CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance gibberellic acid[1] (GA_3)

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

This conclusion, published on 26 March 2012, replaces the earlier version published on 11 January 2012[3]

SUMMARY

Gibberellic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[4], as amended by Commission Regulation (EC) No 1095/2007[5].

Gibberellic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation') and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[6], in accordance with Commission Implementing Regulation (EU) No 540/2011[7], as amended by Commission Implementing Regulation (EU) No 541/2011[8]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[9], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft

[1] On request from the European Commission, Question No EFSA-Q-2009-00282, issued on 16 December 2011

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[3] The relevant short-term NOAEL of 550 mg/kg bw/day (10000 ppm) from the 90-day rat study by Auletta (1990) corresponds to the lowest mean weekly dietary intake in males and is considered a conservative approach. The average weekly dietary intake in males during the whole period of administration is considered more correct resulting in 680 mg/kg bw/day (10000 ppm). The corrected conversion value and the corresponding reference values (AOEL and ADI) have not affected the overall conclusion for consumer and non-consumer exposure risk assessment. The off-field hazard quotient for non-target arthropods in the list of endpoints has been corrected due to an error in the previous calculation where a drift correction factor of 5 was used instead of 10. The corrected hazard quotient value has not affected the previous conclusion for non-target arthropods.

[4] OJ L 379, 24.12.2004, p.13

[5] OJ L 246, 21.9.2007, p.19

[6] OJ L 309, 24.11.2009, p.1

[7] OJ L 153, 11.6.2011, p.1

[8] OJ L 153, 11.6.2011, p.187

[9] OJ L 37, 10.2.2010, p.12

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Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Hungary being the designated rapporteur Member State submitted the DAR on gibberellic acid in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 31 March 2008. The peer review was initiated on 22 July 2008 by dispatching the DAR to the notifier The EU Gibberellic Acid Task Force, and on 24 February 2011 to the Member States. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on gibberellic acid.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of gibberellic acid as a plant growth regulator on grapes, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis data for the surface tension and to identify the hydrolysis products for the active substance were identified as data gaps. For the formulation data gaps were identified for storage stability, attrition and a method of analysis.

Several data gaps were identified in the mammalian toxicology section: to demonstrate the compliance of the batches used in the toxicological studies to the technical specifications (leading to an issue that could not be finalised) and to assess the toxicological relevance of impurities.

A data gap was identified in the residue section for the submission of information on the natural background level of gibberellins in grapes. MRLs were not proposed as residue levels in treated and control samples were below the LOQ and since it would not be possible to distinguish between exogenous and natural gibberellins.

The information available on the environmental fate and behaviour in the environment was insufficient to assess the environmental exposure levels of potential transformation products of gibberellic acid. Consequently the potential for groundwater exposure by gibberellic acid transformation products and the risk assessments to aquatic and soil-dwelling organisms from transformation products could not be finalised.

A data gap was identified to address the risk to aquatic macrophytes, chronic risk to fish and aquatic invertebrates, risk to non-target arthropods and earthworms from exposure to gibberellic acid. Furthermore, the representativeness of the material tested in the ecotoxicological studies to the technical specification should be addressed, leading to a data gap. A low acute risk from exposure to gibberellic acid was concluded for aquatic organisms. A low risk was concluded for mammals, bees, soil micro-organisms and biological methods of sewage treatment processes.

KEY WORDS

Gibberellic acid, gibberellin 3, GA3, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Gibberellic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[10], as amended by Commission Regulation (EC) No 1095/2007[11].

Gibberellic acid was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation') and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[12], in accordance with Commission Implementing Regulation (EU) No 540/2011[13], as amended by Commission Implementing Regulation (EU) No 541/2011[14]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[15] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Hungary being the designated rapporteur Member State submitted the DAR on gibberellic acid in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 31 March 2008 (Hungary, 2008). The peer review was initiated on 22 July 2008 by dispatching the DAR to the notifier The EU Gibberellic Acid Task Force, and on 24 February 2011 to the Member States 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 notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 20 June 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts 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 consultation with Member State experts, and additional information to be submitted by the notifier, 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 discussions where these 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 November – December 2011.

[10] OJ L 379, 24.12.2004, p.13
[11] OJ L 246, 21.9.2007, p.19
[12] OJ L 309, 24.11.2009, p.1
[13] OJ L 153, 11.6.2011, p.1
[14] OJ L 153, 11.6.2011, p.187
[15] OJ L 37, 10.2.2010, p.12

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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 plant growth regulator on grapes, as proposed by the notifier. 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, 2011) 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 (20 June 2011),
- the Evaluation Table (7 December 2011),
- the report(s) of the scientific consultation with Member State experts,
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2011 containing all individually submitted addenda (Hungary, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

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THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Gibberellic acid is the given name for this compound. The IUPAC name is (3*S*,3a*S*,4*S*,4a*S*,7*S*,9a*R*,9b*R*,12*S*)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid. It is one of a group of compounds known as the gibberellins. There is no ISO common name for this compound. The IUPAC name is specific to just one of the possible (64) isomers. In this conclusion the use of the name gibberellic acid is expected to pertain to just this single isomer, though the analytical methodologies used in different studies may not always have been isomer specific, so there is some uncertainty regarding this.

The representative formulated product for the evaluation is 'Berelex' a soluble tablet formulation (ST) containing 10 % w/w gibberellic acid.

The representative use evaluated comprise of outdoor foliar spraying as a plant growth regulator 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), SANCO/10597/2003 rev. 8.1 (European Commission, 2009), and SANCO/825/00 rev. 7 (European Commission, 2004a).

It was considered that the presented sources were not equivalent on the basis of a Tier I assessment and therefore see the Tier II assessment in sections 2 and 5.

The minimum purity of gibberellic acid as manufactured is 850 g/kg. The specifications for Fine, Nufarm and Valent are acceptable except that a data gap is identified for batch data for possible relevant impurities. The other specification for Aifar/Gobbi, Cequisa and Valagro are not acceptable because either the methods of analysis are not validated or there are unidentified impurities. Data gaps have been identified to cover these issues.

In the hydrolysis study the breakdown products were not identified and this has been identified as a data gap. Also the surface tension has not been investigated and a data gap was identified.

The main data regarding the identity of gibberellic acid and its physical and chemical properties are given in Appendix A.

The formulation is a soluble tablet and it should be noted that the disintegration time of the tablet is poor taking over 15 minutes at 10 °C with agitation.

The following data gaps were identified for the formulation: accelerated storage, attrition of the tablet and a method of analysis for the formulation.

Methods of analysis for products of plant and animal origin are not required as no MRLs are proposed. A method of analysis is available for water but data gaps were identified for methods of analysis for soil and air. Methods for body fluids and tissues are not required as the active substance is not classified as toxic or very toxic.

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2. Mammalian toxicity

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

Gibberelic acid was discussed at the Pesticide Peer Review Expert Meeting 88. Based on the available information it is not possible to conclude on whether the presented sources are equivalent on the basis of a Tier II assessment and whether the technical specifications are supported by the batches used in the toxicological studies leading to an issue that could not be finalised. The toxicological relevance of the impurities has not been adequately assessed and a data gap was identified.

Low acute toxicity was observed when gibberelic acid is administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed and there was no potential for skin sensitisation.

In short-term oral studies with rats, the critical effects were observed in kidneys and liver (increased relative weight). The relevant short-term oral NOAEL is 680 mg/kg bw/d (90-day rat study; Auletta, 1990 in Hungary 2008, 2011).

The weight of evidence suggests that gibberelic acid is unlikely to be genotoxic.

In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal and developmental NOAELs are 1000 mg/kg bw/d (highest dose level tested) for the rat and rabbit.

No potential for neurotoxicity was observed in the standard toxicity studies available.

No experimental data on absorption, distribution and excretion of gibberelic acid were submitted. In addition, no acceptable short-term toxicity studies in dogs and long-term and carcinogenicity studies were available and no multigeneration study was submitted. It was also considered that similar molecular structure and biological effects are not a sufficient reason to bridge information from other gibberellins (e.g. gibberellins GA_4/GA_7). However no further data are required to conclude on the risk assessment since these uncertainties (i.e. missing information) have been taken into account for setting the references values (see below).

Based on the effects described above, no classification and labelling are proposed. However, the database is not suitable to assess adequately the hazard for reproductive toxicity and carcinogenic potential.

Based on the available data and the toxicological profile of gibberellic acid the agreed acceptable daily intake (**ADI**) is 0.68 mg/kg bw/d, based on the NOAEL of 680 in the 90-d study in rats and applying a standard safety factor of 100 plus an additional safety factor of 10 because of the use of short-term toxicity and also due to a general database weakness. The agreed acceptable operator exposure level (**AOEL**) is 0.68 mg/kg bw/d, based on the NOAEL of 680 in the 90-d study in rats and applying a standard safety factor of 100 plus an additional safety factor of 10 because of the limited database and the lack of oral absorption data. The setting of an acute reference dose (**ARfD**) is considered not justified.

The relevant dermal absorption values for ‘Berelex’ are 100% for the concentrate and dilution in the absence of experimental data.

Considering the representative use of ‘Berelex’ in grapes the estimated operator exposure is below the AOEL even without the use of personal protective equipment (PPE) according to the UK POEM model (31 and 36% respectively for tractor-mounted and handheld sprayer) and German model (14

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and 8% respectively for tractor-mounted and handheld sprayer). Worker and bystander exposure are below the AOEL (18 and 0.09% respectively).

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document SANCO/1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

No information was submitted and reported in the DAR on gibberellic acid, considering that gibberellins are plant hormones naturally occurring in a wide range of plants. No reliable data were provided on the natural background levels of gibberellins in grapes, to confirm that the use of GA_3 as a plant protection product will result in residue levels similar to the natural levels in plants. A data gap was identified to submit this information.

Eight residue trials conducted in Greece in 2003 and 2004 with a total of 6 applications on seedless table grape varieties were submitted. Samples collected 14 and 28 days after the last application and at normal maturity (59 to 87 days after the last application) were analysed for gibberellic acid GA_3. Residues in control and treated samples were all below the LOQ (<0.05 mg/kg). These results are supported by a storage stability study showing GA_3 residues to be stable up to 2 years when stored frozen at -18°C. Animal metabolism studies, processing studies and rotational crop studies were not submitted and considered not necessary.

No MRLs are proposed for grapes as residues were shown to be below the LOQ of 0.05 mg/kg in treated and control samples and since it would not be possible to distinguish between exogenous and natural occurring gibberellins. It should be noted that considering the LOQ value for grapes in the EFSA PRIMo model, the highest TMDI is calculated to be less than 0.1% of the proposed ADI (0.68 mg/kg bw/d).

4. Environmental fate and behaviour

No information on the route of degradation of gibberellic acid in soil was provided. The lack of carbon dioxide production in a ready biodegradability study (OECD 301B guideline study design that utilises a sewage sludge inoculum for the incubation) gives the indication that rapid mineralisation of gibberellic acid by soil micro-organisms would not be expected. The available laboratory incubations of gibberellic acid in soil that only reported decline of the dosed gibberellic acid (two soils investigated) demonstrated that gibberellic acid exhibits low persistence. Therefore gibberellic acid is expected to be transformed rapidly to compounds other than CO_2 in soil, but there is no information on what these compounds might be. Gibberellic acid exhibits very high mobility in soil. There was no indication that soil adsorption of gibberellic acid was pH dependent in the range of pH of agricultural soils (the pKa of 4.1 indicates significant dissociation would be expected across this range). Gibberellic acid was estimated to exhibit moderate persistence[16] under the conditions of a sterile aqueous hydrolysis study. Investigations of the route and rate of degradation in microbially active natural sediment water systems were not available in the dossier evaluated.

It was appropriately indicated that the plant organs shoot tips and the endosperm and cotyledons of seeds, contain gibberellin compounds including gibberellic acid. Consequently soil and natural surface water systems and biota will be naturally exposed to gibberellic acid and its transformation products. This argumentation was put forward as a reason why information on the route of degradation of gibberellic acid in soil and natural sediment water systems and an assessment of groundwater exposure from soil transformation products is not necessary. However a quantitative

[16] Single first order DT estimated as 27 days at pH 7 and 20ºC

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assessment of the gibberellic acid levels that will occur naturally in soil or natural surface water systems as a consequence plant organs such as leaves from untreated plants reaching soil or natural surface water systems was not provided in the dossier or RMS assessment. Such an assessment and a comparison of these levels to those that would result from the uses being requested would be a pre-requisite to accept that further information on transformation products was not necessary to complete the required environmental exposure assessments for these transformation products. Consequently a data gap is identified and there is the concern that the groundwater exposure assessment and risk assessments to soil-dwelling and aquatic organisms from potential transformation products of gibberellic acid could not be finalised (see sections 5 and 9.1).

The predicted environmental concentrations (PEC) that could only be calculated for gibberellic acid are included in Appendix A, consequent to the representative use applied for. PEC calculations in surface water and sediment were carried out for gibberellic acid using the FOCUS (FOCUS, 2001) step 1 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). Groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the model PEARL 4.4.4[17] for the active substance gibberellic acid. The potential for groundwater exposure by gibberellic acid from the representative use on grapes above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 7 pertinent FOCUS groundwater scenarios.

5. Ecotoxicology

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

A Tier II technical equivalence assessment for ecotoxicology was not presented and therefore it is not possible to conclude that the presented sources are ecotoxicologically equivalent. The representativeness of the material tested in the ecotoxicological studies to the technical specification has been identified as data gap.

The acute and short-term risk to birds was assessed as low for the representative use of gibberellic acid. No avian long-term reproductive toxicity data for gibberellic acid were available. However, a low reproductive risk to birds was concluded on the basis of weight-of-evidence and the low exposure to birds from the representative use. The acute and long-term risk to mammals was assessed to be low.

The acute risk to fish, aquatic invertebrates and algae from exposure to gibberellic acid was assessed as low. Data on the chronic toxicity of gibberellic acid to fish, aquatic invertebrates and aquatic macrophytes were not available and therefore a quantified risk assessment could not be performed. Since gibberellic acid is a plant growth regulator the risk to non-target aquatic plants should be considered. However, no reliable quantitative assessment of the natural levels of gibberellic acid in surface water was available. It was therefore, not possible to conclude negligible exposure following the representative use. Therefore, a data gap was identified to further address the risk to aquatic macrophytes. Since the representative use of gibberellic acid included six applications and the water (hydrolysis) DT_{50} is 27 days, it was not possible to exclude long-term exposure of aquatic organisms and a data gap was identified to further address the chronic risk to fish and aquatic invertebrates. Given that the surface water exposure assessment for transformation products of gibberellic acid was not finalised it is not possible to conclude a low risk to aquatic organisms. Therefore, a data gap was identified to consider the risk to aquatic organisms from major metabolites that may be present in surface water.

[17] Simulations correctly utilised a Q10 of 2.58 (in accordance with EFSA, 2007) and a Walker equation coefficient of 0.7.

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The risk to bees from the representative use of gibberellic acid was assessed as low. No toxicity studies were available with the standard non-target arthropod species and therefore a first tier risk assessment could not be performed. Three glass plate laboratory studies were available with other species; however, the application rates tested were not sufficient to cover the representative use. Furthermore, none of the available studies included an assessment of sub-lethal effects. Therefore, a data gap was identified to address the risk to non-target arthropods.

No acute toxicity data for earthworms were presented in the DAR. Given that it has not been demonstrated that exposure to soil following the representative use of gibberellic acid will be less than the natural background levels it was not possible to conclude a low risk. A data gap was identified to address the acute risk to earthworms. Given that the soil exposure assessment for transformation products of gibberellic acid is not finalised it was not possible to conclude a low risk to soil organisms. A data gap was identified to consider the risk to soil organisms from major soil metabolites. The risk to soil micro-organisms was assessed as low based on a risk assessment using the results from a multi-year field study.

A low risk was identified for non-target terrestrial plants and biological methods of sewage treatment.

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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
gibberellic acid	low persistence Single first-order DT_{50} 2.3 and 4.4 days (20ºC pF 2 soil moisture)	The risk to soil micro-organisms was assessed as low but a data gap was concluded to address the acute risk to earthworms.
A data gap needs to be addressed before this definition can be concluded regarding potential transformation products	Data gap	Data gap to address the risk to soil organisms from the transformation products in soil.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity

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gibberellic acid	very high mobility K_{Foc} 0-29.7 mL/g	No	Yes	Yes	The acute risk to fish, aquatic invertebrates and algae was assessed as low. A data gap was identified to address the chronic risk to fish, aquatic invertebrates and aquatic macrophytes.
A data gap needs to be addressed before this definition can concluded regarding potential transformation products	Data gap	Data gap	-	-	Data gap to address the risk to aquatic organisms from transformation products.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
gibberellic acid	The acute risk to fish, aquatic invertebrates and algae was assessed as low. A data gap was identified to address the chronic risk to fish, aquatic invertebrates and aquatic macrophytes.
A data gap needs to be addressed before this definition can concluded regarding potential transformation products	Data gap to address the risk to aquatic organisms from major metabolites.

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6.4. Air

Compound (name and/or code)	**Toxicology**
gibberellic acid	Low acute toxicity to rats (LC_{50} inhalation > 4.94 mg/L air /4h (nose only))

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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).

- Identify the significant impurities for the Aifar/Gobbi and Valagro sources (relevant for the named sources; submission date proposed by the notifier: unknown; see section 1)
- Batch analysis for possible relevant impurities for all sources (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Validation of the method of analysis used in the 5 batch studies for the Cequisa and Valagro sources (relevant for the named sources; submission date proposed by the notifier: unknown; see section 1)
- Identify the hydrolysis products (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Surface tension of the active substance (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Accelerated storage study for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Attrition of the tablet (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Method of analysis for the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Methods of analysis for soil and air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- The representativeness of the material tested in the toxicological studies to the technical specification should be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Information assessing the toxicological relevance of impurities (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Information on the natural background levels of gibberellins in grapes are required (relevant for all representative uses; submission date proposed by the notifier: unknown; see section 3)
- Information on the route of degradation of gibberellic acid in soil and route and rate of degradation in natural surface water systems was not available in the notifier's dossier. The completion of a soil exposure assessment, groundwater exposure assessment and a surface water exposure assessment for the transformation products of gibberellic acid was therefore not possible. Reliable quantitative information on natural background levels that may occur in soil or natural surface water systems and a demonstration that this level is higher than occurs from the requested use would be one option available for addressing this issue. Such an assessment was not available. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).

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- Information to address the chronic risk to fish and aquatic invertebrates from gibberellic acid (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information to address the risk to aquatic macrophytes from gibberellic acid (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information to address the risk to aquatic organisms from major metabolites (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information to address the risk to non-target arthropods (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information to address the acute risk to earthworms (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Information to address the risk to earthworms from transformation products in soil (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- The representativeness of the material tested in the ecotoxicological studies to the technical specification should be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: 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. The representativeness of the batches used in the toxicology and ecotoxicology studies to the technical specifications.
2. The groundwater exposure assessment for metabolites (soil transformation products) of gibberellic acid was not finalised.
3. The surface water exposure assessment for metabolites that may be formed in soil and drain or runoff to natural surface water (soil transformation products) or transformation products that may be formed in natural surface water systems from gibberellic acid was not finalised. Consequently the aquatic risk assessment for possible transformation products of gibberellic acid was not finalised
4. The chronic risk assessment to aquatic organisms (including macrophytes) from exposure to gibberellic acid could not be finalised with the available data.
5. The risk to non-target arthropods could not be finalised with the available data.

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6. The acute risk to earthworms from exposure to gibberellic acid and the risk to earthworms for potential metabolites could not be finalised with the available data.

9.2. Critical areas of concern

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

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

- none

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9.3. Overview of the concerns 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.)

All columns are grey as the representativeness of the material tested in the toxicology and ecotoxicology studies to the technical specifications could not be defined

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	
	Assessment not finalised	X[5, 6]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[3, 4]
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	X[2]

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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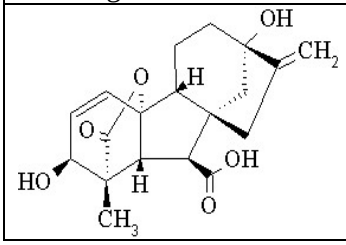
APPENDICES

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) ‡	Gibberellic acid – GA_3 there is no ISO common name for this compound
Function (*e.g.* fungicide)	Plant growth regulator
Rapporteur Member State	Hungary
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(3*S*,3a*S*,4*S*,4a*S*,7*S*,9a*R*,9b*R*,12*S*)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid or (3*S*,3a*R*,4*S*,4a*S*,6*S*,8a*R*,8b*R*,11*S*)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-ethano-3,8b-prop-1-enoperhydroindeno[1,2-b]furan-4-carboxylic acid
Chemical name (CA) ‡	(1*S*,2*S*,4a*R*,4b*R*,7*S*,9a*S*,10*S*,10a*R*)-1,2,4b,5,6,7,8,9,10,10a-decahydro-2,7-dihydroxy-1-methyl-8-methylene-13-oxo-4a,1-(epoxymethano)-7,9a-methanobenz[a]azulene-10-carboxylic acid
CIPAC No ‡	307
CAS No ‡	77-06-5
EC No (EINECS or ELINCS) ‡	EINECS: 201-001-0
FAO Specification (including year of publication) ‡	-
Minimum purity of the active substance as manufactured ‡	850 g/kg (Gibberellic acid Task Force)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	$C_{19}H_{22}O_6$
Molecular mass ‡	346.37 g/mol
Structural formula ‡	

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Not applicable (decomposition)
Boiling point (state purity) ‡	Not applicable (decomposition)
Temperature of decomposition (state purity)	> 200 °C (98 %)
Appearance (state purity) ‡	Technical material (88 % GA_3 and 9.8 % GA_1) white fine powder
Vapour pressure (state temperature, state purity) ‡	1 x 10^{-5} Pa at 25 °C (98 %) (extrapolated)
Henry's law constant ‡	7.5 x 10^{-7} Pa m^3 mol^{-1} at 25 °C (calculated)
Solubility in water (state temperature, state purity and pH) ‡	at 20°C (98 %) in pure water 4.28 g/L pH 4 buffer 11.7 g/L pH 7 buffer >250 g/L pH 10 buffer >250 g/L at 20°C (91.1 %) 4.28 g/L at 25°C (88 % GA_3) 4.6 g/L (at both later studies the effect of pH was no investigated)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C (98 %) n-hexane < 0.01 g/L toluene < 0.01 g/L dichloromethane 0.032 g/L methanol 273 g/L acetone 30.8 g/L ethyl acetate 3.1 g/L at 25 °C (88 % GA_3) isopropanol 26.0 g/L chloroform 0.028 g/L
Surface tension ‡ (state concentration and temperature, state purity)	Open
Partition co-efficient ‡ (state temperature, pH and purity)	in pH 2.2 buffer at 22°C (98 %): P_{ow} = 5.19 log P_{ow} = 0.72 (in a non OECD other study pH dependency was observed)
Dissociation constant (state purity) ‡	98 % pKa: 4.1 (Ka = 8 x 10^{-5}) The pKa value was calculated from the points on the titration curve.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	The molar absorption coefficients, ε, for gibberellic acid aqueous solutions in acidic, neutral and basic media are not calculable. Absorbance changes (increases) in time in the acidic and neutral medium near 250 nm. In basic medium there is no measurable absorption near 250 nm.

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Flammability ‡ (state purity)	No ignition under test conditions. Technical grade (91.1 %) GA_3 is not highly flammable. The compound is not auto-flammable.
Explosive properties ‡ (state purity)	GA_3 is not considered as explosive (91.1 % technical))
Oxidising properties ‡ (state purity)	GA_3 has no oxidising properties (91.1 %)

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Summary of representative uses evaluated (Gibberellic Acid GA_3)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled Function (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	g a.s./hL min max	water (L/ha) min max	g a.s./ha min max		
Grapes	North and South EU	Berelex	F	PGR	ST	10% w/w gibberellic acid	spraying	berry sizing 9 mm (BBCH stage 75-76) earlier applications at BBCH stages 57-65 and 68	1-6	7-12 days	0.125-6	1000	1.25-60 maximum 280 g/ha	Not relevant	specific rates vary with cultivar and growing conditions

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

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Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV; HPLC-MS detection system
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Not relevant
Food of animal origin	Not relevant
Soil	Gibberellic acid (pending on data gaps in section 4)
Water surface	Gibberellic Acid (pending on data gaps in section 4)
drinking/ground	Gibberellic acid (pending on data gaps in section 4)
Air	Gibberellic acid

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no MRLs are proposed
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no MRLs are proposed
Soil (analytical technique and LOQ)	Open
Water (analytical technique and LOQ)	Surface water: No. ADC 1922-1 method Concentrated by C18 extraction cartridge, eluted with methanol. LC/MS/MS LOQ: 0.1 µg/L
Air (analytical technique and LOQ)	Open
Body fluids and tissues (analytical technique and LOQ)	Not required. Gibberellic acid is not classified as toxic (T) or very toxic (T^+)

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

	RMS/peer review proposal
Active substance	No classification proposed

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Impact on Human and Animal Health

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

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

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	-
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	-
Rat LC_{50} inhalation ‡	> 4.94 mg/L air /4h (nose only)	-
Skin irritation ‡	Non-irritant	-
Eye irritation ‡	Non-irritant	-
Skin sensitisation ‡	Non sensitising (M & K)	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Kidney and liver (increased relative weight); rats. Limited data in dogs. No further data required.	
Relevant oral NOAEL ‡	90-day rat: 680 mg/kg bw/day	-
Relevant dermal NOAEL ‡	Not required	-
Relevant inhalation NOAEL ‡	Not required	-

Genotoxicity ‡ (Annex IIA, point 5.4)

Gibberellic acid is unlikely to be genotoxic.	-

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

Target/critical effect ‡	Limited data available. No further data required.	
Relevant NOAEL ‡		
Carcinogenicity ‡		

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available. No further data required.	-
Relevant parental NOAEL ‡		-
Relevant reproductive NOAEL ‡		-
Relevant offspring NOAEL ‡		-

Developmental toxicity

Developmental target / critical effect ‡	No effect seen in the highest dose (rats and rabbits)	-
Relevant maternal NOAEL ‡	1000 mg/kg bw/day (rats and rabbits)	-
Relevant developmental NOAEL ‡	1000 mg/kg bw/day (rats and rabbits)	-

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available. No further data required.	-

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Repeated neurotoxicity ‡	No data available. No further data required.	-
Delayed neurotoxicity ‡	No data available. No further data required.	-

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available. No further data required.
Studies performed on metabolites or impurities ‡	No data available. No further data required.

Medical data ‡ (Annex IIA, point 5.9)

No adverse reaction or poisoning have been reported

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.68 mg/kg bw/day	90 day oral rat	1000
AOEL ‡	0.68 mg/kg bw/day	90-day oral rat	1000
ARfD ‡	Not required	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

Berelex: no study available, default value of 100% was used

Exposure scenarios (Annex IIIA, point 7.2)

Operator	The estimated exposure for Berelex according to the UK POEM and German model (application rate 0.06 kg a.s./ha) was below the AOEL without the use of PPE. <u>Tractor-mounted equipment:</u> UK POEM: 31% of the AOEL German model: 14% of the AOEL <u>Handheld equipment:</u> UK POEM: 36% of the AOEL German model: 8% of the AOEL
Workers	18% of the AOEL
Bystanders	0.09% of the AOEL

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

	peer review proposal
Substance classified (name)	No classification is proposed. However, the database is not suitable to assess adequately the reproductive toxicity and carcinogenic potential.

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

Plant groups covered	Not relevant. Gibberellic acid occurs naturally in a wide range of plants. It is therefore not relevant to propose MRLs for GA_3 since it will not be possible to distinguish naturally occurring levels from those resulting from the use of plant growth regulators. Metabolism data are not relevant.
Rotational crops	Not provided and not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant
Processed commodities	Not relevant
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Not necessary as no MRLs proposed and since not possible to distinguish exogenous and natural gibberellins.
Plant residue definition for risk assessment	Not necessary as no MRLs proposed and since not possible to distinguish exogenous and natural gibberellins.
Conversion factor (monitoring to risk assessment)	Not relevant

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

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

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

Grapes are not grown in rotation but in established vineyards, therefore residues in succeeding crops are not relevant.

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

Residues of GA_3 in grapes stable for up to 24 months when stored frozen at -18°C.

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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):	No relevant	No relevant	No relevant
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No relevant	No relevant	No relevant
	Feeding studies not required Residue levels in matrices: not relevant		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

Crop	Northern Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	**MRL** estimated from trials according to representative use	**HR** (c)	**STMR** (b)
Grape	Southern Region	8x <0.05	At normal harvest (59 to 87 days after last application). Residues <0.05 mg/kg in interim samples collected 14 and 28 days after last application	no MRL proposed		

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, , 2x 0.1, 2x 0.10
(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

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Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

ADI	0.68 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo model	Informative only as no MRL proposed: Highest TMDI <0.1% ADI when calculations performed using the LOQ of 0.05 mg/kg for grapes
TMDI (% ADI) according to national (to be specified) diets	Not necessary
IEDI (WHO European Diet) (% ADI)	Not necessary
NEDI (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not relevant
ARfD	Not proposed and not required
IESTI (% ARfD)	Not relevant
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not relevant
Factors included in IESTI and NESTI	Not relevant

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Not provided and not required				

Proposed MRLs

No MRL proposed

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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 submitted, data gap
Non-extractable residues after 100 days ‡	No data submitted, not required
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data submitted, data gap

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

Anaerobic degradation ‡

Mineralization after 100 days	No data submitted, not required
Non-extractable residues after 100 days	No data submitted, not required
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted, not required

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted, 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						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa*	St. (r^2)	Method of calculation
Clay	1.4	5.9	25 °C / 60 %	2.96/9.77	4.4	0.923	SFO
Loam	4.79	7.01	25 °C / 60 %	1.46/4.82	2.3	0.859	SFO

*normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7.

Field studies ‡	Two Japanese studies were submitted. Determination of any degradation rate was not possible.

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

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Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡

Soil Type	OC %	Soil pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	1.0	4.5	0.039	3.92	0.98
Sandy clay loam	5.9	7.4	0.052	0.875	0.96
Silt loam	6.6	7.0	0.074	1.13	0.51
loam	3.2	5.4	0.94	29.7	0.91
Sand	2.1	6.2	0	0	-
Arithmetic mean			0.221	7.125	0.84*
pH dependence (yes or no)			no		

* Arithmetic mean of 4 studies

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

Column leaching ‡	No data submitted, not required
Aged residues leaching ‡	No data submitted, not required
Lysimeter/ field leaching studies ‡	No data submitted, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 5 days Kinetics: SFO Field or Lab: representative worst case from lab study.
Application data	Crop: grape Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 50% Number of applications: 6 Interval (d): 7 Application rate(s): 60 g as/ha

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PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.040		0.064	
Short term	24h	0.035	0.037	0.056	0.060
	2d	0.030	0.035	0.049	0.056
	4d	0.023	0.031	0.037	0.049
Long term	7d	0.015	0.026	0.024	0.041
	28d	0.001	0.010	0.001	0.016
	50d	0.000	0.006	0.000	0.009
	100d	0.000	0.003	0.000	0.005
Plateau concentration		not relevant			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: DT_{50} 216.5 h at 30 °C (1st order, r^2=0.9997)
	pH 7: DT_{50} 163.6 h at 30 °C (1st order, r^2=0.9999) pH 7: DT_{50}: 27 days at 20°C (calculated by Arrhenius activation energy ~101950 J/mol)* *this is an uncertain value as it is derived from measurements at just 2 temperatures.
	pH 9: DT_{50} 46.2 h at 30 °C (1st order, r^2=0.9999)
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 249 - 271 h at pH 5 and pH 7.51
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data available.
Readily biodegradable ‡ (yes/no)	No
Degradation in water / sediment ‡	No data were submitted. Data gap

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

Parent Parameters used in FOCUSsw step 1	Molecular weight (g/mol): 346.37 Water solubility (mg/L): 4280 Koc (L/kg): 7.1 DT50 water (d): 27
Application rate	Crop: vine Crop interception: late application Number of applications: 6 Application rate(s): 60 g as/ha Depth of water body: 30 cm

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Main routes of entry	8% drift from 3 meters 10% runoff/drainage (at FOCUSsw Step 1)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	128.5083		8.4401	
	1	125.1631	126.8357	8.8866	8.6633
	2	21.9908	25.2029	8.6613	8.7184
	4	15.8854	22.0574	8.2279	8.5806
	7	107.2953	117.5479	7.6180	8.2970
	14	89.6470	107.8775	6.3649	7.6349
	21	74.9016	99.2695	5.3180	7.0319
	28	62.5816	91.5914	4.4433	6.4908
	42	43.6875	78.5842	3.1018	5.5713
	50	35.5765	72.3297	2.5259	5.1286
	100	9.8560	46.1837	0.6998	3.2756

Metabolite	No metabolite determined and modelled

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL 4.4.4 Scenarios (list of names): Chateaudun (C); Hamburg (H); Kremsmünster (K); Piacenza (P); Porto (O); Sevilla (S),; Thiva (T) Crop: grape DT_{50lab} 4.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{FOC}: parent, arithmetic mean 7.1 mL/g (K_{FOM}=4.1 mL/g) $^1/_n$= 0.84 Q10 2.58, Walker equation coefficicient 0.7
Application rate	Application rate: 60g/ha. No. of applications: 6 Time of application (month or season): 1st application 1 July, all scenarios. Interval: 7 days Crop interception: 85 %

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

	Scenario	Parent (µg/L)
PEARL 4.4.4 /Grape	Chateaudun (C), irrigated	0.0002
	Hamburg (H)	0.0018
	Kremsmünster (K)	0.001
	Piacenza (P), irrigated	0.0001
	Porto (O)	<0.0001
	Sevilla (S), irrigated	<0.0001
	Thiva (T), irrigated	<0.0001

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 DT_{50}: 0.98 hrs (Calculated by Atkinson model)
Photochemical oxidative degradation in air	DT_{50air}: 0.98 hrs with OH radicals (Calculated by Atkinson model) DT_{50air}: 12.1 hrs with ozone (Calculated by Atkinson model)
Volatilisation ‡	Not studied - no data requested

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PEC (air)	
Method of calculation	No calculation.
$PEC_{(a)}$	
Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: gibberellic acid, but data gap in relation to transformation products Surface Water: gibberellic acid, but data gap in relation to transformation products Sediment: gibberellic acid, but data gap in relation to transformation products Ground water: gibberellic acid, but data gap in relation to transformation products Air: gibberellic acid

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

Soil (indicate location and type of study)	No data provided – not requested
Surface water (indicate location and type of study)	No data provided – not requested
Ground water (indicate location and type of study)	No data provided – not requested
Air (indicate location and type of study)	No data provided – not requested

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

Candidate for R53

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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 ‡				
Mallard duck	Gibberellic acid (GA_3)	Acute	LD_{50} >2000 mg/kg bw	-
	Preparation	Acute	No data submitted	
	Metabolite 1	Acute	No data submitted	
Bobwhite quail	Gibberellic acid (GA_3)	Short-term	LD_{50} >904	LC_{50} >5200
	Gibberellic acid (GA_3)	Long-term	No data submitted	Not available
Mammals ‡				
Rat	Gibberellic acid (GA_3)	Acute	LD_{50} >5000 mg/kg bw	-
	Preparation	Acute	No data submitted	
	Metabolite 1	Acute	No data submitted	
Rat, Rabbit	Gibberellic acid (GA_3)	Long-term	NOEL = 1000 mg/kg bw/day[1]	
Additional higher tier studies ‡				
not required				

[1] Highest dose tested in the rabbit developmental study

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

Vines (6 x 60 g a.s./ha with a 7 day interval between applications)

Indicator species/Category	Time scale	ETE (mg a.s./kg bw/day)	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	3.24	> 616	10
Insectivorous bird	Short-term	1.81	> 500	10
Insectivorous bird	Long-term		Not required[1]	5
Higher tier refinement (Birds)				
	Acute		Not required	10
	Short-term		Not required	10
	Long-term		Not required	5
Tier 1 (Mammals)				
Herbivorous mammal	Acute	22.5	> 222	10
Herbivorous mammal	Long-term	8.4	119	5

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Indicator species/Category	Time scale	ETE (mg a.s./kg bw/day)	TER	Annex VI Trigger
Higher tier refinement (Mammals)				
	Acute		Not required	10
	Long-term		Not required	5

[1]A low reproductive risk to birds for the representative use was concluded on the basis of weight-of-evidence.

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 (mg a.s./L)
Laboratory tests				
Fish				
Oncorhynchus mykiss	Gibberellic acid (GA_3)	96 hr (static)	Mortality, LC_{50}	>120 (nom)
Oncorhynchus mykiss	Gibberellic acid (GA_3)	96 hr (static)	Mortality, LC_{50}	>180 (nom)
Oncorhynchus mykiss	Gibberellic acid (GA_3)	96 hr (semi-static)	Mortality, LC_{50}	> 150 (nom)
Cyprinus carpio	Gibberellic acid (GA_3)	96 hr (semi-static)	Mortality, LC_{50}	> 100 (nom)
Aquatic invertebrate				
Daphnia magna	Gibberellic acid (GA_3)	48 h (static)	Immobility, EC_{50}	76 (nom)
Daphnia magna	Gibberellic acid (GA_3)	48 h (static)	Immobility, EC_{50}	>120 (nom)
Daphnia magna	Gibberellic acid (GA_3)	48 h (semi-static)	Immobility, EC_{50}	>150 (nom)
Daphnia magna	Gibberellic acid (GA_3)	48 h (static)	Immobility, EC_{50}	488 (nom)
Algae				
Pseudokirchneriella subcapitata	Gibberellic acid (GA_3)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	17 (mm) 25 (mm)
Pseudokirchneriella subcapitata	Gibberellic acid (GA_3)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100 (nom) >100 (nom)
Microcosm or mesocosm tests				
Not required				

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

FOCUS Step1

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GA_3 is applied to grapes at late growth stages at up to 60 g a.s./ha on up to 6 occasions (max. 280 g a.s./ha/annum).

Test substance	Organism	Toxicity end point (mg a.s./L)	Time scale	PEC_{swi} (mg a.s./L)	TER	Annex VI Trigger
Gibberellic acid (GA_3)	Fish	>100	Acute	0.1285	>778	100
Gibberellic acid (GA_3)	Aquatic invertebrates	76	Acute	0.1285	591	100
Gibberellic acid (GA_3)	Algae	17		0.1285	132	10

Bioconcentration

	Active substance
$logP_{O/W}$	0.72
Bioconcentration factor (BCF)	Not required
Annex VI Trigger for the bioconcentration factor	Not relevant
Clearance time (days) (CT_{50})	Not relevant
(CT_{90})	Not relevant
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not relevant

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)
Gibberellic acid (GA_3)	No data submitted.[1]	> 25
Preparation	No data submitted	No data submitted
Metabolite 1	No data submitted	No data submitted
Field or semi-field tests		
not required		

[1] A study from the literature indicated a low acute oral toxicity to honey bee brood. Therefore a standard acute oral toxicity study with adult bees was not considered necessary.

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

Vines (6 x 60 g a.s./ha with a 7 day interval between applications)

Test substance	Route	Hazard quotient	Annex VI Trigger
Gibberellic acid (GA_3)	Contact	< 2.4	50
Gibberellic acid (GA_3)	Oral	No data submitted	50
Preparation	Contact	No data submitted	50
Preparation	Oral	No data submitted	50

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

Laboratory tests with standard sensitive species

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Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri	Gibberellic acid (GA_3)	Mortality	No data submitted.
Aphidius rhopalosiphi	Gibberellic acid (GA_3)	Mortality	No data submitted.
Aphidius colemani (Glass-plate)[1]	Gibberellic acid (GA_3)	Mortality	>10 g a.s./ha
Chrysoperla carnea (Glass-plate)[1]	Gibberellic acid (GA_3)	Mortality	>10 g a.s./ha
Orius strigicollis (Glass-plate)[1]	Gibberellic acid (GA_3)	Mortality	>10 g a.s./ha

[1]Study did not include an assessment of sub-lethal effects.

Vines (late application, 6 x 60 g a.s./ha with a 7 day interval between applications)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Gibberellic acid (GA_3)	*Typhlodromus pyri*	No data submitted	-	-	2
Gibberellic acid (GA_3)	*Aphidius rhopalosiphi*	No data submitted	-	-	2
Gibberellic acid (GA_3)	*Aphidius colemani*	> 10	<19.2[1]	<1.23[1]	2

[1] *Aphidius colemani* is not a standard tier 1 indicator species recommended in ESCORT 2. The resulting HQ values should therefore not be considered as totally reliable.

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
No data submitted	-	-	-	-	-	50
						50
						50

Field or semi-field tests
not required

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

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	a.s. ‡	Acute 14 days	No data submitted.
	a.s. ‡	Chronic 8 weeks	No data submitted
	Preparation	Acute	No data submitted
	Preparation	Chronic	No data submitted
	Metabolite 1	Acute	No data submitted
	Metabolite 1	Chronic	No data submitted

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Test organism	Test substance	Time scale	End point
Other soil macro-organisms			
Soil mite	a.s. ‡		No data submitted
	Preparation		No data submitted
	Metabolite 1		No data submitted
Collembola			
	a.s. ‡	Chronic	No data submitted
	Preparation		No data submitted
	Metabolite 1		No data submitted
Soil micro-organisms			
Nitrogen mineralisation	Gibberellic acid (GA_3)	2 years	The addition of GA_3 at concentrations of up to 100 ppm did not influence the content of soil nitrogen substantially.
	Metabolite 1		No data submitted
Carbon mineralisation	Gibberellic acid (GA_3)	2 years	Applications of GA3 at concentrations of up to 100 ppm lead to significant increases in soil organic carbon content.
	Metabolite 1		No data submitted
Field studies			
No data submitted			

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	Gibberellic acid (GA_3)	Acute		No data submitted	10
	a.s. ‡	Chronic		No data submitted	5
	Preparation	Acute		No data submitted	10
	Preparation	Chronic		No data submitted	5
	Metabolite 1	Acute		No data submitted	10
	Metabolite 1	Chronic		No data submitted	5
Other soil macro-organisms					
Soil mite	a.s. ‡			No data submitted	
	Preparation			No data submitted	
	Metabolite 1			No data submitted	
Collembola	a.s. ‡			No data submitted	

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Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
	Preparation			No data submitted	
	Metabolite 1			No data submitted	

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

Not required

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

Test type/organism	Activated sludge
Activated sludge	> 100 mg/l

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

Compartment	
soil	Gibberellic acid (GA_3)
water	Gibberellic acid (GA_3)
sediment	Gibberellic acid (GA_3)
groundwater	Gibberellic acid (GA_3)

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	Hazard symbol: None Indication of danger: None Risk phrases: R52-R53 Safety phrases: S61

	RMS/peer review proposal
Preparation	Hazard symbol: None Indication of danger: None Risk phrases: None Safety phrases: None

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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
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

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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
HCD	historical control database
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-UV	high pressure liquid chromatography – ultraviolet detection
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
MN	micronucleus
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet

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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
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
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
ST	soluble tablet formulation
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
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment

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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

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