

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance dithianon<sup>1</sup>

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#### SUMMARY

Dithianon is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002<sup>3</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>4</sup>. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as ‘the Commission’), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Greece, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant’s decision, in accordance with Article 11e, to withdraw support for the inclusion of dithianon in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)<sup>5</sup> concerning the non-inclusion of dithianon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant BASF SE made a resubmission application for the inclusion of dithianon in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008<sup>6</sup>. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Greece, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 27 January 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 1 February 2010. The EFSA collated and forwarded all comments received to the Commission on 18 March 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology and ecotoxicology and to deliver its conclusions on dithianon.

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1 On request from the European Commission, Question No EFSA-Q-2010-00776, issued on 15 November 2010.

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<sup>3</sup> OJ L224, 21.08.2002, p.25

<sup>4</sup> OJ L 246, 21.9.2007, p. 19

<sup>5</sup> OJ L 333, 11.12.2008, p.11

<sup>6</sup> OJ L 15, 18.01.2008, p.5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of dithianon as a fungicide on pome fruit and table and wine grapes as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No critical areas of concern were identified in the area of identity, and physical and chemical properties, however several data gaps were identified.

A data gap was identified in the mammalian toxicology section for the submission of a new valid Comet assay.

An acute consumer intake concern was identified for table grapes (149% of the ARfD). Given the identified areas of uncertainty regarding the storage stability of dithianon incurred residues in pome fruit and grape wine and the nature of the residues in processed products under standard hydrolytic conditions, the consumer risk assessment can only be considered as provisional at this stage, and the potential for exceedance of the ADI (grapes and pome fruit) and the ARfD (pome fruit) cannot be excluded.

With regard to environmental fate and behaviour, information is lacking regarding the route of aerobic degradation, and specifically the quantification/identification of the unidentified soil transformation products formed in two aerobic soil degradation studies that would trigger a further exposure assessment in the environmental compartments. Although anaerobic conditions are unlikely to occur under the representative uses, a complete assessment of the degradation pathway of dithianon in soil under anaerobic conditions is not available. As a consequence of the lack of information on reliable soil degradation rates for the major soil photolysis degradation product phthalic acid, data gaps were identified for surface water and groundwater exposure assessments for this photodegradation product. A data gap was also identified for an aquatic exposure assessment for the major aqueous photolysis degradation products phthalaldehyde and 1,2-benzenedimethanol.

A high long-term risk for insectivorous birds was identified for all representative uses, even though several options for refinement and ecological data were taken into account. Therefore a critical area of concern and a data gap are identified. The long-term risk for herbivorous mammals was assessed as low on the basis of ecological data and further refinements. Dithianon is very toxic to aquatic organisms. The risk was assessed as low for fish and invertebrates for the representative use on grapes at FOCUS<sub>sw</sub> step 4, including drift and run-off mitigation measures and refined toxicity endpoints. However, the risk for fish (chronic) and invertebrates (acute) was assessed as high for the representative use on pome fruit and a data gap was identified. Data gaps were also identified to further address the risk to soil and aquatic organisms for the soil and aqueous photodegradation product phthalic acid, and the risk to aquatic organisms for the aqueous photodegradation products phthalaldehyde and 1,2-benzenedimethanol. The acute risk to fish for the metabolite CL 1017911 could not be finalised. Further assessment at FOCUS step 3 is needed.

## KEY WORDS

dithianon, peer review, risk assessment, pesticide, fungicide

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## BACKGROUND

### Legislative framework

Commission Regulation (EC) No 1490/2002<sup>7</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>8</sup> lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008<sup>9</sup> lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

### Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Dithianon is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Greece, which was received by the EFSA on 24 November 2006 (Greece, 2006).

The peer review was initiated on 5 February 2007 by dispatching the DAR to Member States and the applicant BASF AG 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 peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of dithianon in Annex I to Council Directive 91/414/EEC.

### Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)<sup>10</sup> concerning the non-inclusion of dithianon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant BASF SE made a resubmission application for the inclusion of dithianon in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, Greece, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 27 January 2010 (Greece, 2010a).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 1 February 2010. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 18 March 2010. At the same time, the collated comments were forwarded to the RMS

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<sup>7</sup> OJ L224, 21.08.2002, p.25

<sup>8</sup> OJ L246, 21.9.2007, p.19

<sup>9</sup> OJ L 15, 18.01.2008, p.5

<sup>10</sup> OJ L 333, 11.12.2008, p.11

for compilation 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 was evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 15 April 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on dithianon within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information was required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 26 April 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology and that further information should be requested from the applicant in all areas.

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 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 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 October 2010.

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 pome fruit and table and wine grapes, 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, 2010) comprises the following documents:

- the comments received on the DAR and the Additional Report,
- the Reporting Table on the DAR and the Additional Report (revision 1-1; 27 April 2010),
- the Evaluation Table (15 November 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of October 2010 containing all individually submitted addenda) (Greece, 2010b) 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

Dithianon is the ISO common name for 5,10-dihydro-5,10-dioxonaphtho[2,3-*b*]-1,4-dithiine-2,3-dicarbonitrile (IUPAC).

The representative formulated product for the evaluation was ‘Delan 70 WG’, a water dispersible granule (WG), containing 700 g/kg dithianon, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying on table and wine grapes, and pome fruit against various fungal diseases. 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 minimum purity of dithianon technical material is 930 g/kg. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of dithianon or the representative formulation, however data gaps were identified for an amended 5-batch study for one of the manufacturing sources, and for a revised technical specification to remove sulphated ash from the specification. The main data regarding the identity of dithianon and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of dithianon and the impurities in the technical material and for the determination of the active substance in the representative formulation, however a data gap was identified for method validation studies for impurities D3, D6 and D25. Adequate methods are available to monitor dithianon residues in food of plant origin. Residue methods for food of animal origin are available, however no enforcement analytical method is required as no MRLs are proposed for products of animal origin. Adequate analytical methods are available for the monitoring of dithianon residues in the environmental matrices. Dithianon is proposed for classification as T, and an adequate LC-MS/MS method exists for the determination of dithianon in body fluids and tissues.

### 2. Mammalian toxicity

Dithianon mammalian toxicity was discussed during the PRAPeR 81 experts’ meeting held in September 2010.

With regard to the proposed specification (i.e. the specification dated April 2010, as reported in Addendum 1 to Volume 4 of the Additional Report dated July 2010 (Greece 2010b)), it can be concluded that it was adequately tested with the batches used for the mammalian toxicology data package.

Dithianon is currently classified as Xn, R22 “Harmful if swallowed” (25th ATP 67/548/EEC); based on the data available during the peer review, dithianon is proposed for classification as T, R23 “Toxic by inhalation” based on a LC50 of 0.31 mg/L air (males); it is not a skin irritant, but it is a severe eye irritant (R41 “Risk of serious damage to eyes” is proposed), and it is a skin sensitiser (R43 “May cause sensitization by skin contact” is proposed).

After repeated exposure in sub-acute and sub-chronic toxicity studies, the target organs in rats, mice and dogs were the liver and the kidneys, with the relevant No Observed Adverse Effect Levels (NOAELs) of 1.6 mg/kg bw/day (52-week oral study in dog), 200 mg/kg bw/day and < 40 mg/kg bw/day (21-day dermal study, systemic and local NOAELs, respectively), and 1070 mg/m<sup>3</sup> equivalent to 627.9 mg/kg bw/day (14-day inhalation study in rats). With regard to the irritating skin effects in



the 21-day dermal study in rats, R66 “Repeated exposure may cause skin dryness or cracking” was proposed by the RMS but not discussed by the experts (RMS to forward to EChA).

The experts concluded that there is no convincing evidence of the genotoxic potential of dithianon based on the available data (the positive results in the Comet assay *in vivo* were considered unreliable). Since the available assay had limited value, the data gap identified by the RMS for a valid Comet assay was maintained. The relevant chronic NOAEL in rats is 1.0 mg/kg bw/day: dithianon induced kidney tumours after chronic oral administration of 30 mg/kg bw/day dithianon (highest dose) in female rats. Classification of dithianon as a Carcinogen Category 3 with R40: “Limited evidence of a carcinogenic effect” was proposed. Dithianon was not demonstrated to be a reproductive or developmental toxicant. In multigeneration studies the relevant parental NOAEL was 9.0 mg/kg bw/day, and the offspring and reproductive NOAELs were 27.6 mg/kg bw/day. In developmental toxicity studies, the relevant maternal and developmental NOAELs were both 20 mg/kg bw/day in rats, and were 10 mg/kg bw/day and 25 mg/kg bw/day in rabbits, respectively.

The Acceptable Daily Intake (ADI) is 0.01 mg/kg bw/day based on the long-term rat study, using a safety factor (SF) of 100. The proposed Acceptable Operator Exposure Level (AOEL) is 0.0135 mg/kg bw/day based on the 90-day dog study, using a SF of 100 and a correction for an oral absorption value of 45%. The proposed Acute Reference Dose (ARfD) is 0.12 mg/kg bw based on the 7-day and 28-day oral rat studies (mechanistic studies), using a SF of 100. The experts agreed that 12 mg/kg bw/day was the relevant NOAEL in these studies, covering also potential acute effects.

The operator exposure levels during mixing/loading and application of 'Delan 70 WG' by tractor-mounted/trailed broadcast air-assisted sprayer to pome fruit and grapes are below the AOEL with the use of Personal Protective Equipment (PPE) (gloves during mixing/loading and gloves, coverall & sturdy footwear during application). For hand-held application, the estimated exposure is below the AOEL even without the use of PPE. Estimated exposures for re-entry activities are below the AOEL (the use of PPE is triggered only if a default value for dislodgeable foliar residues (DFR) of 3 µg/cm<sup>2</sup> is considered according to a Tier-1 EUROPOEM approach). The estimated bystander exposure is below the AOEL (3% for application to grapes, and 24% for application to pome fruit).

### 3. Residues

The metabolism of dithianon has been investigated in fruit crops (apple and orange), leafy vegetables (spinach) and cereals (wheat). In fruit crops and for all the sampling intervals, the major part of the radioactivity was found in the surface rinse as unchanged parent dithianon, while the remaining radioactive residues in the extracts of apple and orange peel and pulp consisted of a large number of mostly polar compounds. A similar metabolic pattern was observed in wheat and spinach with further characterisation of the metabolites CL 231509, CL 902200 and phthalic acid, all recovered in negligible amounts. The residue definition for monitoring and risk assessment is proposed to include the parent compound only.

A sufficient number of supervised residue trials have been reported to propose MRLs on pome fruit and grapes. Incurred dithianon residues in wine grapes were shown to be stable under frozen conditions for up to 14 months, covering the storage time interval of the samples. In addition storage stability data on fortified processed commodities indicated that dithianon is stable under freezer storage conditions in grape must (24 months), grape juice (18 months), grape pomace (6 months) and also in apple sauce (24 months). However, an almost complete and very fast degradation of the residues was observed in grape wine (recovery <10% within 1 month). A data gap was identified for a new storage stability study on incurred dithianon residues in processed grape wine. A similar degradation was observed in apples (recoveries <70% after 1 month) and a data gap was therefore identified for a storage stability study on incurred dithianon residues in pome fruit.

Dithianon was significantly degraded in water under standard hydrolytic conditions, with the formation of a major compound (CL 1017911). Degradation into numerous uncharacterized metabolites was also observed in apple juice under pasteurisation conditions. EFSA is therefore of the

opinion that the nature of the residues in processed products has not been sufficiently investigated and a data gap was identified for additional hydrolysis studies in the presence of apple or grape juice, where the metabolites formed are sufficiently characterised. Should these studies demonstrate the formation of either toxicologically relevant compounds or significant levels of metabolites, their magnitude in apple and grape processed products (especially for wine) should be confirmed and the residue definitions both for monitoring and risk assessment for primary processed products should be revisited. The period of storage of samples of apple and grape processed products should be covered by reliable storage stability data.

Since the representative uses are permanent crops, no rotational crop studies are required.

The metabolism of dithianon has been investigated in lactating goats and laying hens. The major part of the radioactivity was excreted (80%) and unchanged dithianon was recovered at a very low level in all the matrices when expressed on a 1N rate basis. The residue definition for monitoring and risk assessment is proposed as the parent compound alone. Considering the metabolism studies, and the potential exposure of ruminants through consumption of apple pomace, the residues of the parent compound and any metabolite are expected to be recovered at a trace level and no MRLs for livestock matrices are proposed.

The TMDI calculated using the EFSA PRIMo rev.2 model and the MRLs proposed for pome fruit and grapes was 419% of the ADI. Further refinements using the STMR values showed a chronic exposure (IEDI) of 92% of the ADI. An acute intake concern was identified for table grapes (149% ARfD) but not for wine grapes (18% ARfD) or pome fruit (90% ARfD for apples). However, given the identified areas of uncertainty regarding the storage stability of dithianon and the nature of the residues in processed products, the consumer risk assessment has to be considered as provisional and the potential for an exceedance of the ADI (grapes and pome fruit) and the ARfD (pome fruit) cannot be excluded.

#### **4. Environmental fate and behaviour**

In soil laboratory incubations under aerobic conditions in the dark dithianon exhibits low to moderate persistence forming many different unknown metabolites, non-extractable residues (max. 75% of the applied radioactivity (AR) after 56 days) and mineralizing to carbon dioxide (max. 44% AR after 120 days). It could not be excluded that metabolites exceed 10% AR. Therefore a data gap was identified for adequate characterisation of the route of aerobic degradation of dithianon in soil. In two aerobic degradation studies information was lacking as to whether individual components above 10% AR (or > 5% AR at two consecutive sampling dates) were formed. As a consequence, a data gap was identified for the quantification (and possibly identification) of individual components that would trigger a further exposure assessment in the environmental compartments. Dithianon degraded rapidly in anaerobic conditions forming a number of metabolites but the quantification of the individual components of the extracted radioactivity was not available. Although it was agreed that anaerobic conditions are unlikely to occur under the representative uses, a complete assessment of the degradation pathway of dithianon in soil would be necessary if other uses are to be considered. Under continuous irradiation in soil, one major degradation product was formed, phthalic acid, which reached a maximum of 16% AR after 15 days. The information reported from the open literature data to calculate degradation rates in soil for this metabolite was insufficient to derive endpoints and consequently a data gap was identified. Dithianon is immobile or exhibits low mobility in soil. An adsorption value for the major soil photolysis degradation product phthalic acid was determined by using the PCKOCWIN<sup>TM</sup> model, indicating that this photodegradation product is highly mobile in soil. There was no indication that adsorption of dithianon or phthalic acid was pH dependent.

Dithianon photodegrades readily in aqueous media, forming three major degradation products identified as phthalic acid (max. 38.5% AR after 320 minutes), phthalaldehyde (max. 11.2% AR after 320 minutes) and 1,2-benzenedimethanol (max. 20.9% AR after 1 day). In laboratory incubations in dark aerobic natural sediment water systems (4 systems investigated) dithianon rapidly degraded forming the major metabolite CL1017911 (max 54% AR at 1d). The radioactivity that partitioned to sediment that was not dithianon, was primarily accounted for as the unextractable fraction (max. 73%



AR after 100d). Mineralisation accounted for 19.1-25.6% AR after 100d. Although the kinetic assessment for  $DT_{50\text{ sed}}$  values calculated for the Pond R and River B systems for dithianon, and calculated for the Pond R system for the metabolite CL1017911, indicated that these values are questionable (Addendum 1, July 2010 (Greece 2010b)), it is the EFSA opinion that no impact on the aquatic risk assessment is expected for either of these compounds (see open points 4.16 and 4.17 of the Evaluation table).

Predicted environmental concentrations (PEC) in surface water and sediment were calculated for dithianon according to the GAP proposed for each crop and each step of the FOCUS surface water procedure (FOCUS, 2001; FOCUS 2007)<sup>11</sup>. In the new calculations provided in Addendum 1 (July 2010), the mitigation measures proposed for step 4 calculations for dithianon exceeded the limit of spray drift reduction of 95% for some of the pome fruit scenarios. However, it is noted that the resulting PEC<sub>sw</sub> (with 30m or 40m buffer zones) were not used in the TER calculations reported in section 5. The aquatic exposure assessments for the major soil photodegradation product phthalic acid and for the major aqueous photodegradation products phthalaldehyde and 1,2-benzenedimethanol have not been addressed and consequently data gaps were identified.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2000) scenarios and the models FOCUS PEARL 3.3.3 and FOCUS MACRO 4.4.2<sup>12</sup>. The potential for groundwater exposure from the representative uses by dithianon above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. Due to the lack of information on reliable soil  $DT_{50}$  values for phthalic acid, the PEC<sub>gw</sub> values available for this degradation product can not be considered valid.

The PEC in soil, surface water, sediment and groundwater that could be calculated covering the representative uses can be found in Appendix A.

## 5. Ecotoxicology

Dithianon was discussed during the PRAPeR 80 ecotoxicology experts' meeting in August 2010.

The acute and short-term risk was assessed as low for insectivorous birds at the first tier level, following the Guidance Document (European Commission, 2002), whereas a high long-term risk was identified for both representative uses (i.e. pome fruit and grapes). To refine the long-term risk assessment, ecological data (i.e. focal species, PD and PT data) were provided. In addition, other options for refinement were considered, i.e. RUD for arthropods, weed seeds and plant material, MAF and  $f_{\text{twa}}$ , according to EFSA (2008). Refined deposition factors, based on FOCUS (2000), were applied to correct RUD values for weed seeds and plant material. The focal species proposed by the applicant were considered to be relevant and well supported by the submitted dataset (i.e. radio-tracking data). The proposed PD values were considered acceptable, although the use of mean PT values was questioned due to uncertainties in the derivation of these parameters (i.e. sample size, representativeness of the study location and extrapolation to other areas). Long-term exposure could not be excluded because dithianon can be applied for several weeks according to the representative uses (i.e. max 12 applications for pome fruit and max 8 applications for grapes, with an interval of 7-12 days). Therefore, the experts agreed to use the 90<sup>th</sup> percentile PT values in the risk assessment, as also recommended by EFSA (2009). The PT value for the proposed focal species Black Redstart (*Phoenicurus ochruros*) for the use on grapes in northern Europe was rejected because it was not supported by sufficient data.

After the experts' meeting the RMS provided an addendum with revised TERs to include the 90<sup>th</sup> percentile PT values. In these new calculations all the other previous options for refinement were

<sup>11</sup> At steps 3 and 4 Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA (2007)) and Walker equation coefficient of 0.7

<sup>12</sup> Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA (2007)) and Walker equation coefficient of 0.7

retained, except the MAF factors for arthropods and weed seeds. However, according to the EFSA (2008), multiple applications should be considered for such food items. Therefore, the TERs were subsequently revised during the written procedure on the draft conclusion to include the MAF value of 2.56 and 2.60 for grapes and pome fruit respectively. The revised TERs ranged from **2.84**- 19.50 for the use on grapes and from **2.35** – 6.14 for the use on pome fruit, indicating a high risk for some of the identified focal species, namely Chaffinch (*Fringilla coelebs*, TER=2.84) and Linnet (*Carduelis cannabina* TER=4.27) for grape; Great tit (*Parus major*, TER=2.35), Serin (*Serinus serinus*, TER=4.95) and Chaffinch (*Fringilla coelebs*, TER=2.99) for pome fruit. Overall, a high long-term risk for birds could not be excluded for all representative uses. A critical area of concern and a data gap was identified.

The acute and long-term risk assessment for small herbivorous mammals was assessed as high at the first tier level, following the Guidance Document (European Commission, 2002) for both representative uses (i.e. pome fruit and grape). The chronic endpoint (i.e. NOAEL of 34.9 mg a.s./kg bw) from a rat multi-generation study was questioned by the experts because a lower endpoint (i.e. NOAEL of 25 mg a.s./kg bw) from a developmental study in rabbit was available. Although no effects on the reproductive performance or offspring were observed at 34.9 mg a.s./kg bw in the rat multi-generation study, effects on pre- and post-implantation losses were observed at 40 mg a.s./kg bw in the rabbit developmental study, resulting in a significantly decreased number of live foetuses. Experts expressed concern regarding the comparability of the two species and of the two study types (oral exposure in the rat study against gavage exposure in the rabbit study). It was acknowledged that gavage exposure can affect the toxicokinetics, and thus may lead to different results compared to oral exposure, with the latter more likely in the field. Nevertheless, no consensus could be reached during the meeting and therefore it was recommended to use the lowest endpoint (i.e. NOAEL of 25 mg a.s./kg bw) for the risk assessment. Regarding the refinement of the acute and long-term risk assessment for mammals, two focal species (i.e. *Apodemus silvaticus* and *Lepus europaeus*) were proposed on the basis of radio-tracking data, along with RUD in arthropods, weed seeds and plant material, MAF and  $f_{\text{twa}}$ , from EFSA (2008), and deposition factors from FOCUS (2000). The focal species and related PD values were considered acceptable. However, as for birds, the mean PT values proposed only for the long-term risk refinement was questioned and the 90<sup>th</sup> percentile PT values were recommended to be used. The refined acute TERs indicated a low risk for mammals.

After the experts' meeting the RMS provided an addendum with the revised long-term TERs (i.e. 90<sup>th</sup> percentile PT values and NOAEL of 25 mg a.s./kg bw). However, as for birds, the MAF factors were excluded from the new calculations. Therefore, the TER values were subsequently revised during the written procedure to include the MAF values of 2.56 and 2.60 for grapes and pome fruit respectively, following the EFSA (2008). The revised TERs indicated a high risk for the focal species *Lepus europaeus* (TER =4.07) for the use on pome fruit, however, the risk was finally assessed as low with a further refinement i.e a deposition factor of 0.33. Overall, on the basis of the available data, the risk for mammals was assessed as low for the representative uses.

The risk to earthworm- and fish-eating birds and mammals from secondary poisoning, and consumption of contaminated drinking water was assessed as low for both representative uses.

Dithianon is very toxic to aquatic organisms. Fish were the most sensitive organisms and the lowest endpoint was observed in a chronic study on *Oncorhynchus mykiss* (21d-NOEC 0.46 µg a.s./L – flow-through system). This endpoint was used for the first tier risk assessment although it was based on physiological parameters rather than mortality and chronic parameters (growth, weight). Acute studies with the formulated product 'Delan 70 WG' were available for fish (*O. mykiss*), aquatic invertebrates (*Daphnia magna*), and algae (*Selenastrum capricornutum*). The formulation was more toxic for *D. magna* and algae than the active substance, therefore the formulation endpoints were used for the risk assessment, with drift being the relevant route of entry of the active substance in surface water.

Acute and long-term TERs, calculated according to FOCUS<sub>sw</sub> step 2, were below the Annex VI triggers for all aquatic organisms for both representative uses, indicating a high risk. Subsequent

calculations at FOCUS<sub>sw</sub> step 3 also indicated a high acute and long-term risk for fish, aquatic invertebrates, algae and sediment-dwellers (the latter only for pome fruit). Therefore, the risk was assessed at FOCUS<sub>sw</sub> step 4 including mitigation measures comparable to a no-spray buffer zone up to 20m for the grape use and 20-30m for the use on pome fruit. Additional run-off mitigation measures, comparable to vegetated buffer strips of 20m, were used in some scenarios, namely R3 and R4-stream (grape use) and R4-stream (pome fruit use). TERs for fish (acute and chronic) were still below the triggers in all scenarios for both representative uses. The acute TERs for invertebrates based on formulation endpoint were above the trigger in all scenarios (in scenario R3- and R4-stream with the application of additional run-off mitigation measures), for the use on grape. However, they were below the trigger in the majority of scenarios for the use on pome fruit.

As a further refinement of the assessment of the acute risk to fish, the experts agreed to use the proposed Species Sensitivity Distribution (SSD) approach based on the LC<sub>50</sub>. The agreed endpoint was the median HC<sub>5</sub> of 19.4 µg a.s./L to be used with an assessment factor of 10. On this basis, the acute risk for fish was assessed as low at FOCUS<sub>sw</sub> step 4 including drift and run-off mitigation measures for all scenarios for the grape use; the risk was assessed as high for 5 scenarios out of 10 for the use on pome fruit (the TERs for the scenarios D3-ditch, D4-stream, D5-stream, R2-stream, R3-stream were slightly below the trigger).

For the chronic risk assessment for fish, the endpoint (i.e. NOEC of 3.9 µg a.s./L) from the 79-days semi-static test on *O. mykiss* was considered more appropriate by the experts because pulsed exposure was covered in such a study. Given the mid-range sensitivity of rainbow trout, experts agreed that the acute data from 10 species could be used as a weight of evidence for reducing the Annex VI trigger of 10. An assessment factor of 3 was derived from the relative sensitivity of rainbow trout (LC<sub>50</sub> = 44 µg a.s./L) compared to the most sensitive species (LC<sub>50</sub> = 14.3 µg a.s./L). This assessment factor was considered sufficient to cover the inter-species variability. On this basis, the chronic TERs for fish were above the trigger in all scenarios at FOCUS<sub>sw</sub> step 4 including drift and run-off mitigation measures for the grape use, whereas TERs were still below the trigger in the majority of scenarios for the pome fruit use (i.e. D3- ditch, D4-stream, D5-stream, R1-stream, R2-stream, R3-stream).

Overall, the refined risk assessment indicated a low risk for fish and aquatic invertebrates for the use on grape. However, a high risk for fish (chronic) and aquatic invertebrates (acute) was indicated for the use on pome fruit, and a data gap was identified.

TERs at step 2 for the metabolite CL 1017911 were above the trigger, indicating a low risk, except the acute risk to fish for the pome fruit use (TER=76). A data gap was identified to provide TERs at FOCUS step 3. On the basis of the data gap in the section 4, the risk to soil and aquatic organisms for the soil and aqueous photodegradation product phthalic acid, and the risk to aquatic organisms for the aqueous photodegradation products phthalaldehyde and 1,2-benzenedimethanol needs to be addressed and a data gap was identified.

The risk was assessed as low for earthworms, bees, non-target arthropods, soil-micro-organisms, non-target plants and methods for sewage treatment plants for all representative uses.

## 6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

### 6.1. Soil<sup>(a)</sup>

Compound (name and/or code)	Persistence	Ecotoxicology
dithianon	low to moderate persistence First order DT <sub>50</sub> 2.6-33.3 days (20°C pF 2 soil moisture)	The risk to soil-living organisms was assessed as low.
phthalic acid (soil photolysis degradation product)	no data, data required	The risk to soil-living organisms needs to be addressed, data gap identified.

(a): provisional, as a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding soil contamination

### 6.2. Ground water<sup>(a)</sup>

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
dithianon	immobile to low mobility K <sub>doc</sub> 1167-6004 mL/g	no	Yes	Yes	Very toxic to aquatic organisms in surface water. The endpoint driving the aquatic risk assessment: fish chronic NOEC = 0.46 µg a.s./L (regulatory concentration including a safety factor of 10 = 0.046 µg a.s./L). A high risk to the fish and invertebrates was indicated in the surface water risk assessment for the use in pome fruit.

phthalic acid (soil photolysis product)	no data, data required	no data, data required	No	No data available	The risk to aquatic organisms needs to be addressed, a data gap is identified.
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(a): Provisional as a data gap was identified for the identification/quantification of potential soil metabolites that would trigger further assessment regarding groundwater contamination

### 6.3. Surface water and sediment<sup>(a)</sup>

Compound (name and/or code)	Ecotoxicology
dithianon	Very toxic to aquatic organisms. The endpoint driving the aquatic risk assessment: fish chronic NOEC = 0.46 µg a.s./L (regulatory concentration including a safety factor of 10 = 0.046 µg a.s./L). A high risk to fish and aquatic invertebrates was indicated for the use in pome fruit.
CL 1017911 (water phase)	The risk was assessed as low, except the acute risk to fish for the pome fruit use (TER=76). A data gap was identified to provide TERs at FOCUS step 3.
phthalic acid (soil and aqueous photolysis degradation product)	The risk for aquatic organisms needs to be addressed, a data gap is identified
phthalaldehyde (aqueous photolysis degradation product)	The risk for aquatic organisms needs to be addressed, a data gap is identified
1,2-benzenedimethanol (aqueous photolysis degradation product)	The risk for aquatic organisms needs to be addressed, a data gap is identified

(a): Provisional, as a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding surface water contamination via runoff and drainage

**6.4. Air**

Compound (name and/or code)	Toxicology
dithianon	T, R23 “Toxic by inhalation” based on a LC50 of 0.31 mg/L air in male rats



## LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Amended 5-batch study (DocID 2009/1093306 requested in level 4 of the Additional Report and its amendment Doc ID 2010/1015745) for one of the manufacturing sources (relevant for all representative uses; submission date proposed by the applicant: unknown, see section 1).
- Revised technical specification, removing sulphated ash from the specification (relevant for all representative uses; submission date proposed by the applicant: unknown, see section 1).
- Method validation studies for impurities D3, D6 and D25 (relevant for all representative uses; submission date proposed by the applicant: unknown, see section 1).
- A new valid Comet assay (relevant for all representative uses; submission date proposed by the applicant: unknown, see section 2).
- Storage stability data on incurred residues in pome fruit (relevant for the representative use on pome fruit; submission date proposed by the applicant: unknown, see section 3).
- Storage stability data on incurred residues in grape wine (relevant for the representative use on wine grapes, submission date proposed by the applicant: unknown, see section 3).
- Additional hydrolysis studies in the presence of apple or grape juice simulating pasteurisation, baking, brewing, boiling and sterilization where the metabolites formed are sufficiently characterised. Should these studies result in the formation of either toxicologically relevant compounds or significant levels of metabolites, their magnitude in apples and grape processed products should be confirmed (relevant for all representative uses, submission date proposed by the applicant: unknown, see section 3).
- Adequate route of aerobic degradation of dithianon in soil (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Quantification and, if needed, identification of the individual components formed in unspecified quantity in two aerobic soil degradation studies (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Estimates of aerobic degradation rates in soil of the major soil photodegradation product phthalic acid (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Aquatic exposure assessment for the major aqueous photodegradation products phthalic acid, phthalaldehyde and 1,2-benzenedimethanol (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Groundwater exposure assessment for the major soil photodegradation product phthalic acid (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- The long-term risk to birds to be further addressed (relevant for all representative uses, submission date proposed by the applicant: unknown, see section 5).
- The chronic risk to fish and the acute risk to aquatic invertebrates to be further addressed (relevant for the representative use on pome fruit, submission date proposed by the applicant: unknown, see section 5).

- The acute risk to fish for the metabolite CL 1017911 should be further addressed at FOCUS step 3 (relevant for the representative use on pome fruit, submission date proposed by the applicant: unknown, see section 5).
- The risk to aquatic organisms for the photodegradation products phthalic acid (soil and aqueous photodegradation product), phthalaldehyde (aqueous photodegradation product), 1,2-benzenedimethanol (aqueous photodegradation product) to be addressed (relevant for all representative uses, submission date proposed by the applicant: unknown, see section 5).
- The risk to soil organisms for the soil and aqueous photodegradation product phthalic acid to be addressed (relevant for the all representative uses, submission date proposed by the applicant: unknown, see section 5).

#### **PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED**

- Use of PPE for tractor-mounted/trailed broadcast air-assisted spraying to pome fruit and grapes.
- Mitigation measures comparable to a no-spray buffer zone up to 20m for the grape use. Additional run-off mitigation measures, comparable to vegetated buffer strips of 20m are needed in some scenarios, namely R3 and R4-stream.

#### **ISSUES THAT COULD NOT BE FINALISED**

- The aerobic route of degradation of dithianon in soil could not be finalised.
- The aquatic exposure assessment could not be finalised as a data gap was identified for the quantification/identification of potential soil major metabolites that would trigger further assessment regarding surface water contamination via runoff and drainage; and PEC<sub>sw</sub> and PEC<sub>sd</sub> are not available for the major aqueous photodegradation products phthalic acid, phthalaldehyde and 1,2-benzenedimethanol
- The groundwater exposure assessment could not be finalised as a data gap was identified for the quantification/identification of potential soil metabolites that would trigger further assessment regarding groundwater contamination, and PEC<sub>gw</sub> for the photodegradation product phthalic acid is not available.
- The risk to soil and aquatic organisms for the soil and aqueous photodegradation product phthalic acid, and the risk to aquatic organisms for the aqueous photodegradation products phthalaldehyde and 1,2-benzenedimethanol could not be finalised.
- The chronic risk to fish and the acute risk to aquatic invertebrates could not be finalised for the use on pome fruit for the majority of scenarios.
- The acute risk to fish for the metabolite CL 1017911 could not be finalised for the representative use on pome fruit. Further assessment at FOCUS step 3 is needed.

#### **CRITICAL AREAS OF CONCERN**

- Given the identified areas of uncertainty regarding the storage stability of dithianon incurred residues in pome fruit and grape wine and the nature of the residues in processed products under standard hydrolytic conditions, the consumer risk assessment can only be considered as provisional and the potential for an exceedance of the ADI (grapes and pome fruit) and the ARfD (pome fruit) cannot be excluded. An acute intake concern has already been identified for table grapes (149% of the ARfD).

- The long-term risk to birds was assessed as high for all representative uses.

## REFERENCES

- EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance dithianon.
- Greece, 2006. Draft Assessment Report (DAR) on the active substance dithianon prepared by the rapporteur Member State Greece in the framework of Directive 91/414/EEC, October 2006.
- Greece, 2010a. Additional Report to the Draft Assessment Report on the active substance dithianon prepared by the rapporteur Member State Greece in the framework of Commission Regulation (EC) No 33/2008, January 2010.
- Greece, 2010b. Final Addendum to the Additional Report on dithianon, compiled by EFSA, October 2010.

### Guidance documents<sup>13</sup>:

- European Commission, 2002. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.
- European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.
- EFSA (2007). Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default  $Q_{10}$  value used to describe the temperature effect on transformation rates of pesticides in soil. *The EFSA Journal* (2007) 622, 1-32
- EFSA (2008). Opinion of the Scientific Panel on Plant protection products and their Residues on the science behind the GD on risk assessment for birds and mammals. *The EFSA Journal* (2008) 734: 1-181).
- EFSA (2009.). Guidance Document on Risk Assessment for Birds & Mammals. *EFSA Journal* 2009; 7(12):1438.
- FOCUS (2000). "FOCUS Groundwater Scenarios in the EU review of active substances". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000-rev.2. 202 pp, as updated by the Generic Guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.
- FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.
- FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

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<sup>13</sup> For further guidance documents see [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm#council](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council) (EC) or [http://www.oecd.org/document/59/0,3343,en\\_2649\\_34383\\_1916347\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html) (OECD)

## APPENDICES

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

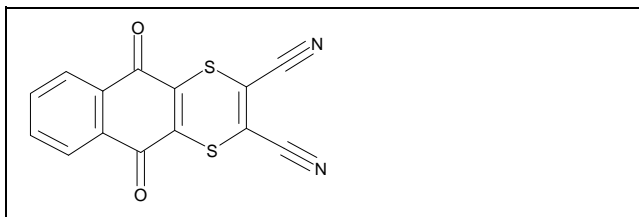
#### Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Dithianon
Function ( <i>e.g.</i> fungicide)	Fungicide
Rapporteur Member State	Hellas
Co-rapporteur Member State	-

#### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	5,10-dihydro-5,10-dioxonaphtho[2,3- <i>b</i> ]-1,4-dithiine-2,3-dicarbonitrile
Chemical name (CA) ‡	5,10-dihydro-5,10-dioxonaphtho[2,3- <i>b</i> ]-1,4-dithiin-2,3-dicarbonitrile
CIPAC No ‡	153
CAS No ‡	3347-22-6
EC No (EINECS or ELINCS) ‡	222-098-6
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	930 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	C <sub>14</sub> H <sub>4</sub> N <sub>2</sub> O <sub>2</sub> S <sub>2</sub>
Molecular mass ‡	296.3 g/mol

Structural formula ‡





## Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Melting range: 215-216 C (99.3% pure)												
Boiling point (state purity) ‡	Not relevant												
Temperature of decomposition (state purity)	approx. 222 C (96.9% techn)												
Appearance (state purity) ‡	pure a.s. (99.9%): dark-brown, powdery, fibrous, fine-crystalline solid, with a faint musty smell												
	technical a.s. (95.5%): medium-brown powdery, fine-crystalline solid, with a characteristic musty-organic smell												
Vapour pressure (state temperature, state purity) ‡	less than $10^{-10}$ Pa at 25 C (96.9% technical)												
Henry's law constant ‡	$H < 1.347 \times 10^{-7} \text{ Pa m}^3 \text{ mol}^{-1}$ at 20 C												
Solubility in water (state temperature, state purity and pH) ‡	deionized water (pH~5.4): 0.22 mg/L at 20 C (96.9% technical)												
	At 20 C (96.9% technical): pH 4: 0.31 mg/L pH 7: 0.38 mg/L pH 9: 0.36 mg/L												
Solubility in organic solvents ‡ (state temperature, state purity)	<table> <tr><td>hexane</td><td>0.00877</td></tr> <tr><td>toluene</td><td>14.7</td></tr> <tr><td>dichloromethane</td><td>25.1</td></tr> <tr><td>methanol</td><td>0.815</td></tr> <tr><td>acetone</td><td>22.2</td></tr> <tr><td>ethyl acetate</td><td>10.6</td></tr> </table> <p>(At 20 C; all values in g/L of solvent) (95.5% techn)</p>	hexane	0.00877	toluene	14.7	dichloromethane	25.1	methanol	0.815	acetone	22.2	ethyl acetate	10.6
hexane	0.00877												
toluene	14.7												
dichloromethane	25.1												
methanol	0.815												
acetone	22.2												
ethyl acetate	10.6												
Surface tension ‡ (state concentration and temperature, state purity)	72.7 mN/m at 20 C (90% saturated aqueous solution of dithianon) (95.5% techn)												
Partition co-efficient ‡ (state temperature, pH and purity)	Log $P_{ow}$ = 3.2 at pH 2, at 20 C (91.6% technical)												
	The log $P_{ow}$ is independent of pH.												
Dissociation constant (state purity) ‡	Dithianon has no chemical functionality which dissociates in water												

UV/VIS absorption (max.) incl.  $\epsilon$  ‡  
(state purity, pH)

In acetonitrile (99.0% pure)		
$\lambda_{\max}$ (nm)	$\epsilon$ (Lx mol <sup>-1</sup> x cm <sup>-1</sup> )	
~198	3.76 x 10 <sup>4</sup>	
New UV/vis (200-800 nm) spectrum (98.6% pure):		
	$\lambda_{\max}$ (nm)	$\epsilon$ (Lx mol <sup>-1</sup> x cm <sup>-1</sup> )
In CH <sub>3</sub> CN:	199	3.5932 x 10 <sup>4</sup>
	233	2.0542 x 10 <sup>4</sup>
	330	0.5083 x 10 <sup>4</sup>
(At 290.5 nm: $\epsilon$ = 0.6535 x 10 <sup>4</sup> Lx mol <sup>-1</sup> x cm <sup>-1</sup> )		
In CH <sub>3</sub> CN:H <sub>2</sub> O:HCl (pH=1.3):	199	1.8102 x 10 <sup>4</sup>
	237	0.9820 x 10 <sup>4</sup>
	342	0.4489 x 10 <sup>4</sup>
(10:85:5)	(At 290.5 nm: $\epsilon$ = 0.5100 x 10 <sup>4</sup> Lx mol <sup>-1</sup> x cm <sup>-1</sup> )	
In CH <sub>3</sub> CN:H <sub>2</sub> O (pH=6.9) :	199	2.2380 x 10 <sup>4</sup>
	250	1.5110 x 10 <sup>4</sup>
	350	0.7207 x 10 <sup>4</sup>
(10:90)	(At 290.5 nm: $\epsilon$ = 0.8724 x 10 <sup>4</sup> Lx mol <sup>-1</sup> x cm <sup>-1</sup> )	

Flammability ‡ (state purity)

Not highly flammable (95.5% technical)  
Not auto-flammable (95.5% technical)

Explosive properties ‡ (state purity)

not explosive (95.5% technical)

Oxidising properties ‡ (state purity)

not oxidising (95.5% technical)

## Summary of representative uses evaluated (*Dithianon*)

Crop and/or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL (l) min – max	water L/ha min – max	kg as/ha (l) min – max		
Pome fruit	EU (South & North)	Delan 70 WG (BAS 216 03F)	F	<i>Venturia inaequalis</i> , <i>Gloeosporium spp.</i> <i>Nectria galligena</i> , <i>Venturia pirina</i>	WG	700	High volume spraying	BBCH 10 - 79	1-12	7 – 12 days	0.0350 – 0.0525	1000 - 1500	0.525	21	Preventive treatment. [1] [2] [3] [5] [6] [7]
Grape (Table and Wine)	EU (South & North)	Delan 70 WG (BAS 216 03F)	F	<i>Plasmopara viticola</i>	WG	700	High volume spraying	BBCH 10 - 79	1 - 8	7 – 12 days	0.047 - 0.140	400 – 1200	0.560	42	Preventive treatment. Water volume is depending on the cropping. [1] [2] [4] [5] [6]

[1] The groundwater exposure assessment has not been finalised.

[2] A high long-term risk to birds has been identified.

[3] A high risk to aquatic organisms (acute for invertebrates and chronic for fish) was indicated for the majority of scenarios at FOCUS step 4.

[4] Consumer acute intake concern for table grapes (149 % of the ARfD)

[5] The consumer exposure assessment has not been finalised. In view of the uncertainties regarding the storage stability of dithianon residues in pome fruit and grape wine and the nature of the residues in processed products under standard hydrolytic conditions the potential for an exceedance of the ADI (grapes and pome fruit) and the ARfD (pome fruit) cannot be excluded.

[6] The risk to soil and aquatic organisms for phthalic acid, and risk to aquatic organisms for phthalaldehyde and 1,2-benzenedimethanol could not be finalised.

[7] The acute risk to fish for the metabolite CL 1017911 could not be finalised.

nr: not relevant

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).		(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b>
(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)		(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)		

<p>(c) <i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) <i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (<i>e.g.</i> 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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## Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV <sub>250nm</sub> fully validated method
Impurities in technical as (analytical technique)	<p>3 methods HPLC-UV<sub>254nm</sub> were submitted for the determination of the impurities of dithianon technical. The methods are inadequately validated (Recovery and further precision and specificity data should be submitted)</p> <p>A new validation data package (accuracy, precision, specificity, linearity) has been submitted for the above three HPLC methods.</p> <p>Acceptable validated HPLC methods are available for the determination of the impurities specified in dithianon technical.</p> <p>The new validation studies for the three impurities specified (using reference substances - not previously available) have been identified as a data gap.</p> <p>Sulphated ash: method based on CIPAC MT 29.1</p> <p>Water: Determined by Karl Fisher titration after water transfer by a nitrogen stream into the titration liquid</p>
Plant protection product (analytical technique)	HPLC-UV <sub>250nm</sub> fully validated method

### Analytical methods for residues (Annex IIA, point 4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	Dithianon
Food of animal origin	Dithianon
Soil	Dithianon
Water surface	Dithianon
drinking/ground	Dithianon
Air	Dithianon
Blood	Dithianon

### Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<p><u>Doc. No.:</u> 2006/1032406</p> <p><u>Substrates:</u> lettuce, grape, apple, whole orange, wheat grain, rape seed and dried hop cones.</p> <p><u>Analysis:</u> LC-MS/MS</p> <p><u>Determined analyte:</u> dithianon</p> <p><u>LOQ:</u> 0.01 mg/kg for lettuce, grape, apple, whole</p>
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Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)

orange, wheat grain, rape seed, 1.0 mg/kg dried hop cones.  
Method fully validated  
ILV data were provided

Doc. No.: 2007/1017102 and Doc 2010/1062111 (ILV for the above method)

Substrates: wheat, sunflower, lettuce, green apple and hop

Analysis: LC-MS/MS

Determined analyte: dithianon

LOQ: 0.01 mg/kg for lettuce, green apple, wheat, sunflower, 1.0 mg/kg for hop.

Method fully validated for the representative uses (pome fruit and grapes)

Std No. M 3435 (Doc. No.: DT-245-007):

Substrates: bovine muscle, bovine fat, bovine whole milk, chicken egg

Analysis: HPLC-ECD

Determined analyte: dithianon

LOQ: 0.01 mg/kg for each substrate

Method fully validated

ILV data were provided

Confirmatory method (LC-MS) was provided

Doc. No.: 2006/1034178 (confirmatory for the above method)

Substrates: bovine muscle, bovine fat, bovine whole milk, chicken egg

Analysis: LC-MS

Determined analyte: dithianon

LOQ: 0.01 mg/kg for each substrate

Method fully validated

Doc. No.: 2009/1045474

Substrates: cow liver, kidney, fat and milk

Analysis: LC-MS/MS

Determined analyte: dithianon

LOQ: 0.01 mg/kg for each substrate

Method fully validated

No confirmatory method is necessary

No ILV data were provided

Since no MRLs in products of animal origin are proposed no analytical method for post registration control and monitoring purposes is required.

Soil (principle of method and LOQ)

Std No. M3445 (Doc. No.: DT-242-004):

Substrates: soil

Analysis: LC-MS

Determined analyte: dithianon

LOQ: 0.01 mg/kg

Method fully validated

No confirmatory method is necessary

Std No. 365602 (Doc. No.: 2009/7000164)

Substrates: soil



	<u>Analysis:</u> LC-MS/MS <u>Determined analyte:</u> dithianon <u>LOQ:</u> 0.01 mg/kg Method fully validated No confirmatory method is necessary
Water (principle of method and LOQ)	<u>Std No. 289768 (Doc. No.: 2007/7006973)</u> <u>Substrates:</u> surface and drinking water <u>Analysis:</u> LC-MS/MS <u>Determined analyte:</u> dithianon <u>LOQ:</u> 0.05 µg/L Method fully validated No confirmatory method is necessary
Air (principle of method and LOQ)	<u>Std No. FAMS 034-01 Doc. No.: DT-241-002:</u> <u>Substrates:</u> air <u>Analysis:</u> HPLC-UV <u>Determined analyte:</u> dithianon <u>LOQ:</u> 0.001mg/m <sup>3</sup>
Body fluids and tissues (principle of method and LOQ)	<u>Doc. No.: 2007/1033979</u> <u>Substrates:</u> human urine and blood <u>Analysis:</u> LC-MS/MS <u>Determined analyte:</u> dithianon <u>LOQ:</u> 0.05 mg/L Method fully validated No confirmatory method is necessary  For tissues (meat) the method has been investigated under food of animal origin.

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

	RMS/peer review proposal
Active substance	RMS proposal: None

## Impact on Human and Animal Health

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

Rate and extent of absorption ‡

Incomplete (averaged 45% of the dose within 48 hours for the single low dosed bile-cannulated rats) and rapid (the plasma  $C_{max}$  achieved within 6 hrs after single oral low dose administration)

Distribution ‡

Widely distributed; highest concentration in thyroid, kidneys, GI-tract, whole-blood, lungs and heart

Potential for accumulation ‡

No potential for body accumulation

Rate and extent of excretion ‡

Rapid and extensive (> 90% of the urinary radioactivity was excreted within 24 hrs) firstly *via* feces (43.46-72.15% of the dose), secondly *via* urine (23.54-31.43% of the dose) and lastly *via* bile (7.21-11.59% of the dose) at 168 hrs

Metabolism in animals ‡

Extensive metabolism leading to the formation of mostly polar products.  
The metabolic reactions included oxidation of the sulphur atoms, cleavage of the dithiane ring, reduction of the 1,4-naphthoquinone moiety, glucuronidation as well as substitution of the carbonitrile moieties by amino and carboxy groups.  
The only predominant metabolite in quantitative terms was M216F020, detected mainly in urine (up to 10%) and secondly in kidney and plasma.

Toxicologically relevant compounds ‡  
(animals and plants)

Parent compound

Toxicologically relevant compounds ‡  
(environment)

Parent compound

### Acute toxicity (Annex IIA, point 5.2)

Rat LD<sub>50</sub> oral ‡

300 mg/kg b.w. (females) **R22**

Rat LD<sub>50</sub> dermal ‡

> 2000 mg/kg b.w. (males & females)

Rat LC<sub>50</sub> inhalation ‡

0.31 mg/L air (males) **R23**  
0.58 mg/L air (females)

Skin irritation ‡

Non-irritant

Eye irritation ‡

Severe eye irritant **R41**

Skin sensitisation ‡

Skin sensitizer (GPMT) **R43**

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡

Liver & kidneys (rat, dog, mouse)

Relevant oral NOAEL ‡

1.6 mg/kg b.w./day (40 ppm), 52-week, dog

Relevant dermal NOAEL ‡

Systemic: 200 mg/kg b.w./day, 21-day, rat Local: < 40 mg/kg b.w./day, 21-day, rat	<b>R66</b>
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Relevant inhalation NOAEL ‡

1070 mg/m <sup>3</sup> (627.9 mg/kg b.w./day), 14-day, rat	
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**Genotoxicity ‡ (Annex IIA, point 5.4)**

<i>In vitro</i> genotoxic agent (gene mutation inducer and clastogen) No convincing evidence of genotoxic potential relevant to humans	
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**Long term toxicity and carcinogenicity (Annex IIA, point 5.5)**

Target/critical effect ‡

Kidneys (rat, mouse)
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Relevant NOAEL ‡

1.0 mg/kg b.w./day (20 ppm); chronic toxicity & carcinogenicity, rat
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**Carcinogenicity ‡**

Induction of kidney tumors after chronic oral administration of 30 mg/kg b.w./day dithianon (highest dose) in female rats	<b>R40 *</b>
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\* the hazard statement according to Reg. 1272/2008 is **H351**

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

Reproduction target / critical effect ‡

Decreased feed consumption and body weight gain at 27.6-34.9 mg/kg b.w./day (rat) No effects on the reproductive parameters (rat)	
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Relevant parental NOAEL ‡

200 ppm (males: 9.0 mg/kg b.w./day, females: 11.4 mg/kg b.w./day)	
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Relevant reproductive NOAEL ‡

600 ppm (males: 27.6 mg/kg b.w./day, females: 34.9 mg/kg b.w./day)	
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Relevant offspring NOAEL ‡

600 ppm (males: 27.6 mg/kg b.w./day, females: 34.9 mg/kg b.w./day)	
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**Developmental toxicity**

Developmental target / critical effect ‡

Embryo-/foetotoxic effects [increased resorption incidence (rat), post implantation losses (rat, rabbit), abortions, pre-implantation losses, decreased number of live fetuses per litter (rabbit)] at maternally toxic doses No teratogenic effects (rat, rabbit)	
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Relevant maternal NOAEL ‡

Rat: 20 mg/kg b.w./day Rabbit: 10 mg/kg b.w./day	
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Relevant developmental NOAEL ‡

Rat: 20 mg/kg b.w./day Rabbit: 25 mg/kg b.w./day	
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### Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡

Repeated neurotoxicity ‡

Delayed neurotoxicity ‡

No data available - not required	
NOAEL = 15 mg/kg b.w./day 4-week oral, rats No specific neurotoxic effects observed	
No data available - not required	

### Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡

- 7-day oral nephrotoxicity study, rat  
NOAEL = 12 mg/kg b.w./day  
Critical effect: pale kidneys, hydropic degeneration of the proximal tubular epithelial cells and electron microscopy changes on the mitochondria in the proximal tubular cells at 60 mg/kg b.w./day
- 28-day oral nephrotoxicity study, rat  
NOAEL = 12 mg/kg b.w./day  
Critical effect: increase in tubular cell turnover rate at 60 mg/kg b.w./day
- 7-day oral S-phase response study, rat  
Males: Marginal exacerbation of basophilic tubules in kidney parenchyma (OSOM and cortex), cell proliferation in OSOM area and increased apoptosis in cortex area at all doses.  
Females: Increased kidney weight, degenerative lesions in the kidney parenchyma and significant increase of cell proliferation in OSOM area of high-dose animals.
- 28-day oral S-phase response study, rat  
Males: Increased kidney and liver weight at all doses, marginal exacerbation of basophilic tubules at all doses, cell proliferation and secondary apoptosis in the OSOM area of kidney of high-dose animals.  
Females: Decreased body weight and increased relative kidney weight in high-dose animals. Multifocally distributed, vacuolar degeneration of tubular epithelial cells of the proximal tubules in the kidney parenchyma, significant increase of cell proliferation in the OSOM area of high-dose animals.

Studies performed on metabolites or impurities ‡

No data available

### Medical data‡ (Annex IIA, point 5.9)

- Skin-related effects have been reported in manufacturing plant personnel (erythema, swelling and itching), dithianon-exposed workers (skin and eye irritation) and spraying operators (erythema, swelling, itching, blistering, and peeling of the skin).
- Epicutaneous patch testing has demonstrated that sensitization to products containing dithianon may occur.
- No specific antidote is known. First aid measures

include symptomatic and supportive treatment.

### Summary (Annex IIA, point 5.10)

ADI ‡

AOEL ‡

ARfD ‡

Value	Study	Safety factor
0.01 mg/kg b.w./day	Long-term toxicity/carcinogen icity study in the rat	100
0.0135 mg/kg b.w./day	90-day oral toxicity in the dog	100*
0.12 mg/kg b.w	7-day & 28-day oral toxicity in the rat (mechanistic studies)	100

\*in addition, correction for 45% oral absorption

### Dermal absorption‡ (Annex IIIA, point 7.3)

DELAN 70 WG

0.26% for the concentrate and 3.1% for the spray  
dilution, based on *in vivo* rat and *in vitro* human and rat  
skin data

### Exposure scenarios (Annex IIIA, point 7.2)

Operator

The exposure levels estimated according to the German  
model are lower than the AOEL for the intended use of  
DELAN 70WG on pomefruits & grapes, with a  
maximum application rate of 0.560 kg a.s./ha.  
The exposure levels estimated using UK POEM are in  
all cases higher than the AOEL even when PPE is  
considered.

#### Field application via tractor air-assisted sprayer

**Pome fruits** [0.525 kg a.s./ha, 1000 L/ha]

	<b>UK POEM</b>	<b>German</b>	
No PPE:	513%	172%	of the AOEL
PPE:	426% (gloves)	35% (gloves, coverall & sturdy footwear)	of the AOEL

**Grape** [0.56 kg a.s./ha, 400 L/ha]

	<b>UK POEM</b>	<b>German</b>	
No PPE:	968%	184%	of the AOEL
PPE:	759% (gloves)	37% (gloves, coverall & sturdy footwear)	of the AOEL

#### Field application via knapsack sprayer (high crop)

**Pome fruits** [0.525 kg a.s./ha, 1000 L/ha]

	<b>German</b>	
No PPE:	90%	of the AOEL
PPE(gloves):	69%	of the AOEL

**Grape** [0.56 kg a.s./ha, 400 L/ha]

**German**

Workers	No PPE: 96% of the AOEL PPE(gloves): 74% of the AOEL
	Estimated exposures for re-entry activities are below the AOEL even without PPE (77% of the AOEL in grapes (worst case)) The use of gloves and coverall is triggered only if a default value for DFR of 3 µg/cm <sup>2</sup> is used in the exposure estimation according to a Tier-1 EUROPOEM approach.
Bystanders	Bystander exposure levels below the AOEL (3% for applications on grapes, 24% for application on pome fruits).

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

Dithianon	RMS/peer review proposal
	<p><b><u>Directive 67/548/EEC:</u></b> R22 Harmful if swallowed</p> <p><b><u>RMS proposal</u></b> R23 Toxic by inhalation</p> <p>R41 Risk of serious damage to eyes</p> <p>R43 May cause sensitization by skin contact R40 Limited evidence of a carcinogenic effect <b>(Carc.Cat.3)</b></p> <p>R66 “Repeated exposure may cause skin dryness or cracking“</p> <p><b><u>Discussed and agreed during PRAPeR 81</u></b> R40 Limited evidence of a carcinogenic effect (Carc.Cat.3)</p>

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

Plant groups covered	Fruits (apples, oranges), leafy crop (spinach), wheat (cereals) via foliar treatment
Rotational crops	Not required since intended to be used in permanent crops (pome fruits and grapes)
Metabolism in rotational crops similar to metabolism in primary crops?	Not required since intended to be used in permanent crops (pome fruits and grapes)
Processed commodities	<p>The nature of residues in processed commodities was investigated in two different types of studies. The first study fulfils the requirements specified in the relevant EU Guidance document (7035/VI/95 rev.5) whereas the second study investigated the nature of the residues under hydrolytic conditions simulating pasteurization in apple juice.</p> <p><b>1. Hydrolysis study at exaggerated temperatures in buffer solutions:</b>  <sup>14</sup>C]-BAS 216 F is hydrolytically stable under the simulated processing conditions of pasteurization (pH 4, incubation for 20 minutes at 90°C). However, at 100°C and pH 5 (simulated processing conditions of baking, brewing and boiling) or at 120°C and pH 6 (simulated processing conditions of sterilization) the hydrolytic degradation of <sup>14</sup>C]-BAS 216 F is fast and results in many degradation products. There are no significant differences in the type of products found after hydrolysis at pH 5 versus 6. CL 1017911 was identified as a major degradation product formed under these conditions.</p> <p><b>2. Hydrolysis study under the conditions of juice production:</b>  From the results obtained it can be concluded that BAS 216 F was degraded in natural turbid apple juice during the simulation of pasteurization (pH 3.8, 90°C, 20 min) to a multiple number of unknown degradation products, each of them below 10% of the total applied radioactivity. Dithianon is the major component being present under these relevant realistic conditions.</p>
Residue pattern in processed commodities similar to residue pattern in raw commodities?	<p>No.</p> <p>There is evidence of significant degradation under simulated pasteurisation in the presence of apple juice (although dithianon remains the only significant residue). Significant degradation was also seen during simulated baking, brewing, boiling or sterilisation in water where CL1017911 was found to be the only significant metabolite.</p>
Plant residue definition for monitoring	Dithianon
Plant residue definition for risk assessment	Dithianon
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	Goat, hen
Time needed to reach a plateau concentration in milk and eggs	Goat: 1 - 2 days Hen: > 4 days (not relevant, since the target crops are not fed to poultry)
Animal residue definition for monitoring	Dithianon
Animal residue definition for risk assessment	Dithianon
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log $P_{ow}$ > 3)

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

Not required since intended to be used in permanent crops (pome fruits and grapes)

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

-Pome fruit: Storage stability data indicated a significant degradation of the fortified dithianon residues in apples (the recoveries were below 70% after 1 month of storage).  
 -Grapes: Incurred dithianon residues in wine grapes were shown to be stable under frozen conditions for up to 14 months covering the storage time interval of the samples from the residue trials.  
 -Processed grapes products:  
 Dithianon is stable under freezer storage conditions in grape must (24 months), grape juice (18 months), grape pomace (6 months) and also in apple sauce (24 months). However, an almost complete and rapid degradation of the residues was observed in grape wine (recovery rate below 10% within 1 month of storage).

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

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock $\geq 0.1$ mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.39 mg/kg (dairy) 1.12 mg/kg (beef)	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues $\geq 0.01$ mg/kg in edible tissues (yes/no)	No	No	No
Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)			



Muscle  
Liver  
Kidney  
Fat  
Milk  
Eggs

Residue levels in matrices : Mean (max) mg/kg		
no cow feeding study conducted	no hen feeding study conducted	no pig feeding study conducted;
metabolism results indicate that the residues will be far below the LOQ (milk, tissues 0.01 mg/kg)	metabolism results indicate that the residues will be far below the LOQ (eggs, tissues: 0.01 mg/kg)	metabolism in rat and ruminant similar, residues will be below 0.01 mg/kg (LOQ).

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Apples	Northern	0.36, 2 x 0.48, 0.62, 0.76, 1.5, 1.7, 1.89 mg/kg		3.0 mg/kg <sup>(1)</sup>	1.89 mg/kg	0.62 mg/kg
Pears	Northern	0.19, 0.37, 0.39, 0.87 mg/kg				
Apples	Southern	0.43, 0.59, 0.86, 1.69, 1.73 mg/kg				
Grapes (Table and Wine)	Northern	0.57, 0.62, 0.62, 0.98, 1.01, 1.20, 1.27, 1.41, 1.91, 2.2, 2.65 mg/kg		3.0 mg/kg <sup>(1)</sup>	2.72 mg/kg	1.01 mg/kg
	Southern	0.38, 0.52, 0.59, 1.0, 1.1, 1.48, 2.72 mg/kg				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

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

(c) Highest residue

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

ADI	0.01 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo Model rev.2A	419.4% ADI (German child) <sup>(1)</sup>
NEDI (specify diet) (% ADI)	92.3% ADI (German child) <sup>(1)</sup>
ARfD	0.12 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo Model rev.2A	Apples: 89.4% ARfD <sup>(1)</sup> , Pears: 79% ARfD <sup>(1)</sup> , Table grapes: 148.4% ARfD <sup>(1)</sup> , Wine grapes: 17.6% ARfD <sup>(1)</sup>
Factors included in IESTI	Factors included in IESTI calculation: -The NE and SE residue data set in pome fruit and grapes were respectively pooled as statistically supported. -Pome fruit: HR:1.89 mg/kg/VF: 3.8 (derived from the unit-to-unit variability residue study in apples) -Table/wine grapes: HR:2.72 mg/kg

### 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	
Apple/washed apples	7 trials	0.23 - 1.8 <sup>(1)</sup>		
Apple/juice	10 trials	0.0045 - 0.1 <sup>(1)</sup>		
Apple/wet pomace	10 trials	0.49 - 3.5 <sup>(1)</sup>		
Apple/dry pomace	6 trials	0.43 - 0.77 <sup>(1)</sup>		
Apple/sauce	8 trials	0.006 - 0.125 <sup>(1)</sup>		
Apple/dried apples	2 trials	0.029, 0.033 <sup>(1)</sup>		
Apple/canned apples	4 trials	0.033 - 0.125 <sup>(1)</sup>		
Grapes/must	13 trials	0.01 - 0.33 <sup>(1)</sup>		
Grapes/wine	13 trials	0.002 - 0.08 <sup>(1)</sup>		
Grapes/juice	4 trials	0.002 - 0.003 <sup>(1)</sup>		
Grapes/wet pomace	4 trials	0.19 - 2.18 <sup>(1)</sup>		
Grapes/dry pomace	4 trials	0.08 - 0.28 <sup>(1)</sup>		
Grapes/young wine	4 trials	0.002 - 0.003 <sup>(1)</sup>		
Grapes/must deposit	1 trial	1.2 <sup>(1)</sup>		
Grapes/lees	2 trials	0.002, 0.01 <sup>(1)</sup>		

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

.....	Pome fruits: 3.0 mg/kg <sup>(1)</sup>
.....	Wine grapes: 3.0 mg/kg <sup>(1)</sup>

<sup>(1)</sup>Provisional proposals pending the outcome of the storage stability of dithianon incurred residues in pome fruit and grape wine and also of the nature of the residues in processed products under standard hydrolytic conditions.

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

Mineralization after 100 days ‡	24.5% - 44% AR after 120 days [ <sup>14</sup> C-dithianon](n= 4) 16% AR after 99 days [ <sup>14</sup> C-dithianon](n=1) 14% - 16% AR after 123 days [ <sup>14</sup> C-dithianon](n=2) 2.1% AR (sterile) after 120 days [ <sup>14</sup> C-dithianon] (n=1)
Non-extractable residues after 100 days ‡	42.5% - 70.5% after 91 days [ <sup>14</sup> C -dithianon](n=5) 21% after 99 days [ <sup>14</sup> C -dithianon](n=1) 64.8% - 74.9% after 56 days [ <sup>14</sup> C -dithianon](n=2) 53% (sterile) after 120 days [14C-dithianon] (n=1)
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	7.3 % AR after 30 d [ <sup>14</sup> C-dithianon] (n= 1) 5.9 % AR after 60 d [ <sup>14</sup> C-dithianon] (n= 1)
Non-extractable residues after 100 days	31.9 % AR after 62 d, [ <sup>14</sup> C-dithianon] (n= 1) 63.6 % AR after 60 d, [ <sup>14</sup> C-dithianon] (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Identified metabolites in clay loam system:  CL 902198: max. 4% after 8 d, 0.5% after 30d CL 902200*: max 5% after 8d, 3% after 60d CL 1025: max 8.5% after 8 d, 2.5% after 120 d
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Photoproducts: Phthalic acid 16% after 15 d, 6.5% after 30d (less than 1% in dark control) CL 902200 maximum 2%, after 15 d CL 902198 maximum 3%, after 7 d CL 1025 maximum 4%, after 15 d

\* quantified by Class & An (2001), could not be quantified in the earlier study by Steinfuhrer et al. (1994)

## 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	X <sup>14</sup>	pH (CaCl <sub>2</sub> )	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
Ulm- Clay loam		6.8	20°C, 45%	9.2 / 46.4	11.2	0.995	DFOP
Lufa2.3-Sandy loam		6.5	20°C, 45%	12.2 / 59.1	16.2	0.985	FOMC
Bergen-Clay loam		7.6	20°C, 45%	3.7 / 28.1	7.2	0.995	DFOP
Schwalbach-Silt loam		5.1	20°C, 45%	37.6 / 125	33.3	0.976	SFO
Ulm (10°C)		6.8	10°C, 45%	30.8 / 111.4	-	-	best-fit
Ulm (sterile)*		6.8	20°C, 45%	40.7* / 135.1*	-	-	SFO
Lufa2.2- Sandy loam		5.9	20°C, 41%	6.5 / 39.8	11.6	0.991	DFOP
Bruch West-Loamy sand		7.1	20°C, 45%	2.55 / 8.48	2.6	0.974	SFO
Geometric mean					<b>10.5</b>		

\* sterilized soil, DT<sub>50</sub> / DT<sub>90</sub> not to be used for further assessment

**Data gap:** degradation rates in soil for metabolite phthalic acid were not available.

### Field studies ‡

Parent	Not required since DT <sub>50lab</sub> at 20°C < 60 d and DT <sub>50lab</sub> at 10°C < 90 d
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pH dependence ‡  
(yes / no) (if yes type of dependence)

No

Soil accumulation and plateau concentration ‡

Not required

### Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X <sup>15</sup>	pH (CaCl <sub>2</sub> )	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C pF2/10kPa	St. (r <sup>2</sup> )	Method of calculation
Sandy loam		5.9	20°C, 40%	5.4 / 59.2			
Clay loam		6.8	20°C, flooded	1.4 / 4.7			

<sup>14</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

<sup>15</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Geometric mean/median					
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### Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH (H <sub>2</sub> O)	K <sub>d</sub> (mL/g)	K <sub>oc</sub> (mL/g)	K <sub>f</sub> (mL/g)	K <sub>foc</sub> (mL/g)	1/n
Borstel Boden, Sandy Loam	2.13	6.3	59	2750			
Bruch West, Sandy Loam	2.62	7.8	157	6004			
LUFA 2.2, Loamy Sand	2.08	6.2	85	4091			
LUFA 3A, Loam	2.96	7.7	122	4122			
1680, Loamy Sand	0.78	6.9	9	1167			
Arithmetic mean for the 5 soils				3627			
pH dependence, Yes or No			No				

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

Column leaching ‡\*

Elution (mm): 200 mm 0.01M CaCl<sub>2</sub>  
Time period (d): 2 d

Leachate: 0.01 - 0.17% total residues/radioactivity in leachate  
19.8-54.4% was dissolved CO<sub>2</sub>  
79-107% AR in top 0-6 cm of soil

Aged residues leaching ‡

Aged for (d): 10 and 31 d  
Elution (mm): 200 mm 0.01M CaCl<sub>2</sub>  
Time period (d): 2 d

Analysis of soil residues post ageing (soil residues pre-leaching):  
10 d - 40.1% dithianon, many unknown metabolites each <1% AR, 22% bound residues  
30 d - 30% bound residues, not enough radioactivity in extracts to analyze

Soil Column Segments:  
>75% AR remain in top 0-6 cm segments  
<1.3% AR remain in 6-12 cm segments  
<0.8% AR in remaining depths

Leachate:  
≤ 0.9% AR

\* application rate 1.5 kg a.s. /ha. This rate is lower than the maximum application rate 12 x 0.525 kg a.s. /ha.

Lysimeter/ field leaching studies ‡

Not Required

### PEC (soil) (Annex IIIA, point 9.1.3)

Parent Dithianon  
Method of calculation

Application data

$DT_{50}$  = 37.6 days (longest first-order laboratory value in six aerobic soils at study conditions of 20°C and 45% MWHC)

Kinetics: SFO

Grape vines:

1 × 560 g a.i./ha and 8 × 560 g a.i./ha, foliar interception of 50% (first leaves, BBCH 11-13) assumed for all applications.

Refinement considers increased foliar interception with crop growth stages, interception (%):  
50/50/60/60/60/60/70/70

Pome fruit:

1 × 525 g a.i./ha and 12 × 525 g a.i./ha, foliar interception of 50% (without leaves) assumed for all applications.

Refinement considers increased crop interception with crop growth stages per FOCUS (2002) generic ground water guidance,  
interception (%) 50/50/50/65/65/70/70/70/80/80/80/80

Depth of soil layer: 5 cm

Soil bulk density: 1.5 g/cm<sup>3</sup>

Application interval for multiple application: 7 days

### Actual and time-weighted average soil concentration of dithianon following 1 or 8 applications to grape vines assuming constant (50%) or increasing (50-70%) crop interception

PEC <sub>(s)</sub>		1 application 50% interception		8 applications 50% interception		8 applications increasing interception 50/50/60/60/60/60/70/70%	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial		0.373	--	1.987	--	1.514	--
Short term	24h	0.367	0.370	1.951	1.969	1.487	1.501
	2d	0.360	0.367	1.916	1.951	1.460	1.487
	4d	0.347	0.360	1.846	1.916	1.407	1.460
Long term	7d	0.328	0.350	1.747	1.865	1.332	1.421
	14d	0.289	0.329	1.536	1.806	1.171	1.407
	21d	0.254	0.310	1.351	1.478	1.029	1.385
	28d	0.223	0.292	1.188	1.706	0.905	1.350
	50d	0.149	0.244	0.793	1.552	0.604	1.245
	100d	0.059	0.171	0.316	1.234	0.241	0.996



**Actual and time-weighted average soil concentration of dithianon following 1 or 12 applications to pome fruit assuming constant (50%) or increasing (50-80%) crop interception**

PEC <sub>(s)</sub>		1 application 50% interception		12 applications 50% interception		12 applications increasing interception 50/50/50/65/65/70/70/70/80/ 80/80/80%	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial		0.350	--	2.280	--	1.358	--
Short term	24h	0.344	0.347	2.238	2.259	1.333	1.345
	2d	0.337	0.344	2.197	2.238	1.309	1.333
	4d	0.325	0.337	2.118	2.198	1.261	1.309
Long term	7d	0.308	0.328	2.004	2.139	1.334	1.292
	14d	0.271	0.309	1.762	2.111	1.313	1.277
	21d	0.238	0.290	1.549	2.071	1.294	1.265
	28d	0.209	0.274	1.362	2.026	1.278	1.258
	50d	0.140	0.229	0.909	1.908	0.853	1.230
	100d	0.056	0.160	0.363	1.614	0.340	1.072

Metabolite – Phthalic Acid

Method of calculation

PEC<sub>soil</sub> values were also calculated for the soil photolysis product phthalic acid.

Phthalic acid formation and degradation:

Maximum formed in soil = 16% (maximum from the soil photolysis study).

DT<sub>50</sub> = not relevant

MW correction =  $166.14/296.3 = 0.561$

Kinetics: SFO

Application data

It is assumed Phthalic acid is formed at a maximum of 16 % of the applied dose of dithianon at every application.

**Actual and time-weighted average soil concentration of phthalic acid following 1 or 8 applications to grape vines assuming constant (50%) or increasing crop (50-70%) interception**

PEC <sub>(s)</sub>	1 application 50% interception		8 applications 50% interception		8 applications increasing interception 50/50/60/60/60/60/70/70%	
	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
	Initial	0.033	--	0.088	--	0.069

**Actual and time-weighted average soil concentration of phthalic acid following 1 or 12 applications to pome fruit assuming constant (50%) or increasing (50-80%) crop interception**

PEC <sub>(s)</sub>	1 application 50% interception		12 applications 50% interception		12 applications increasing interception 50/50/50/65/65/70/70/70/80/ 80/80/80%	
	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
	Initial	0.031	--	0.084	--	0.063

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

pH 5: 12.2 days at 20 °C (1<sup>st</sup> order,  $r^2 = 0.989$ )

Phthalic acid\*: 8.0% AR (30 d)

Phthalaldehyde\*: 9% AR (30 d)

pH 7: 0.594 days at 20 °C (1<sup>st</sup> order,  $r^2 = 0.998$ )

Phthalic acid\*: 28.9% AR (30 d)

Phthalaldehyde\*: 23.6% AR (30 d)

1,2-benzenedimethanol\*: 31% AR (14 d)

pH 9: 8.04 min. at 20 °C (1<sup>st</sup> order,  $r^2 = 0.997$ )

Phthalic acid\*: 31.6% AR (1 d)

Phthalaldehyde\*: 62.3% AR (14 d)

1,2-benzenedimethanol\*: 15.3% AR (6 h)

\* these metabolites were not detected in the biotic natural water/sediment systems

Photolytic degradation of active substance and metabolites above 10 % ‡

### Dithianon:

Direct photolysis, xenon arc lamp, sterile, pH 4 (20°C), 7 d, continuous irradiation:  $DT_{50} = <0.05$  d

Direct photolysis, xenon arc lamp, pH 4 (20°C), 72 h, continuous irradiation:  $DT_{50} = 0.5$  h

Quantum yield of dithianon =  $1.01 \times 10^{-3}$ ,

$DT_{50} = 2.1$  h (latitude 40° north, summer)

$DT_{50} = 2.2$  h (latitude 50° north, summer)

$DT_{50} = 6.9$  h (latitude 40° north, winter)

$DT_{50} = 13.4$  h (latitude 50° north, winter)

### Phthalic acid:

formed and declined during dithianon direct photolysis study, xenon arc lamp, sterile, pH 4 (20°C), 7 d, continuous irradiation:  $DT_{50} = 16$  d, maximum 38.5% @ 320 minutes

### Phthalaldehyde:

formed and declined during dithianon direct photolysis study, xenon arc lamp, sterile, pH 4 (20°C), 7 d, continuous irradiation:  $DT_{50} = 1.4$  d, maximum 11.2% @ 320 minutes

### 1,2-benzenedimethanol:

formed and declined during dithianon direct photolysis study, xenon arc lamp, sterile, pH 4 (20°C), 7 d, continuous irradiation:  $DT_{50} = 4.8$  d, maximum 20.9% @ 1 day

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

$1.01 \times 10^{-3}$  mol Einstein<sup>-1</sup>

Readily biodegradable ‡  
(yes/no)

No

### Degradation in water / sediment

Parent	Distribution – Max. in water 19.4% AR after 1 d. Max. in sed 1.4% AR after 2 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys. (d)	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water* (d)	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> Sed (d)	St. (r <sup>2</sup> )	Method of calculation
System R (river) – Rheinaue	8.3	7.3	20	Same as water		1.4 h / 4.6 h	0.998	Not detected		SFO
System H (pond) – Hellersberger Weiher	8.1	7.2	20	Same as water		2.4 h / 7.9 h	0.998	Not detected		SFO
Pond R – Ranschgraben	7.9	6.5	20	0.196 d / 1.84 d	0.993	0.22 d / 0.74 d	0.963	5.07 d / 111d <sup>#</sup>	0.327	DFOS (sys) SFO (water) FOMC(sed)
River B - Berghauser Altrhein	8.1	7.6	20	0.35 d / 1.16 d	0.983	0.34 d / 1.14 d	0.983	0.62d / 37.3 d <sup>#</sup>	0.689	SFO (sys) SFO (water) FOMC (sed)

\* dissipation

<sup>#</sup> due to the poor goodness of fit, these values are uncertain; however no impact on the aquatic risk assessment is expected as a conservative value of 1000 days was used for PEC calculations.

<b>CL1017911</b>	CL 1017911 rapidly formed after 1 day (32-54%), rapidly degraded and nearly disappeared at 14 days. Other major metabolite was CO <sub>2</sub> Numerous numbers of minor metabolites were formed in both water and sediment (<2% AR).									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys.	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water	r <sup>2</sup>	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Pond R – Ranschgraben	7.9	6.5	20	7.60 d / 25.2 d	0.731	5.90 d / 19.6 d	0.867	87.1 d / 289 d <sup>#</sup>	0.065	SFO
River B - Berghauser Altrhein	8.1	7.6	20	6.05 d / 20.1 d	0.840	5.94 d / 19.8 d	0.914	1.38 d / 4.58 d	0.550	SFO
Pond R – Ranschgraben	7.9	6.5	20	5.92 d / 19.7 d	0.870	-	-	-	-	SFO fit of decline from peak observed
River B - Berghauser Altrhein	8.1	7.6	20	6.28 d / 20.8 d	0.901	-	-	-	-	SFO fit of decline from peak observed
Geometric mean				6.1						

# due to the poor goodness of fit, these values are uncertain; however no impact on the aquatic risk assessment is expected due to the very low toxicity of the compound.

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)
System R (river) – Rheinaue	8.3	7.3	25.6 % after 100 d	70.8 % after 100 d	70.8 % after 100 d
System H (pond) – Hellersberger Weiher	8.1	7.2	19.1 % after 100 d	72.7 % after 100 d	72.7 % after 100 d
Pond R – Ranschgraben	7.9	6.5	20.5 % after 100 d	38.2 % after 100 d	38.2 % after 100 d
River B - Berghauser Altrhein	8.1	7.6	19.4 % after 100 d	51.2 % after 100 d	51.2 % after 100 d

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

Parent Parameters used in FOCUSsw		Value	Remarks	
	Entry routes into surface water	Spray drift Runoff Drainage		
	Molecular weight [g/mol]	296.3	Phys.-chem. Properties	
	Water solubility [mg/L]	0.3754	Phys.-chem. Properties	
	Vapor pressure [Pa]	2.71E-09	Phys.-chem. Properties	
	<i>Degradation in soil</i>			
	DT <sub>50</sub> (soil) [d]	10.5	geometric mean value from the soil laboratory studies (N=6), corrected to 20°C and pF2	
	Temperature correction function			
	Reference temperature [°C]	20	FOCUS recommendation	
	MACRO: gamma exponent [1/K]	0.095	Based on EFSA opinion the	
	PRZM: Q-10 [-]	2.58	Q10 = 2.58	
	Moisture correction function			
	Reference moisture [-]	pF 2	FOCUS recommendation	
	PRZM / MACRO: moisture exponent [-]	0.7		
	<i>Sorption to soil</i>			
	K <sub>OC</sub> [mL/g]	3627	Average (N=5)	
	1/n [-]	0.9	Recommended default value	
	<i>Degradation in aquatic systems</i>			
	DT <sub>50</sub> whole system (Step 1) [d]	0.440	Geometric mean value from two water/sediment systems	
	DT <sub>50</sub> water (Step 2, Step 3, Step 4) [d]	0.505	Geometric mean value from two water/sediment systems	
	DT <sub>50</sub> sediment (Step 2, Step 3, Step 4) [d]	1000	Default value	

	Temperature correction function		
	Reference temperature [°C]	20	FOCUS recommendation
	TOXSWA: activation energy [J/mol]	65400	Based on EFSA opinion the Q10 = 2.58
<i>Management related parameters</i>			
Application rate – Grape Vines	Crop uptake factor [-]	0.5	FOCUS recommendation
	Washoff coefficient [1/cm]	0.01	Calculated from water solubility
	[1/mm]	0.001	according to FOCUS guidance
Application rate – Pome fruit	Crop: Grape vines (early and late)		
	Crop interception in FOCUS step 3: Calculated by SWASH version 2.1		
	Number of applications: 1 and 8		
	Interval (d): 7		
	Application rate(s): 560 g a.s./ha		
	Application window: BBCH growth stages 10-79, which ranges from beginning of leaf development through flowering		
Application rate – Pome fruit	Crop: Pome fruit (early and late)		
	Crop interception in FOCUS step 3: Calculated by SWASH version 2.1		
	Number of applications: 1 and 12*		
	Interval (d): 7		
	Application rate(s): 525 g a.s./ha		
	Application window: BBCH growth stages 10-79, which ranges from prior to leaf emergence to full foliage		
	* FOCUS Step 3-4 models only allow a maximum of 8 applications. However, since dithianon has a water DT <sub>50</sub> of 0.505 days and spray drift is the primary loading route, there is no chance to build up in the water body between applications. The single application scenario (with higher 90 <sup>th</sup> percentile drift) provides a conservative loading assessment for pome fruit.		

### PEC<sub>sw</sub> (surface water): Dithianon Steps 1 and 2

#### FOCUS Step 1 and Step 2 PEC<sub>sw</sub> values for dithianon following 1 or 8 applications of Delan 70 WG to vines with early application timing

Time after max. peak (d)	Step 1		Step 2							
			Vines, early, 1 application				Vines, early, 8 applications			
	Actual (µg/L)	TWA (µg/L)	North Europe		South Europe		North Europe		South Europe	
			Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	37.024	---	5.04	---	6.01	---	7.917	---	15.685	---
1	6.798	21.911	0.579	2.809	1.606	3.808	2.113	5.015	4.109	9.897
2	1.407	12.666	0.189	1.596	1.400	2.656	1.843	3.497	3.583	6.872
4	0.060	6.547	3.064	1.239	1.065	1.941	1.402	2.556	2.725	5.006
7	0.001	3.747	0.645	1.200	0.706	1.484	0.930	1.954	1.808	3.820
14	0.000	1.873	0.248	0.808	0.271	0.970	0.357	1.277	0.694	2.492
21	0.000	1.249	0.095	0.592	0.104	0.705	0.137	0.928	0.266	1.811
28	0.000	0.937	0.036	0.459	0.040	0.545	0.053	0.718	0.102	1.401
42	0.000	0.624	0.005	0.312	0.006	0.369	0.008	0.486	0.015	0.949
50	0.000	0.525	0.002	0.262	0.002	0.311	0.003	0.409	0.005	0.799
100	0.000	0.262	0.000	0.131	0.000	0.156	0.000	0.205	0.000	0.400

**FOCUS Step 1 and Step 2 PEC<sub>sw</sub> values for dithianon following 1 or 8 applications of Delan 70 WG to vines with late application timing**

Time after max. peak (d)	Step 1		Step 2							
			Vines, late, 1 application				Vines, late, 8 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	46.971	---	14.99	---	14.99	---	11.782	---	11.782	---
1	7.150	27.061	1.723	8.354	1.723	8.354	1.548	6.665	1.548	6.665
2	1.480	15.330	0.562	4.748	0.562	4.748	0.625	3.876	0.625	3.876
4	0.063	7.890	2.801	2.897	4.029	3.050	6.881	2.996	10.117	3.400
7	0.001	4.514	0.687	2.146	0.927	2.423	1.509	2.842	2.142	3.572
14	0.000	2.257	0.263	1.294	0.356	1.510	0.579	1.907	0.822	2.476
21	0.000	1.505	0.101	0.919	0.136	1.083	0.222	1.396	0.315	1.827
28	0.000	1.129	0.039	0.706	0.052	0.834	0.085	1.083	0.121	1.421
42	0.000	0.752	0.006	0.476	0.008	0.564	0.013	0.734	0.018	0.965
50	0.000	0.632	0.002	0.401	0.003	0.474	0.004	0.618	0.006	0.813
100	0.000	0.316	0.000	0.201	0.000	0.237	0.000	0.309	0.000	0.407

**FOCUS Step 1 and Step 2 PEC<sub>sw</sub> values for dithianon following 1 or 12 applications of Delan 70 WG to pome fruit with early application timing**

Time after max. peak (d)	Step 1		Step 2							
			Pome fruit, early, 1 application				Pome fruit, early, 12 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	81.081	---	51.09	---	51.09	---	39.799	---	39.799	---
1	8.017	44.549	5.875	28.485	5.875	28.485	5.230	22.514	5.230	22.514
2	1.659	24.293	1.917	16.190	1.917	16.190	2.110	13.092	2.110	13.092
4	0.071	12.398	4.861	9.290	8.545	9.751	11.295	8.626	21.213	9.866
7	0.001	7.091	1.425	6.259	2.145	7.090	2.764	6.905	4.702	9.142
14	0.000	3.546	0.547	3.588	0.823	4.236	1.060	4.343	1.804	6.086
21	0.000	2.364	0.210	2.510	0.316	3.001	0.407	3.123	0.692	4.445
28	0.000	1.773	0.081	1.916	0.121	2.301	0.156	2.408	0.266	3.445
42	0.000	1.182	0.012	1.289	0.018	1.552	0.023	1.628	0.039	2.336
50	0.000	0.993	0.004	1.084	0.006	1.306	0.008	1.370	0.013	1.966
100	0.000	0.496	0.000	0.542	0.000	0.653	0.000	0.686	0.000	0.984

**FOCUS Step 1 and Step 2 PEC<sub>sw</sub> values for dithianon following 1 or 12 applications of Delan 70 WG to pome fruit with late application timing**

Time after max. peak (d)	Step 1		Step 2							
			Pome fruit, late, 1 application				Pome fruit, late, 12 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	57.505	---	27.52	---	27.52	---	15.489	---	15.489	---
1	7.181	32.343	3.164	15.341	3.164	15.341	2.035	8.762	2.035	8.762
2	1.486	17.979	1.033	8.720	1.033	8.720	0.821	5.095	0.821	5.095
4	0.064	9.215	3.397	5.101	4.778	5.274	7.974	3.805	11.694	4.270
7	0.001	5.272	0.920	3.547	1.190	3.858	1.775	3.495	2.501	4.333
14	0.000	2.636	0.353	2.070	0.456	2.312	0.681	2.319	0.960	2.973
21	0.000	1.757	0.135	1.456	0.175	1.640	0.261	1.692	0.368	2.188
28	0.000	1.318	0.052	1.113	0.067	1.258	0.100	1.311	0.141	1.700
42	0.000	0.879	0.008	0.750	0.010	0.849	0.015	0.889	0.021	1.154
50	0.000	0.738	0.003	0.631	0.003	0.714	0.005	0.748	0.007	0.972
100	0.000	0.369	0.000	0.316	0.000	0.357	0.000	0.375	0.000	0.486

**Global maximum dithianon PEC<sub>sw</sub> values at FOCUS Step 3 and Step 4 (considering spray drift mitigation buffers) following application of Delan 70 WG to vines**

Scenario	Water body	Timing	No. of apps.	Step 3 edge of field (µg/L)	Step 4 with spray drift buffer (µg/L)	
					10 m	20 m
D6	Ditch	Early	1	3.106	0.651	0.222
			8	2.613	0.492	0.155
		Late	1	9.570	2.094	0.734
			8	7.437	1.599	0.554
R1	Pond	Early	1	0.107	0.068	0.033
			8	0.082	0.051	0.026
		Late	1	0.340	0.217	0.109
			8	0.263	0.167	0.083
	Stream	Early	1	2.296	0.583	0.235
			8	1.862	0.897	0.897
R2	Stream	Early	1	3.044	0.773	0.263
			8	2.487	0.575	0.567
		Late	1	9.374	2.472	0.866
			8	7.183	1.866	0.646
R3	Stream	Early	1	3.248	0.882	0.882
			8	2.625	2.070	2.069
		Late	1	9.854	2.599	0.911
			8	7.555	1.962	0.680
R4	Stream	Early	1	2.273	0.774	0.774
			8	3.407	3.407	3.407
		Late	1	6.882	1.815	0.636
			8	5.358	1.392	1.051

<sup>1</sup> -- means the buffer distance was not evaluated for this specific scenario.



**Global maximum dithianon  $PEC_{sw}$  values at FOCUS Step 3 and Step 4 (considering both spray drift and runoff mitigation) for runoff scenarios with stream water bodies following 8 applications of Delan 70 WG to vines**

Scenario	Water body	Timing	No. of apps.	Step 3 edge of field ( $\mu\text{g/L}$ )	Step 4 20 m spray drift buffer ( $\mu\text{g/L}$ )	Step 4 20 m spray drift buffer + 20 m runoff buffer ( $\mu\text{g/L}$ )
R1	Stream	Early	8	1.862	0.897	0.192
		Late	8	5.359	0.590	0.482
R2	Stream	Early	8	2.487	0.567	0.182
		Late	8	7.183	0.646	0.646
R3	Stream	Early	8	2.625	2.069	0.485
		Late	8	7.555	0.680	0.680
R4	Stream	Early	8	3.407	3.407	0.809
		Late	8	5.358	1.051	0.482

**Global maximum dithianon PEC<sub>sw</sub> values at FOCUS Step 3 and Step 4  
(considering spray drift mitigation buffers) following application of  
Delan 70 WG to pome fruit**

Scenario	Water body	Timing	No. of apps. <sup>1</sup>	Step 3 edge of field	Step 4			
					buffer zone:		95% spray drift reduct.	
					10 m	20 m		
				(µg/L)				
D3	Ditch	Early	1 8	40.586 29.914	19.577 12.571	4.474 3.073	2.027 1.494	
		Late	1 8	19.204 10.999	5.787 3.766	1.785 1.090	0.959 0.549	
		D4	Pond	Early	1 8	2.466 1.679	1.522 1.044	0.492 0.300
Late	1 8			0.859 0.541	0.545 0.343	0.248 0.140	0.043 0.027	
Stream	Early		1 8	39.496 31.144	20.829 14.555	4.759 3.558	1.972 1.555	
	Late		1 8	19.207 11.137	6.696 4.348	2.065 1.258	0.959 0.556	
D5	Pond		Early	1 8	2.465 1.680	1.522 1.044	0.492 0.300	0.123 0.084
			Late	1 8	0.860 0.537	0.545 0.340	0.248 0.139	0.043 0.027
	Stream	Early	1 8	39.361 33.602	20.758 15.703	4.743 3.838	1.965 1.678	
		Late	1 8	20.175 12.019	7.034 4.693	2.169 1.358	1.007 0.600	
	R1	Pond	Early	1 8	2.466 1.698	1.522 1.056	0.492 0.303	0.123 0.087
			Late	1 8	0.859 0.547	0.545 0.351	0.248 0.150	0.043 0.038
Stream		Early	1 8	32.848 23.817	17.323 11.130	3.958 2.721	1.640 1.189	
		Late	1 8	14.753 8.517	5.143 3.326	1.586 0.963	0.737 0.482	
R2	Stream	Early	1 8	43.520 31.866	22.951 14.892	5.244 3.640	2.173 1.591	
		Late	1 8	19.777 11.418	6.895 4.458	2.127 1.290	0.988 0.570	
R3	Stream	Early	1 8	46.479 33.581	24.511 15.694	5.601 3.836	2.321 1.677	
		Late	1 8	20.797 12.011	7.251 4.690	2.236 1.359	1.039 0.824	
R4	Stream	Early	1 8	33.042 23.813	17.425 11.129	3.982 2.721	1.650 1.999	
		Late	1 8	14.751 8.517	5.143 3.325	1.586 0.963	0.737 0.559	

<sup>1</sup> FOCUS Step 3-4 models allow a maximum of 8 applications

**Global maximum dithianon PEC<sub>sw</sub> values at FOCUS Step 3 and Step 4 (considering both spray drift and runoff mitigation) for runoff scenarios with stream water bodies following 8 applications of Delan 70 WG to pome fruit**

Scenario	Water body	Timing	No. of apps. <sup>1</sup>	Step 3 edge of field (µg/L)	Step 4 95% spray drift reduction (µg/L)	Step 4 95% spray drift reduction + 20 m runoff buffer (µg/L)
R1	Stream	Early	8	23.817	1.189	1.189
		Late	8	8.517	0.482	0.425
R2	Stream	Early	8	31.866	1.591	1.591
		Late	8	11.418	0.570	0.570
R3	Stream	Early	8	33.581	1.677	1.677
		Late	8	12.011	0.824	0.600
R4	Stream	Early	8	23.813	1.999	1.189
		Late	8	8.517	0.559	0.425

<sup>1</sup> FOCUS Step 3-4 models allow a maximum of 8 applications

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D6 following 1 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
D6 - ditch	0	3.106		0.651		0.222	
	1	0.026	1.059	0.005	0.222	0.002	0.076
	2	0.002	0.533	0.000	0.112	0.000	0.038
	4	0.002	0.267	0.000	0.056	0.000	0.019
	7	0.002	0.154	0.000	0.032	0.000	0.011
	14	0.001	0.078	0.000	0.016	0.000	0.006
	21	0.001	0.052	0.000	0.011	0.000	0.004
	28	0.001	0.039	0.000	0.008	0.000	0.003
	42	0.000	0.026	0.000	0.006	0.000	0.002
	50	0.000	0.022	0.000	0.005	0.000	0.002
	100	0.000	0.011	0.000	0.002	0.000	0.001

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D6 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
D6 - ditch	0	2.613		0.492		0.155	
	1	1.033	1.759	0.194	0.331	0.061	0.105
	2	0.424	1.271	0.080	0.239	0.025	0.076
	4	0.091	0.725	0.017	0.136	0.005	0.043
	7	0.022	0.424	0.004	0.080	0.001	0.025
	14	0.018	0.422	0.003	0.079	0.001	0.025
	21	0.009	0.410	0.002	0.077	0.001	0.024

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D6 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
	28	0.006	0.381	0.001	0.072	0.000	0.023
	42	0.002	0.358	0.000	0.067	0.000	0.021
	50	0.002	0.307	0.000	0.058	0.000	0.018
	100	0.000	0.185	0.000	0.035	0.000	0.011

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D6 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
D6 - ditch	0	9.570		2.094		0.734	
	1	2.755	5.477	0.602	1.198	0.211	0.420
	2	0.820	3.565	0.178	0.779	0.062	0.273
	4	0.102	1.951	0.021	0.426	0.007	0.149
	7	0.031	1.137	0.006	0.248	0.002	0.087
	14	0.013	0.578	0.003	0.126	0.001	0.044
	21	0.007	0.389	0.002	0.085	0.001	0.030
	28	0.006	0.293	0.002	0.064	0.001	0.022
	42	0.003	0.197	0.001	0.043	0.000	0.015
	50	0.003	0.166	0.001	0.036	0.000	0.013
	100	0.000	0.084	0.000	0.018	0.000	0.006

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D6 following 8 late applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
D6 - ditch	0	7.437		1.599		0.554	
	1	3.408	5.125	0.732	1.102	0.253	0.382
	2	1.614	3.787	0.346	0.814	0.119	0.282
	4	0.423	2.339	0.090	0.502	0.031	0.174
	7	0.127	1.433	0.027	0.307	0.009	0.106
	14	0.056	1.422	0.013	0.305	0.005	0.105
	21	0.036	1.251	0.008	0.268	0.003	0.093
	28	0.030	1.163	0.007	0.249	0.003	0.086
	42	0.004	1.072	0.001	0.230	0.000	0.080
	50	0.002	0.986	0.000	0.212	0.000	0.073
	100	0.000	0.549	0.000	0.118	0.000	0.041

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 following 1 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R1 - pond	0	0.107		0.068		0.033	
	1	0.066	0.085	0.042	0.053	0.020	0.026
	2	0.041	0.069	0.026	0.043	0.013	0.021
	4	0.016	0.048	0.010	0.030	0.005	0.015
	7	0.003	0.031	0.002	0.019	0.001	0.009
	14	0.000	0.016	0.000	0.010	0.000	0.005
	21	0.000	0.011	0.000	0.007	0.000	0.003
	28	0.000	0.008	0.000	0.005	0.000	0.003
	42	0.000	0.005	0.000	0.003	0.000	0.002
	50	0.000	0.005	0.000	0.003	0.000	0.001
	100	0.000	0.002	0.000	0.001	0.000	0.001
R1 - stream	0	2.296		0.583		0.235	
	1	0.000	0.364	0.000	0.115	0.000	0.115
	2	0.000	0.182	0.000	0.058	0.000	0.058
	4	0.000	0.091	0.000	0.029	0.000	0.029
	7	0.000	0.052	0.000	0.017	0.000	0.017
	14	0.000	0.026	0.000	0.016	0.000	0.016
	21	0.000	0.017	0.000	0.011	0.000	0.011
	28	0.000	0.017	0.000	0.008	0.000	0.008
	42	0.000	0.014	0.000	0.008	0.000	0.007
	50	0.000	0.012	0.000	0.006	0.000	0.006
	100	0.000	0.007	0.000	0.004	0.000	0.003

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R1 - pond	0	0.082		0.051		0.026	
	1	0.039	0.061	0.024	0.037	0.012	0.019
	2	0.016	0.049	0.010	0.030	0.005	0.014
	4	0.003	0.034	0.002	0.021	0.001	0.010
	7	0.000	0.022	0.000	0.013	0.000	0.006
	14	0.012	0.018	0.007	0.011	0.003	0.005
	21	0.005	0.017	0.005	0.011	0.005	0.005
	28	0.002	0.015	0.001	0.009	0.001	0.004
	42	0.025	0.012	0.015	0.008	0.007	0.004
	50	0.000	0.012	0.000	0.007	0.000	0.004
	100	0.000	0.009	0.000	0.005	0.000	0.003
R1 - stream	0	1.862		0.897		0.897	
	1	0.001	0.617	0.000	0.617	0.000	0.617
	2	0.000	0.329	0.000	0.309	0.000	0.309
	4	0.000	0.239	0.000	0.174	0.000	0.161

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )	Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )	Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )
	7	1.862	0.137	0.000	0.100	0.000	0.092
	14	0.000	0.094	0.000	0.065	0.000	0.063
	21	0.000	0.079	0.000	0.046	0.000	0.042
	28	0.000	0.070	0.000	0.046	0.000	0.040
	42	0.000	0.062	0.000	0.041	0.000	0.037
	50	0.000	0.056	0.000	0.036	0.000	0.032
	100	0.000	0.038	0.000	0.020	0.000	0.017

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )	Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )	Actual ( $\mu\text{g/L}$ )	TWA ( $\mu\text{g/L}$ )
R1 - pond	0	0.340		0.217		0.109	
	1	0.132	0.219	0.084	0.140	0.042	0.071
	2	0.049	0.153	0.031	0.098	0.016	0.049
	4	0.006	0.087	0.004	0.056	0.002	0.028
	7	0.001	0.051	0.000	0.033	0.000	0.016
	14	0.000	0.026	0.000	0.017	0.000	0.009
	21	0.000	0.018	0.000	0.011	0.000	0.006
	28	0.000	0.013	0.000	0.009	0.000	0.004
	42	0.000	0.009	0.000	0.006	0.000	0.003
	50	0.000	0.007	0.000	0.005	0.000	0.003
	100	0.000	0.004	0.000	0.002	0.000	0.001
R1 - stream	0	6.997		1.845		0.647	
	1	0.001	1.246	0.000	0.329	0.000	0.115
	2	0.000	0.623	0.000	0.164	0.000	0.058
	4	0.000	0.312	0.000	0.082	0.000	0.029
	7	0.000	0.178	0.000	0.047	0.000	0.017
	14	0.000	0.096	0.000	0.031	0.000	0.016
	21	0.000	0.065	0.000	0.021	0.000	0.011
	28	0.000	0.049	0.000	0.016	0.000	0.008
	42	0.000	0.033	0.000	0.011	0.000	0.006
	50	0.000	0.027	0.000	0.009	0.000	0.005
	100	0.000	0.014	0.000	0.005	0.000	0.002

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 8 late applications to vines**

Scenario	Time after maximum	Step 3 edge of field	Step 4	
			10 m buffer	20 m buffer

	(d)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R1 - pond	0	0.263		0.167		0.083	
	1	0.155	0.203	0.098	0.129	0.049	0.064
	2	0.091	0.162	0.058	0.103	0.029	0.051
	4	0.033	0.110	0.021	0.070	0.010	0.035
	7	0.009	0.071	0.005	0.045	0.003	0.022
	14	0.002	0.070	0.001	0.045	0.001	0.022
	21	0.001	0.069	0.001	0.044	0.000	0.022
	28	0.001	0.053	0.001	0.034	0.000	0.017
	42	0.001	0.043	0.000	0.027	0.000	0.014
	50	0.000	0.036	0.000	0.023	0.000	0.012
	100	0.000	0.023	0.000	0.015	0.000	0.007
R1 - stream	0	5.359		1.392		0.590	
	1	0.001	1.081	0.000	0.371	0.000	0.371
	2	0.001	0.541	0.000	0.186	0.000	0.186
	4	0.001	0.271	0.000	0.093	0.000	0.093
	7	0.001	0.155	0.000	0.053	0.000	0.053
	14	0.000	0.155	0.000	0.040	0.000	0.027
	21	0.000	0.155	0.000	0.040	0.000	0.018
	28	0.000	0.116	0.000	0.030	0.000	0.013
	42	0.000	0.103	0.000	0.027	0.000	0.011
	50	0.000	0.086	0.000	0.022	0.000	0.009
	100	0.000	0.060	0.000	0.016	0.000	0.007

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R2 following 1 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R2 - stream	0	3.044		0.773		0.263	
	1	0.000	0.248	0.000	0.179	0.000	0.179
	2	0.000	0.124	0.000	0.090	0.000	0.090
	4	0.000	0.062	0.000	0.045	0.000	0.045
	7	0.000	0.035	0.000	0.026	0.000	0.026
	14	0.211	0.022	0.211	0.013	0.211	0.013
	21	0.000	0.020	0.000	0.012	0.000	0.010
	28	0.000	0.015	0.000	0.009	0.000	0.007
	42	0.000	0.010	0.000	0.006	0.000	0.005
	50	0.000	0.009	0.000	0.005	0.000	0.004
	100	0.000	0.004	0.000	0.003	0.000	0.002

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R2 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)

R2 - stream	0	2.487		0.575		0.567	
	1	0.000	0.557	0.000	0.557	0.329	0.557
	2	0.000	0.298	0.000	0.298	0.001	0.298
	4	0.000	0.150	0.000	0.149	0.001	0.149
	7	2.485	0.120	0.000	0.093	0.000	0.088
	14	0.001	0.078	0.000	0.051	0.000	0.045
	21	0.000	0.064	0.000	0.037	0.000	0.031
	28	0.000	0.048	0.000	0.028	0.000	0.023
	42	0.000	0.043	0.000	0.021	0.000	0.016
	50	0.000	0.040	0.000	0.019	0.000	0.014
	100	0.000	0.026	0.000	0.012	0.000	0.009

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R2 - stream	0	9.374		2.472		0.866	
	1	0.000	0.946	0.000	0.249	0.000	0.096
	2	0.000	0.473	0.000	0.125	0.000	0.051
	4	0.000	0.237	0.000	0.062	0.000	0.026
	7	0.000	0.135	0.000	0.036	0.000	0.015
	14	0.000	0.068	0.000	0.018	0.000	0.007
	21	0.000	0.050	0.000	0.017	0.000	0.009
	28	0.000	0.038	0.000	0.013	0.000	0.007
	42	0.000	0.025	0.000	0.008	0.000	0.005
	50	0.000	0.021	0.000	0.007	0.000	0.004
	100	0.000	0.011	0.000	0.004	0.000	0.002

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 following 8 late applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R2 - stream	0	7.183		1.866		0.646	
	1	0.001	0.746	0.000	0.342	0.000	0.342
	2	0.001	0.373	0.000	0.171	0.000	0.171
	4	0.000	0.187	0.000	0.086	0.000	0.086
	7	0.000	0.139	0.000	0.064	0.000	0.049
	14	0.000	0.107	0.000	0.038	0.000	0.030
	21	0.000	0.106	0.000	0.036	0.000	0.024
	28	0.000	0.092	0.000	0.034	0.000	0.020
	42	0.000	0.075	0.000	0.024	0.000	0.015
	50	0.000	0.063	0.000	0.020	0.000	0.013
	100	0.001	0.044	0.000	0.013	0.000	0.007



**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 1 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	3.248		0.882		0.882	
	1	0.002	0.891	0.002	0.787	0.002	0.787
	2	0.001	0.446	0.002	0.414	0.001	0.414
	4	0.001	0.223	0.001	0.208	0.001	0.208
	7	0.001	0.128	0.001	0.119	0.001	0.119
	14	0.001	0.124	0.000	0.076	0.000	0.065
	21	0.001	0.083	0.000	0.051	0.000	0.044
	28	0.000	0.062	0.000	0.038	0.000	0.033
	42	0.000	0.042	0.000	0.026	0.000	0.022
	50	0.000	0.035	0.000	0.021	0.000	0.018
	100	0.000	0.018	0.000	0.011	0.000	0.009

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	2.625		2.070		2.069	
	1	0.005	1.846	0.005	1.846	0.004	1.846
	2	0.002	0.971	0.004	0.971	0.004	0.971
	4	0.002	0.663	0.003	0.525	0.003	0.497
	7	0.001	0.382	0.077	0.302	0.026	0.286
	14	0.001	0.243	0.001	0.164	0.001	0.148
	21	0.000	0.197	0.001	0.117	0.001	0.101
	28	0.000	0.148	0.001	0.088	0.000	0.076
	42	0.000	0.127	0.000	0.066	0.000	0.053
	50	0.000	0.107	0.000	0.055	0.000	0.045
	100	0.000	0.075	0.000	0.033	0.000	0.024

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	9.854		2.599		0.911	
	1	0.006	2.499	0.001	0.659	0.000	0.231
	2	0.003	1.251	0.001	0.330	0.000	0.116
	4	0.002	0.627	0.001	0.165	0.000	0.058
	7	0.002	0.359	0.000	0.095	0.000	0.033

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
	14	0.001	0.180	0.000	0.048	0.000	0.017
	21	0.000	0.120	0.000	0.032	0.000	0.011
	28	0.000	0.090	0.000	0.024	0.000	0.008
	42	0.000	0.060	0.000	0.016	0.000	0.006
	50	0.000	0.051	0.000	0.013	0.000	0.005
	100	0.000	0.025	0.000	0.007	0.000	0.002

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 8 late applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	7.555		1.962		0.680	
	1	0.009	2.070	0.002	0.538	0.001	0.352
	2	0.004	1.037	0.001	0.302	0.000	0.302
	4	0.003	0.520	0.001	0.154	0.000	0.154
	7	0.002	0.306	0.001	0.098	0.001	0.088
	14	7.555	0.283	0.001	0.074	0.000	0.044
	21	0.003	0.280	0.000	0.073	0.000	0.041
	28	0.001	0.224	0.001	0.067	0.000	0.031
	42	0.003	0.196	0.000	0.057	0.000	0.025
	50	0.001	0.168	0.001	0.049	0.000	0.021
	100	0.001	0.131	0.000	0.039	0.000	0.019

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 1 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	2.273		0.774		0.774	
	1	0.000	0.742	0.162	0.742	0.162	0.742
	2	0.000	0.563	0.001	0.563	0.001	0.563
	4	0.000	0.286	0.001	0.286	0.001	0.286
	7	0.000	0.163	0.000	0.163	0.000	0.163
	14	0.600	0.082	0.000	0.082	0.000	0.082
	21	0.000	0.068	0.000	0.058	0.000	0.056
	28	0.000	0.051	0.000	0.044	0.000	0.042
	42	0.000	0.034	0.000	0.029	0.000	0.028
	50	0.000	0.029	0.000	0.025	0.000	0.024
	100	0.000	0.014	0.000	0.012	0.000	0.012

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 8 early applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	3.407		3.407		3.407	
	1	0.712	3.266	0.712	3.266	0.712	3.266
	2	0.004	2.487	0.004	2.487	0.004	2.487
	4	0.003	1.320	0.003	1.276	0.003	1.267
	7	0.002	0.756	0.002	0.730	0.002	0.725
	14	0.001	0.395	0.001	0.370	0.001	0.364
	21	0.001	0.280	0.001	0.251	0.001	0.245
	28	0.001	0.218	0.001	0.190	0.000	0.184
	42	0.000	0.159	0.000	0.130	0.000	0.124
	50	0.000	0.134	0.000	0.109	0.000	0.104
	100	0.000	0.073	0.000	0.056	0.000	0.053

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 1 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	6.882		1.815		0.636	
	1	0.000	0.865	0.000	0.228	0.000	0.080
	2	0.000	0.433	0.000	0.114	0.000	0.040
	4	0.000	0.217	0.000	0.057	0.000	0.020
	7	0.000	0.124	0.000	0.033	0.000	0.011
	14	0.000	0.062	0.000	0.016	0.000	0.006
	21	0.000	0.041	0.000	0.011	0.000	0.004
	28	0.000	0.031	0.000	0.008	0.000	0.003
	42	0.000	0.021	0.000	0.005	0.000	0.002
	50	0.000	0.017	0.000	0.005	0.000	0.002
	100	0.000	0.009	0.000	0.002	0.000	0.001

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 8 late applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
				10 m buffer		20 m buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	5.358		1.392		1.051	
	1	0.001	1.007	0.000	1.007	0.219	1.007
	2	0.001	0.759	0.000	0.759	0.001	0.759

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 8 late applications to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4			
		Actual (µg/L)	TWA (µg/L)	10 m buffer		20 m buffer	
				Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
	4	0.001	0.448	0.000	0.385	0.001	0.385
	7	0.001	0.315	1.392	0.245	0.001	0.229
	14	0.000	0.205	0.000	0.135	0.000	0.119
	21	0.000	0.168	0.000	0.098	0.000	0.082
	28	0.000	0.126	0.000	0.074	0.000	0.062
	42	0.000	0.110	0.000	0.049	0.000	0.041
	50	0.000	0.092	0.000	0.041	0.000	0.035
	100	0.000	0.066	0.000	0.033	0.001	0.026

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 - stream following 8 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R1 - stream	0	1.862		0.192	
	1	0.001	0.617	0.000	0.139
	2	0.000	0.329	0.000	0.070
	4	0.000	0.239	0.000	0.041
	7	1.862	0.137	0.000	0.024
	14	0.000	0.094	0.000	0.014
	21	0.000	0.079	0.000	0.010
	28	0.000	0.070	0.000	0.011
	42	0.000	0.062	0.000	0.010
	50	0.000	0.056	0.000	0.008
	100	0.000	0.038	0.000	0.005

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R1 - stream	0	5.359		0.482	
	1	0.001	1.081	0.000	0.097
	2	0.001	0.541	0.000	0.049
	4	0.001	0.271	0.000	0.024
	7	0.001	0.155	0.000	0.014
	14	0.000	0.155	0.000	0.014
	21	0.000	0.155	0.000	0.014

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
	28	0.000	0.116	0.000	0.011
	42	0.000	0.103	0.000	0.009
	50	0.000	0.086	0.000	0.008
	100	0.000	0.060	0.000	0.005

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 - stream following 8 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R2 - stream	0	2.487		0.182	
	1	0.000	0.557	0.000	0.130
	2	0.000	0.298	0.000	0.070
	4	0.000	0.150	0.000	0.035
	7	2.485	0.120	0.182	0.023
	14	0.001	0.078	0.000	0.013
	21	0.000	0.064	0.000	0.009
	28	0.000	0.048	0.000	0.007
	42	0.000	0.043	0.000	0.005
	50	0.000	0.040	0.000	0.005
	100	0.000	0.026	0.000	0.003

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R2 - stream	0	7.183		0.646	
	1	0.001	0.746	0.000	0.080
	2	0.001	0.373	0.000	0.040
	4	0.000	0.187	0.000	0.020
	7	0.000	0.139	0.000	0.018
	14	0.000	0.107	0.000	0.010
	21	0.000	0.106	0.000	0.010
	28	0.000	0.092	0.000	0.010
	42	0.000	0.075	0.000	0.008

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
	50	0.000	0.063	0.000	0.006
	100	0.001	0.044	0.000	0.004

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 - stream following 8 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	2.625		0.485	
	1	0.005	1.846	0.001	0.432
	2	0.002	0.971	0.001	0.227
	4	0.002	0.663	0.001	0.126
	7	0.001	0.382	0.024	0.073
	14	0.001	0.243	0.000	0.040
	21	0.000	0.197	0.000	0.029
	28	0.000	0.148	0.000	0.022
	42	0.000	0.127	0.000	0.017
	50	0.000	0.107	0.000	0.014
	100	0.000	0.075	0.000	0.009

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R3 - stream	0	7.555		0.680	
	1	0.009	2.070	0.001	0.186
	2	0.004	1.037	0.000	0.093
	4	0.003	0.520	0.000	0.047
	7	0.002	0.306	0.000	0.031
	14	7.555	0.283	0.680	0.025
	21	0.003	0.280	0.000	0.025
	28	0.001	0.224	0.000	0.022
	42	0.003	0.196	0.000	0.019
	50	0.001	0.168	0.000	0.016
	100	0.001	0.131	0.000	0.013

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 - stream following 8 early application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	3.407		0.809	
	1	0.712	3.266	0.179	0.776
	2	0.004	2.487	0.001	0.578
	4	0.003	1.320	0.001	0.298
	7	0.002	0.756	0.000	0.170
	14	0.001	0.395	0.000	0.087
	21	0.001	0.280	0.000	0.059
	28	0.001	0.218	0.000	0.045
	42	0.000	0.159	0.000	0.031
	50	0.000	0.134	0.000	0.026
	100	0.000	0.073	0.000	0.013

**Step 3 and Step 4 (considering spray drift and runoff mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 - stream following 8 late application to vines**

Scenario	Time after maximum (d)	Step 3 edge of field		Step 4 20 m drift buffer and 20 m runoff buffer	
		Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
R4 - stream	0	5.358		0.482	
	1	0.001	1.007	0.000	0.239
	2	0.001	0.759	0.000	0.176
	4	0.001	0.448	0.000	0.090
	7	0.001	0.315	0.000	0.060
	14	0.000	0.205	0.000	0.034
	21	0.000	0.168	0.000	0.026
	28	0.000	0.126	0.000	0.019
	42	0.000	0.110	0.000	0.013
	50	0.000	0.092	0.000	0.011
	100	0.000	0.066	0.000	0.009

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario D3 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4					
				10 m buffer		20 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
Pome fruit - 1 application (early)									
D3 - ditch	0	40.586		19.577		4.474		2.027	
	1	11.352	25.539	5.472	12.318	1.249	2.814	0.565	1.275
	2	0.881	15.063	0.420	7.263	0.094	1.658	0.042	0.751
	4	0.117	7.664	0.054	3.693	0.011	0.843	0.005	0.381
	7	0.075	4.420	0.036	2.129	0.008	0.485	0.003	0.220
	14	0.027	2.234	0.013	1.076	0.003	0.245	0.001	0.111
	21	0.014	1.496	0.007	0.721	0.002	0.164	0.001	0.074
	28	0.009	1.124	0.005	0.542	0.001	0.124	0.001	0.056
	42	0.005	0.752	0.002	0.362	0.001	0.083	0.000	0.037
	50	0.004	0.632	0.002	0.305	0.000	0.070	0.000	0.032
100	0.001	0.317	0.001	0.153	0.000	0.035	0.000	0.016	
Pome fruit - 8 applications (early)									
D3 - ditch	0	29.914		12.571		3.073		1.494	
	1	6.816	18.687	2.863	7.851	0.699	1.919	0.340	0.933
	2	1.387	11.023	0.580	4.630	0.141	1.131	0.068	0.550
	4	0.140	5.608	0.058	2.354	0.014	0.574	0.006	0.279
	7	0.084	3.234	0.035	1.357	0.009	0.331	0.004	0.161
	14	0.043	2.998	0.019	1.258	0.005	0.307	0.002	0.149
	21	0.027	2.831	0.012	1.188	0.003	0.290	0.002	0.141
	28	0.019	2.195	0.009	0.921	0.002	0.225	0.001	0.109
	42	0.015	2.008	0.006	0.843	0.002	0.206	0.001	0.100
	50	0.010	1.694	0.004	0.711	0.001	0.174	0.001	0.084
	100	0.006	1.656	0.002	0.695	0.001	0.170	0.000	0.083



**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario D3 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4					
				10 m buffer		20 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
Pome fruit - 1 application (late)									
D3 - ditch	0	19.204		5.787		1.785		0.959	
	1	4.501	10.418	1.355	3.139	0.417	0.968	0.224	0.520
	2	0.552	6.258	0.164	1.885	0.050	0.581	0.027	0.312
	4	0.051	3.207	0.014	0.965	0.004	0.297	0.002	0.160
	7	0.032	1.850	0.009	0.556	0.003	0.171	0.001	0.092
	14	0.013	0.935	0.004	0.281	0.001	0.087	0.001	0.047
	21	0.007	0.627	0.002	0.189	0.001	0.058	0.000	0.031
	28	0.005	0.471	0.001	0.142	0.000	0.044	0.000	0.024
	42	0.002	0.315	0.001	0.095	0.000	0.029	0.000	0.016
	50	0.002	0.265	0.001	0.080	0.000	0.025	0.000	0.013
100	0.001	0.133	0.000	0.040	0.000	0.012	0.000	0.007	
Pome fruit - 8 applications (late)									
D3 - ditch	0	10.999		3.766		1.090		0.549	
	1	2.638	6.386	0.902	2.186	0.261	0.633	0.131	0.319
	2	0.627	4.018	0.214	1.375	0.062	0.398	0.031	0.200
	4	0.070	2.090	0.023	0.715	0.007	0.207	0.003	0.104
	7	0.048	1.213	0.016	0.415	0.005	0.120	0.002	0.060
	14	0.022	1.131	0.008	0.387	0.002	0.112	0.001	0.056
	21	0.012	1.033	0.005	0.353	0.001	0.102	0.001	0.051
	28	0.009	0.833	0.003	0.285	0.001	0.082	0.001	0.042
	42	0.029	0.874	0.010	0.299	0.003	0.086	0.002	0.044
	50	0.017	0.748	0.006	0.256	0.002	0.074	0.001	0.037
	100	0.002	0.622	0.001	0.213	0.000	0.062	0.000	0.031

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario D4 following 1 and 8 early applications to pome fruit**

Scen ario	Tim e afte r max · (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actua l (µg/L)	TWA (µg/L)	actua l (µg/L)	TWA (µg/L)	actua l (µg/L)	TWA (µg/L)	actua l (µg/L)	TWA (µg/L)
Pome fruit - 1 application (early)													
D4 - pond	0	2.466		1.522		0.492		0.238		0.139		0.123	
	1	1.739	2.073	1.073	1.279	0.347	0.413	0.168	0.200	0.098	0.116	0.087	0.103
	2	1.230	1.768	0.759	1.091	0.245	0.353	0.119	0.171	0.069	0.099	0.061	0.088
	4	0.625	1.335	0.385	0.824	0.124	0.266	0.060	0.129	0.035	0.075	0.031	0.067
	7	0.238	0.935	0.147	0.577	0.047	0.186	0.023	0.090	0.013	0.052	0.012	0.047
	14	0.020	0.516	0.012	0.318	0.004	0.103	0.002	0.050	0.001	0.029	0.001	0.026
	21	0.005	0.347	0.003	0.214	0.001	0.069	0.001	0.033	0.000	0.019	0.000	0.017
	28	0.003	0.262	0.002	0.161	0.001	0.052	0.000	0.025	0.000	0.015	0.000	0.013
	42	0.001	0.175	0.001	0.108	0.000	0.035	0.000	0.017	0.000	0.010	0.000	0.009
	50	0.001	0.147	0.000	0.091	0.000	0.029	0.000	0.014	0.000	0.008	0.000	0.007
100	0.000	0.074	0.000	0.046	0.000	0.015	0.000	0.007	0.000	0.004	0.000	0.004	
D4 - stream	0	39.496		20.829		4.759		-	-	-	-	1.972	
	1	0.001	2.532	0.000	1.335	0.000	0.305	-	-	-	-	0.000	0.126
	2	0.001	1.266	0.000	0.668	0.000	0.153	-	-	-	-	0.000	0.063
	4	0.000	0.633	0.000	0.334	0.000	0.076	-	-	-	-	0.000	0.032
	7	0.000	0.362	0.000	0.191	0.000	0.044	-	-	-	-	0.000	0.018
	14	0.000	0.181	0.000	0.096	0.000	0.022	-	-	-	-	0.000	0.009
	21	0.000	0.121	0.000	0.064	0.000	0.015	-	-	-	-	0.000	0.006
	28	0.000	0.091	0.000	0.048	0.000	0.011	-	-	-	-	0.000	0.005
	42	0.000	0.060	0.000	0.032	0.000	0.007	-	-	-	-	0.000	0.003
	50	0.000	0.051	0.000	0.027	0.000	0.006	-	-	-	-	0.000	0.003
	100	0.000	0.025	0.000	0.013	0.000	0.003	-	-	-	-	0.000	0.001

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D4 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
Pome fruit - 8 application (early)													
D4 - pond	0	1.679		1.044		0.300		0.129		-	-	0.084	
	1	0.622	1.406	0.387	0.874	0.111	0.251	0.048	0.108	-	-	0.031	0.070
	2	0.233	1.199	0.145	0.746	0.042	0.214	0.018	0.092	-	-	0.012	0.060
	4	0.037	0.905	0.023	0.563	0.007	0.161	0.003	0.069	-	-	0.002	0.045
	7	0.007	0.634	0.004	0.394	0.001	0.113	0.001	0.048	-	-	0.000	0.032
	14	0.003	0.350	0.002	0.217	0.001	0.062	0.000	0.027	-	-	0.000	0.017
	21	0.002	0.243	0.001	0.151	0.000	0.043	0.000	0.019	-	-	0.000	0.012
	28	0.002	0.241	0.001	0.150	0.000	0.043	0.000	0.018	-	-	0.000	0.012
	42	0.001	0.238	0.001	0.148	0.000	0.042	0.000	0.018	-	-	0.000	0.012
	50	0.001	0.201	0.001	0.125	0.000	0.036	0.000	0.015	-	-	0.000	0.010
	100	0.001	0.141	0.000	0.087	0.000	0.025	0.000	0.011	-	-	0.000	0.007
D4 - stream	0	31.144		14.555		3.558		-	-	-	-	1.555	
	1	0.022	7.780	0.010	3.636	0.002	0.889	-	-	-	-	0.001	0.388
	2	0.017	3.899	0.008	1.822	0.002	0.445	-	-	-	-	0.001	0.195
	4	0.013	1.957	0.006	0.914	0.001	0.223	-	-	-	-	0.001	0.098
	7	0.009	1.123	0.004	0.525	0.001	0.128	-	-	-	-	0.000	0.056
	14	0.005	1.123	0.002	0.525	0.001	0.128	-	-	-	-	0.000	0.056
	21	0.003	1.119	0.001	0.523	0.000	0.128	-	-	-	-	0.000	0.056
	28	0.002	1.117	0.001	0.522	0.000	0.128	-	-	-	-	0.000	0.056
	42	0.001	1.087	0.001	0.508	0.000	0.124	-	-	-	-	0.000	0.054
	50	0.001	0.914	0.000	0.427	0.000	0.104	-	-	-	-	0.000	0.046
	100	0.000	0.492	0.000	0.230	0.000	0.056	-	-	-	-	0.000	0.025

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D4 following 1 and 8 late applications to pome fruit**

Scen ario	Tim e afte r max · (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actu al (µg/ L)	TW A (µg/ L)	actu al (µg/ L)	TW A (µg/ L)	actu al (µg/ L)	TW A (µg/ L)	actu al (µg/ L)	TW A (µg/ L)	actu al (µg/ L)	TW A (µg/ L)	actu al (µg/ L)	TW A (µg/ L)
Pome fruit - 1 application (late)													
D4 - pond	0	0.859		0.54 5		0.24 8		0.14 9		0.10 1		0.04 3	
	1	0.300	0.53 1	0.19 0	0.33 7	0.08 7	0.15 3	0.05 2	0.09 2	0.03 5	0.06 2	0.01 5	0.02 7
	2	0.105	0.36 1	0.06 7	0.22 9	0.03 0	0.10 4	0.01 8	0.06 3	0.01 2	0.04 3	0.00 5	0.01 8
	4	0.014	0.20 4	0.00 9	0.12 9	0.00 4	0.05 9	0.00 2	0.03 5	0.00 2	0.02 4	0.00 1	0.01 0
	7	0.002	0.11 9	0.00 1	0.07 5	0.00 0	0.03 4	0.00 0	0.02 1	0.00 0	0.01 4	0.00 0	0.00 6
	14	0.001	0.06 0	0.00 0	0.03 8	0.00 0	0.01 7	0.00 0	0.01 0	0.00 0	0.00 7	0.00 0	0.00 3
	21	0.000	0.04 0	0.00 0	0.02 5	0.00 0	0.01 2	0.00 0	0.00 7	0.00 0	0.00 5	0.00 0	0.00 2
	28	0.000	0.03 0	0.00 0	0.01 9	0.00 0	0.00 9	0.00 0	0.00 5	0.00 0	0.00 4	0.00 0	0.00 2
	42	0.000	0.02 0	0.00 0	0.01 3	0.00 0	0.00 6	0.00 0	0.00 3	0.00 0	0.00 2	0.00 0	0.00 1
	50	0.000	0.01 7	0.00 0	0.01 1	0.00 0	0.00 5	0.00 0	0.00 3	0.00 0	0.00 2	0.00 0	0.00 1
	100	0.000	0.00 8	0.00 0	0.00 5	0.00 0	0.00 2	0.00 0	0.00 1	0.00 0	0.00 1	0.00 0	0.00 0
D4 - strea m	0	19.20 7		6.69 6		2.06 5		1.02 6		-	-	0.95 9	
	1	0.005	4.26 0	0.00 2	1.48 5	0.00 0	0.45 8	0.00 0	0.22 7	-	-	0.00 0	0.21 3
	2	0.004	2.13 2	0.00 1	0.74 3	0.00 0	0.22 9	0.00 0	0.11 4	-	-	0.00 0	0.10 6
	4	0.003	1.06 8	0.00 1	0.37 2	0.00 0	0.11 5	0.00 0	0.05 7	-	-	0.00 0	0.05 3
	7	0.002	0.61 1	0.00 1	0.21 3	0.00 0	0.06 6	0.00 0	0.03 3	-	-	0.00 0	0.03 1
	14	0.001	0.30 6	0.00 0	0.10 7	0.00 0	0.03 3	0.00 0	0.01 6	-	-	0.00 0	0.01 5
	21	0.001	0.20 5	0.00 0	0.07 1	0.00 0	0.02 2	0.00 0	0.01 1	-	-	0.00 0	0.01 0
	28	0.000	0.15 4	0.00 0	0.05 4	0.00 0	0.01 7	0.00 0	0.00 8	-	-	0.00 0	0.00 8
	42	0.000	0.10 2	0.00 0	0.03 6	0.00 0	0.01 1	0.00 0	0.00 5	-	-	0.00 0	0.00 5
	50	0.000	0.08 6	0.00 0	0.03 0	0.00 0	0.00 9	0.00 0	0.00 5	-	-	0.00 0	0.00 4
	100	0.000	0.04 3	0.00 0	0.01 5	0.00 0	0.00 5	0.00 0	0.00 2	-	-	0.00 0	0.00 2

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D4 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
Pome fruit - 8 application (late)													
D4 - pond	0	0.541		0.343		0.140		0.078		0.050		0.027	
	1	0.280	0.387	0.178	0.245	0.072	0.100	0.040	0.056	0.026	0.036	0.014	0.019
	2	0.161	0.303	0.102	0.192	0.042	0.078	0.023	0.044	0.015	0.028	0.008	0.015
	4	0.055	0.201	0.035	0.128	0.014	0.052	0.008	0.029	0.005	0.019	0.003	0.010
	7	0.014	0.128	0.009	0.081	0.003	0.033	0.002	0.018	0.001	0.012	0.001	0.006
	14	0.003	0.119	0.002	0.075	0.001	0.031	0.000	0.017	0.000	0.011	0.000	0.006
	21	0.001	0.116	0.001	0.073	0.000	0.030	0.000	0.017	0.000	0.011	0.000	0.006
	28	0.001	0.114	0.001	0.072	0.000	0.029	0.000	0.016	0.000	0.011	0.000	0.006
	42	0.001	0.089	0.001	0.057	0.000	0.023	0.000	0.013	0.000	0.008	0.000	0.004
	50	0.001	0.076	0.000	0.048	0.000	0.020	0.000	0.011	0.000	0.007	0.000	0.004
	100	0.000	0.054	0.000	0.034	0.000	0.014	0.000	0.008	0.000	0.005	0.000	0.003
D4 - stream	0	11.137		4.348		1.258		0.570		-	-	0.556	
	1	0.006	2.768	0.002	1.080	0.001	0.313	0.000	0.142	-	-	0.000	0.138
	2	0.005	1.385	0.002	0.541	0.000	0.156	0.000	0.071	-	-	0.000	0.069
	4	0.004	0.694	0.001	0.271	0.000	0.078	0.000	0.036	-	-	0.000	0.035
	7	0.003	0.397	0.001	0.155	0.000	0.045	0.000	0.020	-	-	0.000	0.020
	14	0.001	0.390	0.001	0.152	0.000	0.044	0.000	0.020	-	-	0.000	0.019
	21	0.001	0.387	0.000	0.151	0.000	0.044	0.000	0.020	-	-	0.000	0.019
	28	0.001	0.386	0.000	0.151	0.000	0.044	0.000	0.020	-	-	0.000	0.019
	42	0.003	0.322	0.001	0.126	0.000	0.036	0.000	0.017	-	-	0.000	0.016
	50	0.001	0.271	0.000	0.106	0.000	0.031	0.000	0.014	-	-	0.000	0.014
	100	0.000	0.215	0.000	0.084	0.000	0.024	0.000	0.011	-	-	0.000	0.011

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario D5 following 1 and 8 early applications to pome fruit**

Scenario	Time after max · (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (early)													
D5 - pond	0	2.465		1.522		0.492		0.238		0.138		0.123	
	1	1.494	1.928	0.922	1.190	0.298	0.385	0.144	0.186	0.084	0.108	0.075	0.096
	2	0.909	1.556	0.561	0.960	0.181	0.310	0.088	0.150	0.051	0.087	0.045	0.078
	4	0.344	1.072	0.212	0.662	0.068	0.214	0.033	0.103	0.019	0.060	0.017	0.054
	7	0.088	0.694	0.054	0.428	0.017	0.138	0.008	0.067	0.005	0.039	0.004	0.035
	14	0.011	0.363	0.006	0.224	0.002	0.072	0.001	0.035	0.001	0.020	0.001	0.018
	21	0.004	0.244	0.003	0.151	0.001	0.049	0.000	0.024	0.000	0.014	0.000	0.012
	28	0.001	0.184	0.001	0.113	0.000	0.037	0.000	0.018	0.000	0.010	0.000	0.009
	42	0.001	0.123	0.000	0.076	0.000	0.025	0.000	0.012	0.000	0.007	0.000	0.006
	50	0.000	0.103	0.000	0.064	0.000	0.021	0.000	0.010	0.000	0.006	0.000	0.005
	100	0.000	0.052	0.000	0.032	0.000	0.010	0.000	0.005	0.000	0.003	0.000	0.003
D5 - stream	0	39.361		20.758		4.743		-	-	-	-	1.965	
	1	0.000	1.479	0.000	0.780	0.000	0.178	-	-	-	-	0.000	0.074
	2	0.000	0.740	0.000	0.390	0.000	0.089	-	-	-	-	0.000	0.037
	4	0.000	0.370	0.000	0.195	0.000	0.045	-	-	-	-	0.000	0.019
	7	0.000	0.211	0.000	0.112	0.000	0.026	-	-	-	-	0.000	0.011
	14	0.000	0.106	0.000	0.056	0.000	0.013	-	-	-	-	0.000	0.005
	21	0.000	0.071	0.000	0.037	0.000	0.009	-	-	-	-	0.000	0.004
	28	0.000	0.053	0.000	0.028	0.000	0.006	-	-	-	-	0.000	0.003
	42	0.000	0.035	0.000	0.019	0.000	0.004	-	-	-	-	0.000	0.002
	50	0.000	0.030	0.000	0.016	0.000	0.004	-	-	-	-	0.000	0.001
	100	0.000	0.015	0.000	0.008	0.000	0.002	-	-	-	-	0.000	0.001

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D5 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 8 application (early)													
D5 - pond	0	1.680		1.044		0.300		0.129		-	-	0.084	
	1	1.022	1.316	0.635	0.818	0.182	0.235	0.078	0.101	-	-	0.051	0.066
	2	0.624	1.064	0.388	0.661	0.111	0.190	0.048	0.081	-	-	0.031	0.053
	4	0.239	0.735	0.148	0.457	0.042	0.131	0.018	0.056	-	-	0.012	0.037
	7	0.064	0.477	0.039	0.296	0.011	0.085	0.005	0.036	-	-	0.003	0.024
	14	0.005	0.259	0.003	0.161	0.001	0.046	0.000	0.020	-	-	0.000	0.013
	21	0.343	0.323	0.213	0.201	0.061	0.058	0.026	0.025	-	-	0.017	0.016
	28	0.006	0.247	0.004	0.154	0.001	0.044	0.000	0.019	-	-	0.000	0.012
	42	0.009	0.217	0.006	0.135	0.002	0.039	0.000	0.017	-	-	0.000	0.011
	50	0.258	0.205	0.160	0.128	0.046	0.037	0.020	0.016	-	-	0.013	0.010
	100	0.002	0.164	0.002	0.102	0.000	0.029	0.000	0.013	-	-	0.000	0.008
D5 - stream	0	33.602		15.703		3.838		-	-	-	-	1.678	
	1	0.076	10.627	0.035	4.966	0.008	1.214	-	-	-	-	0.004	0.530
	2	0.026	5.332	0.012	2.491	0.003	0.609	-	-	-	-	0.001	0.266
	4	0.019	2.677	0.009	1.250	0.002	0.305	-	-	-	-	0.001	0.133
	7	0.013	1.536	0.006	0.718	0.002	0.175	-	-	-	-	0.001	0.077
	14	0.007	1.533	0.003	0.716	0.001	0.175	-	-	-	-	0.000	0.076
	21	0.004	1.026	0.002	0.479	0.001	0.117	-	-	-	-	0.000	0.051
	28	0.003	0.939	0.001	0.439	0.000	0.107	-	-	-	-	0.000	0.047
	42	0.002	0.760	0.001	0.355	0.000	0.087	-	-	-	-	0.000	0.038
	50	0.001	0.846	0.001	0.395	0.000	0.097	-	-	-	-	0.000	0.042
	100	0.001	0.510	0.000	0.238	0.000	0.058	-	-	-	-	0.000	0.026

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D5 following 1 and 8 late applications to pome fruit**

Scenario	Time after max · (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (late)													
D5 - pond	0	0.860		0.545		0.248		0.149		0.101		0.043	
	1	0.387	0.589	0.246	0.374	0.112	0.170	0.067	0.102	0.046	0.069	0.019	0.029
	2	0.175	0.432	0.111	0.274	0.051	0.124	0.030	0.075	0.021	0.051	0.009	0.022
	4	0.037	0.261	0.024	0.166	0.011	0.075	0.006	0.045	0.004	0.031	0.002	0.013
	7	0.004	0.156	0.002	0.099	0.001	0.045	0.001	0.027	0.000	0.018	0.000	0.008
	14	0.001	0.079	0.000	0.050	0.000	0.023	0.000	0.014	0.000	0.009	0.000	0.004
	21	0.000	0.053	0.000	0.033	0.000	0.015	0.000	0.009	0.000	0.006	0.000	0.003
	28	0.000	0.040	0.000	0.025	0.000	0.011	0.000	0.007	0.000	0.005	0.000	0.002
	42	0.000	0.026	0.000	0.017	0.000	0.008	0.000	0.005	0.000	0.003	0.000	0.001
	50	0.000	0.022	0.000	0.014	0.000	0.006	0.000	0.004	0.000	0.003	0.000	0.001
	100	0.000	0.011	0.000	0.007	0.000	0.003	0.000	0.002	0.000	0.001	0.000	0.001
D5 - stream	0	20.175		7.034		2.169		1.078		-	-	1.007	
	1	0.002	2.972	0.001	1.036	0.000	0.320	0.000	0.159	-	-	0.000	0.148
	2	0.002	1.487	0.001	0.518	0.000	0.160	0.000	0.079	-	-	0.000	0.074
	4	0.002	0.745	0.001	0.260	0.000	0.080	0.000	0.040	-	-	0.000	0.037
	7	0.002	0.426	0.001	0.149	0.000	0.046	0.000	0.023	-	-	0.000	0.021
	14	0.001	0.214	0.000	0.075	0.000	0.023	0.000	0.011	-	-	0.000	0.011
	21	0.001	0.143	0.000	0.050	0.000	0.015	0.000	0.008	-	-	0.000	0.007
	28	0.000	0.107	0.000	0.037	0.000	0.012	0.000	0.006	-	-	0.000	0.005
	42	0.000	0.072	0.000	0.025	0.000	0.008	0.000	0.004	-	-	0.000	0.004
	50	0.000	0.060	0.000	0.021	0.000	0.006	0.000	0.003	-	-	0.000	0.003
	100	0.000	0.030	0.000	0.011	0.000	0.003	0.000	0.002	-	-	0.000	0.002



**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario D5 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4									
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
Pome fruit - 8 application (late)													
D5 - pond	0	0.537		0.340		0.139		0.077		0.050		0.027	
	1	0.201	0.367	0.127	0.232	0.052	0.095	0.029	0.053	0.019	0.034	0.010	0.018
	2	0.076	0.269	0.048	0.170	0.020	0.069	0.011	0.039	0.007	0.025	0.004	0.013
	4	0.012	0.163	0.008	0.103	0.003	0.042	0.002	0.023	0.001	0.015	0.001	0.008
	7	0.002	0.097	0.001	0.061	0.001	0.025	0.000	0.014	0.000	0.009	0.000	0.005
	14	0.001	0.080	0.001	0.051	0.000	0.021	0.000	0.012	0.000	0.007	0.000	0.004
	21	0.001	0.078	0.000	0.049	0.000	0.020	0.000	0.011	0.000	0.007	0.000	0.004
	28	0.001	0.076	0.000	0.048	0.000	0.020	0.000	0.011	0.000	0.007	0.000	0.004
	42	0.000	0.063	0.000	0.040	0.000	0.016	0.000	0.009	0.000	0.006	0.000	0.003
	50	0.000	0.053	0.000	0.034	0.000	0.014	0.000	0.008	0.000	0.005	0.000	0.003
	100	0.000	0.037	0.000	0.024	0.000	0.010	0.000	0.005	0.000	0.003	0.000	0.002
D5 - stream	0	12.019		4.693		1.358		0.616		-	-	0.600	
	1	0.031	3.798	0.012	1.483	0.003	0.429	0.002	0.194	-	-	0.001	0.190
	2	0.011	1.904	0.004	0.743	0.001	0.215	0.001	0.098	-	-	0.000	0.095
	4	0.008	0.955	0.003	0.373	0.001	0.108	0.000	0.049	-	-	0.000	0.048
	7	0.006	0.547	0.002	0.214	0.001	0.062	0.000	0.028	-	-	0.000	0.027
	14	0.003	0.546	0.001	0.213	0.000	0.062	0.000	0.028	-	-	0.000	0.027
	21	0.002	0.543	0.001	0.212	0.000	0.061	0.000	0.028	-	-	0.000	0.027
	28	0.001	0.541	0.001	0.211	0.000	0.061	0.000	0.028	-	-	0.000	0.027
	42	0.001	0.450	0.000	0.176	0.000	0.051	0.000	0.023	-	-	0.000	0.022
	50	0.001	0.379	0.000	0.148	0.000	0.043	0.000	0.019	-	-	0.000	0.019
	100	0.000	0.265	0.000	0.103	0.000	0.030	0.000	0.014	-	-	0.000	0.013

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (early)															
R1 - pond	0	2.466		1.522		0.492		0.238		0.138		0.123		NC *	NC *
	1	1.516	1.942	0.936	1.199	0.302	0.387	0.146	0.187	0.085	0.109	0.076	0.097		
	2	0.936	1.575	0.577	0.972	0.186	0.314	0.090	0.152	0.053	0.088	0.047	0.079		
	4	0.364	1.094	0.224	0.675	0.072	0.218	0.035	0.105	0.020	0.061	0.018	0.055		
	7	0.067	0.704	0.041	0.434	0.013	0.140	0.006	0.068	0.004	0.039	0.003	0.035		
	14	0.007	0.362	0.004	0.224	0.001	0.072	0.001	0.035	0.000	0.020	0.000	0.018		
	21	0.003	0.243	0.002	0.150	0.001	0.048	0.000	0.023	0.000	0.014	0.000	0.012		
	28	0.002	0.183	0.001	0.113	0.000	0.036	0.000	0.018	0.000	0.010	0.000	0.009		
	42	0.001	0.122	0.000	0.076	0.000	0.024	0.000	0.012	0.000	0.007	0.000	0.006		
	50	0.000	0.103	0.000	0.064	0.000	0.021	0.000	0.010	0.000	0.006	0.000	0.005		
	100	0.000	0.052	0.000	0.032	0.000	0.010	0.000	0.005	0.000	0.003	0.000	0.003		
R1 - stream	0	32.848		17.323		3.958		1.513		0.762		1.640		NC *	NC *
	1	0.003	5.435	0.002	2.866	0.000	0.655	0.000	0.250	0.000	0.126	0.000	0.271		
	2	0.003	2.719	0.001	1.434	0.000	0.328	0.000	0.125	0.000	0.063	0.000	0.136		
	4	0.002	1.361	0.001	0.718	0.000	0.164	0.000	0.063	0.000	0.032	0.000	0.068		
	7	0.001	0.778	0.001	0.410	0.000	0.094	0.000	0.036	0.000	0.018	0.000	0.039		
	14	0.000	0.389	0.000	0.205	0.000	0.047	0.000	0.018	0.000	0.012	0.000	0.019		
	21	0.000	0.260	0.000	0.137	0.000	0.031	0.000	0.012	0.000	0.008	0.000	0.013		
	28	0.000	0.197	0.000	0.105	0.000	0.026	0.000	0.011	0.000	0.007	0.000	0.012		
	42	0.000	0.134	0.000	0.073	0.000	0.020	0.000	0.010	0.000	0.007	0.000	0.011		
	50	0.000	0.111	0.000	0.066	0.000	0.019	0.000	0.009	0.000	0.006	0.000	0.010		

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
		0	3	0	1	0	7	0	9	0	6	0	9		
	100	0.00	0.05	0.00	0.03	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
		0	7	0	1	0	9	0	5	0	4	0	5		

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 8 application (early)															
R1 - pond	0	1.698		1.056		0.303		0.132		0.072		0.087		NC *	NC *
	1	0.890	1.317	0.553	0.819	0.159	0.235	0.062	0.101	0.034	0.054	0.041	0.066		
	2	0.470	1.068	0.292	0.664	0.084	0.191	0.025	0.082	0.014	0.044	0.017	0.053		
	4	0.137	0.742	0.085	0.461	0.024	0.132	0.004	0.057	0.002	0.030	0.003	0.037		
	7	0.029	0.477	0.018	0.296	0.006	0.085	0.001	0.036	0.000	0.019	0.000	0.024		
	14	0.006	0.380	0.004	0.236	0.001	0.068	0.001	0.029	0.001	0.016	0.003	0.019		
	21	0.026	0.379	0.016	0.236	0.005	0.068	0.003	0.029	0.003	0.015	0.003	0.019		
	28	1.675	0.313	1.042	0.194	0.299	0.056	0.004	0.024	0.002	0.013	0.002	0.016		
	42	0.269	0.260	0.167	0.162	0.048	0.047	0.041	0.020	0.022	0.011	0.027	0.013		
	50	1.675	0.254	1.041	0.158	0.299	0.045	0.000	0.020	0.000	0.010	0.000	0.013		
	100	0.001	0.178	0.000	0.110	0.000	0.032	0.000	0.014	0.000	0.007	0.000	0.009		
R1 - stream	0	23.817		11.130		2.721		0.902		0.812		1.189		1.189	
	1	0.006	4.488	0.003	2.097	0.001	0.520	0.000	0.520	0.181	0.520	0.000	0.520	0.000	0.224
	2	0.005	2.247	0.002	1.050	0.001	0.384	0.000	0.270	0.000	0.261	0.000	0.288	0.000	0.122
	4	0.004	1.231	0.002	0.645	0.000	0.256	0.000	0.172	0.000	0.149	0.000	0.185	0.000	0.084
	7	0.003	0.705	0.001	0.369	0.000	0.147	0.902	0.099	0.000	0.086	1.189	0.106	0.000	0.048
	14	0.001	0.674	0.001	0.335	0.000	0.110	0.000	0.062	0.000	0.051	0.000	0.069	0.000	0.040
	21	0.001	0.664	0.000	0.324	0.000	0.098	0.000	0.049	0.000	0.037	0.000	0.057	0.000	0.037
	28	0.001	0.499	0.000	0.243	0.000	0.082	0.000	0.050	0.000	0.041	0.000	0.055	0.000	0.029
	42	0.000	0.509	0.000	0.245	0.000	0.069	0.000	0.042	0.324	0.035	0.000	0.046	0.000	0.028
	50	0.000	0.437	0.000	0.214	0.000	0.067	0.000	0.037	0.000	0.030	0.000	0.042	0.000	0.025

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
	100	0.000	0.320	0.000	0.156	0.000	0.047	0.000	0.024	0.000	0.017	0.000	0.027	0.000	0.018

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)	actual (µg/ L)	TW A (µg/ L)
Pome fruit - 1 application (late)															
R1 - pond	0	0.859		0.545		0.248		0.149		0.101		0.043		NC*	NC*
	1	0.334	0.554	0.212	0.351	0.096	0.160	0.058	0.096	0.039	0.065	0.017	0.028		
	2	0.130	0.388	0.083	0.246	0.038	0.112	0.023	0.067	0.015	0.046	0.006	0.019		
	4	0.021	0.225	0.013	0.142	0.006	0.065	0.004	0.039	0.002	0.026	0.001	0.011		
	7	0.002	0.132	0.002	0.084	0.001	0.038	0.000	0.023	0.000	0.016	0.000	0.007		
	14	0.001	0.067	0.000	0.043	0.000	0.020	0.000	0.012	0.000	0.008	0.000	0.004		
	21	0.000	0.045	0.000	0.029	0.000	0.013	0.000	0.008	0.000	0.005	0.000	0.002		
	28	0.000	0.034	0.000	0.021	0.000	0.010	0.000	0.006	0.000	0.004	0.000	0.002		
	42	0.000	0.023	0.000	0.015	0.000	0.007	0.000	0.004	0.000	0.003	0.000	0.001		
	50	0.000	0.019	0.000	0.012	0.000	0.006	0.000	0.004	0.000	0.002	0.000	0.001		
	100	0.000	0.010	0.000	0.006	0.000	0.003	0.000	0.002	0.000	0.001	0.000	0.001		
R1 - stream	0	14.753		5.143		1.586		0.788		0.478		0.737		NC*	NC*
	1	0.002	2.841	0.001	0.990	0.000	0.305	0.000	0.233	0.000	0.233	0.000	0.233		
	2	0.002	1.421	0.001	0.496	0.000	0.153	0.000	0.117	0.000	0.117	0.000	0.117		
	4	0.001	0.711	0.000	0.248	0.000	0.077	0.000	0.059	0.000	0.059	0.000	0.059		
	7	0.001	0.407	0.000	0.142	0.000	0.044	0.000	0.034	0.000	0.034	0.000	0.034		
	14	0.001	0.221	0.000	0.088	0.000	0.039	0.000	0.028	0.000	0.023	0.000	0.027		
	21	0.000	0.147	0.000	0.059	0.000	0.026	0.000	0.019	0.000	0.016	0.000	0.018		
	28	0.000	0.110	0.000	0.044	0.000	0.019	0.000	0.014	0.000	0.012	0.000	0.014		
	42	0.000	0.076	0.000	0.032	0.000	0.016	0.000	0.012	0.000	0.010	0.000	0.012		
	50	0.000	0.060	0.000	0.022	0.000	0.011	0.000	0.011	0.000	0.010	0.000	0.011		

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)	actual (µg/L)	TWA (µg/L)
		0	4	0	7	0	3	0	0	0	9	0	0		
	100	0.00	0.03	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
		0	2	0	3	0	7	0	5	0	4	0	5		

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R1 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 8 application (late)															
R1 - pond	0	0.547		0.351		0.150		0.089		0.061		0.038		NC *	NC *
	1	0.188	0.365	0.121	0.231	0.052	0.094	0.031	0.055	0.021	0.038	0.013	0.024		
	2	0.066	0.266	0.042	0.169	0.018	0.069	0.011	0.038	0.007	0.028	0.005	0.021		
	4	0.009	0.161	0.006	0.102	0.002	0.041	0.001	0.025	0.001	0.019	0.001	0.014		
	7	0.001	0.096	0.001	0.061	0.000	0.025	0.000	0.015	0.000	0.011	0.000	0.008		
	14	0.064	0.082	0.041	0.052	0.017	0.021	0.009	0.013	0.006	0.009	0.003	0.006		
	21	0.064	0.072	0.041	0.046	0.017	0.019	0.009	0.011	0.006	0.007	0.003	0.005		
	28	0.001	0.062	0.001	0.039	0.000	0.017	0.000	0.010	0.000	0.007	0.000	0.004		
	42	0.192	0.061	0.122	0.039	0.050	0.016	0.028	0.009	0.018	0.006	0.010	0.004		
	50	0.001	0.056	0.001	0.036	0.000	0.015	0.000	0.009	0.000	0.006	0.000	0.004		
	100	0.000	0.046	0.000	0.029	0.000	0.012	0.000	0.007	0.000	0.005	0.000	0.003		
R1 - stream	0	8.517		3.326		0.963		0.482		0.482		0.482		0.425	
	1	0.002	1.665	0.001	0.678	0.000	0.359	0.000	0.359	0.000	0.359	0.000	0.359	0.000	0.093
	2	0.001	0.933	0.001	0.433	0.000	0.237	0.000	0.206	0.000	0.195	0.000	0.205	0.000	0.068
	4	0.001	0.467	0.001	0.217	0.000	0.119	0.000	0.103	0.000	0.098	0.000	0.103	0.000	0.034
	7	0.001	0.267	0.000	0.124	0.000	0.068	0.000	0.059	0.000	0.056	0.000	0.059	0.000	0.019
	14	0.001	0.251	0.000	0.108	0.000	0.048	0.000	0.039	0.000	0.036	0.000	0.039	0.000	0.016
	21	0.475	0.246	0.475	0.103	0.475	0.037	0.000	0.028	0.000	0.025	0.000	0.028	0.112	0.014
	28	0.001	0.185	0.000	0.081	0.000	0.038	0.000	0.029	0.000	0.026	0.000	0.029	0.000	0.013
	42	0.001	0.163	0.000	0.071	0.000	0.032	0.000	0.023	0.000	0.020	0.000	0.023	0.000	0.011
	50	0.001	0.153	0.000	0.068	0.000	0.029	0.000	0.021	0.000	0.017	0.000	0.021	0.000	0.010



**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon  $PEC_{sw}$  values for scenario R1 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
	100	0.000	0.120	0.000	0.051	0.000	0.020	0.000	0.013	0.000	0.010	0.000	0.012	0.000	0.007

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (early)															
R2 - stream	0	43.520		22.951		5.244		2.005		1.009		2.173		NC *	NC *
	1	0.001	3.586	0.001	1.891	0.000	0.432	0.000	0.169	0.000	0.169	0.000	0.179		
	2	0.001	1.794	0.001	0.946	0.000	0.216	0.000	0.085	0.000	0.085	0.000	0.090		
	4	0.001	0.897	0.000	0.473	0.000	0.108	0.000	0.042	0.000	0.042	0.000	0.045		
	7	0.001	0.513	0.000	0.271	0.000	0.062	0.000	0.024	0.000	0.024	0.000	0.026		
	14	0.199	0.261	0.199	0.140	0.199	0.035	0.199	0.016	0.199	0.012	0.199	0.017		
	21	0.000	0.179	0.000	0.098	0.000	0.029	0.000	0.016	0.000	0.012	0.000	0.017		
	28	0.000	0.135	0.000	0.074	0.000	0.022	0.000	0.012	0.000	0.009	0.000	0.013		
	42	0.000	0.090	0.000	0.049	0.000	0.014	0.000	0.008	0.000	0.006	0.000	0.008		
	50	0.000	0.075	0.000	0.041	0.000	0.012	0.000	0.007	0.000	0.005	0.000	0.007		
	100	0.000	0.038	0.000	0.021	0.000	0.006	0.000	0.004	0.000	0.003	0.000	0.004		
Pome fruit - 8 application (early)															
R2 - stream	0	31.866		14.892		3.640		1.208		0.569		1.591		1.591	
	1	0.003	3.285	0.001	1.535	0.000	0.556	0.000	0.556	0.357	0.556	0.000	0.556	0.000	0.164
	2	0.002	1.644	0.001	0.768	0.000	0.299	0.000	0.299	0.001	0.299	0.000	0.299	0.000	0.082
	4	0.002	0.823	0.001	0.385	0.000	0.150	0.000	0.150	0.001	0.150	0.000	0.150	0.000	0.041
	7	0.002	0.553	0.002	0.304	0.000	0.139	0.000	0.103	0.000	0.093	0.000	0.103	0.000	0.043
	14	0.001	0.512	0.001	0.262	0.000	0.096	0.000	0.060	0.000	0.051	0.000	0.060	0.000	0.033
	21	0.001	0.498	0.000	0.248	0.000	0.082	0.000	0.046	0.000	0.037	0.000	0.052	0.000	0.030
	28	0.001	0.470	0.001	0.220	0.000	0.062	0.000	0.035	0.000	0.028	0.000	0.039	0.000	0.024
	42	0.000	0.390	0.000	0.190	0.000	0.057	0.000	0.029	0.000	0.021	0.000	0.033	0.000	0.022

	50	0.00 0	0.38 0	0.00 0	0.18 4	0.00 0	0.05 4	0.00 0	0.02 6	0.00 0	0.01 8	0.00 0	0.03 0	0.00 0	0.02 1
	100	0.00 0	0.25 1	0.00 0	0.12 1	0.00 0	0.03 6	0.00 0	0.01 7	0.00 0	0.01 2	0.00 0	0.02 0	0.00 0	0.01 4

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R2 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (late)															
R2 - stream	0	19.777		6.895		2.127		1.056		0.641		0.988		NC *	NC *
	1	0.001	2.041	0.000	0.711	0.000	0.219	0.000	0.109	0.000	0.066	0.000	0.102		
	2	0.001	1.021	0.000	0.356	0.000	0.110	0.000	0.055	0.000	0.033	0.000	0.051		
	4	0.001	0.511	0.000	0.178	0.000	0.055	0.000	0.027	0.000	0.017	0.000	0.026		
	7	0.000	0.301	0.000	0.111	0.000	0.041	0.000	0.025	0.000	0.019	0.000	0.024		
	14	0.000	0.151	0.000	0.056	0.000	0.020	0.000	0.012	0.000	0.009	0.000	0.012		
	21	0.000	0.101	0.000	0.037	0.000	0.014	0.000	0.008	0.000	0.006	0.000	0.008		
	28	0.000	0.075	0.000	0.028	0.000	0.010	0.000	0.006	0.000	0.005	0.000	0.006		
	42	0.000	0.050	0.000	0.019	0.000	0.007	0.000	0.004	0.000	0.003	0.000	0.004		
	50	0.000	0.042	0.000	0.016	0.000	0.006	0.000	0.003	0.000	0.003	0.000	0.003		
	100	0.000	0.021	0.000	0.008	0.000	0.003	0.000	0.002	0.000	0.001	0.000	0.002		
Pome fruit - 8 application (late)															
R2 - stream	0	11.418		4.458		1.290		0.585		0.332		0.570		0.570	
	1	0.001	1.183	0.000	0.462	0.000	0.187	0.000	0.187	0.000	0.187	0.000	0.187	0.000	0.059
	2	0.001	0.592	0.000	0.231	0.000	0.094	0.000	0.094	0.000	0.094	0.000	0.094	0.000	0.030
	4	0.001	0.328	0.000	0.148	0.000	0.067	0.000	0.049	0.000	0.047	0.000	0.048	0.000	0.022
	7	0.000	0.188	0.000	0.085	0.000	0.038	0.000	0.028	0.000	0.027	0.000	0.028	0.000	0.013
	14	0.000	0.178	0.000	0.075	0.000	0.029	0.000	0.018	0.000	0.015	0.000	0.018	0.000	0.011
	21	0.000	0.166	0.000	0.065	0.000	0.019	0.000	0.012	0.000	0.011	0.000	0.012	0.000	0.008
	28	0.000	0.165	0.000	0.065	0.000	0.019	0.000	0.011	0.000	0.011	0.000	0.011	0.000	0.008
	42	0.000	0.110	0.000	0.043	0.000	0.013	0.000	0.009	0.000	0.009	0.000	0.009	0.000	0.006

	50	0.00 0	0.09 3	0.00 0	0.03 6	0.00 0	0.01 1	0.00 0	0.00 7	0.00 0	0.00 7	0.00 0	0.00 7	0.00 0	0.00 5
	100	0.06 1	0.07 2	0.06 1	0.02 9	0.06 1	0.01 0	0.06 1	0.00 5	0.06 1	0.00 5	0.06 1	0.00 5	0.01 4	0.00 4

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (early)															
R3 - stream	0	46.479		24.511		5.601		2.141		1.078		2.321		NC *	NC *
	1	0.045	13.458	0.023	7.097	0.005	1.621	0.002	0.620	0.001	0.600	0.002	0.672		
	2	0.020	6.741	0.010	3.554	0.002	0.812	0.001	0.318	0.000	0.318	0.001	0.336		
	4	0.015	3.379	0.007	1.782	0.002	0.407	0.001	0.160	0.000	0.160	0.001	0.169		
	7	0.009	1.936	0.005	1.021	0.001	0.233	0.000	0.092	0.000	0.092	0.000	0.097		
	14	0.004	0.971	0.002	0.512	0.001	0.117	0.000	0.046	0.000	0.046	0.000	0.048		
	21	0.003	0.679	0.002	0.372	0.001	0.109	0.000	0.061	0.000	0.061	0.000	0.063		
	28	0.002	0.510	0.001	0.280	0.001	0.082	0.000	0.045	0.000	0.045	0.000	0.047		
	42	0.001	0.340	0.000	0.187	0.000	0.055	0.000	0.030	0.000	0.030	0.000	0.032		
	50	0.001	0.286	0.000	0.157	0.000	0.046	0.000	0.026	0.000	0.026	0.000	0.027		
100	0.000	0.143	0.000	0.079	0.000	0.023	0.000	0.013	0.000	0.013	0.000	0.013			
Pome fruit - 8 application (early)															
R3 - stream	0	33.581		15.694		3.836		1.554		1.554		1.677		1.677	
	1	0.052	9.799	0.024	4.579	0.006	1.392	0.004	1.392	0.004	1.392	0.002	1.392	0.002	0.489
	2	0.024	4.913	0.011	2.334	0.003	0.739	0.019	0.739	0.092	0.739	0.001	0.739	0.001	0.273
	4	0.018	2.800	0.008	1.506	0.002	0.648	0.003	0.463	0.002	0.412	0.001	0.492	0.001	0.208
	7	0.013	1.608	0.006	0.865	0.002	0.372	0.002	0.266	0.002	0.237	0.001	0.282	0.001	0.119
	14	0.006	1.502	0.003	0.758	0.001	0.265	0.001	0.159	0.001	0.130	0.000	0.176	0.000	0.095
	21	0.004	1.466	0.002	0.722	0.001	0.230	0.001	0.124	0.000	0.095	0.000	0.140	0.000	0.086
	28	0.003	1.102	0.001	0.543	0.000	0.173	0.011	0.093	0.005	0.072	0.000	0.106	0.000	0.065
42	0.002	0.934	0.001	0.437	0.000	0.116	0.024	0.062	0.011	0.048	0.000	0.071	0.000	0.047	

	50	0.00 1	0.78 8	0.00 1	0.38 4	0.00 0	0.11 7	0.00 0	0.05 9	0.00 0	0.04 3	0.00 0	0.06 8	0.00 0	0.04 5
	100	0.00 1	0.78 7	0.00 0	0.37 6	0.00 0	0.10 3	0.00 0	0.04 4	0.00 0	0.02 8	0.00 0	0.05 4	0.00 0	0.04 2

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R3 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (late)															
R3 - stream	0	20.797		7.251		2.236		1.111		0.674		1.039		NC *	NC *
	1	0.027	5.903	0.009	2.058	0.003	0.635	0.001	0.315	0.001	0.191	0.001	0.295		
	2	0.009	2.957	0.003	1.031	0.001	0.318	0.000	0.158	0.000	0.096	0.000	0.148		
	4	0.006	1.482	0.002	0.517	0.001	0.159	0.000	0.079	0.000	0.048	0.000	0.074		
	7	0.004	0.849	0.001	0.296	0.000	0.091	0.000	0.045	0.000	0.028	0.000	0.042		
	14	0.002	0.426	0.001	0.148	0.000	0.046	0.000	0.023	0.000	0.014	0.000	0.021		
	21	0.001	0.284	0.000	0.099	0.000	0.031	0.000	0.015	0.000	0.009	0.000	0.014		
	28	0.001	0.214	0.000	0.074	0.000	0.023	0.000	0.011	0.000	0.007	0.000	0.011		
	42	0.000	0.143	0.000	0.050	0.000	0.015	0.000	0.008	0.000	0.005	0.000	0.007		
	50	0.000	0.120	0.000	0.042	0.000	0.013	0.000	0.006	0.000	0.004	0.000	0.006		
	100	0.000	0.060	0.000	0.021	0.000	0.006	0.000	0.003	0.000	0.002	0.000	0.003		
Pome fruit - 8 application (late)															
R3 - stream	0	12.011		4.690		1.359		0.835		0.647		0.824		0.600	
	1	0.016	3.408	0.006	1.331	0.017	0.390	0.017	0.379	0.017	0.375	0.017	0.379	0.001	0.170
	2	0.009	1.708	0.004	0.667	0.001	0.246	0.001	0.246	0.001	0.246	0.001	0.246	0.000	0.086
	4	0.007	0.907	0.003	0.429	0.001	0.212	0.001	0.164	0.001	0.146	0.001	0.163	0.000	0.067
	7	0.006	0.521	0.003	0.247	0.001	0.122	0.001	0.094	0.001	0.084	0.001	0.094	0.000	0.039
	14	0.003	0.506	0.001	0.231	0.000	0.107	0.000	0.079	0.000	0.069	0.000	0.078	0.000	0.035
	21	0.002	0.487	0.001	0.213	0.000	0.087	0.000	0.065	0.000	0.055	0.000	0.065	0.000	0.031
	28	0.001	0.478	0.001	0.204	0.000	0.079	0.000	0.051	0.000	0.041	0.000	0.050	0.000	0.029
	42	0.000	0.392	0.000	0.164	0.000	0.061	0.000	0.038	0.000	0.030	0.000	0.037	0.000	0.023



	50	0.00 0	0.33 0	0.00 0	0.13 8	0.00 0	0.05 1	0.00 0	0.03 2	0.00 0	0.02 5	0.00 0	0.03 1	0.00 0	0.01 9
	100	0.00 0	0.24 0	0.00 0	0.10 1	0.00 1	0.03 8	0.00 0	0.02 4	0.00 0	0.01 9	0.00 0	0.02 3	0.00 0	0.01 4

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 1 and 8 early applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (early)															
R4 - stream	0	33.042		17.425		3.982		1.522		0.766		1.650		NC *	NC *
	1	0.004	6.232	0.002	3.286	0.000	0.751	0.000	0.309	0.000	0.309	0.000	0.311		
	2	0.004	3.118	0.002	1.644	0.000	0.376	0.000	0.235	0.000	0.235	0.000	0.235		
	4	0.003	1.560	0.001	0.823	0.000	0.188	0.000	0.119	0.000	0.119	0.000	0.119		
	7	0.002	0.893	0.001	0.471	0.000	0.108	0.000	0.068	0.000	0.068	0.000	0.068		
	14	0.001	0.465	0.001	0.253	0.000	0.071	0.000	0.047	0.000	0.047	0.000	0.047		
	21	0.000	0.310	0.000	0.169	0.000	0.048	0.000	0.032	0.000	0.032	0.000	0.032		
	28	0.000	0.239	0.000	0.133	0.000	0.042	0.000	0.032	0.000	0.032	0.000	0.032		
	42	0.000	0.171	0.000	0.100	0.000	0.040	0.000	0.029	0.000	0.029	0.000	0.029		
	50	0.000	0.143	0.000	0.084	0.000	0.033	0.000	0.024	0.000	0.024	0.000	0.024		
	100	0.000	0.072	0.000	0.043	0.000	0.017	0.000	0.013	0.000	0.013	0.000	0.013		
Pome fruit - 8 application (early)															
R4 - stream	0	23.813		11.129		2.721		1.999		1.999		1.999		1.189	
	1	0.005	4.484	0.002	2.096	0.001	1.914	0.340	1.914	0.340	1.914	0.340	1.914	0.000	0.454
	2	0.004	2.244	0.002	1.454	0.001	1.454	0.002	1.454	0.002	1.454	0.002	1.454	0.000	0.338
	4	0.472	1.162	0.471	0.736	0.471	0.736	0.002	0.736	0.002	0.736	0.002	0.736	0.106	0.171
	7	0.003	0.722	0.002	0.422	0.001	0.421	0.001	0.421	0.001	0.421	0.001	0.421	0.000	0.098
	14	0.002	0.682	0.001	0.355	0.001	0.285	0.001	0.270	0.001	0.266	0.001	0.272	0.000	0.070
	21	0.001	0.586	0.001	0.298	0.000	0.205	0.001	0.185	0.001	0.180	0.001	0.189	0.000	0.053
	28	0.001	0.564	0.001	0.318	0.000	0.192	0.000	0.165	0.000	0.157	0.000	0.169	0.000	0.052
	42	0.000	0.447	0.000	0.262	0.000	0.140	0.000	0.114	0.000	0.107	0.000	0.118	0.000	0.040

	50	0.00 0	0.43 0	0.00 0	0.24 6	0.00 0	0.12 4	0.00 1	0.09 8	0.00 1	0.09 1	0.00 1	0.10 2	0.00 0	0.03 7
	100	0.00 0	0.36 2	0.00 0	0.20 0	0.00 0	0.09 3	0.00 0	0.07 0	0.00 0	0.06 4	0.00 0	0.07 4	0.00 0	0.02 8

\* NC = not calculated, runoff is not a relevant entry route

**Step 3 and Step 4 (considering spray drift mitigation buffers) actual and time-weighted average dithianon PEC<sub>sw</sub> values for scenario R4 following 1 and 8 late applications to pome fruit**

Scenario	Time after max. (d)	Step 3 edge of field		Step 4											
				10 m buffer		20 m buffer		30 m buffer		40 m buffer		95% drift reduction		95% drift reduction & 20m runoff buffer	
		actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)	actual (µg/L)	TW A (µg/L)
Pome fruit - 1 application (late)															
R4 - stream	0	14.751		5.143		1.586		0.788		0.478		0.737		NC *	NC *
	1	0.002	2.728	0.001	0.951	0.000	0.293	0.000	0.170	0.000	0.170	0.000	0.171		
	2	0.002	1.365	0.000	0.476	0.000	0.147	0.000	0.086	0.000	0.086	0.000	0.086		
	4	0.230	0.698	0.230	0.253	0.229	0.088	0.229	0.052	0.229	0.043	0.229	0.050		
	7	0.001	0.415	0.000	0.161	0.000	0.066	0.000	0.045	0.000	0.037	0.000	0.044		
	14	0.000	0.208	0.000	0.081	0.000	0.033	0.000	0.023	0.000	0.020	0.000	0.022		
	21	0.000	0.144	0.000	0.059	0.000	0.027	0.000	0.020	0.000	0.018	0.000	0.020		
	28	0.000	0.110	0.000	0.046	0.000	0.022	0.000	0.017	0.000	0.015	0.000	0.017		
	42	0.000	0.074	0.000	0.032	0.000	0.016	0.000	0.013	0.000	0.011	0.000	0.012		
	50	0.000	0.063	0.000	0.027	0.000	0.014	0.000	0.011	0.000	0.010	0.000	0.011		
100	0.000	0.031	0.000	0.014	0.000	0.007	0.000	0.005	0.000	0.005	0.000	0.005			
Pome fruit - 8 application (late)															
R4 - stream	0	8.517		3.325		0.963		0.559		0.559		0.559		0.425	
	1	0.002	1.576	0.001	0.615	0.000	0.498	0.058	0.498	0.058	0.498	0.058	0.498	0.000	0.118
	2	0.002	0.799	0.001	0.327	0.000	0.255	0.001	0.255	0.001	0.255	0.001	0.255	0.000	0.061
	4	0.001	0.464	0.001	0.223	0.000	0.175	0.001	0.175	0.001	0.175	0.001	0.175	0.000	0.040
	7	0.001	0.319	0.001	0.185	0.000	0.125	0.001	0.110	0.001	0.106	0.001	0.110	0.000	0.034
	14	0.001	0.270	0.001	0.136	0.000	0.079	0.001	0.063	0.001	0.061	0.001	0.063	0.000	0.023

21	0.00 1	0.25 3	0.00 1	0.12 1	0.00 0	0.06 6	0.00 0	0.05 7	0.00 0	0.05 4	0.00 0	0.05 7	0.00 0	0.01 9
28	0.26 8	0.20 1	0.26 7	0.10 1	0.00 0	0.05 5	0.00 0	0.04 5	0.00 0	0.04 2	0.00 0	0.04 5	0.05 7	0.01 7
42	0.00 1	0.21 2	0.00 0	0.10 1	0.00 0	0.05 2	0.04 1	0.04 3	0.04 1	0.04 0	0.04 1	0.04 3	0.00 0	0.01 6
50	0.00 0	0.21 2	0.00 0	0.10 0	0.00 1	0.04 9	0.00 0	0.04 0	0.00 0	0.03 6	0.00 0	0.04 0	0.00 0	0.01 6
100	0.00 0	0.14 7	0.00 0	0.07 2	0.00 0	0.03 8	0.00 0	0.03 0	0.00 0	0.02 7	0.00 0	0.03 0	0.00 0	0.01 2

\* NC = not calculated, runoff is not a relevant entry route

### PEC<sub>sed</sub> (sediment): Dithianon

#### FOCUS Step 1 and Step 2 PEC<sub>sed</sub> values for dithianon following 1 or 8 applications of Delan 70 WG to vines with early application timing

Time after max. peak (d)	Step 1		Step 2							
			Vines, early, 1 application				Vines, early, 8 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	1160.00	---	121.61	---	228.52	---	300.715	---	582.454	---
1	246.551	703.330	119.729	120.670	226.561	227.539	298.186	299.451	579.730	581.092
2	51.021	413.725	104.415	116.371	197.583	219.806	260.046	289.283	505.578	561.873
4	2.185	214.613	79.413	103.929	150.271	196.462	197.777	258.566	384.516	502.426
7	0.019	122.832	52.672	87.344	99.670	165.165	131.179	217.377	255.037	422.465
14	0.000	61.417	20.208	60.642	38.239	114.694	50.328	150.952	97.847	293.401
21	0.000	40.945	7.753	44.769	14.671	84.676	19.309	111.445	37.539	216.617
28	0.000	30.709	2.974	34.825	5.628	65.870	7.408	86.694	14.402	168.510
42	0.000	20.472	0.438	23.659	0.829	44.750	1.090	58.897	2.120	114.480
50	0.000	17.197	0.147	19.916	0.277	37.671	0.365	49.579	0.709	96.370
100	0.000	8.598	0.000	9.969	0.000	18.856	0.000	24.816	0.001	48.237

#### FOCUS Step 1 and Step 2 PEC<sub>sed</sub> values for dithianon following 1 or 8 applications of Delan 70 WG to vines with late application timing

Time after max. peak (d)	Step 1		Step 2							
			Vines, late, 1 application				Vines, late, 8 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	1160.00	---	132.83	---	177.37	---	286.500	---	403.891	---
1	259.344	709.727	127.389	130.109	171.902	174.637	279.977	283.239	397.287	400.589
2	53.668	420.144	111.095	124.675	149.915	167.773	244.166	272.655	346.471	386.234
4	2.298	218.224	84.493	111.007	114.017	149.563	185.700	243.295	263.508	344.903
7	0.020	124.906	56.042	93.178	75.624	125.603	123.169	204.399	174.776	289.853
14	0.000	62.454	21.501	64.644	29.014	87.166	47.254	141.882	67.054	201.236
21	0.000	41.636	8.249	47.714	11.131	64.343	18.129	104.738	25.726	148.560
28	0.000	31.227	3.165	37.115	4.271	50.050	6.956	81.474	9.870	115.564
42	0.000	20.818	0.466	25.213	0.629	34.001	1.024	55.350	1.453	78.509
50	0.000	17.487	0.156	21.225	0.210	28.622	0.343	46.593	0.486	66.089
100	0.000	8.744	0.000	10.624	0.000	14.327	0.000	23.322	0.001	33.080

**FOCUS Step 1 and Step 2 PEC<sub>sed</sub> values for dithianon following 1 or 12 applications of Delan 70 WG to pome fruit with early application timing**

Time after max. peak (d)	Step 1		Step 2							
			Pome fruit, early, 1 application				Pome fruit, early, 12 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	1090.00	---	282.77	---	416.40	---	534.449	---	894.169	---
1	290.779	689.191	264.339	273.553	397.879	407.140	512.712	523.581	872.183	883.176
2	60.173	417.788	230.529	260.494	346.988	389.787	447.133	501.752	760.625	849.790
4	2.577	218.035	175.328	231.240	263.901	346.906	340.066	446.761	578.491	758.118
7	0.023	124.823	116.289	193.859	175.037	291.135	225.555	375.008	383.695	636.862
14	0.000	62.412	44.615	134.396	67.154	201.961	86.535	260.174	147.207	442.050
21	0.000	41.608	17.117	99.180	25.764	149.065	33.200	192.036	56.477	326.318
28	0.000	31.206	6.567	77.142	9.885	115.949	12.737	149.375	21.668	253.837
42	0.000	20.804	0.967	52.404	1.455	78.768	1.875	101.476	3.189	172.444
50	0.000	17.476	0.323	44.114	0.487	66.307	0.627	85.423	1.067	145.164
100	0.000	8.738	0.000	22.080	0.001	33.189	0.001	42.757	0.001	72.660

**FOCUS Step 1 and Step 2 PEC<sub>sed</sub> values for dithianon following 1 or 12 applications of Delan 70 WG to pome fruit with late application timing**

Time after max. peak (d)	Step 1		Step 2							
			Pome fruit, late, 1 application				Pome fruit, late, 12 applications			
			North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	1090.00	---	180.55	---	230.66	---	337.793	---	472.688	---
1	260.458	674.031	170.601	175.574	220.679	225.668	329.243	333.518	464.045	468.366
2	53.899	402.576	148.780	167.632	192.453	216.117	287.131	320.853	404.690	451.367
4	2.308	209.475	113.154	148.996	146.369	192.370	218.377	286.216	307.786	402.975
7	0.021	119.908	75.052	124.975	97.082	161.454	144.842	240.429	204.145	338.624
14	0.000	59.955	28.794	86.668	37.246	112.005	55.570	166.880	78.321	235.084
21	0.000	39.970	11.047	63.963	14.290	82.670	21.320	123.189	30.048	173.545
28	0.000	29.977	4.238	49.752	5.482	64.304	8.179	95.826	11.528	134.999
42	0.000	19.985	0.624	33.798	0.807	43.684	1.204	65.100	1.697	91.713
50	0.000	16.787	0.209	28.451	0.270	36.773	0.403	54.801	0.568	77.204
100	0.000	8.394	0.000	14.241	0.000	18.406	0.000	27.430	0.001	38.643

Metabolite CL 1017911

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 330.33 g/mol  
 Water solubility (mg/L): default value of 1000 mg/L  
 Soil or water metabolite: Water only  
 Koc: default  $K_{oc}$  of 10 mL/g  
 DT<sub>50</sub> soil (d): default value of 1000 days  
 DT<sub>50</sub> water/sediment system: 6.10 days  
 DT<sub>50</sub> water (d): 6.10 days  
 DT<sub>50</sub> sediment (d): 6.10 days  
 Crop interception (%): not applicable  
 Maximum occurrence observed:  
 Soil: 0.00001%  
 Water: 52.01%  
 Sediment: 3.6%

Application rate

Metabolite not applied, but formed from parent according to maximum occurrence.

Main routes of entry

Spray drift of the parent

**PEC<sub>sw</sub> (surface water): CL 1017911 (Step 2 presented)**

**PEC<sub>sw</sub> (surface water) Step 2 level: Actual and time-weighted average surface water concentration of CL 1017911 following 1 or 8 applications to vines with early application timing**

Time after max. peak (d)	Step 2							
	Vines, early, 1 application				Vines, early, 8 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	3.0583	---	3.0583	---	4.6517	---	4.6517	---
1	2.7059	2.8821	2.7059	2.8821	4.1320	4.3918	4.1320	4.3918
2	2.4151	2.7213	2.4151	2.7213	3.6881	4.1509	3.6881	4.1509
4	1.9242	2.4420	1.9242	2.4420	2.9383	3.7267	2.9383	3.7267
7	1.3623	2.0925	1.3623	2.0925	2.0804	3.1940	2.0804	3.1940
14	0.6150	1.5166	0.6150	1.5166	0.9391	2.3152	0.9391	2.3152
21	0.2776	1.1526	0.2776	1.1526	0.4239	1.7596	0.4239	1.7596
28	0.1253	0.9123	0.1253	0.9123	0.1913	1.3929	0.1913	1.3929
42	0.0255	0.6292	0.0255	0.6292	0.0390	0.9605	0.0390	0.9605
50	0.0103	0.5312	0.0103	0.5312	0.0157	0.8110	0.0157	0.8110
100	0.0000	0.2665	0.0000	0.2665	0.0001	0.4069	0.0001	0.4069

**PEC<sub>sw</sub> (surface water) Step 2 level: Actual and time-weighted average surface water concentration of CL 1017911 following 1 or 8 applications to vines with late application timing**

Time after max. peak (d)	Step 2							
	Vines, late, 1 application				Vines, late, 8 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	9.0968	---	9.0968	---	12.678	---	12.678	---
1	8.0485	8.5726	8.0485	8.5726	11.261	11.969	11.261	11.969
2	7.1837	8.0943	7.1837	8.0943	10.051	11.313	10.051	11.313
4	5.7233	7.2636	5.7233	7.2636	8.0081	10.157	8.0081	10.157
7	4.0522	6.2240	4.0522	6.2240	5.6699	8.7050	5.6699	8.7050
14	1.8291	4.5109	1.8291	4.5109	2.5593	6.3099	2.5593	6.3099
21	0.8257	3.4283	0.8257	3.4283	1.1553	4.7956	1.1553	4.7956
28	0.3727	2.7137	0.3727	2.7137	0.5215	3.7961	0.5215	3.7961
42	0.0759	1.8714	0.0759	1.8714	0.1063	2.6178	0.1063	2.6178
50	0.0306	1.5800	0.0306	1.5800	0.0428	2.2102	0.0428	2.2102
100	0.0001	0.7927	0.0001	0.7927	0.0001	1.1088	0.0001	1.1088

**PEC<sub>sw</sub> (surface water) Step 2 level: Actual and time-weighted average surface water concentration of CL 1017911 following 1 or 12 applications to pome fruit with early application timing**

Time after max. peak (d)	Step 2							
	Pome fruit, early, 1 application				Pome fruit, early, 12 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	31.016	---	31.016	---	42.893	---	42.893	---
1	27.442	29.229	27.442	29.229	38.101	40.497	38.101	40.497
2	24.493	27.598	24.493	27.598	34.007	38.275	34.007	38.275
4	19.514	24.766	19.514	24.766	27.094	34.364	27.094	34.364
7	13.816	21.221	13.816	21.221	19.183	29.452	19.183	29.452
14	6.2366	15.380	6.2366	15.380	8.6591	21.349	8.6591	21.349
21	2.8152	11.689	2.8152	11.689	3.9087	16.225	3.9087	16.225
28	1.2708	9.2527	1.2708	9.2527	1.7644	12.844	1.7644	12.844
42	0.2589	6.3807	0.2589	6.3807	0.3595	8.8571	0.3595	8.8571
50	0.1043	5.3870	0.1043	5.3870	0.1448	7.4778	0.1448	7.4778
100	0.0004	2.7027	0.0004	2.7027	0.0005	3.7516	0.0005	3.7516

**PEC<sub>sw</sub> (surface water) Step 2 level: Actual and time-weighted average surface water concentration of CL1017911 following 1 or 12 applications to pome fruit with late application timing**

Time after max. peak (d)	Step 2							
	Pome fruit, late, 1 application				Pome fruit, late, 12 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)	Actual (µg/L)	TWA (µg/L)
0	16.705	---	16.705	---	16.694	---	16.694	---
1	14.780	15.742	14.780	15.742	14.828	15.761	14.828	15.761
2	13.192	14.864	13.192	14.864	13.235	14.896	13.235	14.896
4	10.510	13.338	10.510	13.338	10.545	13.374	10.545	13.374
7	7.4413	11.429	7.4413	11.429	7.4659	11.463	7.4659	11.463
14	3.3589	8.2836	3.3589	8.2836	3.3701	8.3087	3.3701	8.3087
21	1.5162	6.2955	1.5162	6.2955	1.5212	6.3147	1.5212	6.3147
28	0.6844	4.9833	0.6844	4.9833	0.6867	4.9986	0.6867	4.9986
42	0.1395	3.4365	0.1395	3.4365	0.1399	3.4471	0.1399	3.4471
50	0.0562	2.9014	0.0562	2.9014	0.0564	2.9103	0.0564	2.9103
100	0.0002	1.4556	0.0002	1.4556	0.0002	1.4601	0.0002	1.4601



**PEC<sub>sed</sub> (sediment): CL 1017911 (Step 2)**

**PEC<sub>sed</sub> (sediment) Step 2 level: Actual and time-weighted average sediment concentration of CL 1017911 following 1 and 8 applications to vines with early application timing**

Time after max. peak (d)	Step 2							
	Vines, early, 1 application				Vines, early, 8 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	14.847	---	14.847	---	23.759	---	23.759	---
1	14.225	14.536	14.225	14.536	22.023	22.891	22.023	22.891
2	12.966	14.066	12.966	14.066	19.884	21.922	19.884	21.922
4	10.791	13.025	10.791	13.025	16.478	20.121	16.478	20.121
7	7.6735	11.366	7.6735	11.366	11.718	17.489	11.718	17.489
14	3.4638	8.3319	3.4638	8.3319	5.2894	12.790	5.2894	12.790
21	1.5635	6.3518	1.5635	6.3518	2.3876	9.7438	2.3876	9.7438
28	0.7058	5.0337	0.7058	5.0337	1.0778	7.7200	1.0778	7.7200
42	0.1438	3.4737	0.1438	3.4737	0.2196	5.3266	0.2196	5.3266
50	0.0579	2.9330	0.0579	2.9330	0.0885	4.4975	0.0885	4.4975
100	0.0002	1.4716	0.0002	1.4716	0.0003	2.2565	0.0003	2.2565

**PEC<sub>sed</sub> (sediment) Step 2 level: Actual and time-weighted average sediment concentration of CL 1017911 following 1 and 8 applications to vines with late application timing**

Time after max. peak (d)	Step 2							
	Vines, late, 1 application				Vines, late, 8 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	44.162	---	44.162	---	64.752	---	64.752	---
1	42.311	43.237	42.311	43.237	60.021	62.387	60.021	62.387
2	38.567	41.838	38.567	41.838	54.190	59.746	54.190	59.746
4	32.096	38.741	32.096	38.741	44.908	54.839	44.908	54.839
7	22.824	33.806	22.824	33.806	31.936	47.663	31.936	47.663
14	10.303	24.783	10.303	24.783	14.416	34.857	14.416	34.857
21	4.6506	18.893	4.6506	18.893	6.5071	26.555	6.5071	26.555
28	2.0993	14.973	2.0993	14.973	2.9373	21.040	2.9373	21.040
42	0.4277	10.332	0.4277	10.332	0.5985	14.517	0.5985	14.517
50	0.1723	8.7241	0.1723	8.7241	0.2411	12.257	0.2411	12.257
100	0.0006	4.3772	0.0006	4.3772	0.0008	6.1498	0.0008	6.1498

**PEC<sub>sed</sub> (sediment) Step 2 level: Actual and time-weighted average sediment concentration of CL 1017911 following 1 or 12 applications to pome fruit with early application timing**

Time after max. peak (d)	Step 2							
	Pome fruit, early, 1 application				Pome fruit, early, 12 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	150.57	---	150.57	---	219.10	---	219.10	---
1	144.26	147.42	144.26	147.42	203.08	211.09	203.08	211.09
2	131.50	142.65	131.50	142.65	183.35	202.15	183.35	202.15
4	109.43	132.09	109.43	132.09	151.94	185.54	151.94	185.54
7	77.822	115.27	77.822	115.27	108.05	161.26	108.05	161.26
14	35.128	84.499	35.128	84.499	48.773	117.93	48.773	117.93
21	15.857	64.418	15.857	64.418	22.016	89.847	22.016	89.847
28	7.1576	51.050	7.1576	51.050	9.9379	71.186	9.9379	71.186
42	1.4584	35.229	1.4584	35.229	2.0249	49.117	2.0249	49.117
50	0.5876	29.746	0.5876	29.746	0.8159	41.471	0.8159	41.471
100	0.0020	14.925	0.0020	14.925	0.0028	20.807	0.0028	20.807

**PEC<sub>sed</sub> (sediment) Step 2 level: Actual and time-weighted average sediment concentration of CL 1017911 following 1 or 12 applications to pome fruit with late application timing**

Time after max. peak (d)	Step 2							
	Pome fruit, late, 1 application				Pome fruit, late, 12 applications			
	North Europe		South Europe		North Europe		South Europe	
	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)	Actual (µg/kg)	TWA (µg/kg)
0	81.967	---	81.967	---	85.271	---	85.271	---
1	77.698	79.398	77.698	79.398	79.037	82.154	79.037	82.154
2	70.823	76.829	70.823	76.829	71.357	78.675	71.357	78.675
4	58.939	71.143	58.939	71.143	59.134	72.212	59.134	72.212
7	41.913	62.080	41.913	62.080	42.052	62.762	42.052	62.762
14	18.920	45.510	18.920	45.510	18.982	45.899	18.982	45.899
21	8.5401	34.694	8.5401	34.694	8.5684	34.968	8.5684	34.968
28	3.8550	27.495	3.8550	27.495	3.8677	27.705	3.8677	27.705
42	0.7855	18.974	0.7855	18.974	0.7881	19.116	0.7881	19.116
50	0.3165	16.021	0.3165	16.021	0.3175	16.140	0.3175	16.140
100	0.0011	8.0381	0.0011	8.0381	0.0011	8.0980	0.0011	8.0980

Metabolite Phthalic Acid

Parameters used in FOCUSsw step 1 and 2

No data, data required

Application rate

Main routes of entry

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter )

PEC<sub>gw</sub> values were calculated for dithianon and the soil photolysis metabolite phthalic acid

Models: FOCUS PEARL version 3.3.3 and FOCUS MACRO version 4.4.2

Crops: Grape vines and Pome fruit

#### Dithianon

Molecular weight: 296.3 g/mol

DT<sub>50,soil</sub> 33.3 d (Longest laboratory DT<sub>50</sub> -normalisation to pF2, studies conducted at 20°C).

Water solubility : 0.3754 mg/L

K<sub>OC</sub>: 3627 mL/g, arithmetic mean (N=6),  $1/n = 0.9^*$ .

#### Phthalic Acid

No data, data required

Application rate

Grape vines: 8 applications at 560 g a.s./ha, with 50% crop interception (first leaves), 7-day interval

Pome fruit: 12 applications at 525 g a.s./ha, with 50% crop interception (without leaves), 7-day interval

Phthalic acid was simulated independently from dithianon. Soil loading was calculated by assuming the maximum formation in soil (16%) after each dithianon application and a MW correction (0.561).

\* default value 0.9 was used instead of 1. However, no influence is expected on PEC<sub>gw</sub> due to the strong adsorption of dithianon.

PEC<sub>(gw)</sub>

80<sup>th</sup> percentile concentration

Dithianon: All values were <0.001 µg/L in all scenarios for grape vines and pome fruit

### PEC(gw) - FOCUS modelling results: 80<sup>th</sup> percentile PEC<sub>gw</sub> values for dithianon

Model	Scenario	Vines (grape vines)		Apple (pome fruit)	
		Dithianon (µg/L)		Dithianon (µg/L)	
MACRO	Châteaudun	<0.001		<0.001	
PEARL	Châteaudun	<0.001		<0.001	
	Hamburg	<0.001		<0.001	
	Jokioinen	---		<0.001	
	Kremsmünster	<0.001		<0.001	
	Okehampton	---		<0.001	
	Piacenza	<0.001		<0.001	
	Porto	<0.001		<0.001	
	Sevilla	<0.001		<0.001	
	Thiva	<0.001		<0.001	

<sup>1</sup> There is not a defined FOCUS scenario for this crop at this location.

### 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	active substance: $1.01 \times 10^{-3}$ mol/Einstein
Photochemical oxidative degradation in air ‡	DT <sub>50</sub> of < 6.3 h derived by the Atkinson model (v. 1.89). Hydroxyl-radical concentration of $1.5 \times 10^6$ radicals/cm <sup>3</sup> over a 12 hour day
Volatilisation ‡	from plant surfaces (BBA guideline): No data
	from soil surfaces (BBA guideline): No data
Metabolites	None

### PEC (air)

Method of calculation	Volatilization highly unlikely, if present in atmosphere would rapidly degrade by reaction with hydroxyl radicals, therefore no calculation performed.
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### PEC<sub>(a)</sub>

Maximum concentration	not calculated
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### Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: provisionally dithianon, phthalic acid (soil photolysis); however, a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding soil contamination  Groundwater: provisionally dithianon, phthalic acid
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(soil photolysis); however, a data gap was identified for the identification/quantification of potential soil metabolites that would trigger further assessment regarding groundwater contamination

Surface water: dithianon, phthalic acid (soil and aqueous photolysis), CL 1017911, phthalaldehyde (aqueous photolysis), 1,2-benzenedimethanol (aqueous photolysis), (provisional, as a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding surface water contamination via runoff and drainage)

Sediment: dithianon (provisional, as a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding sediment contamination via runoff and drainage)

Air: dithianon

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

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

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

Candidate for R53

## Effects on Non Target Species

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

Species	Test substance	Time scale	End point (mg as/kg bw/day)	End point (mg as/kg feed)
Birds ‡				
<i>C. virginianus</i>	Dithianon	Acute oral toxicity	LD <sub>50</sub> = 309	not applicable
<i>A. platyrhynchos</i>	Dithianon	Acute oral toxicity	LD <sub>50</sub> > 2000	not applicable
<i>C. virginianus</i>	Dithianon	Short-term dietary toxicity	LC <sub>50</sub> > 1198.5	LC <sub>50</sub> > 5200 NOEC = 1300
<i>A. platyrhynchos</i>	Dithianon	Short-term dietary toxicity	LC <sub>50</sub> > 790	LC <sub>50</sub> > 5000 NOEC = 568
<i>C. virginianus</i>	Dithianon	sub-chronic toxicity and reproduction	NOEC = 22.8	NOEC = 345
Mammals ‡				
Rat	Dithianon	Acute oral toxicity	LD <sub>50</sub> > 300 < 500	not applicable
Rabbit	Dithianon	Teratogenicity study	NOEAE <sub>Ldevelopmental</sub> = 25 *  Based on effects on pre- and post-implantation losses at 40 mg a.s./kg bw	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

\*Lower endpoint (25 mg a.s./kg bw/d based on prenatal effects in rabbit) derived from developmental studies, from single gavage exposure.

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

**Pome fruit** (12 appl. with a min spray interval of 7 days and max single appl. rate of 0.525 kg a.s./ha)

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	28.39	10.88	10
Insectivorous bird	Short-term	15.83	50	10
Insectivorous bird	Long-term	15.83	<b>1.44</b>	5
Fish-eating bird	Long-term	0.033	690.9	5
Earthworm-eating bird	Long-term	0.536	42.5	5
Drinking water consumption of small insectivorous bird	Acute	0.024	12 875	10
Higher tier refinement (Birds) <sup>1)</sup>				
<b>Pome fruit (Northern Europe)</b>				
Great tit (insectivorous)	Long-term	9.7	<b>2.35</b>	5
Serpin (granivorous)	Long-term	4.61	<b>4.95</b>	5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Chaffinch(omnivorous)	Long-term	7.64	<b>2.99</b>	5
<b>Pome fruit (Southern Europe)</b>				
Serin (granivorous)	Long-term	4.61	<b>4.95</b>	5
Crested lark (omnivorous)	Long-term	3.72	6.40	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	124.06	<b>&gt;2.42</b>	10
Small herbivorous mammal	Long-term	68.95	<b>0.51</b>	5
Fish-eating mammal	Long-term	0.02	1745	5
Earthworm-eating mammal	Long-term	0.682	51.2	5
Drinking water consumption of small herbivorous mammal	Acute	0.013	> 23 077	10
Higher tier refinement (Mammals) <sup>1)</sup>				
Hare	Acute	11.28	>26.6	10
Wood mouse	Acute	4.49	> 66.82	10
Hare	Long-term	6.14 4.05	<b>4.07</b> 6.17*	5
Wood mouse	Long-term	4.12	6.06	5

1) Refined TER based on focal species including ecological data on PD and 90<sup>th</sup> percentile PT (for long-term only), refinements in residue values of the various feed items and residue dynamics [MAF and (f<sub>twa</sub>)] from EFSA (2008) and deposition factors from FOCUS (2000);

\*with deposition factor of 0.33

**Grape** (8 appl. with min spray interval of 7 days and max single appl. rate of 0.56 kg a.s./ha)

Grape (8 appl. / 1000 mm spray interval of 7 days and max single appl. rate of 0.50 kg a.s./ha)				
Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Insectivorous bird	Acute	30.29	10.20	10
Insectivorous bird	Short-term	16.89	46.77	10
Insectivorous bird	Long-term	16.89	<b>1.35</b>	5
Fish-eating bird	Long-term	covered by pomefruit use <sup>1)</sup>		5
Earthworm-eating bird	Long-term	covered by pomefruit use <sup>1)</sup>		5
Drinking water consumption of small insectivorous birds	Acute	covered by pomefruit use <sup>2)</sup>		10
Higher tier refinement (Birds) <sup>3)</sup>				
<b>Grape (Northern Europe)</b>				
Great tit (insectivorous)	Long-term	1.17	19.5	5
Black redstart (insectivorous)	Long-term	3.53	6.46*	5
Linnet (granivorous)	Long-term	5.33	<b>4.27</b>	5
Woodlark (omnivorous)	Long-term	3.3	6.9	5
Chaffinch(omnivorous)	Long-term	8.02	<b>2.84</b>	5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Grape (Southern Europe)				
Linnet (granivorous)	Long-term	5.33	4.27	5
Crested lark (omnivorous)	Long-term	3.9	6.10	5
Tier 1 (Mammals)				
Small herbivorous mammal	Acute	132.33	>2.27	10
Small herbivorous mammal	Long-term	72.41	0.48	5
Fish-eating mammal	Long-term	covered by pomefruit use <sup>1)</sup>		5
Earthworm-eating mammal	Long-term	covered by pomefruit use <sup>1)</sup>		5
Drinking water consumption of small herbivorous mammal	Acute	covered by pomefruit use <sup>2)</sup>		10
Higher tier refinement (Mammals) <sup>3)</sup>				
Wood mouse	Acute	4.49	62.63	10
Wood mouse	Long-term	1.78	14.07	5

1)The risk of secondary poisoning was calculated based on the worst case PEC values for soil and surface water in pome fruit orchards. Thus, the risk of secondary poisoning in vineyards is covered by the orchard use.

2)For the drinking water risk assessment, the maximum overspray concentration corresponding to early applications of the formulation BAS 21603 F in pome fruit orchards (0.081 mg dithianon/L) was applied as worst case thereby covering the use in vineyards

3)Refined TER based on focal species including ecological data on PD and 90<sup>th</sup> percentile PT (for long-term only), refinements in residue values of the various feed items and residue dynamics [MAF and (f<sub>tw</sub>)] from EFSA (2008) and deposition factors from FOCUS (2000);

\*The PT for the focal species black redstart was assumed =1 the proposed refined value was not accepted because it was not supported by sufficient data.

### 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)	LC <sub>50</sub> /EC <sub>50</sub> [µg a.s./L]	NOEC [µg a.s./L]
Laboratory tests				
Fish				
channel catfish <i>Ictalurus punctatus</i>	▪ dithianon	Static - 96 h	40 <sup>4)</sup>	20 <sup>4)</sup>
rainbow trout <i>O. mykiss</i>			70 <sup>4)</sup>	20 <sup>4)</sup>
bluegill sunfish <i>Lepomis macrochirus</i>	dithianon	Semi-static – 96 h	36 <sup>4)</sup>	18 <sup>4)</sup>
goldfish <i>Carassius auratus</i>	dithianon	Static - 96 h	47.5 <sup>5)</sup>	12.1 <sup>5)</sup>
stickleback <i>Gasterosteus aculeatus</i>	▪ dithianon	Static - 96 h	27.3 <sup>5)</sup>	9.84 <sup>5)</sup>
zebra fish <i>Brachydanio rerio</i>	dithianon	Static - 96 h	47.8 <sup>5)</sup>	20.0 <sup>5)</sup>
guppy <i>Poecilia reticulata</i>	dithianon	Static - 96 h	50.8 <sup>5)</sup>	20.4 <sup>5)</sup>
ricefish <i>Oryzias latipes</i>	dithianon	Static - 96 h	41.6 <sup>5)</sup>	19.2 <sup>5)</sup>
channel catfish <i>Ictalurus punctatus</i>	dithianon	Static - 96 h	<b>14.3</b> <sup>5)</sup>	9.53 <sup>5)</sup>



Group	Test substance	Time-scale (Test type)	LC <sub>50</sub> /EC <sub>50</sub> [µg a.s./L]	NOEC [µg a.s./L]
common carp <i>Cyprinus carpio</i>	dithianon	Static - 96 h	59.6 <sup>5)</sup>	24.6 <sup>5)</sup>
fathead minnow <i>Pimephales promelas</i>	dithianon	Static - 96 h	53.6 <sup>5)</sup>	38.4 <sup>5)</sup>
rainbow trout <i>O. mykiss</i>	dithianon	Static - 96 h	44 <sup>4)</sup>	17 <sup>4)</sup>
rainbow trout <i>O. mykiss</i>	dithianon	Static - 96 h	>30<54 <sup>5)</sup>	--
Fish - Species Sensitivity Distribution (SSD)	dithianon	SSD	HC <sub>5</sub> of <b>19.4</b> µg a.s./L	
rainbow trout <i>O. mykiss</i>	dithianon	Semi-static - 79 d	8.3 <sup>6)</sup>	<b>3.9</b> <sup>6)</sup>
stickleback <i>Gasterosteus aculeatus</i>	dithianon	Static - 28 d	20.0 <sup>6)</sup>	8.3 <sup>6)</sup>
rainbow trout <i>O. mykiss</i>	dithianon	Flow-through – 21 d	> 11 <sup>4)</sup>	4 <sup>4)</sup> 2.6 <sup>5)</sup>
rainbow trout <i>O. mykiss</i>	dithianon	Flow-through – 21 d	> 2.5 <sup>4)</sup>	0.625 <sup>4)</sup> <b>0.46</b> <sup>5)</sup>
rainbow trout <i>O. mykiss</i> , ELS	dithianon	Semi-static – 90 d	--	4.7 <sup>6)</sup>
<i>O. mykiss</i>	Delan 70 WG (BAS 216 03 F)	Acute (96 h), static	23	16
<i>O. mykiss</i>	Delan 70 WG (BAS 216 03 F)	Chronic (28 d), semi-static	> 9.4	2.2
<i>O. mykiss</i>	Delan 70 WG (BAS 216 03 F)	Chronic (28 d), Flow-through	1.3	< 0.43
<i>O. mykiss</i>	Metabolite CL 1017911	Static - 96 h	3 260	< 3 200
Aquatic invertebrate				
<i>Daphnia magna</i>	dithianon	Static - 48 h	<b>260</b> <sup>6)</sup>	50 <sup>6)</sup>
<i>Daphnia magna</i>	dithianon	Semi-static - 21 d	--	60 <sup>4)</sup>
<i>Daphnia magna</i>	dithianon	Semi-static - 21 d	126 <sup>4)</sup> 75 <sup>5)</sup>	100 <sup>4)</sup> <b>59.5</b> <sup>5)</sup>
<i>Daphnia magna</i>	Delan 70 WG (BAS 216 03 F)	Acute (48 h), static	<b>110</b>	
<i>Daphnia magna</i>	Metabolite CL 1017911	Static - 48 h	45 600	25 000
Sediment dwelling organisms				
<i>Chironomus riparius</i>	dithianon	Static - 28 d	> 500 <sup>4)</sup>	<b>125</b> <sup>4)</sup>
Algae				
<i>Selenastrum capricornutum</i>	dithianon	Static - 72 h	<b>90</b> <sup>1) 5)</sup>	25 <sup>5)</sup>
<i>Selenastrum capricornutum</i>	dithianon	Static - 72 h		140 <sup>4)</sup>

Group	Test substance	Time-scale (Test type)	LC <sub>50</sub> /EC <sub>50</sub> [µg a.s./L]	NOEC [µg a.s./L]
<i>Selenastrum capricornutum</i>	Delan 70 WG (BAS 216 03 F)	72 h, static	<b>64</b> <sup>1)</sup>	10
<i>P. subcapitata</i>	Metabolite CL 1017911	Static - 72 h	4 340 <sup>7)</sup> 1 970 <sup>1)</sup>	1 260 <sup>8)</sup> 850 <sup>9)</sup>
Microcosm or mesocosm tests <sup>10)</sup>				
<i>O. mykiss</i> <i>Zooplankton</i>	Delan 70 WG (BAS 216 03 F)		13 > 130	4.3 130

1) = biomass, 2) EC<sub>0</sub>, 3) Pre-incubation of test medium for 48 hours, 4) results based on nominal concentrations, 5) results based on initial measured concentrations, 6) results based on mean of initial measured concentrations, 7) E<sub>r</sub>C<sub>50</sub>, 8) E<sub>r</sub>C<sub>10</sub>, 9) E<sub>y</sub>C<sub>10</sub>; 10) The mesocosm study has several limitations and therefore cannot be used in the risk assessment. However, it confirms the higher sensitivities of fish.

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

**FOCUS Step 2 - Grape use (0.560 g a.s./ha x 8 applications): TERs based on maximum PEC<sub>sw</sub> (i.e multiple early applications South Europe)**

Species	LC/EC <sub>50</sub> [µg a.s./L]	NOEC [µg a.s./L]	PEC <sub>sw</sub> [µg a.s./L]	TERa (trigger 100)	TERIt (trigger 10)
<i>Ictalurus punctatus</i>	14.3	-	15.685	<b>0.91</b>	
<i>O. mykiss</i> , (21 d)	-	0.46	15.685		<b>0.03</b>
<i>Daphnia magna</i>	260	-	15.685	<b>16.6</b>	
<i>Daphnia magna</i> (21 d)	--	59.5	15.685		<b>3.79</b>
<i>Selenastrum capricornutum</i>	90 <sup>1)</sup>	-	15.685		<b>5.74</b>
<i>Chironomus riparius</i>		125	15.685		<b>7.9</b>
<b>Metabolite CL 1017911</b>					
<i>Oncorhynchus mykiss</i>	3 260	-	12.678	257	
<i>Daphnia magna</i>	45 600	-	12.678	> 1 000	
<i>Pseudokirchneriella subcapitata</i>	4 340 <sup>1)</sup> 1 970 <sup>2)</sup>	-	12.678		342 155
<b>Delan 70 WG (BAS 216 03 F)</b>					
<i>Daphnia magna</i>	110		15.685	<b>7.01</b>	
<i>Selenastrum capricornutum</i>	64		15.685		<b>4.08</b>

1) E<sub>b</sub>C<sub>50</sub> 2) E<sub>t</sub>C<sub>50</sub>

**FOCUS Step 2 - Pome fruit use (0.525 g a.s./ha x 12 applications): TERs based on maximum PEC<sub>sw</sub> (i.e single early application)**

Species	LC/EC <sub>50</sub> [µg a.s./L]	NOEC [µg a.s./L]	PEC <sub>sw</sub> [µg a.s./L]	TERa (trigger 100)	TERIt (trigger 10)
<i>Ictalurus punctatus</i>	14.3	-	51.09	<b>0.28</b>	
<i>O. mykiss</i> , (21 d)	-	0.46	51.09		<b>0.01</b>
<i>Daphnia magna</i>	260	-	51.09	<b>5.09</b>	
<i>Daphnia magna</i> (21 d)	-	59.5	51.09		<b>1.16</b>
<i>Selenastrum capricornutum</i>	90 <sup>1)</sup>	-	51.09		<b>1.76</b>
<i>Chironomus riparius</i>	-	125	51.09		<b>2.45</b>
<b>Metabolite CL 1017911</b>					
<i>Oncorhynchus mykiss</i>	3 260	-	42.893	<b>76</b>	
<i>Daphnia magna</i>	45 600	-	42.893	> 1 000	
<i>Pseudokirchneriella subcapitata</i>	4 340 <sup>2)</sup> 1 970 <sup>1)</sup>	-	42.893		101 46
<b>Delan 70 WG (BAS 216 03 F)</b>					
<i>Daphnia magna</i>	110		51.09		
<i>Selenastrum capricornutum</i>	64		51.09		<b>1.25</b>

1) E<sub>b</sub>C<sub>50</sub> 2) E<sub>t</sub>C<sub>50</sub>

**FOCUS Step 3 – Grape use (0.560 g a.s./ha x 8 applications): – TERs based on global maximum PEC<sub>sw</sub>**

FOCUS Step 3 Scenarios, global maximum values		D6, Thiva ditch	R1, Weiher- bach - pond	R1, Weiher- bach - stream	R2, Porto stream	R3, Bologna stream	R4, Roujan stream
PEC <sub>sw</sub> (global maximum value) [µg a.s./L]		9.570	0.340	6.997	9.374	9.854	6.882
	LC/EC <sub>50</sub> [µg/L]	TER <sub>a</sub> (trigger 100)					
<i>Ictalurus punctatus</i>	14.3	<b>1.5</b>	<b>42.05</b>	<b>2.04</b>	<b>1.52</b>	<b>1.4</b>	<b>2.07</b>
<i>Daphnia magna</i> , 48 h	260.0	<b>27</b>	765	<b>37</b>	<b>28</b>	<b>26</b>	<b>38</b>
<i>Daphnia magna</i> , 48 h (Delan 70 WG)	110	<b>11.5</b>	323.53	<b>15.7</b>	<b>11.73</b>	<b>11.2</b>	<b>16</b>
	NOEC [µg/L]	TER <sub>It</sub> (trigger 10)					
<i>O. mykiss</i> , (21 d)	0.46	<b>0.04</b>	<b>1.35</b>	<b>0.06</b>	<b>0.04</b>	<b>0.04</b>	<b>0.06</b>
<i>Daphnia magna</i> , 21 d	59.5	<b>6.2</b>	175	<b>8.5</b>	<b>6.4</b>	<b>6.1</b>	<b>8.7</b>
<i>Chironomus riparius</i> , 28 d	125	13	368	18	13	13	18
<i>Selenastrum capricornutum</i>	90.0*	<b>9.4</b>	265	13	<b>9.6</b>	<b>9.1</b>	13.1
<i>Selenastrum capricornutum</i> , (Delan 70 WG)	64*	<b>6.7</b>	188.2	<b>9.15</b>	<b>6.8</b>	<b>6.5</b>	<b>9.3</b>

\*E<sub>b</sub>C<sub>50</sub>,

**FOCUS Step 3 – Pome fruit use (0.525 g a.s./ha x 12 applications): TERs based on maximum PEC<sub>sw</sub>**

FOCUS Step 3 Scenarios, global maximum values		D3, Vredepol ditch,	D4, Skousbo pond,	D4, Skousbo stream	D5, La Jaill. pond	D5, La Jaill. stream	R1, Weiherb. pond,	R1, Weiherb. stream,	R2, Porto stream	R3, Bologna stream	R4, Roujan stream
PEC <sub>sw</sub> [µg a.s./L]		40.586	2.466	39.496	2.465	39.361	2.466	32.848	43.520	46.479	33.042
	LC/EC <sub>50</sub> [µg/L]	TER <sub>a</sub> (trigger 100)									
<i>Ictalurus punctatus</i>	14.3	<b>0.35</b>	<b>5.8</b>	<b>0.36</b>	<b>5.8</b>	<b>0.36</b>	<b>5.8</b>	<b>0.44</b>	<b>0.33</b>	<b>0.31</b>	<b>0.43</b>
<i>D. magna</i> , 48 h	260.0	<b>6.4</b>	105	<b>6.6</b>	<b>106</b>	<b>6.6</b>	<b>105</b>	<b>7.9</b>	<b>6.0</b>	<b>5.6</b>	<b>7.9</b>
<i>Daphnia magna</i> , 48 h (Delan 70 WG)	110	<b>2.71</b>	<b>44.61</b>	<b>2.79</b>	<b>44.62</b>	<b>2.79</b>	<b>44.61</b>	<b>3.35</b>	<b>2.53</b>	<b>2.37</b>	<b>3.33</b>
	NOEC [µg/L]	TER <sub>It</sub> (trigger 10)									
<i>O. mykiss</i> , (21 d)	0.46	<b>0.01</b>	<b>0.19</b>	<b>0.01</b>	<b>0.19</b>	<b>0.01</b>	<b>0.19</b>	<b>0.01</b>	<b>0.01</b>	<b>0.01</b>	<b>0.01</b>
<i>D. magna</i> , 21 d	59.5	<b>1.5</b>	24	<b>1.5</b>	24	<b>1.5</b>	24	<b>1.8</b>	<b>1.4</b>	<b>1.3</b>	<b>1.8</b>
<i>C. riparius</i> , 28 d	125	<b>3.08</b>	50.7	<b>3.2</b>	50.7	<b>3.2</b>	50.7	<b>3.8</b>	<b>2.9</b>	<b>2.7</b>	<b>3.8</b>
<i>S. capricornutum</i> ,	90.0*	<b>2.2</b>	37	<b>2.3</b>	37	<b>2.3</b>	37	<b>2.7</b>	<b>2.1</b>	<b>1.9</b>	<b>2.7</b>
<i>Selenastrum capricornutum</i> , (Delan 70 WG)	64	<b>1.58</b>	25.9	<b>1.62</b>	25.9	<b>1.63</b>	25.9	<b>1.95</b>	<b>1.47</b>	<b>1.38</b>	<b>1.94</b>

\*E<sub>b</sub>C<sub>50</sub>

**Refined aquatic risk assessment using higher tier FOCUS modelling and higher tier endpoints.**

**FOCUS Step 4 Grape use (0.560 g a.s./ha x 8 applications): – TERs based on global maximum PEC<sub>sw</sub> including buffer zone for drift mitigation up to 20m and vegetated buffer strip for runoff mitigation of 20m**

FOCUS Step 4 Scenarios with different buffer zones		D6, ditch, 20 m #	R1, pond, 3 m	R1, stream, 20 m #	R1, stream, 20 m *	R2, stream, 20 m #	R3, stream, 20 m #	R3, stream, 20 m *	R4, stream, 20 m #	R4, stream, 20 m *	trigger
PEC <sub>sw</sub> (at respective buffers) [µg a.s./L]		0.734	0.340	0.897	0.482	0.866	2.069	0.680	3.407	0.809	
LC/EC <sub>50</sub> [µg/L]		TER <sub>a</sub>									
<i>Ictalurus punctatus</i>	14.3	<b>19.5</b>	<b>42.1</b>	<b>15.9</b>	<b>29.7</b>	<b>16.5</b>	<b>6.9</b>	<b>21.0</b>	<b>4.2</b>	<b>17.7</b>	100
<b>Fish HC<sub>5</sub>, 96h**</b>	<b>19.4</b>	26.4	57	22	40	22	<b>9</b>	29	<b>6</b>	24	<b>10</b>
<i>Daphnia magna</i> , 48 h	260.0	354	765	290	539	300	126	382	<b>76</b>	321	100
<i>Daphnia magna</i> , 48 h (Delan 70 WG)	110	150	324	123	228	127	<b>53</b>	162	<b>32</b>	136	100
NOEC [µg/L]		TER <sub>lt</sub>									
<i>O. mykiss</i> , (21 d)	0.46	<b>0.63</b>	<b>1.35</b>	<b>0.51</b>	<b>0.95</b>	<b>0.53</b>	<b>0.22</b>	<b>0.68</b>	<b>0.14</b>	<b>0.57</b>	10
<b><i>O. mykiss</i>, 79d**</b>	<b>3.9</b>	5.3	11	4.3	8.1	4.5	<b>1.9</b>	5.7	<b>1.1</b>	4.8	3
<i>Daphnia magna</i> , 21 d	59.5	81	175	66	123	69	29	87	17	73	10
<i>Chironomus riparius</i> , 28 d	125	170	368	139	259	144	60	184	37	155	10
<i>Selenastrum capri-cornutum</i> , 72 h	90.0	123	265	100	187	104	43	132	26	111	10
<i>Selenastrum capri-cornutum</i> , 72 h (Delan 70 WG)	64	87	188	71	132	74	31	94	19	79	10

# considering drift mitigation only

\* considering drift and runoff mitigation

\*\*Based on the conclusion of a PRAPeR meeting 80 in Aug 2010 the studies in **bold** are driving the aquatic risk assessment using a safety factor of 10 to the HC<sub>5</sub> value and a safety factor of 3 to the lowest relevant endpoint from the chronic studies (*O. mykiss* 79 d, NOEC of 3.9 µg a.s./L). For the chronic exposure the experts in the meeting considered the pulsed study to be most appropriate, because it simulates the real exposure (12 applications). An assessment factor of 3 was agreed based on the relative sensitivity of rainbow trout (LC<sub>50</sub> = 44 µg a.s./L) from acute exposure compared to the most sensitive species (LC<sub>50</sub> = 14.3 µg a.s./L).

**FOCUS Step 4 Pome fruit use (0.525 g a.s./ha x 12 applications): TERs based on maximum PEC<sub>sw</sub> including 95% drift reduction measures (reflecting buffer zones of ≥20 to <30 m) and vegetated buffer strip of 20m**

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FOCUS Step 4 Scenarios with different buffer zones		D3, ditch	D4, pond	D4, stream	D5, pond	D5, stream	R1, pond	R1, stream	R2, stream	R3, stream	R4, stream	trigger
PEC <sub>sw</sub> [µg a.s./L]		2.027	0.492	1.972	0.492	1.965	0.492	1.64	2.173	2.321	1.189* 1.999	
LC/EC <sub>50</sub> [µg/L]		TERa										
<i>Ictalurus punctatus</i>	14.3	7.05	29.07	7.2	29.07	7.3	29.07	8.7	6.6	6.2	12.03 7.15	100
Fish HC <sub>5</sub> , 96 h**	19.4	9.6	39	9.8	39	9.9	39	12	8.9	8.4	16.3 9.7	10
<i>D. magna</i> , 48 h	260.0	128	528	132	528	132	528	159	120	112	219 130	100
<i>Daphnia magna</i> , 48 h (Delan 70	110	54.3	223.6	55.8	223.6	56.0	223.6	67.1	50.6	47.4	92.5 55.0	100

WG)												
NOEC [ $\mu\text{g/L}$ ]		TER lt										
<i>O. mykiss</i> , (21 d)	0.46	<b>0.2</b>	<b>0.93</b>	<b>0.22</b>	<b>0.92</b>	<b>0.22</b>	<b>0.92</b>	<b>0.3</b>	<b>0.2</b>	<b>0.20</b>	<b>0.4</b> <b>0.2</b>	10
<i>O. mykiss</i> , 79 d**	<b>3.9</b>	<b>1.9</b>	7.9	<b>2</b>	7.9	<b>2.4</b>	8	<b>2.4</b>	<b>1.8</b>	<b>1.7</b>	3.3 <b>2</b>	3
<i>D. magna</i> , 21 d	59.5	29.4	121	30	122	31	120	36	27	26	50 30	10
<i>C. riparius</i> , 28 d	125	62	254	63	254	64	254	76	58	54	105 63	10
<i>S. capricornutum</i> , 72 h	90.0	44	183	46	183	46	183	55	41	39	76/45	10
<i>S. capricornutum</i> , 72 h (Delan 70 WG)	64	32	130	32	130	33	130	39	29	28	54 32	10

\* PEC value considering spray drift and runoff mitigation

\*\*Based on the conclusion of a PRAPeR meeting 80 in Aug 2010 the studies in **bold** are driving the aquatic risk assessment using a safety factor of 10 to the HC5 value and a safety factor of 3 to the lowest relevant endpoint from the chronic studies (*O. mykiss* 79 d, NOEC of 3.9 ug a.s./L). For the chronic exposure the experts in the meeting considered the pulsed study to be most appropriate, because it simulates the real exposure (12 applications). An assessment factor of 3 was agreed based on the relative sensitivity of rainbow trout ( $LC_{50} = 44$  ug a.s./L) from acute exposure compared to the most sensitive species ( $LC_{50} = 14.3$  ug a.s./L).

Bioconcentration	
	Active substance Dithianon
logP <sub>O/W</sub>	3.2
Bioconcentration factor (BCF)*	4 and 7 edible 39 and 38 non-edible 26 and 28 whole fish
Annex VI Trigger for the bioconcentration factor	100
Clearance time (days) (CT <sub>50</sub> )	CT <sub>50</sub> = 15-27 h
Level and nature of residues (%) in organisms after the 14 day depuration phase	Below detection limit, respectively radioactive residues at background level.

<sup>1</sup> only required if log P<sub>O/W</sub> > 3.

\* based on total <sup>14</sup>C

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

Test substance	Acute oral toxicity (LD <sub>50</sub> $\mu\text{g/bee}$ )	Acute contact toxicity (LD <sub>50</sub> $\mu\text{g/bee}$ )
<b>a.s. dithianon</b>	<b>&gt; 25.4 <math>\mu\text{g a.s./bee}</math></b>	<b>&gt; 100.0 <math>\mu\text{g a.s./bee}</math></b>
<b>Delan 70 WG (BAS 216 03 F)<sup>1</sup></b>	> 131.1 $\mu\text{g/bee}$	> 142.9 $\mu\text{g/bee}$
	<b>&gt; 91.77 <math>\mu\text{g a.s./bee}</math><sup>1</sup></b>	<b>&gt; 100.00 <math>\mu\text{g a.s./bee}</math><sup>1</sup></b>
Field or semi-field tests: <u>not required</u>		

1) = based on the content of the active substance in the product (nominal)

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

**Grape** (worst case scenario) maximum single field application rate of:

0.8 kg/ha Delan 70 WG (BAS 216 03 F) equivalent to 0.56 kg/ha dithianon.

Test substance	Route	Hazard quotient	Annex VI Trigger
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Test substance	Route	Hazard quotient	Annex VI Trigger
a.s. dithanone	oral	<22.0	50
a.s. dithanone	Contact	<5.6	50
Delan 70 WG (BAS 216 03 F)	oral	<6.1	50
Delan 70 WG (BAS 216 03 F)	Contact	<5.6	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 <sub>50</sub> g/ha)
<i>Typhlodromus pyri</i>	Delan 70 WG	Mortality	LR <sub>50</sub> > 0.96 kg Delan 70 WG /ha
	Delan 70 WG	Mortality	LR <sub>50</sub> > 6.0 kg Delan 70 WG /ha
<i>Aphidius rhopalosiphi</i>	Delan 70 WG	Mortality	LR <sub>50</sub> > 6.0 kg Delan 70 WG /ha

**Grape** scenario (worst case in field): maximum in-crop rate 0.8 kg Delan 70 WG /ha

**Pome fruit** scenario (worst case off field): maximum in-crop rate 0.75 kg Delan 70 WG /ha

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in-field	HQ off-field <sup>†</sup>	Trigger
Delan 70 WG	<i>Typhlodromus pyri</i>	LR <sub>50</sub> > 6.0 kg Delan 70 WG /ha	<0.47 (vine, pome)	<0.1 (3m, pome fruit)	2
Delan 70 WG	<i>Aphidius rhopalosiphi</i>	LR <sub>50</sub> > 6.0 kg Delan 70 WG /ha	<0.47 (vine, pome)	<0.1 (3m, pome fruit)	2

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (kg Delan 70 WG /ha)	End point	% effect lethal	% effect sub-Lethal	Trigger value
<i>A. rhopalosiphi</i>	Adult	natural substrate	0.718 1.221 2.076 3.530 6.000	LR <sub>50</sub> > 3.02 kg Delan 70 WG/ha ER <sub>50</sub> > 2.076 kg Delan 70 WG/ha	7 20 23 63 77	-6 10 26 -- --	50 %
<i>A. rhopalosiphi</i>	Adult	natural substrate aged residues	DAT 0: 4.0 6.0 DAT 7: 4.0 6.0	DAT 7: ER <sub>50</sub> > 6.0 kg Delan 70 WG /ha	DAT 0: 47 80 DAT 7: 0 0	DAT 0: 50 -- DAT 7: - 47 -41	50 %
<i>C. carnea</i>	Larvae	natural substrate	0.8 2.4 4.8 6.0	ER <sub>50</sub> > 6.0 kg Delan 70 WG /ha	10 25 4 11	no effects no effects no effects no effects	50 %

Species	Life stage	Test substance, substrate and duration	Dose (kg Delan 70 WG /ha)	End point	% effect lethal	% effect sub-Lethal	Trigger value
<i>Pardosa</i> spp.	Adult	natural substrate direct application	0.8 2.4 6.0	ER <sub>50</sub> > 6.0 kg Delan 70 WG /ha	0.0 -3.0 6.0	0.0 8.0 2.0	50 %
Field or semi-field tests: <b><u>not required</u></b>							

DAT = days after treatment



**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 <sup>1</sup>
<b>Earthworms</b>			
<i>E. fetida</i>	a.s. Dithianon	Acute 14-d toxicity test	LC <sub>50</sub> 578.4 mg a.s./kg d.w.soil (mg a.s./ha) LC <sub>50corr</sub> = 289.2 <sup>1)</sup> mg a.s./kg d.w.soil (mg a.s./ha)
<i>E. fetida</i>	a.s. Dithianon	Chronic 56-d repro test	NOEC = 48 mg a.s./kg d.w.soil (mg a.s./ha) NOEC <sub>corr</sub> = 24 mg a.s./kg d.w.soil (mg a.s./ha) <sup>1)</sup>
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Acute 14-d toxicity test	LC <sub>50</sub> > 700 mg a.s./kg soil dry weight LC <sub>50corr</sub> > 350 mg a.s./kg soil dry weight <sup>1)</sup>
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic 56-d repro test (artificial substrate)	NOEC 22.3 mg a.s./kg soil dry weight (NOEC 56 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel) NOEC <sub>corr</sub> = 11.15 <sup>1)</sup> mg a.s./kg soil dry weight (NOEC <sub>corr</sub> 28 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel)
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic 56-d repro test (field soil)	NOEC 3.7 a.s./kg soil dry weight (NOEC 9.3 mg a.s./kg soil dry weight, refined calculation based on the actual amount of soil dry weight per test vessel)
<b>Soil micro-organisms</b>			
Nitrogen mineralisation	DELAN 70 WG (BAS 216 03 F)	28 days after treatment	+5.4 % effect at day 28 at 26.71 mg a.s./kg d.w.soil (eq. 14 kg a.s./ha) <sup>2)</sup>
Carbon mineralisation	DELAN 70 WG (BAS 216 03 F)	28 days after treatment	-9.5 % effect at day 28 at 26.71 mg a.s./kg d.w.soil (eq. 14 kg a.s./ha) <sup>2)</sup>
Field studies: not required			

<sup>1)</sup> The toxicity data have been adjusted by a conversion factor of 2 (log P<sub>ow</sub> = 3.2) to address the organic matter content of the soil; for original values

<sup>2)</sup> - = inhibition; + = stimulation

### Toxicity/exposure ratios for soil organisms

**Pome fruit scenario (worst case):** maximum rate 12 x 0.75 kg Delan 70 WG /ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
<i>Tier 1</i>					
<i>E. fetida</i>	a.s. Dithianon	Acute <sup>3)</sup>	2.280 <sup>1)</sup>	<b>127</b>	10
<i>E. fetida</i>	a.s. Dithianon	Chronic <sup>3)</sup>	2.280 <sup>1)</sup>	<b>10.5</b>	5
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Acute <sup>3)</sup>	2.280 <sup>1)</sup>	<b>&gt; 154</b>	10
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic <sup>3)</sup>	2.280 <sup>1)</sup>	<b>5</b>	5
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic	2.280 <sup>1)</sup>	1.6	5
<i>Refined Risk Assessment</i>					
Pome fruit scenario					
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic NOEC = 28.0 <sup>3)</sup>	1.358 <sup>2)</sup>	<b>21</b>	5
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic NOAEC = 9.3 <sup>4)</sup>	1.358 <sup>2)</sup>	<b>6.9</b>	5
Grapevine scenario					
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic NOEC = 28.0 <sup>3)</sup>	1.514 <sup>4,5)</sup>	<b>18.5</b>	5
<i>E. fetida</i>	DELAN 70 WG (BAS 216 03 F)	Chronic NOAEC = 9.3 <sup>4)</sup>	1.514 <sup>4,5)</sup>	<b>6.1</b>	5

- 1) PEC-calculation based on pome fruit scenario with 12 x 0.75 kg/ha DELAN 70 WG (BAS 216 03 F) corresponding to 12 x 0.525 kg/ha Dithianon, 50% interception.
- 2) PEC-calculation based on pome fruit scenario with 12 x 0.75 kg/ha DELAN 70 WG (BAS 216 03 F) corresponding to 12 x 0.525 kg/ha Dithianon, 3 x 50%, 2 x 65%, 3 x 70% and 4 x 80% interception
- 3) The toxicity data have been adjusted by a conversion factor of 2 (log Pow = 3.2) to address the organic matter content of the soil; for original values
- 4) Refined toxicity data: calculation is based on the actual amount of soil dry weight per test vessel
- 5) PEC-calculation based on grapevine scenario with 8 x 0.56 kg a.s./ha each, 2 x 50%, 4 x 60%, 2 x 70% interception.

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

Preliminary screening data

### 21 DAA - pre-emergence application

DELAN 70 WG (BAS 216 03 F) [kg/ha]	Onion	Oats	Sugar beet	Radish	Soybean	Lettuce	Field corn
Seedling emergence [% of control]							
Control	100	100	100	100	100	100	100
2.0	109	100	118	100	107	95	100
6.0	122	95	108	100	105	87	98
Plant weight [% of control]							
Control	100	100	100	100	100	100	100
2.0	120	95	95	102	105	105	97
6.0	124	89	98	106	106	105	103
Mean visible damage [% damage compared to control]							
2.0	0	0	0	0	0	0	0
6.0	0	0	0	0	0	0	0

### 21 DAA - post-emergence application

DELAN 70 WG (BAS 216 03 F) [kg/ha]	Onion	Oats	Sugar beet	Radish	Soybean	Lettuce	Field corn
Seedling emergence [% of control]							
Control	100	100	100	100	100	100	100
2.0	96	100	100	96	102	102	100
6.0	94	106	97	100	102	102	100
Plant weight [% of control]							
Control	100	100	100	100	100	100	100
2.0	98	93	111	108	96	95	99
6.0	98	100	102	99	96	100	104
Mean visible damage [% damage compared to control]							
2.0	0	0	0	0	0	0	0
6.0	0	0	0	0	0	0	0

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

Test type/organism	end point
Respiration inhibition test (activated sludge)	Dithianon: EC <sub>50</sub> > 1000 mg a.s./L

## Ecotoxicologically relevant compounds

Compartment	
soil	Parent (dithianon)
water	Parent (dithianon)
sediment	Parent (dithianon)
groundwater	Parent (dithianon)

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

Active substance (Dithianon)

RMS/peer review proposal

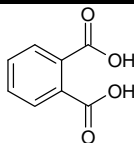
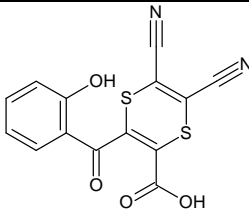
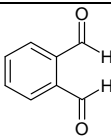
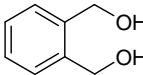
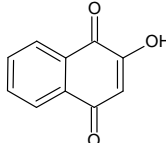
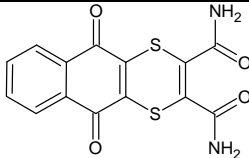
N, R 50

Preparation (DELAN 70 WG)

RMS/peer review proposal

N, R 50

**APPENDIX B – USED COMPOUND CODE(S)**

Code/Trivial name	Chemical name*	Structural formula*
phthalic acid	phthalic acid	
CL 1017911	5,6-dicyano-3-[(2-hydroxyphenyl)carbonyl]-1,4-dithiine-2-carboxylic acid	
phthalaldehyde	phthalaldehyde	
1,2-benzenedimethanol	benzene-1,2-diyl dimethanol	
CL 231509	2-hydroxynaphthalene-1,4-dione	
CL 902200	5,10-dioxo-5,10-dihydronaphtho[2,3-b][1,4]dithiine-2,3-dicarboxamide	

\* 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
$\lambda$	wavelength
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
$\mu\text{g}$	microgram
$\mu\text{m}$	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 Abstract 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
DFR	dislodgeable foliar residues
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	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 <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	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-ECD	high pressure liquid chromatography – electrochemical detector
HPLC-UV	high pressure liquid chromatography – ultra violet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IENTI	international estimated short-term intake
ILV	independent laboratory validation
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 <sub>doc</sub>	organic carbon linear adsorption coefficient
kg	kilogram
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC <sub>50</sub>	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	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
mN	millinewton
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
nm	nanometre

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
OSOM	outer stripe of outer medulla
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
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