20% TRR in the different tissues. Based on the representative uses, the setting of MRLs was considered not necessary for products of animal origin and therefore, a residue definition for animal products was not proposed in the course of the peer review.

No chronic or acute concerns were identified for the consumers. Using the EFSA PRIMo model and the MRL value of 0.05 mg/kg proposed for apple and pear, the highest TMDI was calculated to be only 3% of the ADI (DE child) and the highest IESTI, 6% of the ARfD (apple, UK infant).

4. Environmental fate and behaviour

Acequinocyl was discussed at the PRAPeR Experts' meeting on fate and behaviour (PRAPeR 07), in November 2006.

In soil under aerobic conditions acequinocyl exhibits very low to low persistence. The major metabolite was R1 (max 33.8% AR after 2 days) which exhibits low to moderate persistence. A second major metabolite was identified as AKM-18 (max 21.9% AR after 2 days), which exhibited low persistence. Mineralisation to carbon dioxide accounted for 15.0-57.7 % AR after 120/180 days. The formation of unextractable residues (not extracted by acetonitrile/water) was also a significant sink accounting for 46.3% AR after 120 days. Under anaerobic soil conditions no novel breakdown products were identified. Photolysis at the soil surface is a process that can contribute to the transformation of acequinocyl. Acequinocyl and these major metabolites can be considered immobile in soil. There was no indication that adsorption of either acequinocyl or metabolites R1 and AKM-18 was pH dependent. In field dissipation studies from 3 sites in the USA acequinocyl exhibited very low persistence. The metabolite AKM-18 was only incidentally found within the first 15-72 hours. R1 though analysed for was not detected (LOQ= 0.01mg/kg). The necessary soil exposure assessments (Predicted environmental concentrations (PEC) calculations) can be found in Appendix A

Under sterile aqueous photolysis conditions acequinocyl was impersistent forming the metabolite AKM-18. In the aerobic water/sediment studies acequinocyl dissipated rapidly from the water by partitioning to sediment (max 26.4% AR after 1d). Unextracted sediment residues (not extracted by acetonitrile followed by acetonitrile/water) were a significant sink for radioactivity, representing 59.7-

62.0% AR after 30-60 days, reducing to 46-56 % AR after 100 days. In the whole system acequinocyl exhibited very low persistence also forming the metabolites R1 and CBAA, being major in the water phase (max 12 and 11.3 % AR respectively) and metabolite AKM-18 in the sediment phase (max 19%). Mineralisation to carbon dioxide accounted for 30-33 % AR after 120/180 days. Surface water and sediment exposure assessments (PEC calculations), were carried out for the representative use on pome fruit for acequinocyl and the metabolites R1 and CBAA using the FOCUS (FOCUS, 2001) step 3 and step 4 approach[10]. Metabolite R1 was simulated as if applied as active substance (dose rate adjusted for maximum observed formation) to soil, with no spray drift entry. The same was done for CBAA except only spray drift entry was simulated, with there being no input of pesticide mass to TOXSWA from the soil column (which is appropriate as CBAA was not identified as a major transformation product in the available soil incubations). Acequinocyl was simulated using the standard approach with inputs via both spray drift and from the soil column being parameterised. Where drift was simulated, 'late' spray drift values were used. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 71 – 90.7 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80 % and erosion run-off by 95%) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in these simulations. For the uses on ornamentals in the field, only the spray drift route of entry to a static 30 cm deep water body was considered when calculating PEC surface water, using the approach outlined in European Commission (2001) guidance with no-spray drift buffer zones of up to 15m being implemented (which respects the FOCUS, (2007) guidance that sets a ceiling of 95% on the mitigation of the spray drift route of entry). For the representative protected use, the necessary surface water exposure assessments (PEC) were appropriately calculated on the basis of a 0.1 % and 0.2 % emission of acequinocyl from greenhouses being re-deposited on an adjacent static 30 cm deep surface water body. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in FOCUS (2008) guidance as being appropriate. The 0.1% emission assumption is associated with standard hydraulic spray application equipment and the 0.2% emission assumption is associated with ultra low volume application techniques. All these PEC except the sediment PEC at FOCUS step 3 and 4 are included in Appendix A. Though Appendix A does not include any PEC in sediment, exceptionally this was considered not essential in this case for the representative uses at the EU level. This exception was accepted as the risk characterisation to sediment dwelling organisms was completed with a water spiked effects study design, the GAP outdoors only includes a single application (so a single dose in the effects study can be considered comparable) and the strong soil adsorption of acequinocyl and AKM-18 in combination with the very low or low persistence in soil of these compounds means multiple inputs into an individual edge of field surface water body would not be expected. Therefore the risk characterisation to sediment-dwellers was completed using the maximum PEC in the water column for acequinocyl. This was also considered to cover the risk from exposure to AKM-18, due to the rapid sterile hydrolysis of acequinocyl to AKM-18 that would have occurred in the available acequinocyl water spiked effects sediment-dweller study.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the model PEARL 1.1.1[11] for the active substance acequinocyl. Since FOCUS PEARL has no standard scenario for ornamentals, scenarios for strawberries, vines and sunflowers were selected. Simulations were performed for a single application of 281 g a.s./ha on apples and for a single application of 600 g a.s./ha on ornamentals on May 1st (early application) and September 1st (late application). PECgw values for the soil major metabolites R1 and AKM-18 were calculated assuming that the metabolites are formed at a maximum of respectively 33.8% and 21.9% of the applied dose. The predicted annual average concentrations of acequinocyl and its metabolites R1 and AKM-18 in leachate leaving the top 1 m soil column were estimated to be < 0.001 µg/L at all

[10] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7
[11] Simulations used Q10 of 2.2 and Walker equation coefficient of 0.7

FOCUS groundwater scenarios (significantly less than the parametric drinking water limit of 0.1 µg/L).

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001), and EFSA (2009).

Using the 'Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC' (European Commission, 2002c), the acute and short-term (birds only) risk to birds and mammals from dietary exposure was assessed as low based on the first tier risk assessment. However, the long-term risk to birds and mammals from dietary exposure indicated a high risk at the first tier. Further long-term risk assessments, performed in accordance with the 'Risk Assessment for Birds and Mammals' (EFSA, 2009) guidance document, were available and indicated a high risk to several of the tier-1 generic focal species. A refined risk assessment for a 'small insectivorous bird' foraging in apple and pear orchards was discussed during the Pesticides Peer Review Experts' Teleconference 74 (September, 2012). The experts agreed that the blue tit was a suitable focal species and, on the basis of available data, a refined 90th percentile PT (proportion of active time spent in the field) value was used in the risk assessment. In addition, the TWA (time-weighted average) factor was refined using a DT_{50} value on insects. On the basis of the available information a low risk to small insectivorous birds foraging in apple and pear orchards was concluded. No ecological data were available for small insectivorous birds in ornamentals; however, it was proposed to use the same refined parameters discussed above for orchards. The resulting TER value was less than the trigger value, however, the experts at the Teleconference 74 (September, 2012) considered that a low risk could be concluded on the basis of a weight-of-evidence approach. The first-tier TER value for the generic focal species, 'small granivorous bird', resulted in a TER value less than the trigger indicating a high risk. No refined risk assessment was available and therefore a data gap was concluded to address the long-term risk to small granivorous birds (relevant for the representative use in apple and pear orchards).

For the representative use in apple and pear orchards, a low risk was concluded for the generic focal species 'large herbivorous mammal' and the 'small omnivorous mammal'. However, the first-tier assessment indicated a high long-term risk to a 'small herbivorous mammal' and a 'frugivorous mammal'. No further data were available to refine the risk assessment and therefore a data gap was concluded to address the long-term risk to small herbivorous mammals and frugivorous mammals relevant for the representative use in apple and pear orchards. For the representative use in outdoor ornamentals, a low risk to the 'small insectivorous mammal' was concluded. However, the risk assessment for the 'small omnivorous mammal' (earlier growth stages) and 'small herbivorous mammal' (all growth stages) indicated a high risk. No further data were available to refine the risk assessment and therefore a data gap was concluded to address the risk to small omnivorous mammals and small herbivorous mammals (relevant for the representative use on outdoor ornamentals).

The first-tier risk assessment for earthworm-eating birds and earthworm-eating mammals resulted in TERs below the trigger of 5 indicating a high risk. A refined risk assessment was based on an experimentally derived bioconcentration factor (BCF) for earthworms was available and was sufficient to conclude a low risk. The risk from secondary poisoning of fish-eating birds and mammals was assessed as low. No major plant metabolites were found in the residue studies and hence the risk from plant metabolites to herbivorous birds and mammals is considered as low. A low risk to birds and mammals was concluded for the representative glasshouse use on ornamentals.

For the representative use in orchards a low risk to fish, algae and sediment-dwelling organisms was concluded. Using FOCUS Step 4 surface water PEC values (risk mitigation of 20 m no-spray buffer zone combined with a 20 m vegetative buffer strip for run-off scenarios), a high acute and chronic risk to aquatic invertebrates was indicated. A microcosm study was available and was discussed at the PRAPeR 08 Experts' Meeting on ecotoxicology (November, 2006). It was concluded that the $NOEC_{population}$ should be used for risk assessment and the associated trigger value should be between 3 and 5. Assuming a trigger value of 5 and FOCUS Step 4 PEC values, the resulting TER values for all FOCUS scenarios (for the worst-case water body) indicated a high risk to aquatic invertebrates. Therefore, a high risk to aquatic invertebrates was concluded. A data gap was identified to address the risk to aquatic invertebrates for the representative use in apple and pear orchards.

For the representative use on outdoor ornamentals only spray-drift PEC values were available. Using the available PEC values a low risk to fish, algae and sediment-dwelling organisms was concluded. With a 15 m no-spray buffer zone a high acute and chronic risk to aquatic invertebrates was indicated. Using the microcosm study $NOEC_{population}$ with a trigger value of 5 a high risk to aquatic invertebrates was indicated for outdoor ornamentals even with a 15 m no-spray buffer zone as risk mitigation. Therefore, a data gap was concluded to address the risk to aquatic invertebrates for the representative outdoor use on ornamentals.

The major metabolites in the water phase (R1 and CBAA) were tested with fish indicating a low toxicity. No studies were conducted with invertebrates or algae. However, it was considered possible that the metabolites could have been formed in the microcosm study. Hence the risk from these metabolites to invertebrates and algae is likely to be covered by the risk assessment for the active substance based on the microcosm endpoint. Metabolite AKM-18 is a major sediment metabolite. No toxicity data were available to perform a risk assessment, however, the risk was concluded to be low as it was expected to have been formed via hydrolysis in the toxicity study with *Chironomus riparius* performed with the parent, acequinocyl (see section 4).

A low risk to fish, algae, sediment-dwelling organisms and aquatic invertebrates was concluded for the representative glasshouse use on ornamentals.

The risk to bees, other non-target arthropods, earthworms, other soil non-target macro and microorganisms, non-target plants and biological methods of sewage treatment was assessed as low.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
acequinocyl	Very low to low persistence 1st order DT_{50lab} = 1.1 – 2.7 d (20ºC and 40% MWHC) 1st order $DT_{50field}$ = 0.09-0.26 d	Low risk to earthworms and soil micro organisms
R1	Low to moderate persistence 1st order DT_{50lab} = 2.0 – 33 d (20ºC and 40% MWHC)	No tests available. Potential adverse effects on earthworms and soil micro organisms are covered by the risk assessment for acequinocyl.
AKM-18	Low persistence 1st order DT_{50lab} = 3.5 d (20ºC and 40% MWHC)	No tests available. Potential adverse effects on earthworms and soil micro organisms are covered by the risk assessment for acequinocyl.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
acequinocyl	Immobile (K_{doc} = 39900 – 123000 L/kg)	No	Yes	Yes	High acute risk to aquatic invertebrates for the surface water risk assessment.

R1	Immobile (K_{Foc} = 9000 – 230000 L/kg)	No	No data available	Yes, based on the existing classification of the parent compound as ‘toxic’, R39/23 (ECHA 2010) Low acute oral and dermal toxicity Unlikely to be genotoxic	Low risk to aquatic organisms concluded for the surface water risk assessment.
AKM-18	Immobile (K_{Foc} = 9697 – 52750 L/kg)	No	No data available	Yes, based on the existing classification of the parent compound as ‘toxic’, R39/23 (ECHA 2010) Low acute oral toxicity Unlikely to be genotoxic	No data available

6.3. (Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
acequinocyl (water and sediment)	High risk to aquatic invertebrates. Low risk to fish, algae and sediment-dwelling organisms.
R1 (water)	Low toxicity and risk to fish. No studies conducted with invertebrates or algae. However the risk assessment covers potential adverse effects on algae and invertebrates since it is based on a microcosm endpoint.
CBAA (water)	Low toxicity and risk to fish. No studies conducted with invertebrates or algae. However the risk assessment covers potential adverse effects on algae and invertebrates since it is based on a microcosm endpoint.
AKM-18 (sediment)	No test with AKM-18 is available. However it is likely that the metabolite was formed in the test with acequinocyl and *Chironomus riparius* and hence the risk is considered to be covered by the endpoint derived in the test.

6.4. Air

Compound (name and/or code)	Toxicology
acequinocyl	Rat LC_{50} inhalation > 0.84 mg/L air (4h, nose-only); R39/23 'toxic: danger of very serious irreversible effects through inhalation'

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Analytical method for residues in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 1 and 2)
- The toxicological relevance of the impurities present in the technical specification has not been addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2)
- Information to address the long-term risk to small granivorous birds (relevant for use in apple and pear orchards; submission date proposed by the applicant: unknown; see section 5).
- Information to address the long-term risk to small herbivorous mammals and small frugivorous mammals (relevant for use in apple and pear orchards; submission date proposed by the applicant: unknown; see section 5).
- Information to address the long-term risk to small omnivorous mammals and small herbivorous mammals (relevant for use on outdoor ornamentals; submission date proposed by the applicant: unknown; see section 5).
- Information to address the risk to aquatic invertebrates (relevant for use in apple and pear orchards and outdoor ornamentals; submission date proposed by the applicant: unknown; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Worst case scenario of operator exposure is estimated to be lower than the AOEL when PPE as protective gloves are used during mixing and loading operations and when gloves, protective garment, sturdy footwear and broad brimmed headgear are used during application, according to the German model (see section 2).
- Worker re-entry exposure after application on ornamentals (outdoor and in greenhouses) is estimated to be lower than the AOEL when PPE is used, as protective gloves and assuming that arms, body and legs are covered (see section 2).
- If there are some local situations where certain ornamental crops are commonly rotated with edible crops, a plant back period might be considered.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

None.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

None.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Ornamentals glasshouse**	**Ornamentals field**	**Apple/pear**
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified		X	X
	Assessment not finalised			
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Risk to aquatic organisms	Risk identified		X	X
	Assessment not finalised			
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised			

Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached			
	Assessment not finalised			
Comments/Remarks				

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

The list of endpoints has been copied from the EFSA conclusion (published 29 January 2008): EFSA Scientific Report (2007) 125, 1-79 (revision of 10 January 2008)

Revisions based on submitted risk refinements (see addendum October 2011) are highlighted

Revisions based on the reporting and evaluation table (July 2012) are highlighted

Revisions after the Pesticide Peer review Meeting TC 74 (see also addenda of July 2012 and October 2012) are highlighted

Revisions based on the fate addendum (December 2012) are highlighted

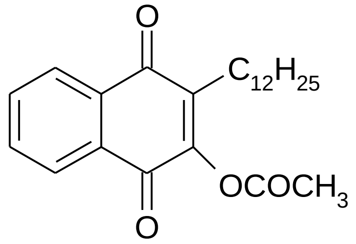
EFSA December 2012

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Acequinocyl
Function (e.g. fungicide)	Acaricide

Rapporteur Member State	The Netherlands
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate
Chemical name (CA) ‡	2-(acetyloxy)-3-dodecyl-1,4-naphtalenedione
CIPAC No ‡	760
CAS No ‡	57960-19-7
EC No (EINECS or ELINCS) ‡	None
FAO Specification (including year of publication) ‡	Not established
Minimum purity of the active substance as manufactured ‡	Minimum 96%
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	~~No relevant impurities~~ Open
Molecular formula ‡	$C_{24}H_{32}O_4$
Molecular mass ‡	384.5 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	59.6 °C (99.5%)
Boiling point (state purity) ‡	It was concluded that the substance has no boiling point below 200°C, as decomposition takes place above 200°C.
Temperature of decomposition (state purity)	At 200°C the test substance changed colour to brown and to black at 300°C. No bubbles where visible. It was concluded that the substance has no boiling point below 200°C, as decomposition takes place above 200°C
Appearance (state purity) ‡	Light brown flakes (98.25%) Soft yellow crystals (99.9%)
Vapour pressure (state temperature, state purity) ‡	1.69×10^{-6} Pa (25°C)
Henry's law constant ‡	9.7×10^{-2} Pa.m^3/mol
Solubility in water (state temperature, state purity and pH) ‡	6.69×10^{-6} g/L (25°C) Not pH dependent
Solubility in organic solvents ‡ (state temperature, state purity)	Solvent — Solubility g/L (20°C) methanol 6.1 acetone > 250 heptane 36.0 1-octanol 29.2 1,2-dichloroethane > 250 ethyl acetate > 250 xylene >250
Surface tension ‡ (state concentration and temperature, state purity)	Not determined (solubility in water is < 1 mg/L)
Partition co-efficient ‡ (state temperature, pH and purity)	Log Kow > 6.2 (25°C) Not pH dependent
Dissociation constant (state purity) ‡	No dissociation, at least within the range of pH 3 - 10
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	see table below
Flammability ‡ (state purity)	Not highly flammable

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH):

	λmax (nm)	ε (L.mol^{-1}.cm^{-1})
Acidic (0.1 M HCL in methanol/ water 90/10)	242	16524
	248	16989
	270	13905
	335	2836
Neutral (methanol/ water 90/10)	242	16582
	248	16873
	270	13207
	271	2851
Basic (0.1 M NaOH in methanol/water 90/10)	232	19055
	245	13149
	275	2172
	362	8999

Explosive properties ‡ (state purity)	No explosive properties
Oxidising properties ‡ (state purity)	Non-oxidising

Summary of representative uses evaluated (*acequinocyl*)*

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	Interval between applications (min)	g as/hL min-max (l)	Water L/ha min-max	g as/ha min-max (l)		
Ornamentals	NL, DE, FR, DK, BE	KANEMITE	G	*Tetranychus urticae*	SC	164	spraying	BBCH 30-80	1-3	7 d	15-30	1000-2000	150-600	n.a.	
Ornamentals	NL, DE, FR, DK, BE	KANEMITE	F	*Tetranychus urticae*	SC	164	spraying	BBCH 30-80	1		15-30	1000-2000	150-600	n.a.	
Apple/Pear	NL, DE, FR, DK, BE, IT, ES, GR, UK, AU, PT	KANEMITE	F	*Panonychus ulmi*	SC	164	spraying	BBCH ~~52~~ 57-77	1		15-19	1000-1500	150-281	30	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Reversed Phase-HPLC UV (235 nm)
Impurities in technical as (analytical technique)	Reversed Phase-HPLC UV (235 nm)
Plant protection product (analytical technique)	Reversed Phase-HPLC UV (235 nm)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Acequinocyl
Food of animal origin		Not necessary considering that livestock exposure is very low
Soil		Acequinocyl
Water	surface	Acequinocyl
	drinking/ground	Acequinocyl
Air		Acequinocyl

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS; LOQ: 0.01 mg/kg (acequinocyl and metabolite R1 separately, apples, oranges, egg plant, grapes) ~~*ILV required*~~
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method for animal products is required as no MRL is set
Soil (analytical technique and LOQ)	HPLC-MS/MS, LOQ: 0.01 mg/kg (acequinocyl and metabolites R1 and AKM-18 individually)
Water (analytical technique and LOQ)	HPLC-MS/MS, LOQ: 0.1 µg/L (acequinocyl and metabolite R1 individually, in surface, drinking and ground water) ~~*Validated method for CBAA in surface water is required*~~.
Air (analytical technique and LOQ)	HPLC-MS/MS, LOQ: 0.075 mg/m^3 (acequinocyl and metabolite R1 individually)
Body fluids and tissues (analytical technique and LOQ)	Not relevant, acequinocyl is not a toxic compound.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	No classification is proposed

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	At least 28%, after low dose, 48h after administration, based on radiolabel recovered from urine, bile, cage wash and carcass (rat). At least 4.8%, after high dose, 48h after administration, based on radiolabel recovered from urine, bile, cage wash and carcass (rat).
Distribution ‡	24 hours after single oral low dose (10 mg/kg bw), highest concentrations GI-tract and its contents; intermediate concentrations were in fat, kidneys, liver, lungs, lymph nodes, pancreas, pituitary, skin, uterus and whole blood.
Potential for accumulation ‡	No evidence of accumulation.
Rate and extent of excretion ‡	Within 24 h ca. 75% of low dose was excreted and ca. 40% of high dose; within 120 h ca. 95% was excreted, after oral high and low dose, mainly via faeces (ca. 87%).
Metabolism in animals ‡	Extensively metabolised (no parent compound in urine, 2% parent compound of total radiolabel in faeces and 2.5% of total radiolabel in bile).
Toxicologically relevant compounds ‡ (animals and plants)	Acequinocyl
Toxicologically relevant compounds ‡ (environment)	Acequinocyl

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 0.84 mg/L air /4h (aerosol, nose only)	**T; R39/23** **STOT SE 1 - H370**
Skin irritation ‡	Non-irritatant	
Eye irritation ‡	Non-irritatant	
Skin sensitisation ‡	Sensitising (Maximisation test)	**Xi; R43** **Skin Sens. 1 - H317**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Blood (prolongation of blood clotting time, increased platelet levels) in rats, mice and dogs;

	Ocular heamorrage in rats; Liver (increased liver weight and hepatocyte vacuolation) in mice.	
Relevant oral NOAEL ‡	1-year, dog: 5 mg/kg bw per day 90-day, rat: 30 mg/kg bw per day 90-day, mouse: LOAEL 16 mg/kg bw per day	**STOT RE 2 – H373**
Relevant dermal NOAEL ‡	28-day, rat: 200 mg/kg bw per day	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Blood (prolongation of blood clotting time, increased platelet levels) in rats and mice; Ocular effects in rats; Liver (increased incidence of brown pigmented and inflamatory cells, generalised fat and increased enzyme activity in mice.	
Relevant NOAEL ‡	2.3 mg/kg bw per day (2-year, rat) 2.7 mg/kg bw per day (80-week, mouse)	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: haemorrhages and protruding eyes; Offspring: haemorrhagic effects, delayed physical and functional development before weaning at parental toxic doses; No reproductive effects.	
Relevant parental NOAEL ‡	6.9 mg/kg bw per day	
Relevant reproductive NOAEL ‡	107 mg/kg bw per day (the highest dose tested)	
Relevant offspring NOAEL ‡	6.9 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal: haemorrhagic effects and thin blood; Developmental: increased number of major abnormalities in presence of severe maternal	

	toxicity, including mortality. Rabbit: Maternal: intra-uterine haemorrhage, pale liver and lungs, blood in urine and resorption of foetuses; Developmental: increased incidence of 13th rib at maternal toxic doses, including mortality.	
Relevant maternal NOAEL ‡	Rat: 150 mg/kg bw per day Rabbit: 60 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat: 500 mg/kg bw per day Rabbit: 60 mg/kg bw per day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data – not required	
Repeated neurotoxicity ‡	No data – not required	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Acute effects on blood clotting: Single oral administration of acequinocyl in doses ranging from 20 to 600 mg/kg bw to rats causes transient prolongation of blood clotting time (effects within 1 to 6 hours and ceased after 48 hours). An overall NOAEL for blood clotting effects of 8 mg/kg bw was established. Single oral administration of acequinocyl to rhesus monkeys in a dose of 1000 mg/kg bw seemed to produce minor increases in PT (prothrombin time) and PTT (partial thromboplastin time); no well founded conclusion possible.
Studies performed on metabolites or impurities ‡	**AKM-18**: Mouse oral LD_{50} > 5000 mg/kg bw Negative Ames test and negative *in vitro* chromosome aberration test. **R1**: Rat oral LD_{50} > 5000 mg/kg bw Rat dermal LD_{50} > 2000 mg/kg bw Negative *in vivo* micronucleus test (mouse bone marrow)

Medical data ‡ (Annex IIA, point 5.9)

	No evidence of adverse effects in plant manufacturing personnel over a period of three years

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.023 mg/kg bw per day	2-year, rat	100
AOEL ‡	0.014 mg/kg bw per day	1-year, dog supported by 2-generation, rat	357* (100 + 28%*)
ARfD ‡	0.08 mg/kg bw	mechanistic studies, single dose, rat	100

* Corrected by 28% oral absorption

Dermal absorption ‡ (Annex IIIA, point 7.3)

Kanemite (164 g acequinocyl/L SC formulation)	3.6% (undiluted formulation) 16.7% (diluted formulation) based on *in vitro* (human, rat) and *in vivo* studies (rat) conducted with acequinocyl diluted in blank formulation

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Outdoor, high crop tractor mounted, application rate 0.6 kg acequinocyl/ha (ornamentals) % of AOEL *UK POEM* Without PPE: 2489 With PPE (gloves during M/L & appl): 651 *German model* Without PPE: 992 With PPE (gloves during M/L & applic, coverall, sturdy footwear & broadbrimmed headgear during appl – appl high crops): 98.4 Outdoor, high crop tractor mounted, application rate 0.281 kg acequinocyl/ha (apples/pears) % of AOEL *UK POEM* Without PPE: 645 With PPE (gloves during M/L & appl): 343 *German model* Without PPE: 465 With PPE (gloves during M/L & applic and coverall & sturdy footwear during appl): 69 Outdoor,field crop tractor mounted, application rate 0.6 kg acequinocyl/ha (ornamentals) % of AOEL *UK POEM* Without PPE: 5893 With PPE (gloves during M/L & appl): 325 *German model*

	Without PPE: 524.9 With PPE (gloves during M/L & applic and coverall & sturdy footwear during appl): 32.4 Outdoor, high crop hand held: not considered Indoor, up and downward hand held, application rate 0.6 kg acequinocyl/ha (ornamentals) % of AOEL *Dutch model* Without PPE: 2102 With PPE (gloves & coverall): 210 *German model (M/L) and data by Mich (1996) (application)* Without PPE: 1455 With PPE (gloves during M/L & appl and coverall during appl): 33
Workers	In apples/pears, PHI is 30 days, so re-entry shortly after application refers only to inspection activities. Workers are assumed to have arms, body and legs covered. Re-entry activities in apple/pear, based on field studies and EUROPOEM II, re-entry at day 3 (1h exposure) Without PPE: 31% of AOEL With PPE (gloves): 3% of AOEL Re-entry activities in apple/pear, based on field studies and EUROPOEM II, re-entry at day 0 (1h exposure) Without PPE: 39% of AOEL With PPE (gloves): 4% of AOEL Re-entry activities in ornamentals outdoors, based on field studies and EUROPOEM II (6h exposure) Without PPE: 500% of AOEL With PPE (gloves): 50% of AOEL Re-entry activities in ornamentals indoors, based on field studies and EUROPOEM II (6h exposure) Without PPE: 500% of AOEL With PPE (gloves): 50% of AOEL
Bystanders	Apple/pear: 48% of AOEL Ornamentals outdoors: 10% of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation[12], 3rd ATP[13]):
Acequinocyl	In accordance with the CLP Regulation: Skin Sens. 1 – H317 'May cause an allergic skin reaction' STOT SE 1 – H370 'Causes damage to organs (lung) (if inhaled)' STOT RE 2 – H373 'May cause damage to organs (blood system) through prolonged or repeated exposure' In accordance with Directive 67/548/EEC[14]: T 'Toxic' R39/23 'Toxic: danger of very serious irreversible effects through inhalation' Xi 'Irritant' R43 'May cause sensitisation by skin contact'

[12] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[13] Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. OJ L 179, 11.7.2012, p. 3-10.

[14] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196, 16.8.1967, p. 1–98.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruit crops (apple, orange, egg plant)
Rotational crops	Not applicable due to the representative uses
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable (representative uses on perennial crops only)
Processed commodities	Not required (low residue levels in raw commodities)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	acequinocyl
Plant residue definition for risk assessment	acequinocyl
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	No study required considering the representative uses One study on lactating ruminants available
Time needed to reach a plateau concentration in milk and eggs	Milk: not determined (above 5 days)
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (in principle. However, no residues expected)

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	To be evaluated at member state level depending on rotational practices of ornamentals at national level.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

	Acequinocyl residues stable at least 18 months in apple fruit when stored at -18°C

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	Not under livestock exposure resulting from representative uses		
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

Summary of residues data according to the representative uses on raw agricultural commodities and feeding stuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according representative use	HR (c)	STMR (b)
Apples	NEU and SEU	**NEU:** 3x <0.01; 2x 0.011; 0.014; 0.039; 0.042 **SEU:** 2x <0.01; 0.011; 0.012; 0.013; 0.014; 0.018; 0.025; 0.026; 0.030	Except one trial, all the other ones were conducted with two treatments (instead of a single application as stated in the cGAP). However, due to the fast decline of the residues, no significant contribution of the first application to the finally residue levels is expected at the intended PHI and therefore, these trials were considered for the MRL calculation (merged NEU and SEU datasets): R_{ber}: 0.05 mg/kg R_{max}: 0.04 mg/kg Extrapolation to pears	0.05	0.042	0.013

(a) Numbers of trials in which particular residue levels were reported e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 0.17

(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	**0.023 mg/kg bw per day**
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 3% ADI (DE, Child)
TMDI (% ADI) according to WHO European diet	Calculation not necessary
TMDI (% ADI) according to national diets	Calculation not necessary
IEDI (WHO European Diet) (% ADI)	Calculation not necessary
NEDI (specify diet) (% ADI)	Calculation not necessary
Factors included in IEDI and NEDI	no
ARfD	**0.08 mg/kg bw**
IESTI (% ARfD) according to EFSA PRIMo Model	Highest IEDI: 6% ARfD (Apple, UK infant)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Calculation not necessary
Factors included in IESTI and NESTI	MRL, variability factor of 5, no processing factor

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
No processing studies are required, since human TMDI accounts for less than 10% of the ADI.				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Apples	0.05 mg/kg
Pears	0.05 mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	39.2 – 57.7% a.r. after 120/180d [14C-Phenyl] label (n=4), normal application rate (0.5 mg/kg), 20°C 43.9 – 45.8% a.r. after 180d [14C-Dodecyl] label (n=2), normal application rate (0.5 mg/kg), 20°C 15.0 – 15.9% a.r. after 176/309d [14C-Phenyl] label (n=2), high application rate (20 mg/kg), 20°C 15.1% a.r. after 176d [14C-Dodecyl] label (n=2), high application rate (20 mg/kg), 20°C 26.6% a.r. after 120d [14C-Phenyl] label (n=1), normal application rate (0.5 mg/kg), 10°C Sterile conditions: < 0.1% a.r. after 90d [14C-Phenyl] label (n=1), normal application rate (0.5 mg/kg), 20°C
Non-extractable residues after 100 days ‡	25.1 – 46.3% a.r. after 120/180d [14C-Phenyl] label (n=4), normal application rate (0.5 mg/kg), 20°C 30.6 – 41.3% a.r. after 180d [14C-Dodecyl] label (n=2), normal application rate (0.5 mg/kg), 20°C 55.9% a.r. after 120d [14C-Phenyl] label (n=1), normal application rate (0.5 mg/kg), 10°C Sterile conditions: 7.8% a.r. after 90d [14C-Phenyl] label (n=1), normal application rate (0.5 mg/kg), 20°C
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	R1 (2-dodecyl-3-hydroxy-1,4-naphtalenedione) - 15.7 – 33.8% a.r. after 2 – 10d (n = 4) AKM-18 (2-(1',2'-dioxotetradecyl) benzoic acid) 4.3 – 21.9% a.r. after 2 – 7d (n = 4) [14C-Phenyl] and [14C-Dodecyl] labels

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	2.8% after 365d
Non-extractable residues after 100 days	5.1% a.r. after 365d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	R1 – 41.1% a.r. after 7d AKM-18 – 23.2% a.r. after 269d [14C-Phenyl] label
Soil photolysis ‡	Mineralisation – 3.0% after 13d Non-extractable residues 12.9% a.r. after 13d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Metabolites (Irradiated test) AKM-18 – 23.7% a.r. after 6d Metabolite A – 13.8% a.r. after 2d Polars – 26.2% a.r. after 13d [^{14}C-Phenyl] label Metabolites (Non-Irradiated test) R1 – 10.4% a.r. after 13d

	AKM-18 – 46.1% a.r. after 6d Metabolite A – 15.9% a.r. after 13d Polars – 23.4% a.r. after 13d [^{14}C-Phenyl] label

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	first-order kinetics
Laboratory studies (range or median, with n value)	Parent DT50lab (20ºC, aerobic): 1.1 - 2.7d (n = 4, r^2 = 0.87 – 0.97); mean 2d R1: DT50lab (20ºC, aerobic): 2.0 – 33 d (n = 4); mean 12.7d AKM-18: DT50lab (20ºC, aerobic): 3.5d (n = 1)
	Parent DT90lab (20ºC, aerobic): 3.6 - 8.9 days (n = 4, r^2 = 0.87 – 0.97) according to DT50 quoted above); mean 6.6d. R1: DT90lab (20ºC, aerobic): 6.6 – 108 days (n = 4); mean 41.8 d AKM-18: DT90lab (20ºC, aerobic): 12d (n = 1)
	DT50lab (10ºC, aerobic): 1.8d (n = 1, r^2 = 0.90)
	DT50lab (20ºC, anaerobic): 1.8d (n = 1, r^2 = 0.87)
	Degradation in the saturated zone: no data submitted and no data required.
Field studies (state location, range or median with n value)	Parent: $DT50_f$: California (US), bare soil, 2.9h (n = 1, r^2 = 0.95) 1st order, New York (US), bare soil, 2.2h (n = 1, r^2 = 0.90) 1st order, Georgia (US), bare soil, 6.2h (n = 1, r^2 = 0.94) 1st order Metabolite R1: $DT50_f$: California (US), bare soil, 2.8h (n = 1, r^2 = 0.95) 1st order, New York (US), bare soil, 7.2h (n = 1, r^2 = 0.90) 1st order, Georgia (US), bare soil, 3.5h (n = 1, r^2 = 0.94) 1st order
Soil accumulation and plateau concentration	Plateau concentration not relevant, due to very high dissipation rate.

Soil adsorption/desorption (Annex IIA, point 7.1. 2, Annex IIIA, point 9.1.2)

K_f / K_{oc}	K_{oc}: parent 39900 – 123000 L/kg (mean 66033 L/kg, 1/n could not be determined, 3 soils) Kf_{oc} R1: 9000 – 230000 L/kg (mean 100666 L/kg, 1/n = 0.6 – 1.0, 3 soils) Kf_{oc} AKM-18: 9697 – 67000 L/kg (mean 43081 L/kg, 1/n = 1.30 – 1.62, 4 soils) indicative values only
K_d	K_d: parent 678 –1620 L/kg (mean 1020 L/kg, 3 soils) R1: 72 – 3400 L/kg (mean 1284 L/kg, 3 soils) AKM-18: 201 – 686 L/kg (mean 355 L/kg, 4 soils) indicative values only

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No data, not required

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Guideline: BBA Guidelines, Part IV, 4-2 Precipitation (mm): 200 mm Time period (d): 2d Leachate: < 1% a.r. total residues/ radioactivity in leachate in three soils, 4% a.r. total residues/ radioactivity in leachate in one soil, which was later identified as polar radioactive material > 74% total residues/ radioactivity retained in top 10 cm.
Aged residues leaching ‡	Guideline: BBA Guidelines, Part IV, 4-2 Precipitation (mm): 200 mm Time period (d): 2d Leachate: < 1% a.r. total residue / radioactivity in leachate > 73% total residues/ radioactivity retained in top 5 cm.
Lysimeter/ field leaching studies ‡	No data submitted and no data required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50}: 2.7 d (worst case lab studies) First-order
Application data	Crop: apples and ornamentals % plant interception: 80% apples and 50% ornamentals Number of applications: 1 for apples and ornamentals in the field; 3 for ornamentals in glasshouses Interval (d): 7 Application rate(s): 281 g as/ha (apples) 600 g as/ha (ornamentals)

Actual TWA PECs (mg/kg) of acequinocyl following application in orchards and ornamentals in the field and in glasshouses.

Day after application	Orchards apples (0.281 kg a.s./ha)		Ornamentals in the field (0.600 kg a.s./ha)		Ornamentals in glasshouses (0.600 kg a.s./ha; 3 times)	
	Actual PEC	TWA PEC	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	0.075	0.075	0.400	0.400	0.483	0.483
1	0.059	0.066	0.312	0.354	0.377	0.428
2	0.046	0.059	0.244	0.315	0.295	0.381
4	0.028	0.048	0.149	0.254	0.180	0.307
7	0.013	0.036	0.071	0.190	0.085	0.230
14	0.002	0.021	0.013	0.112	0.015	0.135
21	<0.001	0.014	0.002	0.077	0.003	0.092
28	<0.001	0.01	<0.001	0.058	<0.001	0.070

50	<0.001	0.006	<0.001	0.032	<0.001	0.039
100	<0.001	0.003	<0.001	0.016	<0.001	0.020

Metabolite R1 Method of calculation	DT_{50}: 33d (worst case lab studies) First-order
Application rate	Crop: apples and ornamentals % plant interception: 80% apples and 50% ornamentals Number of applications: 1 for apples and ornamentals in the field; 3 for ornamentals in glasshouses Interval (d): 7 Application rate(s): 281 g as/ha (apples) 600 g as/ha (ornamentals) (assumed R1 is formed at a maximum of 33.8% of the applied dose)

Actual and TWA PECs (mg/kg) of the major metabolite R1 following application of acequinocyl in orchards (0.281 kg a.s./ha for apples, resulting in a maximum of 85 g R1/ha) and ornamentals (0.600 kg a.s./ha, resulting in a maximum of 181 g R1/ha) in the field and in glasshouses.

Days after application	Orchards apples (0.85 kg R1/ha)		Ornamentals in the field (0.181 kg R1/ha)		Ornamentals in glasshouses (0.181 kg R1/ha; 3 times)	
	Actual PEC	TWA PEC	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	0.023	0.023	0.121	0.121	0.315	0.315
1	0.022	0.022	0.118	0.119	0.308	0.311
2	0.022	0.022	0.116	0.118	0.302	0.308
4	0.021	0.022	0.111	0.116	0.289	0.302
7	0.020	0.021	0.104	0.112	0.272	0.293
14	0.017	0.020	0.09	0.105	0.235	0.273
21	0.015	0.018	0.078	0.098	0.202	0.255
28	0.013	0.017	0.067	0.091	0.175	0.238
50	0.008	0.014	0.042	0.075	0.110	0.195
100	0.003	0.009	0.015	0.050	0.039	0.132

Metabolite AKM-18 Method of calculation	DT_{50}: 3.5 days (worst case lab studies) First-order
Application rate	Crop: apples and ornamentals % plant interception: 80% apples and 50% ornamentals Number of applications: 1 for apples and ornamentals in the field; 3 for ornamentals in glasshouses Interval (d): 7 Application rate(s): 281 g as/ha (apples) 600 g as/ha (ornamentals) (assumed AKM 18 is formed at a maximum of 21.9% of the applied dose)

Actual and TWA PECs (mg/kg) of the major metabolite AKM-18 following application of acequinocyl in orchards (0.281 kg a.s./ha for apples, resulting in a maximum of 56 g AKM-18/ha) and ornamentals (0.600 kg a.s./ha, resulting in a maximum of 118 g AKM-18/ha) in the field and in glasshouses.

Days after application	Orchards apples (0.56 kg AKM-18/ha)		Ornamentals in the field (0.118 kg AKM-18/ha)		Ornamentals in glasshouses (0.118 kg AKM-18/ha)	
	Actual PEC	TWA PEC	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	0.015	0.015	0.079	0.079	0.103	0.103
1	0.012	0.014	0.065	0.071	0.085	0.094
2	0.010	0.012	0.053	0.065	0.096	0.085
4	0.007	0.010	0.036	0.054	0.047	0.071
7	0.004	0.008	0.020	0.043	0.026	0.056
14	0.001	0.005	0.005	0.027	0.006	0.035
21	<0.001	0.004	0.001	0.019	0.002	0.024
28	<0.001	0.003	<0.001	0.014	<0.001	0.019
50	<0.001	0.002	<0.001	0.008	<0.001	0.01
100	<0.001	0.001	<0.001	0.004	<0.001	0.005

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH4: 25ºC, DT_{50} 74 days R1: 23 % AR (30 d, incubation at 25°C) AKM-18: 11% AR
	pH7: 25ºC, DT_{50} 52 hours R1: 55 % AR (96 h, incubation at 25°C) AKM-18: 16.9% AR
	pH9: 25ºC, DT_{50} 67 minutes R1: 49 % AR (90 min, incubation at 25°C) AKM-18: 14.6% AR

Photolytic degradation of active substance and metabolites above 10 % ‡	Xenon lamp >290 nm, pH sterile 5 buffer ; DT50 14 minutes AKM-08: 12.9% AR (120 min after irradiation) o-phthalic acid : 12.7% (24 h, end of study)
Quantum yield of direct phototransformation in water at Σ > 290 nm	Φ = 0.065
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

	Due to the limited amount of data > LOQ (estimated by RMS), no reliable kinetic analysis is possible for degradation of acequinocyl and its metabolites in the water phase. However, estimations could be made with the measured concentrations at successive time intervals:
-DT_{50} water	< 0.25 and < 0.75d (n = 2)
-DT_{90} water	< 2d (n = 2)
-DT_{50} whole system	0.42 – 0.47d (1st order, r^2 = 0.94 – 0.98, n = 2)
-DT_{90} whole system	1.4 – 1.6d (1st order, r^2 = 0.94 – 0.98, n = 2)
Mineralisation	30.2 – 32.6% a.r. (at 100 d, study end, n = 2)
Non-extractable residues	46.4 –56.4% a.r. (at 100 d, study end, n = 2)
Distribution in water / sediment systems (active substance)	Maximum of 8.4 –26.4% a.r. in sediment after 0.25 – 1 days. DT_{50} values in sediment could not be determined
Distribution in water / sediment systems (metabolites)	Water: CBAA (2-(carboxycarbonyl)benzoic acid) max of 9.6 – 11.3% a.r. (2-4 days, n = 2 [DT_{50} could not be determined]) R1: max 12% AR at 0d [DT_{50} could not be determined] Sediment: AKM-18 max of 15.3 –19.0% a.r. (1 day, n= 2 [DT_{50} could not be determined])

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent	For spray drift input only calculations: Water DT_{50}: 0.75d Kinetics: 1st order (from water phase) For FOCUS step 4 calculations, late applications to pome fruit: SWASH 3.1.2, MACRO 4.4.2, PRZM 1.5.6, TOXSWA 3.3.1 and SWAN 1.1.4. Water: DT_{50}: 0.47d Sediment: DT_{50}: 0.47d Soil: DT_{50}: 2.7d

	Koc: 66033 mL/g, 1/n 0.9 Q10 2.58, Walker equation coefficient 0.7
Application rate	Crop: apples and ornamentals Number of applications: max 1 for apples and 3 for ornamentals Interval (d): 7 Application rate(s): 281 g as/ha (apples) 600 g as/ha (ornamentals) Depth of water body: 30 cm, or for apples late applications FOCUS definitions. For FOCUS calculations PAT selected application dates were between 4 May (R3) and 21 June (D3).
Main routes of entry	15.73 % drift from 3 meter (apples) late 8.02% drift from 3 meter (ornamentals) or FOCUS values for FOCUS Step 4 calculations late to apples

Actual and TWA PECsw actual (µg/L) of acequinocyl following late application at maximum dose (281 g a.s./ha) to orchards.

Day after application	Orchards, late application; actual and TWA PECsw of acequinocyl at distance (drift %)	
	3 m (15.73)	
	Actual PEC	TWA PEC
0	14.73	14.73
1	5.85	9.17
2	2.32	6.72
4	0.37	3.89
7	0.02	2.27
14	<0.01	0.76
21	<0.01	1.14
28	<0.01	0.57
50	<0.01	0.32
100	<0.01	0.16

Step 4 calculations according to FOCUS L&M for pome fruit

Global maximum concentrations in the water phase for Acequinocyl on step 4* (10m buffer) late spray drift values

Location	water body	Global max (µg/L)	21 day TWA (µg/L)
D3 (spray drift +drainage)	Ditch	2.99	0.059
D4 (spray drift +drainage)	Pond	0.28	0.0092
D4 (spray drift +drainage)	Stream	3.47	0.0322
D5 (spray drift +drainage)	Pond	0.28	0.0119
D5 (spray drift +drainage)	Stream	3.64	0.024

R1 (spray drift +runoff)	Pond	0.28	0.0104
R1 (spray drift +runoff)	Stream	2.65	0.0216
R2 (spray drift +runoff)	stream	3.56	0.0166
R3 (spray drift +runoff)	Stream	3.73	0.0389
R4 (spray drift +runoff)	Stream	2.60	0.0143

(* Compared to step 3 a 10 m distance to the water body was assumed for the simulations)

Global maximum concentrations in the water phase for Acequinocyl on step 4* (20m buffer) late spray drift values

Location	**water body**	**Global max (µg/L)**	**21 day TWA (µg/L)**
D3 (spray drift +drainage)	Ditch	0.914	0.0177
D4 (spray drift +drainage)	Pond	0.124	0.00415
D4 (spray drift +drainage)	Stream	1.058	0.00977
D5 (spray drift +drainage)	Pond	0.124	0.00531
D5 (spray drift +drainage)	Stream	1.112	0.00721
R1 (spray drift +runoff)	Pond	0.124	0.00467
R1 (spray drift +runoff)	Stream	0.809	0.00659
R2 (spray drift +runoff)	stream	1.087	0.00504
R3 (spray drift +runoff)	Stream	1.138	0.0118
R4 (spray drift +runoff)	Stream	0.792	0.00443

(* Compared to step 3 a 20 m distance to the water body was assumed for the simulations)

Actual and TWA PECsw (µg/L) of acequinocyl following application at maximum dose (600 g a.s./ha) to ornamentals < 50 cm height in the field.

Day after application	Ornamentals < 50 cm; actual and TWA PECsw of acequinocyl at distance (drift %)					
	1 m (2.77)		5 m (0.57)		10 m (0.29)	
	Actual PEC	TWA PEC	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	5.54	5.54	1.14	1.14	0.58	0.58
1	2.20	3.62	0.45	0.74	0.23	0.38
2	0.87	2.53	0.18	0.52	0.09	0.26
4	0.14	1.46	0.03	0.30	0.01	0.15
7	0.01	0.86	<0.01	0.18	<0.01	0.09
14	<0.01	0.43	<0.01	0.09	<0.01	0.05
21	<0.01	0.20	<0.01	0.06	<0.01	0.02
28	<0.01	0.21	<0.01	0.04	<0.01	0.02
50	<0.01	0.12	<0.01	0.03	<0.01	0.01
100	<0.01	0.06	<0.01	0.01	<0.01	0.01

Day after application	Ornamentals < 50 cm; actual and TWA PECsw of acequinocyl at distance (drift%)
	15 m (0.2)

	Actual PEC	TWA PEC
0	0.40	0.40
1	0.16	0.26
2	0.06	0.18
4	0.01	0.11
7	<0.01	0.06
14	<0.01	0.03
21	<0.01	0.02
28	<0.01	0.02
50	<0.01	0.01
100	<0.01	<0.01

Actual and TWA PECsw (µg/L) of acequinocyl following application at maximum dose (600 g a.s./ha) to ornamentals > 50 cm height in the field.

Day after application	Ornamentals > 50 cm; actual and TWA PECsw of acequinocyl at distance (drift %)					
	3 m (8.02)		5 m (3.62)		10 m (1.23)	
	Actual PEC	TWA PEC	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	16.04	16.04	7.24	7.24	2.46	2.46
1	6.37	10.47	2.84	4.73	0.98	1.61
2	2.53	7.31	1.14	3.30	0.39	1.12
4	0.40	4.23	0.18	1.91	0.06	0.65
7	0.03	2.48	0.01	1.12	<0.01	0.38
14	<0.01	1.24	<0.01	0.56	<0.01	0.19
21	<0.01	0.83	<0.01	0.37	<0.01	0.13
28	<0.01	0.62	<0.01	0.28	<0.01	0.10
50	<0.01	0.35	<0.01	0.16	<0.01	0.05
100	<0.01	0.17	<0.01	0.08	<0.01	0.03

Day after application	Ornamentals > 50 cm; actual and TWA PECsw of acequinocyl at distance (drift %)	
	15 m (0.65)	
	Actual PEC	TWA PEC
0	1.30	1.30
1	0.52	0.85
2	0.21	0.59
4	0.03	0.34
7	<0.01	0.20
14	<0.01	0.10

21	<0.01	0.07
28	<0.01	0.05
50	<0.01	0.03
100	<0.01	0.01

Actual and TWA PECsw (µg/L) of acequinocyl following application at maximum dose (600 g a.s./ha) to ornamentals in glasshouses, with a maximum of 3 applications at 7 days interval.

Day after Application	Ornamentals; Actual and TWA PECsw of acequinocyl at 0.1 and 0.2% emmission following application in glasshouses			
	Actual PEC	TWA PEC	Actual PEC	TWA PEC
0	0.20	0.20	0.40	0.40
1	0.08	0.13	0.16	0.26
2	0.03	0.09	0.06	0.18
4	0.01	0.05	0.02	0.1
7	<0.01	0.03	0.02	0.06
14	<0.01	0.02	<0.01	0.04
21	<0.01	0.01	<0.01	0.02
28	<0.01	0.01	<0.01	0.02
50	<0.01	<0.01	<0.01	<0.01

Metabolites assumption / calculation approach	For spray drift input only calculations (ornamentals glasshouse): formation in water: R1 12%, CBAA 11.3% For FOCUS step 3 calculations, late applications to pome fruit: SWASH 3.1.2, MACRO 4.4.2, PRZM 1.5.6, TOXSWA 3.3.1 and SWAN 1.1.4. Water: DT_{50}: R1 and CBAA 0.47d Sediment: DT_{50}: R1 and CBAA 0.47d Soil: DT_{50}: R1 33 d CBAA 1.9d Koc: R1 100666mL/g, 1/n 0.9 CBAA 0.19 mL/g, 1/n 0.9, CBAA is a QSAR value Q10 2.58, Walker equation coefficient 0.7
Application rate	Crop: apples and ornamentals Number of applications: max 1 for apples and 3 for ornamentals Interval (d): 7 Application rate(s): parent 281 g as/ha (apples) (calculated to be g 88.8g R1/ha (assuming 33.8% molar formation in soil) and 16.8 g CBAA/ha (assuming 11.3% molar formation in water) for FOCUS Step 3 calculations) 600 g as/ha (ornamentals) Depth of water body: 30 cm, or for apples late applications FOCUS definitions. For FOCUS

	calculations PAT selected application dates were between 4 May (R3) and 21 June (D3).
Main routes of entry	For CBAA Late FOCUS drift values for FOCUS baseline distances for R1 no drift entry only runoff and drainage from soil column for apples. 8.02% drift from 3 meter (ornamentals) 0.1% or 0.2% emmissions from a glasshouse (ornamentals).

Maximum PECsw (µg/L) of major metabolites following application at maximum dose (281 g a.s./ha for orchards and 600 g a.s./ha for ornamentals).

Application	Distance (drift%) or FOCUS scenarios base distances	Max. PECsw (µg/L) major metabolites	
		R1 (max. formation 12%)	CBAA (max formation 11.3%
Orchards (late spray drift values)	D3 ditch	<0.001	0.618
	D4 stream	<0.001	0.617
	D5 stream	<0.001	0.648
	R1 stream	0.001	0.473
	R2 stream	<0.001	0.634
	R3 stream	<0.001	0.663
	R4 stream	0.004	0.436
Ornamentals <50 cm	1 m (2.77%)	0.59	0.32
Ornamentals >50 cm	3 m (8.02%)	1.71	0.92
Ornamentals in glasshouses	0.1% emmission	0.02	0.01
	0.2% emmission	0.04	0.02

PEC (sediment)

Method of calculation	As the RA for both the parent and the metabolite AKM-18 is based on a parent spiked water sediment dweller test, there is no need for PECsed values for a GAP with one application per season in this situation where these compounds have very high Kfoc values so will partition to sediment, when entering by spray drift and will have a low contribution from erroded soil reaching surface water dues to run off events due to low soil persistence. Exceptionally in this case for the representative uses assessed, because AKM-18 is formed under sterile aqueous hydrolysis study conditions at pH 7, the results from the parent spiked effect study were accepted as sufficient to characterise the risk from exposure to AKM-18 even though no PEC sediment was calculated for AKM-18.

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g.	For FOCUS gw modelling, values used –

modelling, field leaching, lysimeter)	Model(s) used: PEARL Scenarios (list of names): Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: apples, and crops selected as substitutes for ornamentals: vines, strawberries, sunflowers Mean parent DT_{50lab} 2.0d (20°C). Kom: parent, mean 38341, 1/n= 0.9 Metabolite R1: Max. 33.8% of applied dose, Mean DT_{50lab} 12.7d (20 °C). Kom: 57700 L/kg Metabolite AKM 18: Max. 21.9% of applied dose Mean DT_{50lab} 3.5 d (20 °C). Kom: 25114 L/kg indicative value
Application rate	Application rate: 281 g as/ha (apples) 600 g as/ha (ornamentals) crop interception: 80% for apples, 50% of ornamentals No. of applications: max. 1 for apples max. 3 for ornamentals Time of application (month or season): 1st of May (apples); 1st of May and 1st of September (ornamentals)

PEC_{GW}

Maximum concentration	Not calculated
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance.)	Annual average concentrations (80th percentile) at 1m according to FOCUS guidance: active substance: < 0.001 µg/L R1: <0.001 µg/L AKM 18: <0.001 µg/L

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

$PEC_{(gw)}$ From lysimeter / field studies

Parent / metabolite	1st year	2nd year	3rd year
Not available – not required			

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not studied – no data requested
Quantum yield of direct phototransformation	Not available and not required
Photochemical oxidative degradation in air ‡	DT_{50} of 1.21h, derived by the Atkinson method of calculation (12 h day)
Volatilisation ‡	Vapour pressure: 1.69 x 10-6 Pa (at 25 °C)) Henry's Law constant: unit less coefficient 3.9 x 10-5 (calculated)

Metabolites	No data available, no data required

PEC (air)

Method of calculation	Not calculated

$PEC_{(a)}$

Maximum concentration	Expected negligible (DT_{50} 1.21h)

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: acequinocyl, R1 and AKM-18 Surface water: acequinocyl, R1 and CBAA Sediment: acequinocyl, AKM 18 Ground water: acequinocyl, R1 and AKM-18 Air: acequinocyl

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not available, new substance
Surface water (indicate location and type of study)	Not available, new substance
Ground water (indicate location and type of study)	Not available, new substance
Air (indicate location and type of study)	Not available, new substance

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53.

Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	LD_{50} > 4855 mg a.s./kg bw
Acute toxicity to birds	Tests with active substance: LD_{50} > 1942 mg a.s./kg bw (Japanese quail) LD_{50} > 1942 mg a.s. /kg bw (Mallard duck) Test with plant protection product: LD_{50} > 300 mg a.s./kg bw (Bobwhite quail)
Dietary toxicity to birds	Tests with active substance: LD_{50} > 847 mg a.s./kg bw (Japanese quail) LD_{50} > 1335 mg a.s./kg bw (Mallard duck) Test with plant protection product: LD_{50} > 159 mg a.s./kg bw (Bobwhite quail)
Reproductive toxicity to birds	NOEL = 217 mg a.s./kg bw (Bobwhite quail) NOEL = 7.48 mg a.s./kg bw (Mallard duck)
Reproductive toxicity to mammals	NOAEL = 6.9 mg a.s./kg bw (rat)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Acute Toxicity Exposure Ratios for exposure of birds to acequinocyl, due to consumption of contaminated small insects, leaves and drinking water[1]

Crop	dose (kg a.s./ ha)	bird type	approx. body weight (g)	route	DFI[2] (g/ day)	DWI[3]	LD_{50} (mg/kg bw)	PECfeed or PECwater (mg/kg wwt or µg/L)	ETE (mg/kg bw per day)	TERa
orchards	0.281	Insecti-vorous bird	10	small insects	10.4	-	> 1942	14.6	15	> 128
				water	-	2.7		27.4	0.0074	> 2.63*10^5
ornamen-tals (field)	0.600	Insecti-vorous bird	10	small insects	10.4	-	> 1942	31.2	32	> 60
				water	-	2.7		16.0	0.0043	> 4.49*10^5
ornamen-tals (field)	0.600	Medium herbivorous bird	300	leafy crops	228	-	> 1942	52.2	40	> 49
				water	-	26.3		16.0	0.0014	> 1.38*10^5
ornamen-tals (glass-house)	0.600	Insecti-vorous bird	10	water	-	2.7	> 1942	0.2	0.000054	> 3.60*10^7
ornamen-tals (glass-house)	0.600	Medium herbivorous bird	300	water	-	26.3	> 1942	0.2	0.00002	> 1.10*10^8

[1] Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2002).
[2] DFI: Daily Food Intake
[3] DWI: Daily Water Intake

Short-term Toxicity Exposure Ratios for exposure of birds to acequinocyl due to consumption of contaminated small insects and leaves[1]

Crop	dose (kg as/ha)	bird type	approx. body weight (g)	route	DFI[2] (g/day)	LC_{50} (mg/kg bw per day)	PEC_{FEED} (mg/kg wwt)	ETE (mg/kg bw per day)	TERst
orchards (late)	0.281	Insectivorous bird	10	small insects	10.4	> 847	8.2	8.5	> 100
ornamentals	0.600	Insectivorous bird	10	small insects	10.4	> 847	17.4	18	> 47
ornamentals	0.600	Medium herbivorous bird	300	leafy crops	228	> 847	24	18	> 47

[1] Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2002).
[2] DFI: Daily Food Intake

Long-term Toxicity Exposure Ratios for exposure of birds to acequinocyl, due to consumption of contaminated small insects and leaves[1]

Crop	dose (kg a.s./ha)	bird type	approx. body weight (g)	route	DFI[2] (g/day)	NOEC (mg/kg bw per day)	PEC_{FEED} (mg/kg wwt)	TWA correction	ETE (mg/kg bw per day)	TERlt
orchards	0.281	Insectivorous bird	10	small insects	10.4	7.48	8.2	-	8.5	**0.88**
ornamentals	0.600	Insectivorous bird	10	small insects	10.4	7.48	17.4	-	18	**0.42**
ornamentals	0.600	Medium herbivorous bird	300	leafy crops	228	7.48	24.0	0.53	10	**0.75**

[1] Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2002).
[2] DFI: Daily Food Intake

Further refined long-term Toxicity Exposure Ratios for exposure of birds to acequinocyl in <u>orchards,</u> according to EFSA (2009) Guidance Document

Growth Stage: BBCH 57 – 77

Crop	dose kg a.s./ha	Bird type	Scenario	MAF	Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
orchards	0.281	Small insectivorous bird "tit"	Spring and summer	1	18.2	1	0.53	7.48	2.71	**2.73**
		Small insectivorous/ worm feeding species "thrush"	Crop directed BBCH ≥ 40	1	2.7	1	0.53		0.40	18.40
		Small	Crop	1	12.6	1	0.53		1.88	**3.94**

		granivorous bird "finch"	directed BBCH ≥ 40							

Refined risk assessment for insectivorous bird

Crop	dose (kg a.s./ha)	Bird type	Scenario	MAF	Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
orchards	0.281	Insectivorous bird (blue tit)		1	18.2	0.58	<0.205	7.48	<0.61	>12.3

Further refined long-term Toxicity Exposure Ratios for exposure of birds to acequinocyl in <u>ornamentals,</u> according to EFSA (2009) Guidance Document

Growth Stage: BBCH 30 - 80

Crop	dose (kg a.s./ha)	Bird type	MAF	Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
ornamentals	0.6	Insectivorous bird "tit"	1	18.2	1	0.53	7.48	5.79	**1.27**
ornamentals	0.6	Small insectivorous/worm feeding species "thrush"	1	2.7	1	0.53	7.48	0.86	8.6

Refined risk assessment for insectivorous bird

Crop	dose (kg a.s./ha)	Bird type	MAF	Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
ornamentals	0.600	Insectivorous bird (blue tit)	1	18.2	1	<0.205	7.48	2.233	**>3.3***

* The risk is considered low based on a Weight of Evidence approach (see addendum October 2012)

Long-term NOEL birds	7.48 mg/kg bw per day
BCF (earthworms)	12 (calculated value: BCF = (0.84+0.01 Kow)/focKoc
BCF (fish)	366 (experimental value)
Absorption, distribution, excretion and metabolism in mammals	Potential for bioaccumulation: none. Highest transitory dose: 3-9 hr (low dose) and 24-48 hr (high dose)
Kow	1584893 (log Pow = 6.2)
Koc	66033 L/kg
PECsoil	0.077 mg/kg (highest time-weighted-average after 3 weeks)
PECsurface water	1.41 µg/L (highest time-weighted-average after 3 weeks)

Food chain from earthworm to earthworm-eating birds, based on a calculated BCF of 12

Crop	dose (kg a.s./ha)	PECsoil (mg/kg) (after 3 weeks)	PECworm (mg/kg)	Daily dose birds (mg/kg bw per day)	TER birds
Orchards	0.281	0.014	0.17	0.19	39.4
Ornamentals (field)	0.600	0.077	0.92	1.02	7.3

Food chain from earthworm to earthworm-eating birds, based on a experimental BCF of 1.86

Crop	dose (kg a.s./ha)	PECsoil (mg/kg) (after 3 weeks)	PECworm (mg/kg)	Daily dose birds (mg/kg bw per day)	TER birds
Orchards	0.281	0.014	0.026	0.029	258
Ornamentals (field)	0.600	0.077	0.143	0.157	47.6

Food chain from fish to fish-eating birds

Crop	dose (kg a.s./ha)	PECsurface water (µg/L) (twa after 3 weeks)	PECfish (mg/kg)	Daily dose birds (mg/kg bw per day)	TER birds
orchards	0.281	1.41	0.52	0.11	68
Ornamentals (field)	0.600	0.83	0.30	0.064	116
Ornamentals (glasshouse)	0.600	0.01	0.0037	0.00077	9714

Acute Toxicity Exposure Ratios for exposure of mammals to acequinocyl due to consumption of contaminated grass and leafy crops and drinking water[1]

Crop	dose (kg as/ha)	mammal type	approx. body weight (g)	route	DFI[2] (g/day)	DWI[3]	LD_{50} (mg/kg bw per day)	PEC_{feed} or PEC_{water} (mg/kg wwt or µg/L)	ETEfeed or ETEwater (mg/kg bw per day)	TERa feed or TERa water
Orchards	0.281	small herbivorous mammal	25	grasses	34.80		> 4855	23.9	33	146
				water		5.0		27.4	0.0055	$8.9*10^5$
Ornamentals (field)	0.600	medium herbivorous mammal	3000	leafy crops	832.0		> 4855	52.2	14	335
				water		123.2		16.0	0.0007	$7.4*10^6$
Ornamentals (glasshouse)	0.600	medium herbivorous mammal	3000	water		123.2	> 4855	0.2	0.00001	$5.9*10^8$

[1] Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2002).

[2] DFI: Daily Food Intake

[3] DWI: Daily Water Intake

Long-term Toxicity Exposure Ratios (First Tier) for exposure of mammals to acequinocyl due to consumption of contaminated grass and leaves[1]

Crop	dose (kg a.s./ha)	mammal type	approx. body weight (g)	route	DFI[2] (g/day)	NOAEL (mg/kg bw per day)	PEC_{FEED} (mg/kg wwt)	TWA correc-tion	ETE (mg/kg bw per day)	TERlt
Orchards	0.281	small herbivorous mammal	25	grasses	34.80	6.9	13	0.53	10	**0.69**
Ornamentals (field)	0.600	medium herbivorous mammal	3000	leafy crops	832.0	6.9	24	0.53	4	**1.73**

[1] Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2002).
[2] DFI: Daily Food Intake

Further refined long-term Toxicity Exposure Ratios for exposure of mammals to acequinocyl in orchards, according to EFSA (2009) Guidance Document, based on a NOAEL of 6.9 mg/kg bw per day (relevant scenario is BBCH 57-77)

Crop	dose (kg a.s./ha)	Bird type	MAF	RUD Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
orchards	0.281	Small herbivorous mammal "vole" (BBCH ≥ 40)	1	21.7	1	0.53	6.9	3.212	**2.1**
		Frugivorous mammal "dormouse" (BBCH 71-79)	1	22.7	1	0.53		3.38	**2.04**
		Large herbivorous mammal "lagomorph" (BBCH ≥ 40)	1	4.3	1	0.53		0.636	10.8
		Small omnivorous mammal "mouse" (BBCH ≥ 40)	1	2.3	1	0.53		0.340	20.14

Further refined long-term Toxicity Exposure Ratios for exposure of mammals to acequinocyl in ornamentals, according to EFSA (2009) Guidance Document, based on a NOAEL of 6.9 mg/kg bw per day (relevant scenario is BBCH 30-80)

Crop	dose (kg a.s./ha)	Bird type	MAF	RUD Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
Ornamentals	0.600	Small insectivorous mammal "shrew"	1	1.9	1	0.53	6.9	0.6	11.4
		Small herbivorous mammal "vole" (BBCH 40-49)	1	72.3	1	0.53		22.99	**0.3**
		Small herbivorous	1	36.1	1	0.53		11.4	**0.6**

Crop	dose (kg a.s./ha)	Bird type	MAF	RUD Shortcut value (mean)	PT	TWA	NOEL (mg/kg bw per day)	DDD (mg/kg bw per day)	TERlt
		mammal "vole" (BBCH ≥ 50)							
		Small omnivorous mammal "mouse" (BBCH 10-49)	1	7.8	1	0.53		2.4	**2.8**
		Small omnivorous mammal "mouse" (BBCH ≥ 50)	1	3.9	1	0.53		1.2	5.6

Long-term NOAEL	6.9 mg/kg bw per day
BCF (earthworms)	12 (calculated value BCF = (0.84+0.01Kow)/focKoc)
BCF (fish)	366 (experimental value)
Absorption, distribution, excretion and metabolism in mammals	Potential for bioaccumulation: none. Highest transitory dose: 3-9h (low dose) and 24-48h (high dose
Kow	1584893 (log Pow=6.2)
Koc	66033
PECsoil	0.077 mg/kg (highest time-weighted-average after 3 weeks)
PECsurface water	1.41 µg/L (highest time-weighted-average after 3 weeks)

Food chain from earthworm to earthworm-eating mammals, based on a calculated BCF of 12

Crop	dose (kg a.s./ha)	PECsoil (mg/kg) (twa after 3 weeks)	PECworm (mg/kg)	Daily dose mammals (mg/kg bw per day)	TER mammals
Orchards	0.281	0.014	0.17	0.24	28.8
Ornamentals (field)	0.600	0.077	0.92	1.29	5.3

Food chain from earthworm to earthworm-eating mammals, based on a experimental BCF of 1.86

Crop	dose (kg a.s./ha)	PECsoil (mg/kg) (twa after 3 weeks)	PECworm (mg/kg)	Daily dose mammals (mg/kg bw per day)	TER mammals
Orchards	0.281	0.014	0.026	0.036	192
Ornamentals (field)	0.600	0.077	0.143	0.200	34.5

Food chain from fish to fish-eating mammals

Crop	dose (kg a.s./ha)	PECsurface water (µg/L) (twa after 3 weeks)	PECfish (mg/kg)	Daily dose mammals (mg/kg bw per day)	TER birds
orchards	0.281	1.41	0.52	0.07	99
Ornamentals (field)	0.600	0.83	0.30	0.04	173
Ornamentals (glasshouse)	0.600	0.01	0.0037	0.00048	14375

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (µg a.s./L)
Laboratory tests				
Oncorhynchus mykiss	AKD-2023 Technical	96 h	Mortality, LC_{50}	> aqueous solubility
Cyprinodon variegatus	AKD-2023 Technical	96 h	Mortality, LC_{50}	> aqueous solubility
Lepomis macrochirus	AKD-2023 Technical	96 h	Mortality, LC_{50}	> aqueous solubility
Brachydanio rerio	AKD-2023 Technical	96 h	Mortality, LC_{50}	> aqueous solubility
Daphnia magna	AKD-2023 Technical	48 h	Immobilisation, EC_{50}	3.9
Daphnia magna	AKD-2023 Technical	21 d	Reproduction and growth, NOEC	0.98
Mysidopsis bahia	AKD-2023 Technical	96 h	Mortality, EC_{50}	0.93
Pseudokirchneriella subcapitata	AKD-2023 Technical	72h	Biomass and growth rate, EC_{50}	> aqueous solubility
Cyprinus carpio	metabolite R1	96 h	Mortality, LC_{50}	> aqueous solubility
Oncorhynchus mykiss	metabolite CBAA	96 h	Mortality, LC_{50}	> 100000
Oncorhynchus mykiss	Formulated Product[3)]	96 h	Mortality, LC_{50}	65000
Cyprinidon variegatus	Formulated Product[3)]	96 h	Mortality, LC_{50}	95000
Lepomis macrochirus	Formulated Product[3)]	96 h	Mortality, LC_{50}	> 68000
Oryzias latipes	Formulated Product[3)]	96 h	Mortality, LC_{50}	> 95000
Orconectes virilis	Formulated Product[3)]	96 h	Mortality, LC_{50}	> 98000
Brachydanio rerio	Formulated Product[3)]	96 h	Mortality, LC_{50}	> 90000
Daphnia magna	Formulated Product[3)]	48 h	Immobilisation, EC_{50}	2.36
Daphnia magna[1)]	Formulated Product[3)]	23 d	Population growth	20
Chironomus riparius	Formulated Product[3)]	96 h	Mortality, EC_{50}	> 86000
Macromia magnifica	Formulated Product[3)]	96 h	Mortality, EC_{50}	> 100000
Simocephalus vetulus	Formulated Product[3)]	48 h	Immobilisation, EC_{50}	16.6
Pseudokirchneriella subcapitata	Formulated product[3)]	72 h	Biomass and growth rate, EC_{50}	930
Selenastrum capricornutum	Formulated product[3)]	72 h	Biomass and growth rate, EC_{50}	2000
Chironomus riparius[2)]	Formulated Product[3)]	29 d	emergence and development rate	479

Outdoor microcosm study:

The outdoor microcosm study can be used to evaluate the ecotoxicological risks of a single application of AKD-2023 15% SC to phytoplankton and zooplankton, including *Chaoborus* sp., typical for a lentic freshwater community. Intended initial concentrations were 0 – 0.5 – 3.0 – 9.0 – 27.0 – 81.0 µg a.s./L. Immediately after application the test compound was mixed in the water layer of the microcosms. For the species groups phytoplankton, zooplankton and *Chaoborus* sp. a NOEAEC of 27 µg a.s./L can be derived. The $NOEC_{community}$ for this study is 9 µg a.s./L, and the $NOEC_{population}$ is 3 µg a.s./L.

The Experts at PRAPeR 08 (November 2006) concluded that the associated trigger value for the $NOEC_{population}$ value from the outdoor microcosm study should be between 3 and 5.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Maximum PEC_{sw} values and TER values for acequinocyl
Application to late orchards at 1 x 0.281 kg a.s./ha

Scenario	PEC global max (µg L)	fish acute	Daphnia acute	Daphnia prolonged	Algae acute	Sed. dweller prolonged
		O. mykiss	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***C. riparius***
		LC_{50}	EC_{50}	NOEC	EC_{50} [a]	NOEC
		65000 µg/L	2.36 µg/L	0.98 µg/L	930 µg/L	479 µg/L
FOCUS Step 4						
10 m no-spray buffer zone combined with 10 m vegetative buffer strip for R scenarios						
D3 / ditch	2.99	21739	**0.8**	**0.3**	311	160
D4 / pond	0.28	232143	**8.4**	**3.5**	3321	1711
D4 / stream	3.47	18732	**0.7**	**0.3**	268	138
D5 / pond	0.28	232143	**8.4**	**3.5**	3321	1711
D5 / stream	3.64	17857	**0.6**	**0.3**	255	132
R1 / pond	0.28	232143	**8.4**	**3.5**	3321	1711
R1 / stream	2.65	24528	**0.9**	**0.4**	351	181
R2 / stream	3.56	18258	**0.7**	**0.3**	261	135
R3 / stream	3.73	17426	**0.6**	**0.3**	249	128
R4 / stream	2.60	25000	**0.9**	**0.4**	358	184
Trigger		100	100	10	10	10

[a] E_rC_{50} and E_bC_{50}

Scenario	PEC global max (µg L)	Daphnia acute	Daphnia prolonged	Microcosm / Mesocosm
		Daphnia magna	***Daphnia magna***	
		EC_{50}	NOEC	NOEC
		2.36 µg/L	0.98 µg/L	3 µg/L
FOCUS Step 4				
20 m no-spray buffer zone combined with 20 m vegetative buffer strip for R scenarios				
D3 / ditch	0.914	**2.6**	**1.1**	**3.3**
D4 / pond	0.124	**19.0**	**7.9**	24.2
D4 / stream	1.058	**2.2**	**0.9**	**2.8**
D5 / pond	0.124	**19.0**	**7.9**	24.2
D5 / stream	1.112	**2.1**	**0.9**	**2.7**
R1 / pond	0.124	**19.0**	**7.9**	24.2
R1 / stream	0.809	**2.9**	**1.2**	**3.7**
R2 / stream	1.087	**2.2**	**0.9**	**2.8**
R3 / stream	1.138	**2.1**	**0.9**	**2.6**
R4 / stream	0.792	**3.0**	**1.2**	**3.8**
Trigger		100	10	5[1]

[1] The Experts at PRAPeR 08 (November 2006) concluded that the associated trigger value for the $NOEC_{population}$ value from the outdoor microcosm study should be between 3 and 5.

Acute TERs for acequinocyl from spray drift at several distances for ornamentals

1 application of 0.6 kg a.s./ha

Spray-drift alone

Crop	Buffer zone (m)	% drift	LC/EC_{50} (µg a.s./L)*			Actual PECsw (µg a.s./L)	TER		
			fish	daphnia	algae		fish	daphnia	algae
Ornamentals < 50 cm height (field)	1	2.77	65000	2.36	930	5.54	11733	**0.42**	168
	5	0.57	65000	2.36	930	1.14	57018	**2.07**	816
	10	0.29	65000	2.36	930	0.58	112069	**4.07**	1603
	15	0.20	65000	2.36	930	0.40	162500	**5.90**	2325
Ornamentals > 50 cm height (field)	3	8.02	65000	2.36	930	16.04	4052	**0.15**	58
	5	3.62	65000	2.36	930	7.24	8978	**0.33**	128
	10	1.23	65000	2.36	930	2.46	26423	**0.96**	378
	15	0.65	65000	2.36	930	1.30	50000	**1.81**	715
Ornamentals (glasshouse)	Std[1] ULV[2]	0.1 0.2	65000	2.36	930	0.2 0.4	325000 16250	11.80 **5.9**	4650 2325

* values are based on the toxicity tests with the formulation
[1] Std: Standard hydraulic spraying
[2] ULV: Ultra Low Volume spraying

Chronic TERs (*Daphnia*) for acequinocyl from spray drift at several distances for ornamentals

1 application of 0.6 kg a.s./ha

Spray-drift PEC-values

crop	Buffer zone (m)	% drift	NOEC (µg a.s./L)	Actual PEC_{SW} (µg a.s./L)	TER
ornamentals < 50 cm height (field)	1	2.77	0.98	5.54	**0.18**
	5	0.57	0.98	1.14	**0.86**
	10	0.29	0.98	0.58	**1.69**
	15	0.20	0.98	0.40	**2.45**
ornamentals > 50 cm height (field)	3	8.02	0.98	16.04	**0.06**
	5	3.62	0.98	7.24	**0.14**
	10	1.23	0.98	2.46	**0.40**
	15	0.65	0.98	1.30	**0.75**

crop	Buffer zone (m)	% drift	NOEC (µg a.s./L)	Actual PEC_{SW} (µg a.s./L)	TER
Ornamentals (glasshouse)	Std[1] ULV[2]	0.1 0.2	0.98	0.01 0.02	98.0 49

[1] Std: Standard hydraulic spraying
[2] ULV: Ultra Low Volume spraying

Chronic TERs for *Chironomus riparius* for acequinocyl from spray drift at several distances for orchards and ornamentals

Crop	buffer zone (m)	% drift	NOEC (µg a.s./L)	Actual PECsw (µg a.s./L)	TER
orchards (late)	3	15.73	479	14.73	32.5
ornamentals < 50 cm height (field)	1	2.77	479	5.54	86
ornamentals > 50 cm height (field)	3	8.02	479	16.04	30
ornamentals (glasshouse)	Std[1] ULV[2]	0.1 0.2	479	0.20 0.40	2395 1197

[1] Std: Standard hydraulic spraying
[2] ULV: Ultra Low Volume spraying

TERs for acequinocyl from spray drift at several distances for ornamentals, based on the NOEC-value of 3.0 µg a.s./L from the microcosm study

crop	Buffer zone (m)	% drift	NOEC-value (µg a.s./L)	Actual PECsw (µg a.s./L)	TER[3]
Ornamentals < 50 cm height (field)	1	2.77	3.0	5.54	**0.54**
	5	0.57	3.0	1.14	**2.63**
	10	0.29	3.0	0.58	5.17
	15	0.20	3.0	0.40	7.50
Ornamentals > 50 cm height (field)	3	8.02	3.0	16.04	**0.19**
	5	3.62	3.0	7.24	**0.41**
	10	1.23	3.0	2.46	**1.22**
	15	0.65	3.0	1.30	**2.31**

crop	Buffer zone (m)	% drift	NOEC-value (µg a.s./L)	Actual PECsw (µg a.s./L)	TER[3]
Ornamentals (glasshouse)	Std[1] ULV[2]	0.1 0.2	3.0	0.20 0.40	15.0 7.5

[1] Std: Standard hydraulic spraying
[2] ULV: Ultra Low Volume spraying
[3] The Experts at PRAPeR 08 (November 2006) concluded that the associated trigger value for the $NOEC_{population}$ value from the outdoor microcosm study should be between 3 and 5.

Bioconcentration

Bioconcentration factor (BCF)	In carp the BCF for total radioactivity was 366 and 288 at exposure levels of 0.17 and 1.7 µg a.s./L respectively in a bioconcentration test with radiolabelled acequinocyl, the fish homogenate did not contain any acequinocyl or R1.
Annex VI Trigger for the bioconcentration factor (BCF)	100
Clearance time (CT_{50}) (CT_{90})	0.7 days at 0.17 µg a.s./L (for total radioactivity) 1.3 days at 1.7 µg a.s./L (for total radioactivity) not determined
Level of residues (%) in organisms after the 14 day depuration phase	After the first day of the depuration period, mean concentrations radioactivity in fish had decreased to about 20% of the values at the end of the exposure period.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	48h-LD_{50} > 100 µg a.s./bee	48h-LD_{50} > 100 µg a.s./bee
Preparation (AKD-2023 15% SC)	72h-LD_{50} > 48.5 µg a.s./bee	72h-LD_{50} > 53.9 µg a.s./bee
Field or semi-field tests No data submitted, no study required.		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Hazard quotients for honey bees using laboratory toxicity studies on technical acequinocyl and the formulation AKD-2023 15% SC

crop	dose (g a.s./ha)	oral toxicity		contact toxicity		Annex IV trigger
		LD_{50} (µg a.s./bee)	hazard quotient	LD_{50} (µg a.s./bee)	hazard quotient	
technical acequinocyl						
orchards	281	> 100	< 2.81	>100	< 2.81	50
ornamentals	600	> 100	< 6	>100	< 6	50

formulation AKD-2023 15% SC						
orchards	281	> 48.5	< 5.8	> 53.9	< 5.2	50
ornamentals	600	> 48.5	< 12.4	> 53.9	< 11.1	50

Acequinocyl does not reveal an IGR-related mode of action. Hence, this compound is not expected to pose a risk to honey bee brood. Data on the effects of acequinocyl on bee brood is therefore not required.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡	Formulated Product 'AKD-2023' 15.6% (300 g a.s./ha) Glass plate	7d Mortality Reproduction E-value	8.52 (M_{corr}) 10.04 (7.84)$^{2)}$ -17
Typhlodromus pyri ‡	Formulated Product 'AKD-2023' 15.6% (624 g a.s./ha) Glass plate	7d Mortality Reproduction E-value	4.3 (M_{corr}) 8.18 (7.13)$^{2)}$ -10
Aphidius rhopalosiphi ‡	Formulated Product 'AKD-2023' 15% (1050 g a.s./ha) Glass plate	24h Mortality Reproduction E-value	0 (Mcorr) -2.2 -2.0

2) Number of offspring per female.

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Initial residues						
Amblyseius andersoni	Protonymph	Formulated Product 'AKD-2023' 15.6% Glass plate 14-day	300	7d Mortality Reproduction E-value	2.15 (M_{corr}) 13.1 (12.1)$^{2)}$ -5.7	30
Amblyseius andersoni	Protonymph	Formulated Product 'AKD-2023' 15.8% Glass plate 14-day	624	7d Mortality Reproduction E-value	1.05 (M_{corr}) 4.66 (4.53)$^{2)}$ -1.9	30

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Initial residues						
Poecilius cupreus	Adult	Formulated Product 'AKD-2023' 15.8% Sand 14-day	1050	7d Mortality Food consumption E-value	-3.41 (M_{corr}) 4.9 (4.8)$^{3)}$ -3.41	30
Aleochara bilineata	Life cycle	Formulated Product 'AKD-2023' 15% Glass plate 73-day	1050	Reproduction	2	30
Pardosa spec.	Adult	Formulated Product 'AKD-2023' 15% Sand 14-day	1050	14d Mortality Food consumption	0 (M_{corr}) 42 (39)$^{4)}$	
Chrysoperla carnea Steph.	Larvae	Formulated Product 'AKD-2023' 15% Glass plate 3-week	1050	Mortality	3.5 (M_{corr})	30
Phytoseiulus persimilis	Protonymph	Formulated Product 'AKD-2023' 15.6% Leaf discs 8-day	300	Mortality Reproduction E-value	52.5 (M_{corr}) 6.3 (5.9)$^{2)}$ 81.2	30
Phytoseiulus persimilis	Protonymph	Formulated Product 'AKD-2023' 15.8% Leaf discs 8-day	600	Mortality Reproduction E-value	-6.0 (M_{corr}) 8.22 (11.19)$^{2)}$ 22.6	30
Aged residue tests						

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Initial residues						
Typhlodromus pyri	Protonymph	Formulated Product 'AKD-2023' 15.6% Aged residue on leaf discs 7-day	1800	Mortality Reproduction	9.2 (0 days ageing) -2.2[5)] (7 days ageing) +5.1[6)] (0 days ageing) 13.6 (7 days ageing)	50
Phytoseiulus persimilis	Protonymph	Formulated Product 'AKD-2023' 15.6% Aged residue on leaf discs 14-day	1800	Mortality Reproduction	25.0 (0 days ageing) 12.0 (7 days ageing) 1.0 (14 days ageing) 39.4 (0 days ageing) 23.7 (7 days ageing) 45.8 (14 days ageing)	50

1) Values between parentheses are for the control treatment.
2) Number of offspring per female.
3) Number of fly pupae per individual.
4) Number of flies per individual.
5) '-' means less mortality than in the control
6) '+' means a stimulating effect

Field or semi-field tests No data, not required.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Acute toxicity	14d-LC_{50} > 1000 mg a.s./kg dw; corrected to 5% o.m. the 14-d LC_{50CORR} > 500 mg a.s./kg dw
Reproductive toxicity	No data.

Toxicity/exposure ratios for soil organisms

Acute risk of acequinocyl to earthworms

Scenario	LC_{50CORR} (mg a.s./kg)	PECs (mg a.s./kg)	Acute TER	Trigger value
Orchards	> 500	0.075	> 6667	10
Ornamentals (field)	> 500	0.400	> 1250	10

Scenario	LC_{50CORR} (mg a.s./kg)	PECs (mg a.s./kg)	Acute TER	Trigger value
Ornamentals (glasshouses)	> 500	0.483	> 1035	10

Effects on other soil macro-organisms

Collembola	According to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final, 17 October 2002), laboratory tests on Collembola reproduction are required for persistent substances (DT_{90} >100 days). Acequinocyl is non persistent (DT_{90} values derived from field test 0.3-1.8 days, see Section 2.5.2). A study on the reproduction toxicity of acequinocyl to Collembola is therefore not required.

Effects on soil micro-organisms

Nitrogen mineralization	Effects on nitrification < 25% after 28 and 50 days of exposure in loamy sand soil and sandy loam soil respectively at 7.0 mg a.s/kg soil (5250 g as/ha).
Carbon mineralization	Effects on respiration < 25% after 28 and 29 days of exposure in loamy sand soil and sandy loam soil respectively at 7.0 mg a.s/kg soil (5250 g as/ha).

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

	No adverse effects of AKD-2023 15% SC on vegetative vigor with respect to phytotoxicity, biomass, seedling emergence and seedling growth were observed in treated non-target plants at doses of approximately 5.0 kg/ha and 15.0 kg/ha.

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	3h-EC_{50} > 974 mg a.s./L

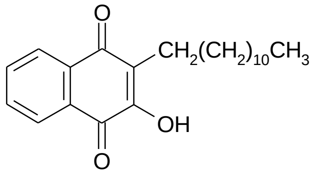
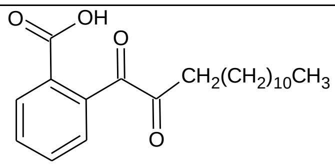
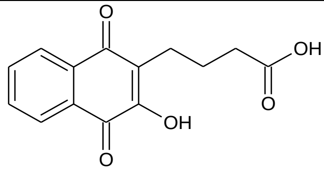
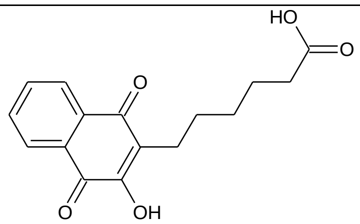
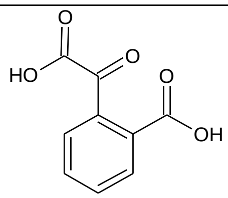
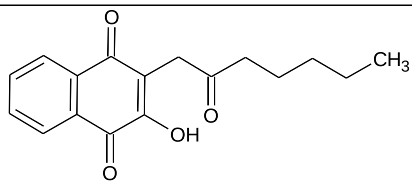
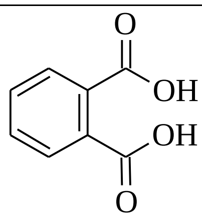
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Acequinocyl
water	Acequinocyl
sediment	Acequinocyl
groundwater	Acequinocyl

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal	
Active substance	N;	Harmful
	R50/53	Very toxic to aquatic organisms, may cause long term adverse effects t the environment

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
R1 AKD-2023-OH AKM-05 HDNQ	2-dodecyl-3-hydroxy-1,4-naphthoquinone	
AKM-18 F1	2-(2-oxotetradecanoyl)benzoic acid	
AKM-14	4-(3-hydroxy-1,4-dioxo-1,4-dihydronaphthalen-2-yl)butanoic acid	
AKM-15	6-(3-hydroxy-1,4-dioxo-1,4-dihydronaphthalen-2-yl)hexanoic acid	
CBAA	2-(carboxycarbonyl)benzoic acid	
AKM-08	2-hydroxy-3-(2-oxoheptyl)-1,4-naphthoquinone	
Phthalic acid	benzene-1,2-dicarboxylic acid	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
appl	application
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
ATP	adaptation to technical and scientific progress
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
CLP	classification, labelling and packaging
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC	European Commission
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
M/L	mixing and loading
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram

NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PRAPeR	Pesticides Risk Assessment Peer Review
PT	proportion of diet obtained in the treated area
PT	prothrombine time
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
STOT RE	specific target organ toxicity – repeated exposure
STOT SE	specific target organ toxicity – single exposure
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UK POEM	United Kingdom Predictive Operator Exposure Model
UV	ultraviolet
W/S	water/sediment

w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year