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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance disodium phosphonate[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, France, for the pesticide active substance disodium phosphonate 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 use of disodium phosphonate as a fungicide in vineyards. 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.

KEY WORDS

Disodium phosphonate, peer review, risk assessment, pesticide, fungicide

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[1] On request from the European Commission, Question No EFSA-Q-2011-01194, approved on 17 April 2013.

[2] Correspondence: pesticides.peerreview@efsa.europa.eu

[3] The specification for the active substance content range of the technical concentrate (TK) for disodium phosphonate has been amended to the range proposed by the applicant (Peer Review Report – p. 104 – comment 1(7)) instead of the range of the five-batches. Corrections have been made to pages 6 and 17.

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SUMMARY

Disodium phosphonate is a new active substance for which, in accordance with Article 6(2) of Council Directive 91/414/EEC, France (hereinafter referred to as the 'RMS') received an application from ISK Biosciences Europe S.A 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 2008/953/EC.

The RMS provided its initial evaluation of the dossier on disodium phosphonate in the Draft Assessment Report (DAR), which was received by the EFSA on 27 August 2009. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an Addendum to the DAR. The peer review was initiated on 13 March 2012 by dispatching the DAR and the Addendum for consultation of the Member States and the applicant ISK Biosciences Europe S.A.

Following consideration of the comments received on the DAR and the Addendum, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology and EFSA should adopt a conclusion on whether disodium phosphonate 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 use of disodium phosphonate as a fungicide in vineyards, as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

No data gaps or areas of concern were identified for the section physical and chemical properties and analytical methods.

No data gaps or areas of concern were identified in the area of mammalian toxicology and the risk assessment was finalised.

No data gaps or areas of concern were identified in the area of residues and the risk assessment was finalised.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative use assessed. However, the assessment of the exposure of natural surface water by phosphate ions, that may result as a consequence of the use of disodium phosphonate, is not finalised in the context of managing/avoiding eutrophication of surface waters.

Data gaps were identified in the ecotoxicology section to further address the risk for aquatic invertebrates, the risk to fish, and the chronic risk to earthworms and soil macroorganisms. Since on the basis of the available information a high risk was indicated for aquatic organisms and earthworms (long-term risk), critical areas of concern were identified.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[4] Council Directive 91/414/EEC[5] 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[6] (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(s) 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, France (hereinafter referred to as the 'RMS') received an application from ISK Biosciences Europe S.A for approval of the active substance disodium phosphonate. 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 2008/953/EC.[7]

The RMS provided its initial evaluation of the dossier on disodium phosphonate in the DAR, which was received by the EFSA on 27 August 2009 (France, 2009). In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an Addendum to the DAR. The peer review was initiated on 13 March 2012 by dispatching the DAR and the Addendum for consultation of the Member States and the applicant ISK Biosciences Europe S.A. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

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 26 June 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 applicant, and the EFSA should

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[4] 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.

[5] 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.

[6] 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.

[7] Commission Decision 2008/953/EC of 8 December 2008 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of *Aureobasidium pullulans* and disodium phosphonate in Annex I to Council Directive 91/414/EEC. OJ No L 338, 17.12.2008, p. 62-63.

organise an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour, and 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 use as a fungicide in vineyards, 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 DAR,
- the Reporting Table (26 June 2012),
- the Evaluation Table (16 April 2013),
- the reports 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 (France 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

The International Organisation for Standardisation does not require a common name for disodium phosphonate (IUPAC).

The representative formulated product for the evaluation was 'Mildicut', a suspension concentrate (SC) containing 250 g/L disodium phosphonate and 25 g/L cyazofamid.

The representative use evaluated comprises application by spraying, for the control of downy mildew on grapes. 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).

Disodium phosphonate is a salt of phosphonic acid, which in acqueous solutions dissociates to phosphonate and/or hydrogen phosphonate and sodium ions, depending on the pH of the solution. The active substance is manufactured only as a technical concentrate (TK) with the concentration range of the active substance being 281 to 337 g/kg. The minimum purity of the active substance on a dry weight basis is 917 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 of the active substance, or the physical, chemical and technical properties of the representative formulation. The main data regarding the identity of disodium phosphonate and the relevant data for the TC and TK are given in Appendix A.

Adequate analytical methods are available for the determination of disodium phosphonate in the technical concentrate and in the representative formulation and for the determination of the impurities in the technical concentrate.

An acceptable HPLC-MS/MS method is available for the determination of phosphonic acid in food of plant origin with LOQs of 0.5 mg/kg, 1 mg/kg, 2 mg/kg and 7.5 mg/kg for grapes, apples, oilseed rape and wheat grain respectively. The need for a method of analysis for monitoring this compound in food of animal origin has been waived as no residue definition is proposed.

Phosphonic acid in soil and air can be determined by HPLC-MS/MS with LOQs of 3 mg/kg and 10 $\mu g/m^3$ respectively. A HPLC-MS/MS method exists for the determination of phosphonic acid in groundwater and surface water with LOQs of 4 µg/L and 5 µg/L respectively. It should be noted that for the monitoring residue methods the justification that for this small molecule a second transition is not possible (used transition $H_2PO_3 \rightarrow PO_2^-$) was accepted.

A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

Disodium phosphonate was discussed in the Pesticide Peer Review Experts' Meeting 95 in September 2012.

The toxicological data package is composed of studies performed with disodium phosphonate, other sodium salts of phosphonic acid, or with fosetyl-Al. Bridging from fosetyl-Al is justified considering that it is rapidly degraded into salts of phosphonic acid (corresponding to about 76% of applied ^{32}Plabelled fosetyl-Al), which are likely to contribute to a great extent to the relevant toxicological effects observed in the toxicological studies performed with fosetyl-Al.

Disodium phosphonate is not acutely toxic via the oral, dermal or inhalation route. It is not a skin or eye irritant, nor a skin sensitiser. The relevant No Observed Adverse Effect Level (NOAEL) for short-term toxicity is bridged from a study performed with phosphonic acid in rat and is 400 mg/kg bw per day, based on soft faeces, increased water intake, and increased urinary sodium and calcium excretion. The NOAEL for long-term toxicity in dogs is 298 mg/kg bw per day based on testes changes (study with fosetyl-Al) and is 390 mg/kg bw per day in rats (combined sexes) based on clinical findings and reduced body weight (study with monosodium phosphonate). Disodium phosphonate is considered not to have genotoxic or carcinogenic potential. Disodium phosphonate did not show any reproductive potential (the relevant maternal NOAEL being >1782 mg/kg bw per day and the offspring and reproductive NOAELs being >1997 mg/kg bw per day, in a study with fosetyl-Al). In developmental toxicity studies the relevant maternal and developmental NOAELs are 275 mg/kg bw per day (rabbit).

The Acceptable Daily Intake (ADI), expressed as phosphonic acid, is 2.25 mg/kg bw per day based on the 2-year rat study with monosodium phosphonate, and applying an uncertainty factor (UF) of 100 (EFSA, 2005). The Acceptable Operator Exposure Level (AOEL) for disodium phosphonate is 2 mg/kg bw per day based on the developmental toxicity study in rabbits, applying an UF of 100 and a correction for oral absorption of 70%. Based on the toxicological profile an Acute Reference Dose (ARfD) is not necessary. The estimated operator and worker exposure is below the AOEL even without the use of Personal Protective Equipment (PPE). The estimated bystander exposure is below 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.

To address the metabolism of disodium phosphonate, scientific publications on the uptake, translocation and distribution of phosphonates and phosphonic acid in plants were submitted, amongst others a tritium radiolabel study with roots of tomato seedlings. All together the information indicates that, upon application to leaves or the root system, phosphonates are rapidly absorbed, vertically translocated into different plant parts and accumulated in sink organs like fruits or roots. Further, the studies suggest that phosphonates are not readily oxidised to phosphate in plants. Having regard to the peer review of potassium phosphonates, it had been concluded that, given the elementary nature of phosphonate salts, only transformation into phosphonic acid is expected in plants.

Due to their C–P bond, phosphonates are resistant to chemical hydrolysis and thermal decomposition, however, degradation can be microbial-enzyme mediated. A case was made that the only reasonably expected behaviour of phosphonates under hydrolysis conditions simulating industrial and household processing would be a change in the conversion rate to phosphonic acid.

The proposed residue definition for monitoring and risk assessment for disodium phosphonate in plant commodities is phosphonic acid and its salts, expressed as phosphonic acid.

A sufficient number of supervised residue trials were conducted on grapes in accordance with the representative use. The reliability of these results is supported by storage stability data showing that residues of phosphonic acid and its salts are stable in grapes under deep freezer conditions for at least 12 months. The analytical method for data generation was sufficiently validated.

Processing studies were submitted to address the magnitude of residues of phosphonic acid and its salts in red and white wines. Since the processing factors for red and white wine were not significantly different, these were combined and a processing factor for wine was established at 1.8.

Investigation of the nature and the magnitude of the residues in animal matrices was not triggered considering the representative use on wine grapes.

Rotational crop studies were not performed as grapevines are perennial crops.

Chronic dietary risk assessments were performed using the MRL for wine grapes, and the STMR for wine grapes plus the processing factor of 1.8 established for wine. The TMDI accounted for 7% of the ADI (FR, all population), and the NEDI for 3% of the ADI (FR, all population). An acute risk assessment is not necessary as an ARfD was not allocated.

Levels of sodium on grapes resulting from the use of disodium phosphonate were not assessed during the peer review, and were not considered of importance given the abundance of sodium in foods.

The consumer exposure for phosphonic acid in drinking water was calculated based on the predicted levels in groundwater (FOCUS modelling) and according to the WHO 2009 guideline. Consumer exposure was highest for the bottle-fed infant (using a bodyweight of 5kg and daily water consumption value of 0.75L), and contributes to 0.01% of the ADI.

As for the representative use, a MRL for phosphonic acid and its salts of 40 mg/kg in wine grapes would be necessary. A MRL of 90 mg/kg has previously been proposed for residues of phosphonic acid and its salts in wine grapes resulting from the assessment of the use of potassium phosphonates. An additional source of residues of phosphonic acid and its salts could result from the use of fosetyl. It is noted that all possible sources of phosphonate/phosphonic acid should be taken into account to set the MRLs, and to conduct a combined consumer exposure and risk assessment.

4. Environmental fate and behaviour

Disodium phosphonate was discussed by the experts in environmental fate and behaviour in January 2013 (Pesticide Peer Review Experts' Teleconference TC 85).

After applying the diluted product to soil, the chemical species in soil will be salts of sodium and predominantly hydrogen phosphonate and phosphonate (the possible salts of phosphonic acid). The levels of sodium ions added to soil from the representative use assessed will be within naturally occurring levels of sodium in mineral soils (0.04-4.45 %, according to De Vos *et al.*, 2006). In soil laboratory incubations under aerobic conditions in the dark, hydrogen phosphonate/phosphonate (that were quantified as phosphonic acid by the analytical methods) exhibited moderate to high persistence, being oxidised (a microbially mediated oxidation) to phosphate ions[8]. The levels of phosphate ions that will be produced by this oxidation are within recommendations for the addition of inorganic phosphate fertiliser to agricultural soils. Phosphonic acid exhibits medium to slight mobility in soil.

Information on the rate of transformation of the soluble salts of phosphonic acid in aerobic natural sediment water systems, was not available. Consequently two environmental exposure assessments were carried out. The first assumed slow oxidation of salts of phosphonic acid to phosphate ions in receiving water and sediment (DT_{50} 1000 days). The second assumed complete oxidation to phosphate ions. Sodium ions in the solution sprayed have the potential to reach surface water via spray drift. The resulting concentrations will be within naturally occurring levels of sodium in surface waters (minimum value 0.231 mg/L, median value 6.58 mg/L, De Vos *et al.* 2006). The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) calculations were carried out for phosphonic acid and phosphate ions for natural water bodies directly adjacent to treated vineyards, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 2.1 of the Steps 1-2 in FOCUS calculator). The resulting theoretical worst case PEC in surface water for phosphate ions (0.264-0.482 mg/L at FOCUS step 2) are higher than those that would be expected

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[8] The RMS evaluation of one of the two aerobic laboratory phosphonic acid test substance soil incubations is only available in the DAR and Final Addendum entitled fosetyl-Al (France, 2003, 2005), subsequently peer reviewed by EFSA (EFSA, 2005).

to be naturally occurring in surface water (streams, 0.01-0.025 mg/L, De Vos *et al.* 2006). These levels also exceed levels expected to be of concern for eutrophication (the US EPA water quality standard in relation to this is 0.1 mg/L in streams and rivers, with lower values where water will enter lakes). Therefore a more refined exposure assessment for phosphate ions that might include consideration of exposure mitigation options appears to be triggered in relation to this and a data gap has been identified.

The necessary groundwater exposure assessments were carried out using FOCUS (FOCUS, 2009) scenarios and the model PELMO 4.4.3[9] for phosphonic acid (in practice the species in the environment will be salts of phosphonic acid). As the standard FOCUS model parameterisations are not designed for the simulation of the leaching of inorganic compounds, the parameterisation was adapted. The standard substance transformation rate factor reductions with depth down the soil profile and routines for adjusting substance transformation rate with changing soil moisture content and temperature were maintained. Member State and EFSA experts accepted that this might be considered defensible in this case, as the oxidation of phosphonic acid and its salts to phosphate had been demonstrated to be a microbially mediated process. As soil adsorption is not expected to be well correlated with organic carbon content down the soil profile, the parameterisation for adsorption was modified. Adsorption in all soil layers was implemented based on a Kd of 10.7mL/g[10]. Factors for adsorption down the soil profile were kept constant. Overall whilst there is uncertainty in this parameterisation, the judgement of Member State and EFSA experts was that it can be used as a conservative estimate of leaching potential out of the root zone. The potential for groundwater exposure from the representative use by phosphonic acid and its salts was estimated, with this modelling approach, to be in the range 0.001 to 1.476 µg/L at the 7 FOCUS groundwater scenarios parameterised for vines, (1m depth annual average recharge values).

The technical concentrate of disodium phosponate is volatile (its measured vapour pressure is significantly higher than that of water), has a Henry's Law coefficient that may be greater than 1 Pa m^3 mol^{-1}, and therefore may have the potential to volatilise from aqueous systems. Independent of these properties, it will enter the atmosphere, as aerosols will be formed at the time of spraying. Therefore phosphonic acid, its ions and salts, may be subject to medium range atmospheric transport. Long range atmospheric transport is considered unlikely as the high water solubility of phosphonic acid, its ions and salts will mean they will be washed out of the atmosphere by precipitation. Therefore following FOCUS (2008) air guidance, an assessment of impact on air quality and risk to aquatic and terrestrial organisms following deposition from the atmosphere, consequent to medium range transport has been completed. This assessment (that included a consideration of eutrophication potential and acid rain generation) does not indicate concerns.

The PEC in soil, surface water, sediment, and groundwater covering the representative use assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

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

Disodium phosphonate was discussed at the Pesticides Peer Review Experts' Meeting 100 in February 2013.

The acute, short-term (birds only) and long-term risk to insectivorous birds and herbivorous mammals was assessed as low. A low risk to birds and mammals from consumption of contaminated water was also concluded.

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[9] Simulations utilised the agreed standard substance Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7

[10] This value for phosphonic acid originates from the dataset for potassium phosphonates (EFSA, 2012). It is a comparable value to the arithmetic mean K_F value in the data supplied by this applicant, in this dossier, which was 11.9mL/g.

Toxicity studies were available with disodium phosphonate on fish, *Daphnia*, sediment-dwelling organisms and algae. Acute toxicity studies were also available for the formulated product 'Mildicut' on fish, *Daphnia* and algae, indicating that the formulated product was more toxic than the active substance to *Daphnia*. The ELS (early life stage) study with disodium phosphonate on fish was discussed at the meeting. The experts agreed that from this study it is not possible to derive a NOEC because the high post-hatch mortality observed in all of the test concentrations was considered to be biologically relevant. To avoid further testing with vertebrates, it was agreed to use the 28-day NOEC for fosetyl aluminium reported in the EFSA Conclusion (EFSA, 2005), expressed as phosphonic acid. However, EFSA noted after the meeting that since the study from fosetyl aluminium is a chronic fish study, the effects on post-hatch survival observed in the available fish ELS study are not covered.

A low risk to fish (acute), aquatic invertebrates (chronic), algae and sediment-dwelling organisms was concluded on the basis of a risk assessment performed using FOCUS step 2 surface water PEC values. However the risk was indicated as high for aquatic invertebrates on the basis of the lowest endpoint for the formulated product expressed as phosphonic acid. In addition, the acute fish TER values, for the active substance in the formulated product, were less than the trigger value indicating that a high risk cannot be excluded for the formulation. Therefore, further data are needed to address these issues, and the chronic risk to fish.

A low risk to honey bees was concluded on the basis of the first tier risk assessment. A low in-field and off-field risk to non-target arthropods was indicated on the basis of a risk assessment using extended laboratory toxicity studies.

The risk assessment for earthworms and soil macroorganisms was discussed at the meeting. A low acute risk to earthworms was concluded. However, a high chronic risk to earthworms was indicated using a toxicity endpoint from a study where the test material was incorporated into the soil. An additional chronic earthworm toxicity study, where the test material was sprayed on to the soil surface, was available and indicated lower toxicity. However, it was agreed that this was not a suitable refinement for the chronic earthworm risk assessment given the persistence of the active substance in soil. As no further refinements were available, a data gap was identified to address the chronic risk to earthworms. Field data on degradation rates in soil were not available. However, considering that presumably the DT_{90} in field will be >100 days, in accordance with the Terrestrial Guidance Document (European Commission, 2002a), a risk assessment for soil macroorganisms would need to be considered (data gap identified).

A low risk to soil microorganisms, non-target plants and biological methods of sewage treatment were concluded for the representative use.

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**
Phosphonic acid	Moderate to high persistence Single first-order DT_{50} 29.7 to 196 days and biphasic DT_{50} 179-191 days (DT_{90} 99- 843 days, 20ºC pF 2-2.5 soil moisture)	Low acute risk for soil-dwelling organisms. Data gap to further address the chronic risk to earthworms and soil macroorganisms

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)(a)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
Phosphonic acid	Medium to slight mobility K_{Foc} 193-3038 mL/g	0.001-1.476 with 5 out of 7 scenarios > 0.1	Yes, though not a consideration in respect of inorganic fungicides, according to the legislation and uniform principles for decision making for plant protection products regarding groundwater	Predicted groundwater concentrations represent only 0.011% of the ADI following the WHO 2009 guideline	Risk to aquatic organisms assessed as low when groundwater becomes surface water

(a): EFSA’s understanding of Council Directive 98/83/EC[11] is that, as an inorganic fungicide, the parametric drinking water limit of 0.1 µg/L for pesticides and their relevant metabolites, degradation and reaction products does not apply to disodium phosphonates/phosphonic acid. Parametric levels are not set in this legislation for phosphate ions or other phosphorous compounds.

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[11] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p.32

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
phosphonic acid (water and sediment)	High risk indicated for aquatic organisms at FOCUS step 2. Data gap for further refinement. Data gap to address the chronic risk to fish.
phosphate (water and sediment)	On the basis of the available information, it is unclear if eutrophication of natural surface waters might result as a consequence of the representative use assessed. Data gap.

6.4. Air

Compound (name and/or code)	**Toxicology**
Phosphonic acid	Not acutely toxic via 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).

- The available information on transformation rate of phosphonic acid to phosphate ions in natural surface water and exposure levels in natural surface water of phosphate ions, consequent to the use assessed is insufficient to conclude that eutrophication of natural surface waters will not occur. In any new assessment consideration of exposure mitigation measures might be considered if indicated as needed (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 4).

- To further address the acute risk to aquatic invertebrates and fish for the active substance in the formulated product. To further address the chronic risk to fish from the active substance with a reliable endpoint (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

- To further address the chronic risk to earthworms and soil macroorganisms (relevant for the representative use evaluated; 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

- None.

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).

1. On the basis of the available information, it is unclear if eutrophication of natural surface waters might result as a consequence of the representative use assessed.

2. The risk to soil macroorganisms could not be finalised with the available information (see section 5).

3. The chronic risk assessment for fish could not be finalised on the basis of the available data (see section 5).

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.

4. The risk to aquatic organisms was indicated as high on the basis of FOCUS step 2 PECsw.

5. The chronic risk to earthworms was indicated as high at the first tier risk assessment.

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		**Grapes**
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	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X[5]
	Assessment not finalised	X[2]
Risk to aquatic organisms	Risk identified	X[4]
	Assessment not finalised	X[1,3]
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

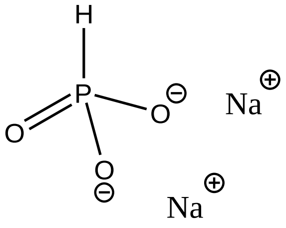
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	No ISO name is allocated. Common name: disodium phosphonate (Syn : sodium phosphite ; disodium salt of phosphonic acid)
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	FRANCE
Co-rapporteur Member State	/

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	disodium phosphonate
Chemical name (CA) ‡	Not available
CIPAC No ‡	808
CAS No ‡	13708-85-5 (other registry numbers : 130184-07-5 ; 16926-95-7)
EC No (EINECS or ELINCS) ‡	EINECS : 237-249-1
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	281 – 337 g/kg (TK) 917 g/kg (TC)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	Na_2HPO_3
Molecular mass ‡	125.96 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	None below 400°C (TC 96 %)
Boiling point (state purity) ‡	None below 400°C (TC 96 %)
Temperature of decomposition (state purity)	None below 400°C (TK 34.85%)
Appearance (state purity) ‡	White solid (TC 93.92 %) Colorless liquid (TK purity: 34.85 %)
Vapour pressure (state temperature, state purity) ‡	TK : 7.54 10^3 Pa (20°C, TK 35.13 %)
Henry's law constant ‡	TK : <1.90 $Pa.m^3.mol^{-1}$
Solubility in water (state temperature, state purity and pH) ‡	TK Miscible in any ratio (20 °C, 34.85 %, pH 2, 7 and 9) TC Miscible in any ratio (20 °C, 96 %, pH 2, 7 and 9)
Solubility in organic solvents ‡ (state temperature, state purity)	Below 10 g/L in all tested solvents (n-heptan ; p-xylene ; 1,2-dichloro-ethane ; methanol ; acetone ; ethyl acetate) (TC, 20°C, 93.92 % and TK, 20°C, 34.85 %)
Surface tension ‡ (state concentration and temperature, state purity)	TK : 72.4 mN/m (0.1 % dilution, 20.2 °C, purity 30.85 %)
Partition co-efficient ‡ (state temperature, pH and purity)	Log Pow < -4 (20°C,TC, 93.92 %)
Dissociation constant (state purity) ‡	pKa_1=2.00 (phosphonic acid) pKa_2=6.59 (phosphonic acid)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Neutral, alkaline and acidic medium no absorption at more than 290 nm (34.5 %)
Flammability ‡ (state purity)	Not highly flammable TC (93.92 %)
Explosive properties ‡ (state purity)	No explosive properties (TC 93.92 % and TK 34.85%)
Oxidising properties ‡ (state purity)	No oxidizing properties expected (statement for TK and study for TC 93.92%)

Summary of representative uses evaluated (name of active substance or the respective variant)*

Crop and/or situation	Product Name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
(a)		(b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number max (k)	Interval between apps. (min)	g a.s./hL min max	water (L/ha) min max	kg a.s./ha min max	(l)	(m)
Vineyards	MILDICUT®	F	grape downy mildew (*Plasmopara viticola*)	SC	25 g cyazofamid/L 250 g disodium phosphonate /L	Foliar application	GS 13-89	8	12 days	7.5 – 37.5 (cyazofamid) 75-375 (disodium phosphonate)	150-1500	➢ 0.1125 (cyazofamid) ➢ ➢ 1.125 (disodium phosphonate)	21	It is recommended to use the product in resistance management programs

* For uses where the column „Remarks“ in 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 classification (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 N° 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 synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage for the treatment window (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

Methods of Analysis

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

Technical as (analytical technique)	Ion chromatography with conductivity detection
Impurities in technical as (analytical technique)	Ion chromatography with conductivity detection for impurity 1 Lyophilisation and drying for impurity 2
Plant protection product (analytical technique)	Disodium phosphonate : HPLC-UV Cyazofamid : HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		phosphonic acid and its salts expressed as phosphonic acid
Food of animal origin		None
Soil		phosphonic acid and its salts
Water	surface	phosphonic acid and its salts
	drinking/ground	phosphonic acid and its salts
Air		phosphonic acid and its salts

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Grapes : HPLC-MS/MS with LOQ 0.5 mg/kg Wheat grain : HPLC-MS/MS with LOQ 7.5 mg/kg Apple: HPLC-MS/MS with LOQ = 1.0 mg/kg Oilseed rape HPLC-MS/MS with LOQ = 2.0 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	HPLC-MS/MS with LOQ = 3 mg/kg
Water (analytical technique and LOQ)	HPLC-MS/MS with LOQ = 4.0 µg/L (ground and drinking water) HPLC-MS/MS with LOQ = 5.0 µg/L (surface water)
Air (analytical technique and LOQ)	HPLC-MS/MS with LOQ = 10.0 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not required

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

	RMS/peer review proposal
Active substance	Not classified

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	More than 67-71% (sodium phosphonate)
Distribution ‡	Widely distributed. Highest residues seen in spleen, liver and kidneys (sodium phosphonate)
Potential for accumulation ‡	No accumulation potential
Rate and extent of excretion ‡	Rapid; Essentially complete excretion within 7 days after multiple application
Metabolism in animals ‡	Mainly excreted unchanged. Minor amounts of phosphate anion in faeces (sodium phosphonate)
Toxicologically relevant compounds ‡ (animals and plants)	Parent
Toxicologically relevant compounds ‡ (environment)	Parent

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw (disodium phosphonate)	/
Rat LD_{50} dermal ‡	> 2000 mg/kg bw (disodium phosphonate)	/
Rat LC_{50} inhalation ‡	> 5.8 mg/L/4h (disodium phosphonate)	/
Skin irritation ‡	Not irritant (disodium phosphonate)	/
Eye irritation ‡	Not irritant (disodium phosphonate)	/
Skin sensitisation ‡	Not sensitising (local lymph node assay) (disodium phosphonate)	/

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat : soft faeces, increased water intake, increased sodium and calcium excretion, reduce bw and food consumption (disodium phosphonate)	
Relevant oral NOAEL ‡	400 mg/kg bw per day (phosphonic acid)	/
Relevant dermal NOAEL ‡	No data (not required)	/
Relevant inhalation NOAEL ‡	No data (not required)	/

Genotoxicity ‡ (Annex IIA, point 5.4)

	Not genotoxic	/

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

Target/critical effect ‡	Rat : soft faeces, reduced bw and food consumption (sodium phosphonate) Dog : very mild changes in testes (Fosetyl-Al)	
Relevant NOAEL ‡	298 mg/kg bw per day (Fosetyl-Al)	
Carcinogenicity ‡	No carcinogenic potential	/

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No study performed with disodium phosphonate. Data based on Fosetyl-Al study	
Relevant parental NOAEL ‡	> 1782 mg/kg bw per day (Fosetyl-Al)	/
Relevant reproductive NOAEL ‡	> 1997 mg/kg bw per day (Fosetyl-Al)	/
Relevant offspring NOAEL ‡	> 1997 mg/kg bw per day (Fosetyl-Al)	/

Developmental toxicity

Developmental target / critical effect ‡	Rats : changes in litter parameters, marginally increased fetal malformations, minor anomalies at maternal toxic dose (Fosetyl-Al) Rabbits : increased post-implantation loss, reduced bw and delayed ossification at maternal toxic dose (disodium phosphonate)	
Relevant maternal NOAEL ‡	275 mg/kg bw per day (disodium phosphonate)	/
Relevant developmental NOAEL ‡	275 mg/kg bw per day (disodium phosphonate)	/

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Not available; no neurotoxic potential expected	
Repeated neurotoxicity ‡	Not available	
Delayed neurotoxicity ‡	Not available	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	No data

Medical data ‡ (Annex IIA, point 5.9)

	No adverse health effects observed

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	2.25 mg/kg bw per day* (as phosphonic acid)	2-yr rat (monosodium phosphonate)	100
AOEL ‡	2 mg/kg bw per day	Developmental rabbit	Overall 138–(100 + 70% correction for oral absorption)
ARfD ‡	Not relevant		

*The batch used in study used to derive the ADI (Spicer, 1981c, Monosodium phosphite: Lifetime chronic toxicity and carcinogenicity study in rats) contained 73% $NaH2PO3$ and 25.9% of water, thus the NOAEL of 390 mg/kg bw per day was for the hydrated monosodium phosphonate. When corrected for the content of water, this gives: 390 x 0.73 = 284.7 mg of $NaH2PO3$. The molecular weight of $NaH2PO3$ is 104, equivalent to 2.7375 moles of $NaH2PO3$. To express the results as phosphonic acid (see the residue definition), this number of moles is corrected by taking into account the molecular weight of $H3PO3$ (i.e. 82): 2.7375 x 82 = 224.47 mg $H3PO3$ /kg bw per day. Applying an uncertainty factor of 100, this results in an ADI of 2.25 mg/kg bw per day.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Mildicut, 250 g/L disodium phosphonate and 25 g/L cyazofamid)	10% by default in absence of studies

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**Tractor mounted** German model (without PPE): 9% disodium phosphonate UK-POEM (without PPE): 52% disodium phosphonate **Hand-held sprayer** German model (without PPE): 20% disodium phosphonate
Workers	Without PPE 10% disodium phosphonate
Bystanders	Potential exposure during outdoor application : <1% disodium phosphonate

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

	RMS/peer review proposal
Substance classified (Disodium phosphonate)	No classification

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

Plant groups covered	Fruits (tomato and grapes according to public literature)
Rotational crops	No study, not required
Metabolism in rotational crops similar to metabolism in primary crops?	-
Processed commodities	No study, a case was made
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-
Plant residue definition for monitoring	Phosphonic acid and its salts expressed as phosphonic acid.
Plant residue definition for risk assessment	Phosphonic acid and its salts expressed as phosphonic acid..
Conversion factor (monitoring to risk assessment)	-

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

Animals covered	Not required
Time needed to reach a plateau concentration in milk and eggs	-
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	no

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

	Not required

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

	Grapes-12 months

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)	-	-	-

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	-	-	-
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Wine grape	Northern	4.47; 5.57; 5.59; 6.64; 6.90; 7.10; 9.96; 11.91	8 x 1.125 kg/ha (+/- 25%)	30.0	11.91	6.77
Wine grape	Southern	5.85; 7.36; 9.18; 9.63; 11.46; 12.11; 18.16; 21.42;	8 x 1.125 kg/ha (+/- 25%)	40.0	21.42	10.54

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 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	2.25 mg/kg bw per day for Phosphonic acid
TMDI (% ADI) according to WHO European diet	3% (Cluster B)
TMDI (% ADI) according to highest national diet	7% (FR, all population)
IEDI (WHO European Diet) % ADI)	2% (Cluster B)
NEDI (specify diet) (% ADI)	3% (FR, all population)
Factors included in IEDI and NEDI	Processing factor wine
ARfD	Not allocated
IESTI (%ARfD)	-
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	-

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Grape/wine	4	1.8	-	-

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

Wine grapes	40 mg/kg

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

Mineralization after 100 days ‡	No data provided, not required
Non-extractable residues after 100 days ‡	No data provided, not required
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	No reliable quantitative data provided. Qualitatively, sodium, phosphate and phosphonic acid are formed.

Table 1:

Table 2:

Table 3: Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	No reliable data provided for soil. Qualitative data demonstrated microbial culture of some soil could convert phosphate to organic phosphate
Soil photolysis ‡	No reliable data provided. Due to the negligible light absorption of phosphonic acid above 290 nm, degradation processes such as photochemical transformation in soil are considered not relevant

Table 4:

Table 5:

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

Laboratory studies ‡

Disodium phosphonate as test substance	Aerobic conditions						
Soil type	X[12]	pH	t. °C / WHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[(a)]	St. (r^2)	Method of calculation
Clay loam		6.97	20°C/pF2.0-2.5	179/750	246	0.975	DFOP K_2
Sandy loam		5.7	20°C/pF2.0-2.5	191/843	281	0.979	DFOP K_2
Silt loam		7.2	20°C/pF2.0-2.5	29.7/98.5	29.7		SFO
Phosphonic acid	Aerobic conditions						
Soil type	X[13]	pH	t. °C / WHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[(a)]	St. (r^2)	Method of calculation
Clay loam		-	28°C/ field capacity	96 / 319	196	0.96	SFO
sandy loam		5	20°C/ 75% 33kPa	133 / 442	88	0.68	SFO
Geomean					129		

(a)=Normalised used a Q10 of 2.58 and Walker equation coefficient of 0.7

Field studies (state location, range or median with n value) ‡	No data available
Soil accumulation and plateau concentration ‡	Estimated by calculation, See PECsoil calculations

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[12] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

[13] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	1.7	7.2			4.177	246	0.88
Silt loam	1.18	6.97			12.819	1086	0.74
Sand	1.08	5.8			32.810	3038	0.66
Silt loam	2.6	6.7			5.013	193	0.78
Loam	1.46	7.1			4.850	332	0.92
Arithmetic mean					11.9	952	-
pH dependence, Yes or No			Yes				

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

Column leaching ‡	^{14}C-Fosetyl : 4 soils (OC 0.76-2.09 %), 200 mm. RA in leachates : 0.36-43.8 % (fosetyl < 3.4 %, ethanol < 36 %, unknowns < 10 %, phosphonic acid <1-12.6 % could derive from degradation of fosetyl in leachates) ^{33}P-Phosphonic acid : 2 soils (clay 5.1-8.9 %, OC 2.4-3.0 %), 508 mm. RA in leachates : < 0.00 %. RA in soil : 78.7-90.9 % in 0-2.5 cm, no or negligible below 5 cm.
Aged residues leaching ‡	^{14}C-Fosetyl : 1 soil (OC 2.09 %), 30 d incubation period, 4.9 mm for 45 d Negligible mobility but incubation period too long.
Lysimeter/ field leaching studies ‡	No data provided but considered not required

PEC (soil) (Annex IIIA, point 9.1.3)

Disodium phosphonate

Method of calculation	4 applications with 50% crop interception 2 applications with 60% crop interception 2 applications with 70% crop interception BD 1.5 g cm^{-3} 5 cm soil layer DT50 lab. 281 days (slow phase from DFOP model, n=3)
Application rate	8 x 1.125 kg as/ha disodium phosphonate

Dissodium phosphonate PEC$_{(s)}$	Multiple application Actual	Multiple application Time weighted average
Initial	**4.552**	-
Short term 24h	4.541	4.546
2d	4.530	4.541

4d	4.507	4.530
Long term 7d	4.474	4.513
21d	4.322	4.436
28d	4.248	4.398
50d	4.024	4.282
100d	3.557	4.034
Plateau concentration	PEC accumulation plateau* : 7.67 mg/kg after 8 years (*i.e.*, 5.0 mg/kg equivalent phosphonic acid)	

*This plateau value represents the top of the saw tooth curve (max value after an application) and not the valley of the saw tooth curve.

Phosphonic acid

Method of calculation	4 applications with 50% crop interception 2 applications with 60% crop interception 2 applications with 70% crop interception BD 1.5 g cm^{-3} 5 cm soil layer DT50 lab. 218 days (slow phase from DFOP model, n=3)
Application rate	8 x 0.7324 kg as/ha phosphonic acid equivalent Corrected by the molar ratio

Phosphonic acid PEC$_{(s)}$	Multiple application Actual	Multiple application Time weighted average
Initial	2.825	
Short term 24h	2.815	2.820
2d	2.805	2.815
4d	2.785	2.805
Long term 7d	2.756	2.790
21d	2.623	2.722
28d	2.558	2.689
50d	2.367	2.589
100d	1.983	2.379
Plateau concentration	PEC accumulation plateau* : 3.90 mg/kg after 5 years	

*This plateau value represents the top of the saw tooth curve (max value after an application) and not the valley of the saw tooth curve.

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

Hydrolysis of active substance and relevant metabolites (DT$_{50}$) (state pH and temperature) ‡	Not a major route in the degradation of the substance

Photolytic degradation of active substance and relevant metabolites ‡	No reliable data provided. Stable to direct aqueous photolytic degradation, no absorbance maxima in the UV/vis wavelengths
Readily biodegradable (yes/no) ‡	No
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	- No information available
Mineralization	No information available
Non-extractable residues	No information available
Distribution in water / sediment systems (active substance) ‡	No information available
Distribution in water / sediment systems (metabolites) ‡	-

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

Disodium phosphonate Parameters used in FOCUSsw step 1 and 2	FOCUS calculator : FOCUS Step 1-2 version 2.1 Applied as parent Molecular weight (g/mol): 125.96 Water solubility at 20°C (mg/L): 1,875,000 Kf_{OC} (L/kg): 10 / 10.000 (two sets of simulations) DT_{50} soil (d): 281 DT_{50} water/sediment system (d): 1000 (default) DT_{50} water (d): 1000 (default) DT_{50} sediment (d): 1000 (default) Crop:vine (early/late) Crop interception (%): Step 1: n.a. Step 2: N and S ; early (march to -may) – minimal crop cover (40%) Step 2: N and S , late (June to Sep)- average crop cover (50%) application Number of applications: 8 Time between individual applications (minimum): 12 d
Parameters used in FOCUSsw step 3 (if performed)	No used for risk assessment
Application rate	8 x 1.125 kg as/ha
Main routes of entry	Drift, drainage and runoff

FOCUS steps 1 and 2; koc 10 mLg

Crop (FOCUS crop scenario)	Step	Number of applications	Application rate [kg a.s./ha]	Region and season of application	Maximum PEC_{SW} actual [µg disodium phosphonate./L]	Maximum PEC_{SW} actual [µg equivalent phosphonic acid./L]

Grapevine (vines, early application)	1	8	1.125	n.r.	3040	1979.04
	2	8	1.125	Northern Europe, March-May	330.15	214.93
	2	8	1.125	Southern Europe, March-May	595.06	387.38
Grapevine (vines, late application)	1	8	1.125	n.r.	3200	2083.20
	2	8	1.125	Northern Europe, June-Sep	416.24	270.97
	2	8	1.125	Southern Europe, June-Sep	336.77	219.24

n.r. not relevant

PECsw after a single application reported in brackets

FOCUS steps 1 and 2; koc 10,000 mLg

Crop (FOCUS crop scenario)	Step	Number of applications	Application rate [kg a.s./ha]	Region and season of application	Maximum PEC_{SED} actual [µg disodium phosphonate kg dry sediment]	Maximum PEC_{sed} actual [µg equivalent phosphonic acid./kg dry weight]
Grapevine (vines, early application)	1	8	1.125	n.r.	21400	13931
	2	8	1.125	Northern Europe, March-May	2330	1517
	2	8	1.125	Southern Europe, March-May	4200	2734
Grapevine (vines, late application)	1	8	1.125	n.r.	22600	14713
	2	8	1.125	Northern Europe, June-Sep	2370	1543
	2	8	1.125	Southern Europe, June-Sep	2940	1914

n.r. not relevant

Phosphate ions

Parameters used in FOCUSsw step 1 and 2

FOCUS calculator : FOCUS Step 1-2 version 2.1
Applied as metabolite
Molecular weight (g/mol): 94.9
Water solubility at 20°C (mg/L): 1,875,000
Kf$_{OC}$ (L/kg): 10 / 10.000 (two sets of simulations)
DT_{50} soil (d): 1000 (default)
DT_{50} water/sediment system (d): 1000 (default)
DT_{50} water (d): 1000 (default)
DT_{50} sediment (d): 1000 (default)
Crop:vine (early/late)
Crop interception (%):
Step 1: n.a.
Step 2: N and S ; early (march to -may) minimal crop cover (40%)
Step 2: N and S , late (June to Sep)- average crop cover (50%)application

	Number of applications: 8 Time between individual applications (minimum): 12 d
Parameters used in FOCUSsw step 3 (if performed)	No used for risk assessment
Application rate	8 x 1.125 kg as/ha
Main routes of entry	Drift, drainage and runoff

FOCUS steps 1 and 2; Koc of 10 mL/g

Crop (FOCUS crop scenario)	Step	Number of applications	Application rate [kg a.s./ha]	Region and season of application	Maximum PEC_{SW} actual [µg phosphate ions./L]
Grapevine (vines, early application)	1	8	1.125	n.r.	2290
	2	8	1.125	Northern Europe, March-May	265.45
	2	8	1.125	Southern Europe, March-May	481.69
Grapevine (vines, late application)	1	8	1.125	n.r.	2410
	2	8	1.125	Northern Europe, June-Sep	263.83
	2	8	1.125	Southern Europe, June-Sep	328.70

n.r. not relevant

FOCUS steps 1 and 2; koc 10,000 mLg

Crop (FOCUS crop scenario)	Step	Number of applications	Application rate [kg a.s./ha]	Region and season of application	Maximum PEC_{SED} actual [µg phosphate ions kg dry sediment]
Grapevine (vines, early application)	1	8	1.125	n.r.	16200
	2	8	1.125	Northern Europe, March-May	1870
	2	8	1.125	Southern Europe, March-May	3400
Grapevine (vines, late application)	1	8	1.125	n.r.	17000
	2	8	1.125	Northern Europe, June-Sep	1860
	2	8	1.125	Southern Europe, June-Sep	2320

n.r. not relevant

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

Phosphonic acid

Application rate	FOCUS Groundwater Modelling ; FOCUS PELMO 4.4.3 1.125 kg disodium phosphonate (a.s.)/ha; phosphonic

	acid applied (0.73237 kg phosphonic acid / ha) Crop interception : 4 applications with 50% crop interception 2 applications with 60% crop interception 2 applications with 70% crop interception Number of application per year : 8 Time between applications : 12 days Application timing: Grapevines, early: 1st application at day of emergence Grapevines, late: last application at PHI (60 days before harvest) Inputs for modelling: Molecular weight: 82.0 g/mol Water Solubility (25 °C): 1,875,000 mg/L Vapour Pressure (25 °C) : 0 Pa Distribution Coefficient (Kd) : 10.7 mL/g Molar enthalpy of sorption: 0 kJ/mol Freundlich sorption exponent (1/n): 1.0 Soil DT50: 196 d Molar activation energy: 65.4 kJ/mol Walker equation coefficient 0.7 Plant uptake: 0

PEC (gw) – FOCUS modelling result (80th percentile annual average concentration at 1m)

	PEC$_{GW}$ /26 years application [µg/L]
	(80th percentile at 1 m depth)
Location	**phosphonic acid**
Châteaudun	0.241
Hamburg	0.276
Kremsmünster	1.059
Piacenza	0.526
Porto	**1.476**
Sevilla	0.009
Thiva	0.001

PEC$_{(gw)}$

Maximum concentration	-
Average annual concentration	-

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

Direct photolysis in air ‡	No data provided, data not required
Quantum yield of direct phototransformation	No data provided. data not required
Photochemical oxidative degradation in air ‡ **Table 6:**	DT50 of 38.2 days derived by the Atkinson model. 12 h OH radical concentration assumed of 1.5 x 10^6 OH radicals/cm³.

Volatilization ‡	The vapour pressure of disodium phosphonate is 7540 Pa at 20 °C and Henry's Law constant <1.90 Pa.m^3.mol^{-1}. Therefore volatilisation of disodium phosphonate is expected to be high.

PEC (air)

Method of calculation	Data not provided, data not required

PEC$_{(a)}$

Maximum concentration	No data provided, not required The potential for long-range transport was addressed.

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: phosphonic acid and its salts Surface water: phosphonic acid and its salts and phosphate ions sediment:phosphonic acid and its salts and phosphate ions Groundwater: phosphonic acid and its salts Air: phosphonic acid and its salts

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

Soil (indicate location and type of study)	No data provided. Not expected to be available.
Surface water (indicate location and type of study)	No data provided. Not expected to be available.
Ground water (indicate location and type of study)	No data provided. Not expected to be available.
Air (indicate location and type of study)	No data provided. Not expected to be available.

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

Candidate for R53

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

Species	Test substance	Time scale	End point (mg/kg bw per day	End point (mg/kg feed)
Bird ‡				
Colinus virginanus	K-phosphite	Acute	> 675 mg/kg bw phosphonic acid	
Anas platyrhynchos	MILDICUT	Acute	> 2250 mg/kg bw MILDICUT > 299.5 mg/kg bw phosphonic acid	
	Phosphonic acid (metabolite)	Acute	No data. All toxicity data with the parent were expressed as equivalent phosphonic acid	
Colinus virginanus	K-phosphite	Short-term	> 508 mg/kg bw phosphonic acid	
Coturnix coturnix japonica	Disodium phosphonate	Long-term	252 mg/kg bw phosphonic acid	2400 ppm disodium phosphonate
Mammals ‡				
rat	Disodium phosphonate	Acute	> 453.7 mg/kg bw phosphonic acid	
rat	MILDICUT	Acute	> 2000 mg/kg bw MILDICUT > 266.3 mg/kg bw phosphonic acid	
rat	Phosphonic acid (metabolite)	Acute	1700 mg/kg bw phosphonic acid	
rat	Fosetyl Aluminium	Long-term	231.8 mg phosphonic acid/kg bw per day.	
Additional higher tier studies ‡				
No data.				

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

Vines / 8 applications of 1125 g disodium phosphonate/ha equivalent to 732.28 g phosphonic acid/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous bird / Vines	Acute	39.59	> 17.05	10
Insectivorous bird /	Short-term	22.08	> 23.01	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Vines				
Insectivorous bird / Vines	Long-term	22.08	11.41	5
Drinking water	Acute	11.617	58.1	10
Drinking water	Long-term	11.617	21.7	5
Tier 1 (Mammals)				
Herbivorous mammal / Vines	Acute	129.73	**> 3.50**	10
Herbivorous mammal / Vines	Long-term	43.61	5.21	5
Drinking water	Acute	6.061	74.9	10
Drinking water	Long-term	6.061	37.5	5
Higher tier refinement (Mammals): Since in the test with disodium phosphonate solution (2007a), no rats died at the limit dose of 453.7 mg phosphonic acid/kg bw, the LD_{50} is considered to be clearly higher. The refined risk assessment is based on the LD_{50} of 1700 mg/kg bw with phosphonic acid.				
Herbivorous mammal / Vines	Acute	129.73	13.1	10

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

[2] for cereals indicate if it is early or late crop stage

[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column

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 (Test type)	End point	Toxicity[1] (mg/L) expressed as equivalent phosphonic acid
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Disodium phosphonate	96 hr (flow-through)	Mortality, LC_{50}	> 61.26 (nom)
Oncorhynchus mykiss	MILDICUT	96 hr (static)	Mortality, LC_{50}	> 100 (nom) MILDICUT > 13.35 (nom)
	Preparation	28 d (flow-through)	Growth NOEC	No data
	Phosphonic acid (metabolite)	96 hr (flow-through)	Mortality, EC_{50}	No data. All toxicity data with the parent were expressed as equivalent phosphonic acid
Aquatic invertebrate				

Group	Test substance	Time scale (Test type)	End point	Toxicity[1] (mg/L) expressed as equivalent phosphonic acid
Daphnia magna	Disodium phosphonate	48 h (static)	Mortality, EC_{50}	> 61.26 (nom)
Daphnia magna	Disodium phosphonate	21 d (semi-static)	Reproduction, NOEC	22.87 (nom)
Daphnia magna	MILDICUT	48 h (static)	Mortality, EC_{50}	21 (nom) MILDICUT **2.8 (nom)**
	Preparation	21 d (static)	Reproduction,NOEC	No data
	Phosphonic acid (metabolite)	48 h (static)	Mortality, EC_{50}	No data. All toxicity data with the parent were expressed as equivalent phosphonic acid
Sediment dwelling organisms				
Chironomus riparius	Disodium phosphonate	26 d (static)	NOEC	68.1 (nom)
	Phosphonic acid (metabolite)	28 d (static)	NOEC	No data. All toxicity data with the parent were expressed as equivalent phosphonic acid
Algae				
Pseudokirchneriella subcapitata	Disodium phosphonate	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	7.29 (nom) > 61.26 (nom)
Scenedesmus subspicatus	MILDICUT	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 68 (mm) MILDICUT > 13.35 (nom)
	Phosphonic acid (metabolite)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No data All toxicity data with the parent were expressed as equivalent phosphonic acid
Higher plant				
Indicate species	a.s.	14 d (static)	Fronds, EC_{50}	No data required
	Preparation	14 d (static)	Fronds, EC_{50}	No data required
	Metabolite 1	14 d (static)	Fronds, EC_{50}	No data required
Microcosm or mesocosm tests				
not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

Vines / 1 application of 9000 g/ha of Disodium phosphonate in equivalent phosphonic acid

Test substance	Organism	Toxicity end point (mg/L) phosphonic acid	Time scale	Season / Scenario	Total PECsw (µg/L) phosphonic acid	TER	Annex VI Trigger[1]
Disodium phosphonate	Fish (*O. mykiss*)	> 61.26	Acute	Northern Europe - Early	214.93	>285	100
				Southern Europe - Early	387.38	>158.1	
				Northern Europe - Late	270.97	>226.1	
				Southern Europe - Late	219.24	>279.4	
Disodium phosphonate	Aquatic invertebrates (*D. magna*)	> 61.26	Acute	Northern Europe - Early	214.93	>285	100
				Southern Europe - Early	387.38	>158.1	
				Northern Europe - Late	270.97	>226.1	
				Southern Europe - Late	219.24	>279.4	
Disodium phosphonate	Aquatic invertebrates (*D. magna*)	22.87	Chronic	Northern Europe - Early	214.93	106.4	10
				Southern Europe - Early	387.38	59	
				Northern Europe - Late	270.97	84.4	
				Southern Europe - Late	219.24	104.3	
Disodium phosphonate	Algae (*Pseudokirchneriella subcapitata*)	7.29	Chronic	Northern Europe - Early	214.93	33.9	10
				Southern Europe - Early	387.38	18.8	
				Northern Europe - Late	270.97	26.9	
				Southern Europe - Late	219.24	33.3	
Disodium phosphonate	Sediment-dwelling[3] organisms (*C. riparius*)	68.1 mg/L	Chronic	Northern Europe - Early	214.93	316.8	10
				Southern Europe - Early	387.38	175.8	
				Northern Europe - Late	270.97	251.3	
				Southern Europe - Late	219.24	310.6	
Phosphonic acid (metabolite)	Relevant organisms	All toxicity data with the parent were expressed as equivalent phosphonic acid. Therefore, the risk of phosphonic acid was assessed.					
MILDICUT	Fish (*O.*	> 13.35 (equivalent phosphonic	Acute	Northern Europe - Early	214.93	**>62.1**	100
				Southern Europe	387.38	**>34.5**	

Test substance	Organism	Toxicity end point (mg/L) phosphonic acid	Time scale	Season / Scenario	Total PECsw (µg/L) phosphonic acid	TER	Annex VI Trigger[1]
	mykiss)	acid)		- Early			
				Northern Europe - Late	270.97	**>49.3**	
				Southern Europe - Late	219.24	**>60.9**	
MILDICUT	Invertebrates (*D.magna*)	2.8 (equivalent phosphonic acid)	Acute	Northern Europe - Early	214.93	**13**	100
				Southern Europe - Early	387.38	**7.2**	
				Northern Europe - Late	270.97	**10.3**	
				Southern Europe - Late	219.24	**12.8**	
MILDICUT	Algae (*S. subspicatus*)	> 13.35 (equivalent phosphonic acid)	Chronic	Northern Europe - Early	214.93	>62.1	10
				Southern Europe - Early	387.38	>34.5	
				Northern Europe - Late	270.97	>49.3	
				Southern Europe - Late	219.24	>60.9	

[1] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

[2] only required for herbicides

[3] consider the need for PEC$_{sw}$ and PEC$_{sed}$ and indicate which has been used

Bioconcentration	
	Disodium phosphonate
logP$_{O/W}$	Based on the high water solubility and the low solubility in n-octanol, P$_{ow}$ is expected to be very low.
Bioconcentration factor (BCF)[1] ‡	Not required
Annex VI Trigger for the bioconcentration factor	1000

[1] only required if log P$_{O/W}$ >3.

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)
Disodium phosphonate ‡	No data	No data
MILDICUT[1]	> 2541 µg preparation/bee*	> 4878 µg preparation/bee
Phosphonic acid	No data	No data
Field or semi-field tests		
not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

* an accurate LD50 could not be estimated as there are some uncertainties on the origin of the mortality (73.3%) observed at the highest tested rate (low intake of the active substance by bees at this rate). Then the LD_{50} value corresponds to the highest tested rate with a normal intake of the substance by bees and for which a mortality of 6.7% was observed.

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

Vines / 1125 g disodium phosphonate/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	No data	50
a.s.	oral	No data	50
MILDICUT	Contact	< 1.13	50
MILDICUT	oral	< 2.16*	50

*indicative value as there are some uncertainties on the oral LD50. However, the margin of safety is considered sufficient to conclude on the risk.

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} kg MILDICUT/ha[1])
Typhlodromus pyri ‡	MILDICUT	Mortality	> 27.44
Aphidius rhopalosiphi ‡	MILDICUT	Mortality	< 4.39 (70% mortality at this rate)

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Vines, 8 applications at 5.49 kg MILDICUT/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field (3 m)	Trigger
MILDICUT	*Typhlodromus pyri*	> 27.44	< 0.7	< 0.02 (early) < 0.04 (late)	2
MILDICUT	*Aphidius rhopalosiphi**	< 4.39	*	*	2

* Calculation of HQ value is not possible

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (kg MILDICUT /ha)	End point (kg MILDICUT/ ha)	% effect	Trigger value
LABORATORY TESTS						

Species	Life stage	Test substance, substrate and duration	Dose (kg MILDICUT /ha)	End point (kg MILDICUT/ ha)	% effect	Trigger value
Chrysoperla carnea	2-3 days old lacewing larvae	MILDICUT, on glass plates , 13-22 days of exposure followed by reproduction test	4.39 and 10.98	LR_{50} > 10.98	No effect on fecundity at both rates. Slight effects on fertility but < 50%	50 %
Poecilus cupreus	adults	MILDICUT, on quartz sand, 2 weeks of exposure	10.98 and 27.44	LR_{50} > 27.44	No effect on behaviour and food consumption.	50 %
EXTENDED LABORATORY TESTS						
Aphidius rhopalosiphi	Adults (2 - 48 hours old)	MILDICUT, on barley plants, 48 hours of exposure followed by fecundity test	10.98 and 27.44	LR_{50} > 27.44	no effect on fecundity at both rates	50 %
Chrysoperla carnea	larvae	MILDICUT, on bean leaves, 11-16 days of exposure followed by fecundity test	0.313 , 0.876, 2.455, 6.874 and 19.247	LR_{50} > 19.247	Effect on reproduction was < 50 % at all doses	50 %
Field or semi-field tests						
No data.						

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)

Test organism	Test substance	Time scale	End point[1]
Earthworms	Disodium phosphonate‡	Acute 14 days	LC_{50} > 944 mg a.s./kg d.w.soil equivalent to > 615 mg phosphonic acid/kg d.w. soil
Earthworms	Disodium phosphonate‡	Chronic 8 weeks (substance incorporated in soil)	NOEC = 7.1 mg a.s./kg d.w.soil equivalent to 4.62 mg phosphonic acid/kg d.w. soil
Earthworms	Disodium phosphonate‡	Chronic 8 weeks (substance sprayed onto the soil)	NOEC = 55 mg a.s./kg d.w.soil equivalent to 35.81 mg phosphonic acid/kg d.w. soil
Earthworms	MILDICUT	Acute 14 days	LC_{50} > 1000 mg Mildicut/kg soil (equivalent to > 126 mg phosphonic acid/kg soil)

Test organism	Test substance	Time scale	End point[1]
Earthworms	MILDICUT	Chronic 8-weeks (substance sprayed onto the soil)	NOEC = 163.18 mg Mildicut/kg soil (equivalent to 20.51 mg phosphonic acid/kg soil)
Earthworms	Phosphonic acid	Acute	No data All toxicity data with the parent were expressed as equivalent phosphonic acid
Earthworms	Phosphonic acid	Chronic	No data All toxicity data with the parent were expressed as equivalent phosphonic acid
Other soil macro-organisms			
Not required (only for the required GAPs)			
Soil micro-organisms			
Nitrogen transformation	MILDICUT	Chronic	< 25 % effect at day 28 up to 12.8 kg MILDICUT/ha (equivalent to 2.27 mg phosphonic acid/kg soil)
Nitrogen transformation	MILDICUT	Chronic	<25 % effect at day 28 up to 36 L MILDICUT/ha (equivalent to 8.03 mg phosphonic acid/kg soil)
Carbon mineralisation	MILDICUT	Chronic	< 25 % effect at day 28 up to 12.8 kg MILDICUT/ha (equivalent to 2.27 mg phosphonic acid/kg soil)
Carbon mineralisation	MILDICUT	Chronic	<25 % effect at day 28 up to 36 L MILDICUT/ha (equivalent to 8.03 mg phosphonic acid/kg soil)
Field studies			
No data.			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

Toxicity/exposure ratios for soil organisms

Vines, 8 x 1.125 kg as/ha disodium phosphonate expressed as equivalent phosphonic acid

Test organism	Test substance	Time scale	Soil PEC[2] (Multiple Application, actual)	TER	Trigger
Earthworms					
Tier I	Disodium phosphonate‡	Acute	5 mg phosphonic acid/kg soil	>123	10

Test organism	Test substance	Time scale	Soil PEC[2] (Multiple Application, actual)	TER	Trigger
Tier I	Disodium phosphonate‡ (substance incorporated in soil)	Chronic	5 mg phosphonic acid/kg soil	**0.92**	5
Tier I	MILDICUT	Acute	5 mg phosphonic acid/kg soil	>25.2	10
Tier II	MILDICUT	Chronic	3.9 mg phosphonic acid/kg soil	5.25	5
Other soil macro-organisms					
No data					
Soil micro-organisms					
Based on the results of the study Feil-Klein (2012) no unacceptable effects were observed on soil micro-organisms for concentrations up to and including 8.03 mg phosphonic acid/kg soil. The maximum PEC_{soil} of phosphonic acid was estimated to be 5 mg/kg soil and the refined PEC_{soil} was estimated to be 3.9 mg/kg soil. Therefore, the risk for soil micro-organisms is low.					

[1] to be completed where first Tier triggers are breached

[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Test species were not sensitive	Mildicut	> 15.75 L/ha	> 15.75 L/ha	0.34 L/ha (early) 0.99 L/ha (late)	> 46.32 (early) > 15.97 (late)	5

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Additional studies (e.g. semi-field or field studies)

No data

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

Test type/organism	end point
Activated sludge	No data
Pseudomonas sp	No data

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

Compartment	
soil	Phosphonic acid
water	Phosphonic acid
sediment	Phosphonic acid
groundwater	Phosphonic acid

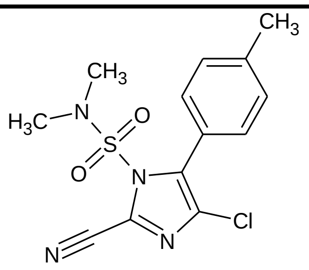
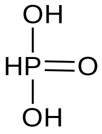
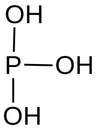
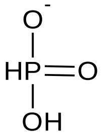
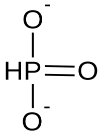
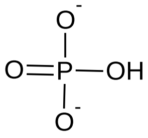
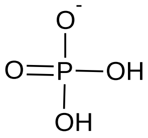
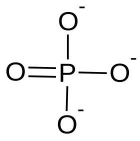
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)*

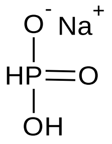
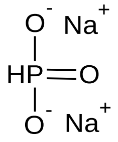
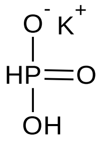
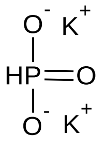
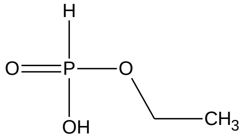
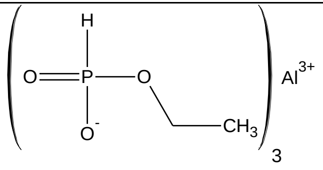
	RMS/peer review proposal
Active substance	R52

	RMS/peer review proposal
Preparation	R52

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
cyazofamid	4-chloro-2-cyano-*N*,*N*-dimethyl-5-*p*-tolylimidazole-1-sulfonamide	
phosphonic acid Phosphorous acid [PHO(OH)$_2$], (HO)$_2$HPO H_3PO_3	phosphonic acid	 $HP(=O)(OH)_2$
phosphorous acid (minor tautomer of phosphonic acid) H_3PO_3, [P(OH)$_3$]	phosphorous acid	 $P(OH)_3$
hydrogen phosphonate dihydrogenphosphite $H_2PO_3^-$ $[PO(OH)_2]^-$	hydrogen phosphonate (ion)	 $HP(=O)(O^-)(OH)$
phosphonate $[PHO_3]^{2-}$	phosphonate (ion)	 $HP(=O)(O^-)_2$
hydrogen phosphate HPO_4^{2-} $[PO_3(OH)]^{2-}$	hydrogen phosphate (ion)	 $O{=}P(O^-)_2(OH)$
dihydrogenphosphate $H_2P0_4^-$ $[PO_2(OH_2)]^-$	dihydrogen phosphate (ion)	 $O{=}P(O^-)(OH)_2$
phosphate $[PO_4]^{3-}$	phosphate (ion)	 $O{=}P(O^-)_3$

Code/Trivial name*	Chemical name	Structural formula
sodium phosphonate sodium phosphite	sodium hydrogen phosphonate	 $\mathrm{HP(=O)(O^{-}\,Na^{+})(OH)}$
disodium phosphonate	disodium phosphonate	 $\mathrm{HP(=O)(O^{-}\,Na^{+})(O^{-}\,Na^{+})}$
Potassium phosphonates are a mixture of potassium hydrogen phosphonate and dipotassium phosphonate	potassium hydrogen phosphonate	 $\mathrm{HP(=O)(O^{-}\,K^{+})(OH)}$
	dipotassium phosphonate	 $\mathrm{HP(=O)(O^{-}\,K^{+})(O^{-}\,K^{+})}$
fosetyl	ethyl hydrogen phosphonate	
fosetyl-Al fosetyl aluminium	aluminium tris(ethyl phosphonate)	

* The metabolite name in bold is the name used in this conclusion, the other trivial names or formulae indicated for these compounds have been used in the DAR and its addenda (France 2005a, 2012) and in the EFSA conclusion for the active substance fosetyl (EFSA 2005). The alternative names indicated have also been used extensively in the reporting and evaluation tables for disodium phosphonates, which are included in the Peer Review Report as a background document to this conclusion (EFSA, 2013). Where the name phosphorous acid was used in these tables in the background documents, then the moiety referred to was phosphonic acid (IUPAC).

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
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
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
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_{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
ELS	early life stage
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
FID	flame ionisation detector
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)
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – 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
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
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
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
NPD	nitrogen phosphorous detector
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
PT	proportion of diet obtained in the treated area
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
$t_{1/2}$	half-life (define method of estimation)
TC	technical material
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
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year