CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance L-ascorbic acid[1]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the Netherlands, for the pesticide active substance L-ascorbic acid are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of L-ascorbic acid as a fungicide on potato, glasshouse tomato and field and glasshouse flower bulbs. 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

Ascorbic acid, L-ascorbic acid, ascorbate, peer review, risk assessment, pesticide, fungicide, bactericide

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SUMMARY

L-Ascorbic acid is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC the Netherlands (hereinafter referred to as the 'RMS') received an application from Citrex Europe B.V. 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 2005/751/EC.

The RMS provided its initial evaluation of the dossier on L-ascorbic acid in the Draft Assessment Report (DAR), which was received by the EFSA on 10 September 2007. The peer review was initiated on 5 October 2011 by dispatching the DAR for consultation of the Member States and the applicant Citrex Europe B.V.

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

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of L-ascorbic acid as a fungicide on potato, glasshouse tomato and field and glasshouse flower bulbs as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified for the section physical and chemical properties and analytical methods.

No data gaps or critical areas of concern were identified in the toxicology and metabolism section.

In the area of residues no data gaps were identified and the risk assessment can be finalised.

The minimal information available on environmental fate and behaviour has been just sufficient to complete a rudimentary environmental exposure assessment at the EU level. This assessment results in the critical area of concern, that for all the representative uses, the potential for vulnerable groundwater to be contaminated above the parametric drinking water limit for a pesticide of 0.1µg/L in geoclimatic situations represented by all the pertinent FOCUS groundwater scenarios (up to six scenarios) is identified as high.

The risk assessment for fish (chronic), aquatic invertebrates (acute and chronic), algae, earthworms and soil micro-organisms could not be finalised with the available data. On the basis of the available data a high risk to non-target arthropod was also indicated for the representative use on potatoes. The risk assessment for non-target arthropods for the representative outdoor use on bulbs could not be finalised. A low risk was concluded for birds, mammals, honey bees, non-target plants and sewage treatment organisms.

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BACKGROUND

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

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

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of up to 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 the Netherlands (hereinafter referred to as the 'RMS') received an application from Citrex Europe B.V. for approval of the active substance L-ascorbic acid. 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 2005/751/EC.[6]

The RMS provided its initial evaluation of the dossier on L-ascorbic acid in the DAR, which was received by the EFSA on 10 September 2007. 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 updated DAR, which was received on 15 July 2011 (Netherlands, 2011). The peer review was initiated on 5 October 2011 by dispatching the updated DAR to Member States and the applicant Citrex Europe B.V. for consultation and comments. 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 30 January 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision (2005/751/EC of 21 October 2005 Commission Decision of 21 October 2005 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of ascorbic acid, potassium iodide and potassium thiocyanate in Annex I to Council Directive 91/414/EEC. OJ No L 282, 26.10.2005, p. 18-19.

concluded that additional information should be requested from the applicant and that the EFSA should organise an expert consultation in the area of mammalian toxicology.

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

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

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

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on potato, glasshouse tomato and field and glasshouse flower bulbs, 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 updated DAR,
- the Reporting Table (6 February 2012),
- the Evaluation Table (12 April 2013),
- the report 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 February 2013 containing all individually submitted addenda (Netherlands, 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

L-ascorbic acid (vitamin C) is a common name for (5*R*)-5-[(1*S*)-1,2-dihydroxyethyl]-3,4-dihydroxyfuran-2(5*H*)-one (IUPAC).

The representative formulated product for the evaluation was 'Dipper', a soluble concentrate (SL) containing 23 g/l L-ascorbic acid.

The representative formulated product for the evaluation also contains a high proportion of citric acid and lactic acid (Netherlands, 2011). Lactic acid has in the past been authorised as an active substance in plant protection products but was subject to non-inclusion in Annex I to Council Directive 91/414/EEC. Consequently plant protection products containing lactic acid had to be withdrawn from the market in accordance with Commission Decision 2004/129/EC of 30 January 2004.[7] The RMS informed EFSA in March 2013 that the formulation 'Dipper' also contains didecyldimethylammonium chloride (DDAC), an active substance included in Annex I to Council Directive 91/414/EEC by Commission Directive 2009/70/EC[8] and subsequently approved under Regulation (EC) No 1107/2009.

The representative uses evaluated comprise foliar spray applications as a fungicide on potatoes and protected tomatoes and applications by dipping on flower bulbs, against seed-borne pathogens, that may then be planted under protection or in the field. 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).

The minimum purity of the active substance is 990 g/kg (pharmaceutical grade). No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of L-ascorbic acid. Methanol and heavy metals were considered relevant impurities with maximum content of 3000 mg/kg and 10 mg/kg respectively. A data gap was identified to confirm that the formulations used in the available data generation studies complied with the declared composition of the representative formulation and did not contain DDAC. Data gaps were identified for accelerated storage stability study and shelf-life study of the formulation. It should be noted that additional label instructions are needed to avoid excessive foaming during application. The main data regarding the identity of L-ascorbic acid and its physical and chemical properties are given in appendix A.

Adequate analytical methods are available for the determination of L-ascorbic acid in technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

Analytical methods for the determination of residues in plant materials, foodstuff of animal origin, air and in body fluids and tissues are not required due to the fact that no residue definitions are proposed. Pending on the final residue definition for soil, an analytical method might be required. A data gap

[7] Commission Decision 2004/129/EC of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ No L 37, 10.2.2004, p.27-31.

[8] Commission Directive 2009/70/EC of 25 June 2009 amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances. OJ No L 164, 26.6.2009, p59-63.

was identified for a residue analytical method for enforcement of the drinking water limit or the groundwater limit of 0.1 µg/l.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 – rev. 10-final (European Commission, 2003a), SANCO/222/2000 rev. 7 (European Commission, 2004), SANCO/10597/2003 – rev. 10.1 (European Commission, 2012).

L-Ascorbic acid (vitamin C) was discussed at the Peer Review 98 Expert's Meeting on mammalian toxicology.

L-Ascorbic acid is pharmaceutical grade (see section 1) and complies with maximum contents for relevant impurities (i.e. 3000 mg/kg methanol and 10 ppm heavy metals).

A complete dossier in accordance to the requirements of Annex II and II of Directive 91/414/EEC was not available. The hazard assessment has been mainly based on published information including the Scientific Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) related to the Tolerable Upper Intake Level of vitamin C (EFSA NDA, 2004). The NDA Panel concluded that there were insufficient data to establish a tolerable upper intake level for vitamin C. Nevertheless, the **average daily intakes** reported in surveys in European Countries were above the Population Reference Intake, with the 95th percentile intake from food and supplements ranging up to about 1 g/day. These dietary intakes do not represent a cause of concern (EFSA NDA, 2004).

A quantitative risk assessment has been performed by the RMS comparing the exposure to L-ascorbic acid derived from the use as plant protection product to the average daily intakes (i.e. 1 g/day) indicating that predicted estimates for operators, workers and bystanders are very low (less than 1 % of the average daily intake).

In **conclusion**, no risks to human health are expected from the use of L-ascorbic acid as a plant protection product (see also section 3). Therefore, data waivers for specific toxicological studies with L-ascorbic acid are supported.

3. Residues

L-Ascorbic acid (vitamin C) is a natural constituent of most plants; it is an essential component of the diet for humans. The amount applied to crops (maximum 44 g/ha) will make no significant impact on the intake of the consumer from their diets. The risk assessment can be finalised a quantitative risk assessment is not necessary. L-Ascorbic acid would be a candidate for inclusion in Annex IV of Regulation (EC) No 396/2005.[9]

As lactic acid is a major constituent of the formulation, it should be noted, consequent to the decision on non inclusion of lactic acid in Annex I to Council Directive 91/414/EEC, that MRLs have been set at an LOQ of 0.01 mg/kg for lactic acid. Lactic acid does not appear to have been included in Annex IV of Regulation (EC) No 396/2005. This dossier did not contain any data to confirm that consequent to the use of the representative product as proposed, that residues of lactic acid would be < 0.01mg/kg.

4. Environmental fate and behaviour

The only experimental measurement results for L-ascorbic acid available in the applicant's dossier useful for assessing their environmental fate and behaviour are:

- a water solubility of 330 g/L (temperature and purity not specified);

[9] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directives 91/414/EE. OJ No L 70, 16.3.2005, p. 1-16. (Including consolidated text dated 1/1/2012).

- a satisfactory OECD 302B guideline inherent biodegradability study indicating this compound is inherently biodegradable and readily biodegradable under the conditions of this test that uses a sewage sludge inoculum (97.5 % mineralisation occurred within 7 days).

Measurements of behaviour in soil or natural sediment water systems were not available.

Using these data (primarily the classification as readily biodegradable from the results of the OECD 302B test) and following REACH guidance (ECHA, 2010), half-lives (single first order DT_{50}) in water, soil and sediment of 15, 30 and 300 days were estimated respectively. L-Ascorbic will exhibit very high mobility in soil based on a QSAR[10] soil adsorption estimate (K_{doc}) of 0.2 mL/g.

It has been accepted that it is likely (based on the high proportion of mineralisation in a relatively short time in the available inherent biodegradability study) that transformation products of L-ascorbic acid (other than those that would be classed as being of no concern)[11] will not be formed at levels that would trigger further consideration for environmental exposure and risk assessment.

The DT_{50} and K_{doc} values indicated above were used to calculate the necessary predicted environmental concentrations (PEC) that are included in appendix A (except for soil where no decline between applications was assumed in those PEC) consequent to the representative uses assessed. PEC calculations in surface water and sediment were carried out for L-ascorbic acid using the FOCUS (2001) step 2, step 3 and for potatoes step 4 approaches.[12] For flower bulbs, at step 3, the scenarios FOCUS prescribes for bulb vegetables were used in calculations, as flower bulbs are not specified as a crop at step 3. The step 4 calculations for the use on potatoes appropriately followed the FOCUS (2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 57.1 – 92.6 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80 % and erosion runoff by 95 %) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (2007) report acknowledges that for substances with K_{Foc} < 2000 mL/g (i.e. L-ascorbic acid), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. For the representative protected tomato use, the necessary surface water and sediment PEC were appropriately carried out using the FOCUS (2001) step 2 approach (version 2.1 of the steps 1 – 2 in FOCUS calculator), which was then modified by post processing the spray drift input results (option no runoff or drainage was selected) to obtain 0.1 % and 0.2 % emissions of L-ascorbic acid from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and the emission values are referred to in FOCUS (2008) guidance as being appropriate. The 0.1 % emission is the relevant value when applications are made by standard hydraulic spraying and 0.2 % is pertinent when ultra low volume spray techniques are used.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[13] for L-ascorbic acid. The potential for groundwater exposure in annual average recharge from the top 1 m soil layer from the representative uses of this active substance above the parametric drinking water limit of 0.1 µg/L was concluded to

[10] Calculation in accordance with European Commission (2003b) based on the Log Pow value of -1.88 which was itself a QSAR calculated using KOWWIN V1.68; EPISUITE 4.1 software (Syracuse Research Corporation).
[11] Definition given in European Commission (2003a) with same criteria also being specified in European Commission (2002a) and European Commission (2002b).
[12] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7.
[13] Simulations complied with EFSA (EFSA PPR (2004)) and correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7.

be high in geoclimatic situations that are represented by all five of the FOCUS groundwater scenarios that the RMS considered relevant for the outdoor uses in northern Europe and all six of the FOCUS scenarios considered relevant for protected tomatoes. These annual average recharge concentrations were in the range 3.02 – 8.48 µg/L for the use assessed on potatoes, 1.57 – 3.9 µg/L for the use on flower bulbs (outdoors) and 0.21 – 4.11 µg/L for the use assessed on protected tomato (note the climate data used in simulations was standard FOCUS data representing outdoor conditions). This is therefore identified as a critical area of concern (see section 9).

5. Ecotoxicology

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

A low risk to birds and mammals was concluded on the basis that L-ascorbic acid is a natural component of their diet and the use of L-ascorbic acid as a plant protection product was not considered to lead to significantly greater exposure than natural background levels.

Toxicity data were available for fish, aquatic invertebrates and algae. However, only the acute study on fish was considered reliable. Using the available endpoint a low acute risk to fish was concluded for all of the representative uses. Since no reliable data were available for fish (chronic), aquatic invertebrates (acute and chronic) and algae, the risk assessment could not be finalised. It should be noted that the available acute risk assessment for aquatic invertebrates (which used an unreliable endpoint) indicated a high risk for all of the representative uses (for potatoes this included using FOCUS Step 4 exposure estimates with mitigation that would be provided by a 20 m no-spray buffer zone and vegetative buffer strip to mitigate runoff of up to 20 m).

A low acute oral and acute contact risk to honey bees was concluded for the representative uses. On the basis of a risk assessment with the standard tier 1 indicator species a high in-field risk to non-target arthropods was indicated for the representative use on potatoes. Insufficient data were available to finalise the risk assessment for soil dwelling non-target arthropods the representative use as a bulb treatment. Therefore, a data gap was concluded for further data to address the risk to non-target arthropods.

No reliable toxicity data were available for soil dwelling organisms and therefore the risk assessment could not be finalised. Data gaps were identified for data to address the risk to earthworms and soil micro-organisms (relevant for all representative uses).

A low risk to non-target plants and sewage treatment organisms was concluded.

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
L-ascorbic acid	Moderately persistent. An estimate made following REACH guidance on the results of an inherent biodegradability study gives a single first order DT_{50} of 30 days.	Data gap.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1[a)] µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
L-ascorbic acid	Very high mobility, a QSAR estimate gives a K_{doc} of 0.2mL/g	Yes for all pertinent FOCUS groundwater scenarios and all representative uses, concentrations are estimated to be in the range 0.21 – 8.48µg/L.	Yes, the applicant has stated that the fungicidal activity of the product is derived from the presence of L-ascorbic acid in the product.	–	A data gap was concluded for reliable toxicity data for fish (chronic), aquatic invertebrates (acute and chronic) and algae.

(a): Should L-ascorbic acid be approved under Regulation (EC) No 1107/2009 as a fungicide, then as an organic fungicide, following the definitions in both Council Directive 98/83/EC[14] and European Parliament and Council Directive 2006/118/EC[15], L-ascorbic acid is a pesticide to which the parametric drinking water limit of 0.1 µg/L applies.

[14] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ No L 330, 5.12.98, p. 32-54

[15] Directive 2006/118/EC of the European Parliament and Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. OJ No L 372, 27.12.2006, p. 19-31

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
L-ascorbic acid	A data gap was concluded for reliable toxicity data for fish (chronic), aquatic invertebrates (acute and chronic) and algae.

6.4. Air

Compound (name and/or code)	Toxicology
L-ascorbic acid	No data available.

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).

- Data to confirm that the formulations used in the available studies to generate regulatory endpoints, where formulation was used as the test substance, complied with the declared composition of the representative formulation and did not contain DDAC (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).

- Accelerated storage stability study and shelf-life study of the formulation (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).

- Residue analytical method for enforcement of the drinking water limit applied for the groundwater at 0.1 µg/l. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).

- Toxicity data for fish (chronic), aquatic invertebrates (acute and chronic) and algae and an updated aquatic risk assessment. If this assessment indicates a high risk, further fate and behaviour data may be necessary to provide a more realistic, less conservative aquatic exposure assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5).

- Further toxicity data for non-target arthropods (relevant for all representative field uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Toxicity data for earthworms and soil micro-organisms and an updated risk assessment. If this assessment indicates a high risk, further fate and behaviour data may be necessary to provide a more realistic, less conservative soil exposure assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 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. The risk assessment for fish (chronic), aquatic invertebrates (acute and chronic), algae, earthworms and soil micro-organisms could not be finalised with the available data for all the uses assessed.

2. The risk assessment for non target arthropods could not be finalised with the available data for the use assessed on flower bulbs planted outdoors.

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.

3. The available groundwater exposure assessment that could be completed with the available data, indicates that for all the representative uses, the potential for vulnerable groundwater to be contaminated above the parametric drinking water limit for a pesticide of 0.1µg/L in geoclimatic situations represented by all the pertinent FOCUS groundwater scenarios (up to six scenarios) is high.

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		Foliar spray potatoes	Flower bulb dipping then field planting	Flower bulb dipping then protected cropping	Foliar spray protected tomatoes
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			
	Assessment not finalised	X[1]	X[1,2]	X[1]	X[1]
Risk to aquatic organisms	Risk identified				
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]
Groundwater exposure active substance	Legal parametric value breached	X[3]	X[3]	X[3]	X[3]
	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, 2003a

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EFSA (European Food Safety Authority), 2013. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance L-ascorbic acid.

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APPENDICES

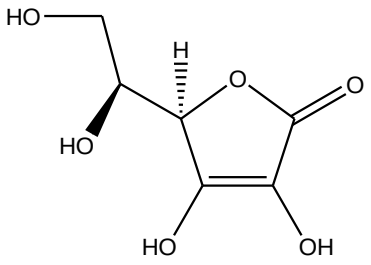
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

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

Active substance (ISO Common Name)	L-ascorbic acid (non-ISO)
Function (*e.g.* fungicide)	fungicide
Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	(5*R*)-5-[(1*S*)-1,2-dihydroxyethyl]-3,4-dihydroxyfuran-2(5*H*)-one (European Pharmacopoeia, 2005)
Chemical name (CA)	not available
CIPAC No	774
CAS No	50-81-7
EEC No (EINECS or ELINCS)	200-066-2 (EINECS)
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured (g/kg)	990 g/kg (pharmaceutical grade)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	methanol max. 3000 mg/kg heavy metals max 10 mg/kg (expressed as Pb)
Molecular formula	$C_6H_8O_6$
Molecular mass	176.1
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	190-192°C (data from public literature, purity not reported)
Boiling point (state purity)	Not applicable (decomposition at melting point)
Temperature of decomposition (state purity)	decomposition started at melting point (190-192°C (data from public literature, purity not reported)
Appearance (state purity)	Pure material: white powder (100.3 %)
	Technical material: yellowish liquid (purity 25 g/kg L-ascorbic acid)
Vapour pressure (state temperature, state purity)	2.19×10^{-5} Pa at 25°C (model estimation)
Henry's law constant	1.16×10^{-8} $Pa.m^3.mol^{-1}$
Solubility in water (state temperature, state purity and pH)	330 g/L at unspecified temperature (data from SIDS data base, purity not reported) Effect of pH was not investigated and is not required in view of the pKa of ascorbic acid.
Solubility in organic solvents (state temperature, state purity)	Solubility (temperature not specified, data from public literature, purity not reported): alcohol 33 g/L absolute alcohol 20 g/L glycerol 10 g/L propylene glycol 50 g/L ether insoluble chloroform insoluble benzene insoluble petroleum ether insoluble oils insoluble fats insoluble fat solvents insoluble acetone no data, not required ethyl acetate no data, not required
Surface tension (state concentration and temperature, state purity)	Not surface active (based on theoretical considerations (chemical structure of the substance))
Partition co-efficient (state temperature, pH and purity)	Log Po/w = -1.88 (model estimation) Effect of pH was not investigated and is not required in view of the relatively low Log Po/w.
Dissociation constant (state purity)	3.94 and 12.78 (model estimation)
UV/VIS absorption (max.) incl. ε (state purity, pH)	buffer (pH 6.4) solution: 1 % λmax (nm); ε (L.mol-1.cm-1) 265 not available (not required) acidic (pH 2) buffer solution: 1 % λmax (nm); ε (L.mol-1.cm-1) 245 not available (not required) basic solution: no data available (not required)

	(data from literature, purity not reported)
Flammability (state purity)	flammability (A.10): not highly flammable (100.3 %) auto-flammability (A.16): > melting point
Explosive properties (state purity)	not explosive (100.3 %)
Oxidising properties (state purity)	not oxidizing (statement)

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	No classification and labelling is needed based on the physical and chemical properties of the active substance L-ascorbic acid

Summary of representative uses evaluated (L-ascorbic acid)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Potato	Northern Europe	Dipper	F	Foliar fungi, *Phytophthora infestans*	SL	23 g/L	Foliar spray	BBCH 15-85	2-5	4 days	0.0070-0.0058	250-300	0.017	30	
Tomato	Northern Europe	Dipper	G	Foliar fungi, *Botrytis spp*	SL	23 g/L	Foliar spray	BBCH 28-80	1-2	7 days	0.0029	500-1500	0.015-0.044	20	
Flower bulbs	Northern Europe	Dipper	F & G	Seed borne pathogens, *Fusarium* spp	SL	23 g/L	Dipping bath	BBCH 00 or 99 (before planting or after harvest)	1	-	0.0029	700(1)	0.020	-	

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Chapter 2.2 Methods of Analysis

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

Technical as (analytical technique)	(1) Titration with iodine of an aqueous acidic solution of ascorbic acid in the presence of starch. (2) Reduction of the oxidation-reduction indicator dye 2,6-dichloroindophenol by ascorbic acid to a colorless solution under acidic conditions (titration). (3) Oxidation of ascorbic acid in the presence of activated charcoal to dehydroascorbic acid, derivatisation with *o*-phenylenediamine and quantification by fluorescence detection.
Impurities in technical as (analytical technique)	European Pharmacopeia methodology
Plant protection product (analytical technique)	Oxidation of L-ascorbic acid in the presence of activated charcoal to dehydroascorbic acid, derivatisation with *o*-phenylenediamine and quantification by fluorescence detection.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition required
Food of animal origin		No residue definition required
Soil		Open pending environmental data gaps being filled
Water	surface	Open pending environmental data gaps being filled
	drinking/ground	L-ascorbic acid and its salts
Air		No residue definition required

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	No methods required because no residue definition for plant products is proposed. Single Method NEN-EN 14130: HPLC-UV LOQ not known (various) Single Method AOAC 967.21: Titration LOQ not known (various) Single Method AOAC 984.26: Fluorescence LOQ not known (various)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No methods required because no residue definition for animal products is proposed.
Soil (analytical technique and LOQ)	Open
Water (analytical technique and LOQ)	Data gap: method for enforcement of the drinking water limit for groundwater limit of 0.1 µg/l.
Air (analytical technique and LOQ)	No method required because no residue definition for air is proposed and because L-ascorbic acid is a naturally occurring non-toxic substance.

Body fluids and tissues (analytical technique and LOQ)	No method required because L-ascorbic acid is not toxic or very toxic. HPLC-UV LOQ ~1mg/L

Chapter 2.3 Impact on Human and Animal Health

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

Rate and extent of oral absorption	Data available of limited validity. No further data required.
Distribution	Data available of limited validity. No further data required.
Potential for accumulation	Data available of limited validity. No further data required.
Rate and extent of excretion	Data available of limited validity. No further data required.
Metabolism in animals	Data available of limited validity. No further data required.
Toxicologically relevant compounds (animals and plants)	Data available of limited validity. No further data required.
Toxicologically relevant compounds (environment)	Data available of limited validity. No further data required.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	No data available - not required	
Rat LD_{50} dermal	No data available - not required	
Rat LC_{50} inhalation	No data available - not required	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	No data available - not required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Data available of limited validity. No further data required.	
Relevant oral NOAEL		
Relevant dermal NOAEL		
Relevant inhalation NOAEL		

Genotoxicity (Annex IIA, point 5.4)

Data available of limited validity. No further data required.	

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

Target/critical effect	Data available of limited validity. No further data required.	
Relevant NOAEL		
Carcinogenicity		

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Data available of limited validity. No further data required.	
Relevant parental NOAEL		
Relevant reproductive NOAEL		
Relevant offspring NOAEL		

Developmental toxicity

Developmental target / critical effect	Data available of limited validity. No further data required.	
Relevant maternal NOAEL		
Relevant developmental NOAEL		

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	No data available - not required	
Repeated neurotoxicity	No data available - not required	
Delayed neurotoxicity	No data available - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	No data available - not required
Studies performed on metabolites or impurities	No data available - not required

Medical data (Annex IIA, point 5.9)

No evidence of adverse effects in the general population or in workers of the production facility.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	No data available. Not needed		

AOEL	No data available. Not needed		
ARfD	No data available. Not needed		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation Dipper	100%, based on physical-chemical properties a.s.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Predicted levels of exposure to L-ascorbic acid for operators without PPE for mechanical dipping of bulbs and bulbous plants, using the Dutch dipping model and UK-POEM are below the average dietary intake of vitamin C (< 1%). Predicted levels of exposure to L-ascorbic acid for operators without PPE for manual up- and downward spraying on tomatoes, using the Dutch glasshouse model are below the average dietary intake of vitamin C (<1%). Predicted levels of exposure to L-ascorbic acid for operators without PPE for mechanical downward spraying on potatoes, using UK-POEM and German model are below the average dietary intake of vitamin C (< 1%).
Workers	Predicted levels of exposure to L-ascorbic acid for workers without PPE during re-entry activities in bulbs, bulbous plants and tomatoes, using EUROPOEM II are below the average dietary intake of vitamin C (<1%). Re-entry activities in potatoes are not anticipated.
Bystanders	Predicted levels of exposure to L-ascorbic acid for bystanders for mechanical downward spraying on potato, using the EUROPOEM II model are below the average dietary intake of vitamin C (<1%). Bystanders should not be allowed in greenhouses.

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

Substance classified	L-ascorbic acid
Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	No harmonised classification and labelling.
Peer review proposal*	Under Council Directive 67/548/EEC16 Data available of limited validity. No further data required.

[16] OJ No 196, 16.08.1967, p. 001-0098

Under Regulation (EC) No 1272/2008)17 Data available of limited validity. No further data required.

* 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.

[17] OJ No L 353, 31.12.2008, p. 0001-1355

Chapter 2.4 Residues

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

Plant groups covered	no data (not required)
Rotational crops	no data (not required)
Metabolism in rotational crops similar to metabolism in primary crops?	not relevant
Processed commodities	no data (not required)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	not relevant
Plant residue definition for monitoring	no residue definition required
Plant residue definition for risk assessment	no residue definition required
Conversion factor (monitoring to risk assessment)	not applicable

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

Animals covered	no data (not required)
Time needed to reach a plateau concentration in milk and eggs	not applicable
Animal residue definition for monitoring	no residue definition required
Animal residue definition for risk assessment	no residue definition required
Conversion factor (monitoring to risk assessment)	not applicable
Metabolism in rat and ruminant similar (yes/no)	no data (not required)
Fat soluble residue: (yes/no)	no (logPow <3)

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

no data (not required)

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

no data

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

	Ruminant:	Poultry:	Pig:
	no data (not required, natural compound)		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
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	Recommendation/com-ments	MRL estimated from trials according to the representative use	HR	STMR
no data (not required)						

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

ADI	Not calculated (not required)
TMDI (% ADI) according to WHO European diet	Not calculated (not required)
TMDI (% ADI) according to national (to be specified) diets	Not calculated (not required)
IEDI (WHO European Diet) (% ADI)	Not applicable.
NEDI (specify diet) (% ADI)	Not applicable
Factors included in IEDI and NEDI	not applicable
ARfD	No ARfD is required.
IESTI (% ARfD)	Not applicable.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not applicable.
Factors included in IESTI and NESTI	Not applicable.

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	
no data (not required)				

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

Proposed MRLs	none proposed (not required for this compound)

Chapter 2.5 – Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	no data (not required)
Non-extractable residues after 100 days ‡	no data (not required)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	none

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

Anaerobic degradation ‡

Mineralization after 100 days	no data (not required)
Non-extractable residues after 100 days	no data (not required)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None expected considering the substance is readily biodegradable.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no data (not required)

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

Laboratory studies ‡

Parent	Aerobic conditions - **persistence endpoints**						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C	St. (r^2)	Method of calculation
no data (not required). For ecotox triggering purposes, the estimated modelling DT50 is the best available endpoint (giving a DT90 of 100 days).							

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

Parent	Aerobic conditions - **modelling endpoints**						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
no data (not required). A value of 30 days can be used in environmental exposure assessments as L-ascorbic acid was demonstrated to be readily biodegradable in a valid OECD 302B inherent biodegradability study and following REACH guidance (ECHA, 2010)							

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

Field studies ‡

Parent	Aerobic conditions **(supplementary data, not required)**								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
no data (not required)									

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

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

Laboratory studies ‡

Parent	Anaerobic conditions **(supplementary data, not required)**						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C	St. (r^2)	Method of calculation
no data (not required)							

[1] 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 (water)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
no experimental data (not required; QSAR estimate K_{doc} 0.2 L/kg)							

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

Column leaching ‡	no data (not required)
Aged residues leaching ‡	no data (not required)
Lysimeter/ field leaching studies ‡	no data (not required)

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	*Northern Europe:*
Method of calculation	DT_{50} (d): no degradation assumed (no reliable data available), hence only initial PECsoil values were estimated. Kinetics: not applicable
Application data	All crops: Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 Crop: tomato & potato % plant interception: 50% (tomato & potato) Number of applications: 2 (tomato) & 5 (potato) Interval (d): not relevant (no degradation assumed) Application rate(s): 2 x 44 (tomato) and 5 x 17 (potato) g as/ha Crop: flower bulbs Application rate(s): 700 L of dipping liquid is transferred to field with transplanting of treated bulbs equivalent to 20 g as/ha. Model: 500000 bulbs with a radius of 1.5 cm are planted per hectare. In calculation the substance assumed to be homogeneously distributed over the top 5 cm.

Northern Europe, tomato

PEC$_{(s)}$ (mg/kg)	Single **application** Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	x		0.059	-
Plateau concentration				not applicable

Northern Europe, potato

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	x		0.057	-
Plateau concentration				not applicable

Northern Europe, flower bulbs

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	x		0.027	-
Plateau concentration				not applicable

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	no data
Photolytic degradation of active substance and metabolites above 10 % ‡	no data (not required)
Quantum yield of direct phototransformation in water at Σ > 290 nm	no data (not required)
Readily biodegradable ‡ (yes/no)	yes

Degradation in water / sediment

Parent	**Persistence endpoints** Distribution (max in water 95.0% after 0 d. Max. sed 37.1% after 3 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water[1]	St. (r^2)	DT_{50}- DT_{90} sed[1]	St. (r^2)	Method of calculation
No data (not required), For ecotox triggering purposes, the estimated modelling DT50 is the best available endpoint.										

[1] half-lives for dissipation

Parent	**Modelling endpoints**									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} whole sys.	St. (r^2)	DT_{50} water	St. (r^2)	DT_{50} sed	St. (r^2)	Method of calculation
No data (not required). Values of 15 days for water and 300 days for sediment were used in environmental exposure assessments as L-ascorbic acid was demonstrated to be readily biodegradable in a valid OECD 302B inherent biodegradability study and following REACH guidance (ECHA, 2010)										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
no data (not required)					

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: vs 1.1 Water solubility (mg/L): 330000 K_{OC} (L/kg): 0.2 DT_{50} soil (d):30 (following REACH guidance) DT_{50} water/sediment system (d): 15 (default REACH) DT_{50} water (d): 15 (following REACH guidance) DT_{50} sediment (d): 300 (following REACH guidance)
Parameters used in FOCUSsw step 3 (if performed)	**field applications:** FOCUS Surface Water - Step 3 SWASH 3.1 (October 2009), with MACRO 4.3b, PRZM 3.20.b and TOXSWA. 2.1.3.F3 Q10=2.58 Walker equation coefficient 0.7

Application rate	Crop: potato & flower bulbs (NE) Number of applications: 5 (potatoes) & 1 (bulbs) Interval (d): 4 (potato) Application rate(s): 17 g as/ha (potato) & 20 g as/ha (flower bulbs) *STEP 2 (worst-case conditions):* Crop interception: 50% (potato) & 0% (flower bulbs) Application window: Mar-May and Jun-Sep (potato) & Oct-Feb (flower bulbs) *STEP 3* Application in spring for both bulbs (FOCUS crop bulb vegetables used for simulations) and potato Crop: tomato (NE) *STEP 2 (worst-case conditions):* Number of applications: 2 Interval (d): 7 Application rate(s): 44 g as/ha Crop interception: not applicable Model: 0.1% and 0.2% emission from greenhouse assumed

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, NE GAP	0 h	2.4671	-	0.0049	-
	24 h	2.3556	2.4113	0.0047	0.0048
	2 d	2.2493	2.3569	0.0045	0.0047
	4 d	2.0508	2.2529	0.0041	0.0045
	7 d	1.7854	2.1082	0.0036	0.0042
	14 d	1.2921	1.8170	0.0026	0.0036
	21 d	0.9351	1.5794	0.0019	0.0032
	28 d	0.6767	1.3843	0.0014	0.0028
	42 d	0.3544	1.0890	0.0007	0.0022
	50 d	0.2449	0.9662	0.0005	0.0019
	100 d	0.0243	0.5288	0	0.0011

FOCUS STEP 3 Scenario	Days after maximum concentration	Step 3 PECSW [µg/L]	
		five applications	
Potato, NE GAP		actual	TWA
D3, ditch	0	0.535	---

FOCUS STEP 3 Scenario	Days after maximum concentration	Step 3 PECSW [µg/L]	
		five applications	
Potato, NE GAP		actual	TWA
	1	0.535	0.535
	2	0.535	0.535
	4	0.535	0.535
	7	0.535	0.535
	14	0.533	0.535
	21	0.531	0.535
	28	0.529	0.534
D4, pond	0	0.632	--
	1	0.629	0.632
	2	0.623	0.631
	4	0.601	0.628
	7	0.558	0.620
	14	0.474	0.598
	21	0.403	0.588
	28	0.342	0.592
D4, stream	0	1.291	--
	1	1.199	1.283
	2	1.092	1.258
	4	0.907	1.196
	7	0.725	1.115
	14	0.644	1.023
	21	0.957	0.930
	28	510	0.862
R1, pond	0	0.0155	--
	1	0.0150	0.0153
	2	0.0146	0.0150
	4	0.0138	0.0146
	7	0.0126	0.0141
	14	0.0130	0.0132

FOCUS STEP 3 Scenario	Days after maximum concentration	Step 3 PECSW [µg/L]	
		five applications	
Potato, NE GAP		actual	TWA
	21	0.0101	0.0127
	28	0.0078	0.0118
R1, stream	0	0.608	--
	1	<0.001	0.176
	2	<0.001	0.0881
	4	<0.001	0.045
	7	<0.001	0.026
	14	<0.001	0.020
	21	<0.001	0.015
	28	<0.001	0.016
R3, stream	0	2.326	--
	1	0.010	0.969
	2	0.004	0.521
	4	<0.001	0.265
	7	<0.001	0.201
	14	<0.001	0.108
	21	<0.001	0.119
	28	<0.001	0.090

FOCUS Step 4 Scenario	Days after maximum concentration	Step 4 PECSW [µg/L] SWAN 1.1.4 92.6% spray drift mitigation (20m no spray zone) runoff 80% solute and 95% errosion reduction, (vegetated strip of 18-20m)	
		five applications	
		actual	TWA
D3, ditch	Global max	0.535	--
D4, pond	Global mx	0.632	--
D4, stream	Global max	1.291	--
R1, pond	Global max	0.005	--
R1, stream	Global max	0.128	--
R3, stream	Global max	0.019	--

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Flower bulbs, NE GAP	0 h	3.3324	-	0.0067	-
	24 h	3.1819	3.2571	0.0064	0.0065
	2 d	3.0382	3.1836	0.0061	0.0064
	4 d	2.7700	3.0430	0.0055	0.0061
	7 d	2.4114	2.8476	0.0048	0.0057
	14 d	1.7450	2.4541	0.0035	0.0049
	21 d	1.2627	2.1331	0.0025	0.0043
	28 d	0.9138	1.8696	0.0018	0.0037
	42 d	0.4785	1.4707	0.0010	0.0029
	50 d	0.3306	1.2994	0.0007	0.0026
	100 d	0.0328	0.7142	0.0001	0.0014

FOCUS STEP 3 Scenario	Days after maximum concentration	PECsw (µg/L) Single application	
Flower bulbs, NE GAP		actual	TWA
D3, ditch	0	0.15	---
	1	0.15	0.15
	2	0.15	0.15
	4	0.15	0.15
	7	0.149	0.15
	14	0.149	0.15
	21	0.148	0.15
	28	0.147	0.15
	42	0.144	0.149
	50	0.143	0.149
	100	0.127	0.145
D4, pond	0	0.126	--
	1	0.126	0.126
	2	0.124	0.126

FOCUS STEP 3 Scenario	Days after maximum concentration	PECsw (µg/L) Single application	
Flower bulbs, NE GAP		actual	TWA
	4	0.120	0.125
	7	0.112	0.124
	14	0.091	0.118
	21	0.073	0.110
	28	0.061	0.102
	42	0.081	0.089
	50	0.087	0.086
	100	0.052	0.085
D4, stream	0	0.372	--
	1	0.341	0.369
	2	0.298	0.366
	4	0.219	0.347
	7	0.137	0.307
	14	0.057	0.222
	21	0.058	0.168
	28	0.043	0.146
	42	0.133	0.135
	50	0.161	0.126
	100	0.055	0.114

Whilst the R1 and R3 scenarios would be pertinent for flower bulbs surface, surface water exposure is not envisaged in situations represented by these scenarios as the substance is not present at the soil surface (so negating runoff exposure) and there will be no spray drift exposure, the potential for dust drift might be considered limited.

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Tomato, NE GAP 0.1% emmission standard hydraulic spraying	0 h	0.0253	-	0.00003	-
	24 h	0.0229	0.0247	0.00003	0.00003
	2 d	0.0230	0.0241	0.00003	0.00003
	4 d	0.0210	0.0231	0.00003	0.00003
	7 d	0.0183	0.0216	0.00002	0.00003
	14 d	0.0132	0.0186	0.00002	0.00002
	21 d	0.0096	0.0162	0.00001	0.00002

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	28 d	0.0069	0.0142	0.00001	0.00002
	42 d	0.0036	0.0112	0.000004	0.00001
	50 d	0.0025	0.0099	0.000004	0.00001
	100 d	0.0003	0.0054	0.000000	0.00001

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Tomato, NE GAP 0.2% emmission Ultra low volume spraying techniques	0 h	0.0506	-	0.00006	-
	24 h	0.0458	0.0494	0.00006	0.00006
	2 d	0.046	0.0482	0.00006	0.00006
	4 d	0.042	0.0462	0.00006	0.00006
	7 d	0.0366	0.0432	0.00004	0.00006
	14 d	0.0264	0.0372	0.00004	0.00004
	21 d	0.0192	0.0324	0.00002	0.00004
	28 d	0.0138	0.0284	0.00002	0.00004
	42 d	0.0072	0.0224	0.000008	0.00002
	50 d	0.005	0.0198	0.000008	0.00002
	100 d	0.0006	0.0108	0	0.00002

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model used: FOCUS-PEARL 3.3.3 and FOCUS PELMO 3.3.2 Scenarios: All NE FOCUS scenarios Crop: potato, (flower bulbs) surrogate onion & (protected tomato) surrogate outdoor winter cereals at Kremsmunster other scenarios surrogate outdoor tomato DT50: 30 d (following REACH guidance)

	K_{OC}: 0.2 L/kg (QSAR estimate); $^1/_n$= 0.9 (default). Metabolites: none Q10=2.58, Walker equation coefficient 0.7
Application rate	Application rate: 17 (potato), 20 (flower bulbs) & 44 g/ha (protected tomato) No. of applications: 5 (potato), 1 (flower bulbs) & 2 (protected tomato) Interval: 4 d (potato) 7 d (protected tomato) Time of application: 4 weeks post-emergence (potato) & 1 December (flower bulbs), 10-25 May (protected tomato) Crop interception: 15% (potato), 0% (flower bulbs) & 70% (tomato)

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

	Scenario	Parent PEARL (µg/L)	Parent PELMO (µg/L)
FOCUS-PEARL 3.3.3/PELMO 3.3.2 Potato / Northern EU GAP	Chateaudun	3.136721	1.720
	Hamburg	3.981052	2.759
	Jokioinen	8.48278	7.344
	Kremsmunster	3.021703	2.625
	Okehampton	2.135141	1.985
	Piacenza	-	-
	Porto	-	-
	Sevilla	-	-
	Thiva	-	-

	Scenario	Parent PEARL (µg/L)	Parent PELMO (µg/L)
FOCUS-PEARL 3.3.3/PELMO 3.3.2 Flower bulbs/North EU GAP	Chateaudun	1.57	1.205
	Hamburg	2.95	3.58
	Jokioinen	3.25	3.90
	Kremsmunster	1.60	1.73
	Okehampton	-(A)	-
	Piacenza	-	-

	Porto	-	-
	Sevilla	-	-
	Thiva	-	-

(A) No scenario for onion available for Okehampton.

	Scenario	Parent PEARL (µg/L)	Parent PELMO (µg/L)
PEARL 3.3.3/PELMO 3.3.2 Tomato / North Prot EU GAP	Chateaudun	0.92	1.73
	Piacenza	0.67	1.42
	Porto	0.24	0.68
	Sevilla	0.55	0.03
	Thiva	0.21	0.02
	Kremsmunster*	1.37	4.11

*crop in simulation winter cereals

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 3.6 hours derived by the Atkinson model. OH (12 h) concentration assumed = $9.7x10^5$ OH/cm^3
Volatilisation ‡	Not studied - no data requested
Metabolites	None

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure and Henry's Law Constant no residues in air are expected.

PEC(a)

Maximum concentration	No data provided - none requested

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil:	L-ascorbic acid and its salts
	Surface Water:	L-ascorbic acid and its salts
	Sediment:	L-ascorbic acid and its salts

Ground water:	L-ascorbic acid and its salts
Air:	L-ascorbic acid

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

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	No data provided - none requested
Ground water (indicate location and type of study)	No data provided - none requested
Air (indicate location and type of study)	No data provided - none requested

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

None.

Chapter 2.6 – Ecotoxicology

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/day)	End point (mg/kg feed)
Birds				
	a.s.	Acute	No data.	No data.
	a.s.	Short-term	No data.	No data.
	a.s.	Long-term	No data.	No data.
Mammals				
Rat	a.s.	Acute	No data.	No data.
Rat	a.s.	Long-term	No data.	No data.
Additional higher tier studies ‡				
No data available,				

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	Toxicity1 (µg/L)
Laboratory tests				
Fish	-	96 hour	LC_{50}	1020 mg a.s./L 32 mg product/L
Aquatic invertebrate	-	48-hour	EC_{50}	Data gap
Algae	-		EC_{50}	Data gap
Higher plant	-		EC_{50}	No data.
Sediment dwelling organisms	-			No data.
Microcosm or mesocosm tests: No data submitted.				

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

FOCUS Step 1 & 2

Application in glasshouse tomatoes standard hydraulic spraying

Test substance	N/S	Organism	Toxicity end point (µg a.s./L)	Time scale	PECsw (global max., µg a.s./L)	TER	Annex VI Trigger
Ascorbic acid	N	*C. carpio*	1020E+03	96 h	0.025	4.1E+07	100

Application in glasshouse tomatoes ultra low volume spraying techniques

Test substance	N/S	Organism	Toxicity end point (µg a.s./L)	Time scale	PECsw (global max., µg a.s./L)	TER	Annex VI Trigger
Ascorbic acid	N	*C. carpio*	1020E+03	96 h	0.046	2.05E+07	100

FOCUS Step 4

Application in potatoes, 92.6% spray drift mitigation (20 m no spray zone), run-off 80% solute and 95% erosion reduction, (vegetated strip of 18-20 m)

Scenario	Global max. (µg/L)	*C. carpio*	
		Asc.acid	Citrex
D3 ditch	0.535	1.82E+06	-
D4 pond	0.632	1.62E+06	-
D4 stream	1.291	7.83E+05	-
R1 pond	0.005	1.97E+08	-
R1 stream	0.128	8.11E+06	-
R3 stream	0.019	5.46E+07	-

Application in bulbs

Species	**L(E)C$_{50}$** [mg as/L]		**Step 1** Single application (PEC_{SW} 6.66 µg/L)		**Step 2** Single application (PEC_{SW} 3.33 µg/L)		**Step 3** Single application (PEC_{SW} 0.372 µg/L)	
	Ascorbic acid µg/L	Product mg/L	Asc.acid	product	Asc.acid	product	Asc.acid	product
C. carpio	>1020	-	1.5E+05	-	3.0E+05	-	2.79E+06	-

Note as in situations represented by pertinent FOCUS scenarios R1 and R3, surface water exposure is not envisaged, it could be concluded that the risk is low in situation represented by these scenarios.

	Active substance	metabolites
logP_{OW}	-1.88	No data.
Bioconcentration factor (BCF)[1]	No data.	No data.
Annex VI Trigger for the bioconcentration factor	100	

[1] only required if log PO/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)
a.s.	no data.	no data.
Preparation (Citrex)	>15 (a.s.)	4.5 (a.s.)
Tunnel tests: No data.		

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Bee brood study: No data.		
Field or semi-field tests: No data.		

Citrex Liquid, purity : 2.5% Vitamin C

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

Tomato, 0.044 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI trigger
Dipper	Oral	< 2.9	50
Dipper	Contact	10	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri	Preparation (Citrex)	Mortality	9.1
Aphidius rhopalosiphi	Preparation (Citrex)	Mortality	>0.7

Potato, 5 x 0.017 kg a.s./ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Dipper	*Typhlodromus pyri*	9.1	5.6	0.1	2
Dipper	*Aphidius rhopalosiphi*	>0.7	<73	<1.3	2

Further laboratory and extended laboratory studies

Species	Life stage	Test type, substrate and duration	Dose (g a.s./ha)	Endpoint	% effect (positive effect is adverse) and LR50 and ER50 values	Trigger value
Poecilus cupreus	Adults	Preparation (Citrex Liquid), laboratory, sand, 14 days	17 (fresh residues)	Mortality	LR_{50} (g a.s./ha): >17	30%
				Reduction of feeding	ER_{50} (g a.s./ha): >17	30%

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
Earthworms:	-	-	No reliable data available
Field studies			
No data.			
Soil micro-organisms			
Nitrogen mineralisation	a.s.		No data submitted.
	Preparation		No data submitted.
Carbon mineralisation	a.s.		No data submitted.
	Preparation		No data submitted.
No data submitted			

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

Preliminary screening data

Vi-Care (=Citrex 100%). Spray application (0.6 L/ha) on 24 vegetable crops was performed and results were reported for 7, 14, 21, 28 and 35 days after application. No effects on the crops reported.

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

No data submitted.

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

Test type/organism	
Activated sludge	Argumentation provided.

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

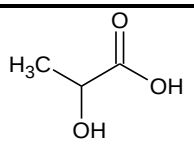
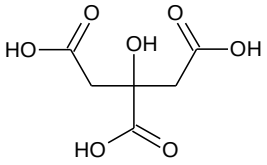
Compartment	
soil	Open whilst data gaps need to be filled
water	Open whilst data gaps need to be filled
sediment	none related to L-ascorbic acid
groundwater	Open whilst data gaps need to be filled

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	Insufficient data available to make a proposal.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
lactic acid	(2*RS*)-2-hydroxypropanoic acid	
citric acid	2-hydroxy-1,2,3-propanetricarboxylic acid	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOAC	AOAC international, Association of Analytical Communities
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
DDAC	didecyldimethylammonium chloride
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
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	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
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
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)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year