CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Propargite is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. 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 Italy, 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 propargite in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of propargite in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant (Chemtura Europe Ltd.) made a resubmission application for the inclusion of propargite in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. 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, Italy, 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 4 March 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 8 March 2010. The DAR was also distributed to Member States and the applicant for comments in view of the fact that the original peer review had been terminated following the applicant's notification of withdrawal of support. The EFSA collated and forwarded all comments received to the Commission on 22 April 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, residues, fate and behaviour and ecotoxicology and deliver its conclusions on propargite.

[1] On request from the European Commission, Question No EFSA-Q-2010-00852, issued on 23 February 2011
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[3] OJ L224, 21.08.2002, p.25
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 333, 11.12.2008, p. 11
[6] 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 propargite as an acaricide on grapes and tomatoes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

Two data gaps were identified in the section on identity.

The technical specification is not supported by the batches used in the toxicological studies leading to a critical area of concern; the toxicological relevance of the impurities has not been adequately addressed and a data gap was identified. In addition, due to the fact that propargite exerts carcinogenic potential on different organs in two strains of rats and a genotoxic mode of action cannot be disregarded, no reliable reference values could be set at this stage until a new valid genotoxicity datapackage with the proposed specification is available. Therefore, the risk assessment could not be conducted leading to a critical area of concern.

Five data gaps and one critical areas of concern were identified in the residues section. The consumer risk assessment could not be conducted.

The information on the environmental fate and behaviour of propargite in relation to the representative use assessed was insufficient to complete the necessary environmental exposure assessment at the EU level. The fate and behaviour of the cyclohexyl ring moiety of propargite in soil and natural sediment water systems has not been addressed. Consequently the environmental exposure assessment for soil, surface water and groundwater for any transformation products that might be formed from this proportion of the molecule (e.g. 1,2-cyclohexanediol and derivatives) could not be finalised. For the metabolite TBPC-sulfate and the unidentified metabolite ascribed as “unk 1“, the groundwater exposure assessment could not be finalised in respect of comparison to the parametric groundwater drinking water limit of 0.1µg/L. Information was not available on the possible preferential degradation and or conversion of the isomers of propargite or its transformation products in the environment.

Eight data gaps and four critical areas of concern were identified in the ecotoxicology section. A high risk of propargite to aquatic organisms was identified (even with use of the risk mitigation measures comparable with 30 m non-spray buffer zones). A high long-term risk to mammals and a high risk to mammals from the consumption of contaminated water were identified. The risk from secondary poisoning to birds was identified as high, except for earthworm-eating bird in the grapes. The risk from secondary poisoning to mammals except for fish-eating mammals in the tomato scenario was assessed as high based on the available data.

KEY WORDS

Propargite, peer review, risk assessment, pesticide, acaricide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] 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[9] 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 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

Propargite is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. The Draft Assessment Report (Italy, 2007) was received by the EFSA on 26 July 2007.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of propargite 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)[10] concerning the non-inclusion of propargite in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant (Chemtura Europe Ltd.) made a resubmission application for the inclusion of propargite 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, Italy, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Italy 2010). The Additional Report was received by the EFSA on 4 March 2010.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 8 March 2010. The DAR was also distributed to Member States for comments in view of the fact that it had not previously been distributed for consultation. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 22 April 2010. At the same time, the collated comments were forwarded to the RMS 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 were evaluated by the RMS in column 3.

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p. 11

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 20 May 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on propargite within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant(s) 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 28 May 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, residues, fate and behaviour and ecotoxicology and that further information should be requested from the applicant in the areas of physical-chemical properties, mammalian toxicology, residues, fate and behaviour and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in 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 January/February 2011.

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 as an acaricide on grapes and tomatoes 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 (EFSA, 2011), 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 comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1, 25 May 2010)
- the Evaluation Table (15 February 2011)
- 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 January 2011 containing all individually submitted addenda; Italy 2011) 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

Propargite is the ISO common name for (1*RS*,2*RS*;1*RS*,2*SR*)-2-(4-*tert*-butylphenoxy)cyclohexyl prop-2-ynyl sulfite (IUPAC).

The representative formulated product for the evaluation was 'Omite 570 EW', an emulsion oil in water formulation (EW) containing 570 g/l propargite, registered under different trade names in Europe.

The representative uses evaluated comprise high volume spraying on grapes and tomatoes against mites. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

It must be noted that propargite is a mixture of two enantiomeric pairs of diastereoisomers around chiral carbons and has a potential chiral sulfur atom resulting in four more possible stereoisomers. The possible preferential metabolism/degradation of each enantiomer in animals, plants and the environment was not investigated in the studies submitted in the dossier and was therefore not considered during the peer review. Moreover, the analytical methods used in the studies reported through all sections were not stereo-selective, and all values mentioned as "propargite" have to be considered as "sum of isomers". The possible impact of each individual isomer on the toxicity, the consumer risk assessment, worker exposure and the environment was not evaluated. Data gaps were therefore identified to address the impact of the isomeric composition of the substance on the risk assessments (see sections 2 -5).

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

The following guidance documents were followed in the production of this conclusion: Guidance for generation and reporting methods of analysis (European Commission, 1999) and Guidance Document on residue analytical methods (European Commission, 2000).

The minimum purity of propargite technical material is 870 g/kg. The minimum purity of propargite technical material in the tentative FAO specification AGP:CP/206 (1984) is 875 g/kg. The ratio of (1*RS*,2*RS*)- and (1*RS*,2*SR*)-isomers (*trans*:*cis*) of the evaluated material was 95:5.

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 propargite or the representative formulation, however data gaps were identified for clarification of the existence of the third chiral center in the molecule and for an updated specification, removing the impurities below 1 g/kg. The main data regarding the identity of propargite and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of propargite and the impurities in the technical material and for the determination of the active substance in the representative formulation. Propargite residues in food of plant origin can be monitored by multi-residue methods using GC-MS. Adequate HPLC-MS/MS methods are available for monitoring the residues of propargite in food of animal origin. Residues of propargite in soil, in water and in the air can be monitored by GC-MS. Propargite residues in body fluids and tissues can be monitored by HPLC-MS/MS.

2. Mammalian toxicity

The guidance document on dermal absorption (European Commission, 2004) was followed for this conclusion.

Propargite was discussed at the PRAPeR TC 45 expert teleconference on mammalian toxicology. The technical specification is not supported by the batches used in the toxicological studies. The

toxicological relevance of the impurities has not been adequately addressed and a data gap was identified.

Valid information addressing the behaviour of the isomers in the mammalian metabolism was missing, as well as data on their potentially different toxicity and an analysis of the material tested in the toxicity studies with regard to different composition of isomers.

Oral absorption was estimated at 75%. There was no evidence for accumulation. The main metabolic pathway identified was hydrolysis of the propynyl sulfite side-chain, subsequent oxidation and conjugation of the ter-butyl moiety, and hydroxylation of the cyclohexyl moiety. An additional pathway is metabolism of the side-chain by glutathione conjugation.

Low acute toxicity is observed when propargite is administered by the oral and dermal route. However, it is toxic by inhalation; it is a skin and eye irritant and skin sensitizer.

In short-term oral studies with rats and dogs the target organ was the jejunum in rats and the hematopoietic system in dogs. The dog was the most sensitive species. The relevant short-term oral NOAEL could not be identified as the lowest dose level tested in the 1-year dog study was a LOAEL (5 mg/kg bw/day).

Four out of six genotoxicity studies were considered acceptable. Although the weight of evidence suggests that the active substance is not genotoxic, the impurity profile is not available in the genotoxicity studies and the purity of the active substance tested was higher than the minimum purity according to the proposed specification (870 g/kg). Therefore, impurities have not been adequately tested. In addition, *in silico* methods performed with the impurities raised concerns associated with alkyl halides, as structural alerts since they are electrophilic species capable of directly alkylating the DNA. Overall, no final conclusion can be drawn with regard to the genotoxic potential of the technical material leading to a data gap.

Long-term studies were performed with rats and mice. In rats, the target organs were the testes, haemolymphoreticular system and jejunum. In mice the potential target organ was the spleen. Non specific effects suxh as reduced body weight gain (rats) and reduced food consumption (rat and mice) were also observed. No carcinogenic potential was observed in mice. However, propargite exerts carcinogenic potential on different organs in two strains of rats (Wistar and CD-SD rats). Mammary tumours were observed in Wistar rats and intestinal (mainly jejunal sarcomas) tumours were observed in both strains. Mechanism studies were performed in rats to investigate the mode of action of intestinal tumours (jejunal sarcomas): transient jejunal cell proliferation was observed after one week but was not confirmed later after 4 weeks and 20 months. However, a clear indication of the mechanism of action is not available and the transient cell proliferation it causes, can not account for all observed tumours. The purity of the active substance tested in the carcinogenic studies in rats was in the range of the proposed specification. Taking into account also the uncertainties related to the material tested in the genotoxicity studies (see above) concerns were raised as a genotoxic mode of action cannot be disregarded. The relevant long-term NOAEL is 3.46 mg/kg bw/day (long-term toxicity study in CD-SD rats).

Fertility and overall reproductive performance was not impaired. The parental, reproductive and offspring NOAELs are 5.1 mg/kg bw/d. In the developmental toxicity studies in rats there was no evidence of developmental toxicity effects. In rabbits, fused sternebrae and fused skull bones occurred at doses producing also maternal toxicity (decreased body weight gain). However, it was agreed that the maternal toxicity could not be clearly linked to the developmental effects. The relevant maternal NOAELs are 18 mg/kg bw/day for the rat and 4 mg/kg bw/day for the rabbit. The relevant developmental NOAELs are 105 mg/kg bw/day for the rat and 6 mg/kg bw/day for the rabbit.

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

Based on the effects described above, classification and labelling with R43 (May cause sensitisation by skin contact), R63 (Possible risk of harm to the unborn child), R48/22 (Danger of serious damage to health by prolonged exposure if swallowed in addition to the current classification and labelling as R23 (Toxic by inhalation), R38 (Irritating to skin), R41 (Risk of serious damage to eyes), R40 (Limited evidence of a carcinogenic effect) (CLP00, Annex VI to Regulation (EC) No 1272/2008) is proposed.

The relevant dermal absorption values for 'Omite 570 EW' are 5% for the concentrate and 14% for the dilution.

Due to the fact that propargite exerts carcinogenic potential on different organs in two strains of rats and a genotoxic mode of action cannot be disregarded, it was agreed that no reliable reference values can be set at until a new valid genotoxicity data package with the proposed specification is available. Therefore, the risk assessment for operators, workers and bystanders cannot be conducted.

3. Residues

The conclusion in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999).

Metabolism of propargite was investigated in apple and tomato. Based on the available data, the main metabolic reactions in the metabolism of propargite in apple and tomato fruits could be established. The significant residues in apple leaves and fruits were propargite and the metabolites TBPC, TBPC diol and HOMe TBPC diol. In tomato fruits residues were primarily present as propargite and the metabolite carboxy TBPC triol. The overall picture of metabolism appeared to be slightly different in apple and tomato, though the actual metabolic pathway is expected to be comparable in both crops. Since the toxicological profile of the major fruit metabolites was insufficiently addressed, it was decided to consider the metabolites as having the same toxicological properties as parent propargite. A data gap was identified for a new hydrolysis study simulating food processing conditions in order to clarify the residue picture in processed fruit commodities. Available data indicate that significant degradation of residues to relevant degradation products might occur under processing conditions.

The residue definition for consumer risk assessment for fruit crops should be set as the sum of propargite and all identified metabolites in fruit11, expressed as propargite.

The proposed residue definition for plant products for enforcement and monitoring for fruit crops is proposed as propargite only. It is noted that the nature of the final residue in plant was not studied with regard to the isomers of propargite and its metabolites. Thus it is not known if any isomer is metabolised or degraded more quickly and to which ratio of isomers consumers may eventually be exposed. The applicant should address the consumer risk assessment with regard to the isomers of propargite and its metabolites.

A sufficient number of supervised residue trials analysing for the proposed residue definition for monitoring are available in Northern and Southern Europe to support the representative uses on grapes, and in Southern Europe for the use on field tomatoes. MRLs could be proposed for grapes and for tomatoes. The trials are supported by valid storage stability data and validated analytical methods, with the exception of some tomato trials where method validation data are still required to demonstrate the validity of the respective residue trials results (data gap). None of the residue trials analyse for the residue definition for risk assessment, i.e. metabolites were not included in the analysis. To convert from the monitoring residue definition to the residue definition for risk assessment, the experts in TC 47 suggested the RMS should establish a conversion factor for tomato based on the cGAP compliant metabolism study in tomato. However, no follow-up assessment has been received by EFSA. For the use in grapes a conversion factor could not be established due to lack of proper data (data gap

[11] Refer to List of Endpoints (Residues) for a listing of all metabolites included

identified). A data gap was also identified for the use in tomatoes to address residues in rotational crops. Pending the outcome of the simulated processing study, additional studies on the magnitude of residues in processed tomato and grape according to the residue definition for risk assessment may be required.

Exposure to livestock is not significant for the representative uses in grape and tomato since these crops are not considered relevant feed items. Although livestock studies were submitted, they were not peer reviewed.

A consumer risk assessment could not be conducted for the following reasons:

1) Insufficient residue occurrence data in primary and rotational crops, and in processed commodities analysed according to the residue definition for risk assessment do not permit performing reliable dietary exposure estimates to be performed, and 2) toxicological reference values could not be set for propargite.

4. Environmental fate and behaviour

As already discussed, the regulatory dossier provides no information on the behaviour of each individual propargite stereoisomer in the environment. It is not known if any of the possible 8 stereoisomers[12] degrade more quickly than the others or if any other conversion may occur in the environmental matrices studied. The identified metabolites TBPC and TBPC-sulfate also contain (4) isomers (2 diastereoisomer pairs). Consequently a data gap is identified. References made to propargite, TBPC and TBPC-sulfate in section 4 therefore relate to the sum of all isomers of unknown ratio. It should be noted that fate and behaviour studies to address the route of degradation of propargite were only radiolabelled in the phenyl ring with no experiments being labelled in the cyclohexyl ring. Whilst the applicant provided some information to address the fate and behaviour of the cyclohexyl ring moiety (e.g. 1,2-cyclohexanediol and derivatives), the information provided was considered inadequate by experts from the Member State . Consequently a data gap is identified.

In soil laboratory incubations under aerobic conditions in the dark, propargite exhibits moderate to high persistence forming the major (>10% applied radioactivity (AR)) metabolite TBPC (max. 10.4% AR at 22-30 days), which exhibited low to moderate persistence. Two minor non-transient metabolites[13] were formed, one in each of two out of the five available soil degradation studies. One of these was identified as TBPC-sulfate (max 7.62% AR at 90 days), whereas the other ascribed as “unk 1” (max 5.29% AR at 92 days) was not identified and is therefore subject to a data gap. Mineralisation of the phenyl ring radiolabel to carbon dioxide accounted for 22-42 % AR after 90-100 days. The formation of unextractable residues (not extracted using acetonitrile:water, methanol:water or acetone) for this radiolabel accounted for 24-38% AR after 90-100 days. In anaerobic soil incubations propargite exhibited moderate persistence forming TBPC (23.7% after 60 days), which was stable. Propargite was essentially immobile in the soil whereas TBPC exhibited medium mobility in soil. There was no indication that the sorption of either of these compounds was pH dependent. In satisfactory field dissipation studies carried out at 4 European sites (spray application to the soil surface on bare soil plots) propargite exhibited moderate persistence. Sample analyses in field dissipation studies were only carried out for propargite.

In laboratory incubations in dark aerobic natural sediment water systems, propargite exhibited moderate persistence, forming the major metabolite TBPC (max. 17% in water and 21% AR in sediment, which also exhibited moderate persistence). At the study end (106 days) the unextractable sediment fraction (not extracted using acetonitrile:water) and mineralisation, (both for the phenyl ring

[12] At least 4 stereoisomers from the 2 chiral carbons do exist for propargite, if the sulfur is also chiral there will be 8 stereoisomers.
[13] In this case these metabolites are considered minor non-transient as they accounted for > 5% AR at 2 consecutive sampling times.

^{14}C radiolabel) accounted for ca. 29 % AR and 40–52% AR respectively. The rate of decline of propargite in a laboratory sterile aqueous photolysis experiment was fast relative to that which occurred in the aerobic sediment water incubations forming TBPC (40% AR after 30 days).

Surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) were carried out for propargite and the metabolite TBPC using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). For the active substance propargite, appropriate step 3 and step 4 (FOCUS, 2001) calculations were available[14]. The latter mitigated spray drift entries by implementing no-spray drift buffer zones with the values retained in Appendix A being mitigated by up to 93.2-95%. In combination with the no-spray drift buffers, at runoff scenarios runoff mitigation was implemented mitigating solute flux input to surface water systems by 80% and eroded soil input by 95%. The results from this step 4 modelling that are included in Appendix A complied with the FOCUS Landscape and mitigation (FOCUS, 2007) guidance.

Groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the model PEARL 3.3.3[15] for the active substance propargite and the metabolite TBPC. For propargite and TBPC the potential for the groundwater exposure from the representative uses above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 7 pertinent FOCUS groundwater scenarios. Groundwater exposure assessments are triggered for the metabolites TBPC-sulfate and "unk 1". Assessments for these metabolites were not available. Consequently a data gap is identified.

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

5. Ecotoxicology

The risk assessment was based on the guidance document to Terrestrial Ecotoxicology (European Commission, 2002a), the guidance document on Aquatic Ecotoxicology (European Commission 2002b), the guidance document on the Risk Assessment for birds and mammals (European Commission, 2002c), the guidance document on Regulatory Testing (SETAC, 2001) and the guidance document on Birds and Mammals (EFSA, 2009).

In the dossier no information is available for the toxicity on non target species of each individual propargite stereoisomer (up to 8). The metabolites TBPC and TBPC-sulfate have 4 isomers. Changes in the isomers ratio may lead to changes in the toxic effects of the active substance and TBPC. As a worst case assumption, the toxic effects of propargite and TBPC would change by a factor of 8 and 4, respectively. The trigger values should be multiplied by a factor of 8 and 4, respectively, to ensure that the current risk assessment covers any change in the isomers ratio. The current risk assessment for non-target species was based on the assumption that there will be no change in the isomer ratio, however data gaps were identified to address this point. Therefore the current risk assessment should be considered as provisional for all the non-target species, except for soil dwelling organisms, where the acute TERsvalues estimated for propargite and TBPC were higher than 80 and 40 for propargite and TBPC, respectively but may need to be revisited.

The acute risk to insectivorous birds via dietary exposure was assessed as low at tier 1 for the representative field uses in tomatoes and grapes. There was no valid short-term dietary toxicity for birds; therefore, a data gap was identified. The long-term risk to insectivorous birds was assessed as high at tier 1. The refined risk assessment was based on the use of frugivorous birds as focal species and residue measured in several residue trials in tomato and grapes. The TER values were above the

[14] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[15] Simulations complied with EFSA (EFSA, 2004) and correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

trigger values for the use on tomato and grapes. For the use on grapes the application timing included in the GAP is the BBCH 53 to 60 as pre-flowering and BBCH 71 to 83 as post-flowering and BBCH 71 to 84 for the use on tomatoes. The residue data provided by the applicant refer to studies applied at BBCH 79-89 on tomato and BBCH 81-89 on grape; therefore the residue data are relevant for the proposed use in tomato (BBCH 71-85) and on grapes at post-flowering (71-83). The long-term risk to birds was assessed as low, for the representative uses on tomatoes and grapes (post flowering application). However, the proposed application to grapes pre-flowering (BBCH 53-60) is not addressed either by the residue trials or by the risk assessment based on frugivorous birds. Therefore a data gap was identified to further address the long-term risk to birds for the pre-flowering use on grapes.

The acute risk to mammals via dietary exposure was assessed as low at tier 1. The chronic endpoint to be used for the long-term risk assessment for mammals was discussed at the PRAPeR 85 meeting. The experts concluded that the effect on pup weight at 800 ppm may have effects on the overall fitness of field populations. A NOEL of 6.3 mg/kg bw/d (80 ppm) was accepted. The long-term risk of propargite to mammals was assessed as high at tier I. Therefore, a data gap was identified, for the applicant to refine the long-term risk to mammals for all the representative uses.

The risk assessment to earthworm-eating birds and mammals was required since the $logP_{ow}$ is 5.7. The risk from secondary poisoning of birds was assessed as high, except for earthworm-eating bird in the grapes scenario. The risk from the secondary poisoning to mammals was assessed as high, except for fish-eating mammals in the tomato scenario. A refinement is needed; therefore, a data gap was identified to refine the risk of propargite from secondary poisoning to birds, except for earthworm-eating bird in the grapes scenario, and the risk from secondary poisoning to mammals, except for fish-eating mammals in the tomato scenario. The risk from secondary poisoning of TBPC metabolite to birds was assessed as low, based on consideration of lipophilicity, persistence in soil and water and the formation of the metabolite in hens. The risk to birds from consumption of contaminated water was assessed as low. However, a high risk to mammals from consumption of contaminated water was identified. A data gap was identified.

Propargite is very toxic to aquatic organisms. The lowest endpoint was derived from the acute toxicity study with *Daphnia magna* with the active substance (EC_{50} of 14 µg a.s. /L). The preparation 'Omite 570 EW' is very toxic to aquatic organisms, although it is less toxic than the active substance. The risk to algae and sediment dwellers was assessed as low at $FOCUS_{sw}$ Step 1 for all the representative uses. At the PRAPeR 85 expert meeting, the adequacy of using the $_{TWA}$ PECsw in the long-term risk assessment for aquatic organisms was discussed. The meeting concluded that the maximum PECsw values should be used. At FOCUSsw step 3 the acute and chronic risk was assessed as high for fish and aquatic invertebrates in the majority of the scenarios, for the uses in tomato and grapes. The risk was subsequently assessed at FOCUS step 4, including risk mitigation measures, comparable to 30 m no-spray buffer zone. The TERs values were calculated based on the use of the most sensitive endpoint (acute toxicity of *D. magna* (EC_{50} = 14 µg a.s. /L)) and the peak FOCUSsw Step 4 values. The risk for aquatic organisms was assessed as high for D6 ditch, R2 stream, R3 stream and R4 stream for the use in tomato. A low risk to aquatic organisms was identified for the R1 pond scenario, while a high risk was identified for the R1 stream, R2 stream, R3 stream and R4 stream scenarios for the use in grapes. A BCF-value of 13964 obtained for whole fish may indicate potential for bioaccumulation. The risk of metabolite TBPC to aquatic organisms was assessed as low with FOCUS step 2 PEC in the situation that there is no change in the isomer ratio of TBPC which is unknown.

The off-field and in-field risk was assessed as high for the two standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, for the representative uses on tomatoes and grapes. There were a few of extended laboratory studies submitted. To conclude on the risk to sensitive species such as *A. rhopalosiphi* and *T. pyri* a field study on real, representative and diverse off-crop arthropod communities would be needed, and therefore a data gap was indentified for the applicant to further address the risk to non-target arthropods.

The risk to earthworms from propargite and its metabolite TBPC was assessed as low.

The effects of propargite on biological methods of sewage treatments should be addressed. A data gap was identified.

The risk to bees, non-target soil micro-organisms and non-target plants was assessed as low for all representative uses.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Propargite	Moderate to highly persistent DT_{50}: 43-84 days (SFO and biphasic, DT_{90}:155-697 days, 20-25 ˚C, 43-44% pF2.5 or 75% 1/3 bar soil moisture) (Field dissipation studies: DT_{50} 10-24 days (biphasic, DT_{90}: 149-468 days)	The risk of Propargite to earthworms was assessed as low:
TBPC	Low to moderate persistence DT_{50}: 6-10 days (SFO and biphasic, DT_{90}:19-163 days, 20˚C, 43-45% MWHC soil moisture)	The toxicity and risk to earthworms was assessed as low.

6.2. Ground water

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

Propargite	Immobile K_{Foc}5293-20985 mL/g	No	Yes	Yes	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: aquatic invertebrates acute EC_{50} = 14 µg a.s./L (regulatory concentration including a safety factor of 100 = 0.14 µg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment in the situation that there is no change in the isomer ratio. Whilst this is unclear the risk assessment was not finalised...
TBPC	Medium mobility K_{Foc} 215-460 mL/g	No	No	No data (assessment not triggered).	Toxic to aquatic organisms, endpoint driving the aquatic risk assessment: fish acute EC_{50} = 1490 µg a.s./L (regulatory concentration including a safety factor of 100 = 14.90 µg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment in the situation that there is no change in the isomer ratio. Whilst this is unclear the risk assessment was not finalised..

TBPC sulfate	Not addressed	Data gap	No data available (may be needed depending on the data gap on ground water exposure)	No data available (may be needed depending on the data gap on ground water exposure)	No data available (may be needed depending on the data gap on ground water exposure)
Unk 1 [a)]	Not addressed	Data gap	No data available (may be needed depending on the data gap on ground water exposure)	No data available (needed depending on the data gap on ground water exposure)	No data available (may be needed depending on the data gap on ground water exposure)

(a): Unidentified minor transient metabolite formed in one of the five soil degradation studies, see section 4.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Propargite	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: aquatic invertebrates acute EC50 = 14 µg a.s./L (regulatory concentration including a safety factor of 100 = 0.14 µg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment.in the situation that there is no change in the isomer ratio. Whilst this is unclear the risk assessment was not finalised..
TBPC	Toxic to aquatic organisms, endpoint driving the aquatic risk assessment: fish acute EC_{50} = 1490 µg a.s./L (regulatory concentration including a safety factor of 100 = 14.90 µg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment in the situation that there is no change in the isomer ratio. Whilst this is unclear the risk assessment was not finalised.

6.4. Air

Compound (name and/or code)	**Toxicology**

Propargite	Acutely toxic via inhalation (rat LC50 0.89 mg/L/4h; nose only)

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

- Updated technical specification removing the impurities below 1 g/kg (relevant for all the representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Clarification of the existence of the third chiral center in the molecule (relevant for all the representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Information addressing the behaviour of propargite isomers in the mammalian metabolism; their potentially different toxicity; the material tested in the toxicity studies with regard to different composition of isomers (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 2).
- The representativeness of the batches used in the toxicological studies with regard to the proposed specification has to be demonstrated by the applicant (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 2).
- A new valid genotoxicity data package with the proposed technical specification has to be submitted (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 2).
- Toxicological relevance of impurities present in the technical specification has to be assessed (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 2).
- Validation data for data generation methods 007/ISPV, 006/CRSA, and 007/ERSA used to generate tomato residue data (relevant for the representative use in tomato, submission date proposed by the applicant: unknown; see section 3).
- Reliable conversion factors to convert from the residue definition for monitoring to the residue definition for risk assessment (relevant for all the representative use on grapes , submission date proposed by the applicant unknown; see section 3).
- A new hydrolysis study according to representative conditions for food processing. Subsequently, additional studies on the magnitude of residues according to residue definition for risk assessment may be required. (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 3).
- Residues in following crops should be addressed further. (relevant for the representative use in tomato, submission date proposed by the applicant: unknown; see section 3).
- The applicant should address the consumer risk assessment with regard to the isomers of propargite and its metabolites. (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 3).
- The exposure patterns and consequent risk assessment to wild non target organisms, except soil dwelling organisms, needs to be characterised further, in relation to the impact that the potentially varying enantiomer ratios of propargite and any transformation products that retain either 3, 2 [16] or one chiral atom may have, on the risks assessed and the extent of risk mitigation required

[16] The identified metabolites TBPC and TBPC sulfate contain 2 chiral atoms

(relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see sections 4 and 5).

- Satisfactory information to address the route and potential transformation product formation of the cyclohexyl ring moiety of propargite was not available for soil and natural sediment water systems, (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 4).

- Identification of the minor transient metabolite ascribed as "unk 1", formed in soils has not been addressed, (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 4).

- Assessments of the potential for groundwater exposure from the metabolite ascribed as "unk 1" and TBPC-sulfate are triggered but are not available. For such and assessments degradation rates and sorption of TBPC sulfate and the unidentified metabolite "Unk 1" in soils would usually be required and these are not available, (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 4).

- A data gap was identified to the applicant should provide the dietary studies with birds (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

- Data gap was identified, for the applicant to further address the long-term risk to birds (relevant for the representative use on grapes (pre-emergence application) evaluated, submission date proposed by the applicant: unknown; see section 5).

- A data gap was identified, for the applicant to refine the long-term risk to mammals for all the representative uses (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

- A data gap was identified, the applicant to refine the risk from secondary poisoning of propargite to birds except for earthworm-eating bird in the grapes scenario and to refine the risk from secondary poisoning to mammals except for fish-eating mammals in the tomato scenario (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

- High risk to mammals from consumption of contaminated water was identified and need to be refined (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

- A data gap was identified for the applicant to further address the risk to non-target arthropods (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

- The effects of propargite on biological methods of sewage treatments should addressed (relevant for all the representative uses evaluated, submission date proposed by the applicant: unknown; see section 5).

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

- none

ISSUES THAT COULD NOT BE FINALISED

- The stereochemistry of the active substance related to the chirality of the sulphur atom in the molecule.
- Risk assessments that account for the consumer and environmental risk (excluding soil organisms) with regard to the isomers of propargite and its metabolites that contain chiral atoms.
- Dietary exposure assessment of propargite metabolites included in the residue definition for risk assessment
- For the metabolites TBPC-sulfate and the unidentified metabolite ascribed as "Unk 1", the groundwater exposure assessment could not be finalised in respect of the legal parametric groundwater limits. Consequently the risk to aquatic organisms for these metabolites in the situation when groundwater becomes surface was not finalised either.
- The fate and behaviour of the cyclohexyl ring moiety of propargite in soil and natural sediment water systems has not been addressed. Consequently the environmental risk assessment and groundwater exposure assessment for any transformation products that might be formed from this proportion of the molecule (e.g. 1,2-cyclohexanediol and derivatives) could not be finalised.
- The short-term risk assessment to birds could not be finalised based on the available data.
- The long-term risk to birds relevant for the representative use on grapes (pre-flowering application) could not be finalised.
- The risk assessment for non-target arthropods could not be finalised.
- The risk of propargite on biological methods of sewage treatments could not be finalised.

CRITICAL AREAS OF CONCERN

- The technical specification is not supported by the batches used in the toxicological studies.
- Due to the fact that propargite exerts carcinogenic potential on different organs in two strains of rats and a genotoxic mode of action cannot be disregarded, no reliable reference values can be set at this stage until a new valid genotoxicity data package with the proposed specification is available. Therefore, the risk assessment for consumers, operators, workers and bystanders cannot be conducted.
- The long-term risk to mammal was identified as high, with the data available.
- The risk from secondary poisoning to birds was identified as high, except for earthworm-eating bird in the grapes. The risk from secondary poisoning to mammals except for fish-eating mammals in the tomato scenario was assessed as high based on the available data.
- The risk to mammals from the consumption of contaminated water was assessed as high based on the available data.
- A high risk of propargite to aquatic organisms was identified (even with the use of risk mitigation measures comparable with 30 m non-spray buffer zone).

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[17] For further guidance documents see 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 (OECD)

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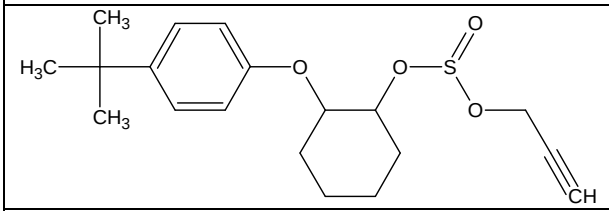
APPENDICES

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

Identity

Active substance (ISO, Common Name)	Propargite
Function	Acaricide
Rapporteur Member State	France (review), Italy (resubmission)

Chemical name (IUPAC)	(1*RS*,2*RS*;1*RS*,2*SR*)-2-(4-*tert*-butylphenoxy)cyclohexyl prop-2-ynyl sulfite
Chemical name (CA)	2-[4-(1,1-dimethylethyl)phenoxy]cyclohexyl-2-propynyl sulphite
CIPAC No	216
CAS No	2312-35-8
EEC No (EINECS or ELINCS)	219-006-1
FAO Specification (including year of publication)	Specification (Tentative) AGP:CP/206 (1984) minimum declared 900 g/kg ±25 g
Minimum purity of the active substance as manufactured (g/kg)	870 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	open
Molecular formula	$C_{19}H_{26}O_4S$
Molecular mass	350.5 g/mol
Structural formula	

Physical-chemical properties

Melting point (state purity)	The material solidified on cooling, but there was no distinct freezing point above –70ºC (99.1%)
Boiling point (state purity)	The material decomposed prior to boiling (99.2%)
Temperature of decomposition	210°C (99.2%)
Appearance (state purity)	brownish yellow colour oily viscous liquid with a strong sweet odour (99.2%) brown colour oily viscous liquid with a sweet musty odour (90.6%)
Vapour pressure (in Pa, state temperature)	4.04×10^{-5} Pa at 20°C
Henrys law constant (Pa m^3 mol^{-1})	6.4×10^{-2} $Pa.m^3.mol^{-1}$ at 20°C
Solubility in water (g.l or mg/l, state temperature)	0.215 mg/l at 20°C (water, pH 6.5)
Solubility in organic solvents (in g/l or mg.l, state temperature)	At 20°C (90.3%) : hexane > 200 g/l toluene > 200 g/l dichloromethane > 200 g/l methanol > 200 g/l acetone > 200 g/l
Surface tension	Not required as water solubility is < 1 mg/l.
Partition coefficient (log P_{ow}) (state pH and temperature)	log P_{ow} = 5.7 (temperature not given) (98.2%)
Dissociation constant	Propargite does not dissociate
UV/VIS absorption (max.) (If absorption > 290 nm state ε at wavelength)	No absorption was observed above 290 nm (98.6%)
Flammability	Propargite is a liquid. Auto-ignition temperature: 336°C.
Explosive properties	none
Oxidizing properties	none

Summary of representative uses evaluated (Propargite)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./ha	water l/ha	kg a.s./hl		
Grapes	EU	Omite 570 EW	F	Mites	EW	570 g/l	High volume spraying	BBCH 53 to 60 (pre-flowering) BBCH 71 to 83 post-flowering	1	-	0.855	200-1000	0.085 - 0.428	15	150 ml formulated product/hl, applied in 1000 l water = 1.5 l formulated product/ha 1, 2, 3, 4, 5
Tomatoes	EU	Omite 570 EW	F	Mites	EW	570 g/l	High volume spraying	BBCH 71 to 84	1	-	0.855	1000	0.085	15	150 ml formulated product/hl, applied in 1000 l water = 1.5 l formulated product/ha 1, 2, 3, 4, 5

1 The fate and behaviour of the cyclohexyl ring moiety of propargite in soil and natural sediment water systems has not been addressed, so the exposure assessments for these environmental compartments and groundwater were not finalised.
2 For the metabolite TBPC-sulfate and the unidentified metabolite ascribed as "Unk 1", the groundwater exposure assessment could not be finalised in respect of comparison to the parametric groundwater drinking water limit of 0.1µg/L

3 Operator, worker and bystander risk assessment not finalised because of the lack of an appropriate reference value.
4 Consumer risk assessment on real, representative and diverse off-crop arthropod communities would be neededunable to be conducted.
5 A high risk of propargite to aquatic organisms.

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

Methods of analysis

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

Technical as (principle of the method)	GC-FID
Impurities in technical as (principle of method)	GC-FID
Additive in technical as (principle of method)	FTIR
Plant protection product (principle of method)	GC-FID

Analytical methods for residues

Residue definitions for monitoring purposes

Food of plant origin		propargite
Food of animal origin		propargite
Soil		propargite
Water	surface	At least propargite, but data gaps need to be filled before the definition can be finalised.
	drinking/ground	At least propargite, but data gaps need to be filled before the definition can be finalised.
Air		propargite

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS : LOQ = 0.01 mg/kg (apples, oranges, grapes, tomatoes) (propargite)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS : LOQ = 0.01 mg/kg (bovine muscle, bovine kidney, bovine liver, bovine fat, chicken egg, milk) (propargite)
Soil (analytical technique and LOQ)	GS-MS : LOQ = 0.01 mg/kg (propargite)
Water (analytical technique and LOQ)	GS-MS : LOQ = 0.05 µg/l (propargite)
Air (analytical technique and LOQ)	GS-MS : LOQ = 0.3 µg/m^3 (propargite)
Body fluids and tissues (analytical technique and LOQ)	HPLC-MS/MS : LOQ = 0.01 mg/kg (bovine blood) (propargite)

Classification and proposed labelling

with regard to physical/chemical data	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rats: 75% based on urinary excretion + fixation in tissues+ biliary excretion evaluated as faecal metabolites at 25 mg/kg bw; same percentage expected at lower concentrations; no influence of a pre-treatment; maximal concentration in blood at 6 hrs. Lower absorption at high dose-levels.
Distribution ‡	Rats: Highest residue levels in kidneys (1-3 mg/kg) , followed by fat tissue, heart and liver, at 96 to 168 h.
Potential for accumulation ‡	Rats: No bioaccumulation potential.
Rate and extent of excretion ‡	Rats: At 25 mg/kg bw: 95% at 48 h, mainly via urine in males (58% at 48 h), similar urinary and faecal excretion in females.
Metabolism in animals ‡	Rats: Hydrolysis of the propynyl sulfite side-chain, subsequent oxidation and conjugation of the ter-butyl moiety, and hydroxylation of the cyclohexyl moiety. An additional pathway is metabolism of the side-chain by glutathione conjugation.
Toxicologically relevant compounds ‡ (animals and plants)	Parent
Toxicologically relevant compounds ‡ (environment)	Parent

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	2639 mg/kg bw	
Rat LD_{50} dermal ‡	> 4000 mg/kg bw	
Rat LC_{50} inhalation ‡	0.89 mg/L air /4h (aerosol, nose only)	**R23**
Skin irritation ‡	Irritant	**R38**
Eye irritation ‡	Irritant	**R41**
Skin sensitisation ‡	Sensitising (modified Buehler method & modified Magnusson & Kligman method)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Significant growth impairment or weight loss at least partially due to lower food intake (rats and dogs) Dogs (oral): hematopoietic system

	Rabbits (dermal): increase in neutrophil counts secondary to local toxicity.	
Relevant oral NOAEL ‡	1-year, dog: lower than 5.0 mg/kg bw/day (females: LOAEL) 13-weeks, rat: 7.1 mg/kg bw/day	
Relevant dermal NOAEL ‡	4-week, rabbit: systemic: 100 mg/kg bw/day	
Relevant inhalation NOAEL ‡	No data required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Inconclusive based on the available data (lack of genotoxicity studies with the proposed specification)	

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

Target/critical effect ‡	Rats: lower weight gain, food intake and efficiency of utilisation (both sexes). Haemolymphoreticular system (regenerative non-ferriprive anaemia; enlargement, reddening, sinus histiocytosis of lymph nodes) and testes (diminished/arrested spermatogenesis, degeneration: in old rats) **R48/22** Mice: Lower food intake. Spleen: potential target organ. (study considered supportive).	
Relevant NOAEL ‡	2-year, rat: 3.46 mg/kg bw/day (males)	
Carcinogenicity ‡	Rats: Jejunal undifferentiated sarcomas (Wistar and CD) and mammary tumours in Wistar rats. Mice: No carcinogenic potential.	**R40** Cat.3

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: lower body weight, lower body weight gain, lower food consumption Reproductive: minimal shortening of the gestation Offspring: lower pup weight from birth until weaning.	
Relevant parental NOAEL ‡	5.1 mg/kg bw/day	
Relevant reproductive NOAEL ‡	5.1 mg/kg bw/day	
Relevant offspring NOAEL ‡	5.1 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat: ano-genital and body surface staining, lower body weight gain Rabbit: decreased defecation, lower weight gain Developmental Rat: no adverse effect osbserved. Rabbit: higher frequency of fused vertebrae and of fused skull bones	**R63** Cat.3
Relevant maternal NOAEL ‡	Rats: 18 mg/kg bw/day Rabbits: 4 mg/kg bw/day (	
Relevant developmental NOAEL ‡	Rats: 105 mg/kg bw/day Rabbits: 6 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data required	
Repeated neurotoxicity ‡	No data required	
Delayed neurotoxicity ‡	No data required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Rats (CD): Transient jejunal cell proliferation was observed after one week but it was not confirmed after 4 weeks and 20 months. Oral 1 week NOAEL=3.1 mg/kg bw/day (female). CD-1 Mice and Wistar rats: not cell proliferation in the jejunum
Studies performed on metabolites or impurities ‡	No data available

Medical data ‡ (Annex IIA, point 5.9)

Eye and skin irritation reported

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not set due to major drawbacks in the genotoxicity datapackage		
AOEL ‡	Not set due to major drawbacks in the genotoxicity datapackage		
ARfD ‡	Not set due to major drawbacks in the genotoxicity datapackage		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Omite 570 EW	Concentrate: 5 % Spray dilution: 14% Rat in vivo

Exposure scenarios

Operator	Open - Risk assessment cannot be conducted
Workers	Open - Risk assessment cannot be conducted
Bystanders	Open - Risk assessment cannot be conducted

Classification and proposed labelling (Annex IIA, point 10)

	Peer review proposal
Propargite	**T (toxic)** **R23** Toxic by inhalation **R38** Irritating to skin **R41** Risk of serious damage to eyes **R43** Sensitizing to skin **R48/22** Harmful: danger of serious damage to health by prolonged exposure if swallowed **R63** Possible risk of harm to the unborn child **R40** Limited evidence of a carcinogenic effect

Residues

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

Plant groups covered	Fruiting vegetable (tomato) - foliar spraying Fruits (apple) – direct application (by painting) on fruits and/or on leaves
Rotational crops	insufficient data (data gap)
Metabolism in rotational crops similar to metabolism in primary crops?	Open
Processed commodities	Data gap
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Open pending further data In wine, TBPC and TBPC-diol were detected in higher amounts than propargite.
Plant residue definition for monitoring	Propargite (fruit only) Processed fruit commodities (if necessary) TBPC (provisional, pending further data)
Plant residue definition for risk assessment	Propargite and all metabolites identified in fruit (TBPC, TBPC diol, HOMeTBPC, HOMeTBPC diol, Carboxy TBPC, Carboxy TBPC diol, Carboxy TBPC triol) expressed as propargite
Conversion factor (monitoring to risk assessment)	Tomato: open, none proposed; Grapes: data don't permit proposing reliable CF

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

Animals covered	Lactating goat Lactating cow Data submitted but not peer reviewed since not required to support the representative uses
Time needed to reach a plateau concentration in milk and eggs	n/a n/a
Animal residue definition for monitoring	n/a
Animal residue definition for risk assessment	n/a
Conversion factor (monitoring to risk assessment)	n/a
Metabolism in rat and ruminant similar (yes/no)	n/a
Fat soluble residue: (yes/no)	Yes

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

	insufficient data (data gap)

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

Propargite was stable in orange juice (and concentrate), grapefruit, grapes, raisins (4 months), peaches (5 months), tomato, green hop (8 months), apple, orange and dry hop (12 months) stored frozen. TBPC and OH-TBPC were stable in grape for up to 3 years.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):	Yes	-	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	-	-
Muscle		-	-
Liver		-	-
Kidney		-	-
Fat		-	-
Milk			
Eggs		-	

1: total residue = sum of propargite, TBPC and OH-TBPC
2: mean group values, including propargite, TBPC and OH-TBPC values
3: maximum values are individual values, including the level of propargite and TBPC only (only mean group values of OH-TBPC were measured).

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	STMR
Table grapes	N S	No trial. 0.05; 0.09; 0.15; 0.18; 0.20; 0.26; 0.39; 0.39	Propargite only according to residue definition for monitoring; **insufficient data** to address residue definition for risk assessment	1.0 mg/kg (provisional)	0.39 mg/kg	0.19 mg/kg
Wine grapes	N S	0.13; 0.24; 0.26; 0.28; 0.29; 0.35; 0.43; 0.51; 0.53; 0.54; 0.66; 0.71; 0.89; 1.12 0.05; 0.09; 0.15; 0.18; 0.20; 0.26; 0.39; 0.39	Propargite only according to residue definition for monitoring; **insufficient data** to address residue definition for risk assessment There was a significant difference (using the Mann Whitney test as recommended by the JMPR) between the range of residues found in Northern and Southern regions. **Thus, the results were first considered separately and the highest values were retained for the risk assessment.**	2.0 mg/kg (provisional)	1.12 mg/kg	0.47 mg/kg
Tomatoes in field	N S	No trial. 0.02; 0.04; 0.04; 0.06; 0.12; 0.18; 0.34; 0.35	Propargite only according to residue definition for monitoring; **insufficient data** to address residue definition for risk assessment	0.5 mg/kg (provisional)	0.35 mg/kg	0.09 mg/kg

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

ADI	unable to allocate
TMDI (% ADI) according to WHO European diet	Not calculated, unable to conduct assessment
IEDI (WHO European Diet) (% ADI)	Not calculated , unable to conduct assessment
Factors included in IEDI and NEDI	None
ARfD	unable to allocate
NESTI (% ARfD) according to national (UK model) large portion consumption data	Not calculated, unable to conduct assessment
Factors included in IESTI and NESTI	none

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4) (provisional, to be reviewed pending further data, see above)

Crop/ process/ processed product	Number of studies	Processing factors for propargite		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Wine	2	0.03p	-	-
Grape juice	2	0.02p	-	-
Dried raisins	1	0.83p	-	-
Washed tomatoes	1	1.0p	-	-
Tomato juice	2	0.25p	-	-
Tomato puree	2	1.80p	-	-
Canned tomato	2	0.15p	-	-
Wet pomace	1	30.25p	-	-

p : provisional

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

MRLs for propargite	Wine grapes : 2.0 mg/kg Table grapes: 1.0 mg/kg Tomatoes (in field): 0.5 mg/kg

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	22-42 % after 90-100 d, [^{14}C-phenyl-Propargite]-label (n= 5)
Non-extractable residues after 100 days ‡	24-38 % after 90-100 d, [^{14}C-phenyl-Propargite]-label (n= 5) max 37.6% at 120 DAT
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	TBPC – 10.4 % at 22-30 d (n= 1) Unk 1 – 5.03-5.29% at 63-92 days TBPC-sulfate – max 7.62% at 90 days; >5%AR at 59-120 days.

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

Anaerobic degradation ‡

Mineralization after 100 days	2.7 % after 60 d, [^{14}C-phenyl-Propargite]-label (n= 1)
Non-extractable residues after 100 days	14.1 % after 60 d, [^{14}C-phenyl-Propargite]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	TBPC – 23.7 % at 60 d (n= 1) Unk 1 – 5.3% at 92 d (n=1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	TBPC – 20.3 % at 15 d (n= 1) (dark control : TBPC – 15.6 % at 15 d (n=1))

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	pH	t. °C / % MWHC	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10k Pa	St. (r^2)	Method of calculation
Silt loam	5.71	20°C / 44% of pF 2.5	91.47	301.4	50.1	χ^2=1.8	SFO
Silty clay loam	7.58	20°C / 43% of pF 2.5	55.56	184.5	29.1	χ^2=3.4	SFO
Sandy clay loam	6.9	25°C / 75% of 33 kPa	43.49	154.9	47.6	χ^2=2.9	SFO

Loamy sand	6.0	22°C / Not reported	54.53	167.3	65.9	χ^2=4.3	SFO
Sandy loam	6.6	25°C / 75% FC	84.4	697	429.3#	χ^2=5.4	DFOP k1=0.0398 k2=0.0026 g=0.64045
Geometric mean					72.2		

#DT_{50} for modelling used the K2 (slow phase) rate constant after normalising to FOCUS temperature (20ºC). **Note**: The normalised DT50 values have been calculated using a Q10 of 2.58.

TBPC	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sand	6.2	20°C/45% MWHC	7.36/51.1	-	12.6#	χ^2=12.1	FOMC α=1.296 ß=10.4125
Loam	5.87	20°C/45% MWHC	6.74/163	-	420$	χ^2=14.7	DFOP k1=0.1262 k2=0.0016 g=0.8707
Clay loam	7.57	20°C/45% MWHC	5.67/18.8	-	5.4	χ^2=14.2	SFO
Silty clay loam	7.58	20°C/43.4% MWHC	9.7/32.22	0.90322	5.2	r^2=0.994 χ^2=4.5	SFO
Geometric mean					19.63		

DT_{50} for modelling calculated as equivalent to SFO by taking the FOMC DT90/3.32=15.4d then normalising to FOCUS soil moisture reference conditions (-10kPa).

$ DT_{50} for modelling uses the K2 (slow phase) rate constant after normalising to FOCUS soil moisture reference conditions (-10kPa).

Field studies ‡

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St.	DT_{50} (d) Norm.	Method of calculation
Bare soil	Northern France	7.6	30	14.2	467.8	$\chi 2$=17.9 %	-	HS K1= 0.05 K2= 0.003 Tb= 22
Bare soil	Germany	5.9	30	10.2	206.2	$\chi 2$=13.9 %	-	DFOP K1= 0.15 K2= 0.007 g= 0.6
Bare soil	Italy	8.1	30	24.2	228.3	$\chi 2$=16.6 %	-	DFOP K1= 2.38 K2= 0.008 g= 0.39
Bare soil	Southern Spain	8.2	30	18.3	148.6	$\chi 2$=15.9 %	-	DFOP K1= 0.76 K2= 0.01 g= 0.37 Pini= 0.58

pH dependence ‡	No
Soil accumulation and plateau concentration ‡	Not calculated, not required

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy clay loam	6.9	25°C/not relevant	66.1/220	-	$\chi 2$=1.5%	SFO
Geometric mean/median		-	-	-	-	-

TBPC	Anaerobic conditions: stable under anaerobic conditions as can be seen in the anaerobic study conducted with parent.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡					
Soil Type	OC %	Soil pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	1.80	5.6	427	23415	1.39
Sandy loam	3.1	6.6	165	5293	0.97
Sandy loam	0.41	6.2	162	39344	1.28
silt loam	1.37	6.81	478	34896	1.13
clay loam	4.03	4.61	2326	57729	1.21
clay loam	2.75	6.86	1192	43378	1.19
sand	0.81	5.1	169	20985	1.03
clay	1.75	7.2	337	19265	1.07
Arithmetic mean			382/657	30538	1.16
pH dependence, Yes or No			No		

TBPC ‡					
Soil Type	OC %	Soil pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	1.80	5.6	8.4	460	0.96
Sandy loam	3.1	6.6	6.7	215	0.89
Sandy loam	0.41	6.2	1.2	284	0.88
Arithmetic mean			5.4	320	0.91
pH dependence, Yes or No			No		

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

Column leaching ‡	Not required
Aged residues leaching ‡	No valid data available/not required
Lysimeter/ field leaching studies ‡	Not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): K1=17.4 days, K2=266.6 days g=0.64045
Method of calculation	Kinetics: DFOP Worst case from lab

Application data	Crop: Grapes/Tomatoes Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 85/50 (respectively) Number of applications: 1 Interval (d): - Application rate(s): 855 g as/ha

PEC$_{(s)}$ (µg/kg)	Grapes		Tomatoes	
	Single application Actual (mg/kg)	Single application Time weighted average (mg/kg)	Single application Actual (mg/kg)	Single application Time weighted average (mg/kg)
Initial	0. 171		0.570	
Short term 24h	0.167	0.169	0.555	0.563
2d	0.162	0.166	0.541	0.555
4d	0.154	0.162	0.514	0.541
Long term 7d	0.143	0.157	0.477	0.522
28d	0.093	0.125	0.310	0.418
50d	0.069	0.105	0.230	0.351
100d	0.049	0.085	0.165	0.270
Plateau concentration	Not calculated, not required			

TBPC Method of calculation	DT_{50} (d): K1= 5.5 days, K2=433 days g=0.8707 Kinetics: DFOP Field or Lab: Lab (No field data available for TBPC)
Application data	Crop: Grapes/Tomatoes Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 85/50 (respectively) Number of applications: 1 Application rate assumed: 77.7 g as/ha (assumed Met I is formed at a

			maximum of 12.8 % of the applied dose and molecular weight relative to the parent: 0.71)	
PEC$_{(s)}$ (mg/kg)	Single application/ Grapes Actual	Single application Time weighted average	Single application/ Tomatoes Actual	Single application Time weighted average
Initial	0.0155		0.0518	
Short term 24h	0.0139	0.0147	0.0464	0.0491
2d	0.0125	0.0140	0.0417	0.0446
4d	0.0102	0.0126	0.0339	0.0421
Long term 7d	0.0076	0.0110	0.0253	0.0367
28d	0.0023	0.0057	0.0077	0.0190
50d	0.0019	0.0041	0.0063	0.0136
100d	0.0017	0.0029	0.0057	0.0098
Plateau concentration	Not calculated, not required			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: stable
	pH 7: DT50 = 64.8 days at 25 °C (SFO, χ^2=2.1) TBPC: 28.9 % AR (29 d) pH 7: DT50 = 8.4 days at 40 °C (SFO, χ^2=8.3) TBPC: 108.8 % AR (29 d)
	pH 9: DT50 = 1.1 days at 25 °C (SFO, χ^2=5.5) TBPC: 105.2 % AR (30 d) pH 9: DT50 = 0.2 days at 40 °C (SFO, χ^2=4.9) TBPC: 101 % AR (30 d)

Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 5.5 days (continuous irradiation) DT_{50} : 13.2 days (equivalent solar days) TBPC: max 43.05% AR (23 days), 39.7 % (30 days) Unk1: max 13.64% AR (23 days), 11.56 % (30 days) Unk4: max 19.37% AR (30 days) Note: further identification of unk1 and unk4 was considered not necessary due to the expected partitioning behaviour of propargite removing it from the top few mm of a water column in a natural system.
Quantum yield of direct phototransformation in water at Σ > 290 nm	3.11 x 10^{-5} mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	No.

Degradation in water / sediment

Parent	Distribution (max in sed 58% after 6 d.)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (d)	St. (r^2)	DT_{50}-DT_{90} water (d)	St. (r^2)	DT_{50}-DT_{90} sed (d)	St. (r^2)	Method of calculation
River	8.2	7.54	20 ± 2°C	19.7/65.4	0.981	8.6/28.6	0.949	29.6/98.4	0.949	SFO
Pond	7.55	7.33		17.7/58.9	0.985	12.6/41.7	0.88	22/73	0.88	
Geometric mean				18.7 /62.2		10.4/34.5		25.5/84.8		

TBPC	Distribution (max 25.6% whole system, max 17% in water and 21% AR in sediment)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
River	8.2	7.54	20 ± 2°C	11.8/39.3	0.981	11.8/39.1	0.949	9.5/31.6	0.949	SFO
Pond	7.55	7.33		25.1/83.5	0.985	16.8/55.6	0.88	30.7/102.1	0.88	
Geometric mean				17.2/57.9		14.1/46.6		17.1/56.8		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River	8.2	7.54	51.8% after 106 d. (end of the study).	Max 29.8 at 63 d.	29.3% at 106 d. (end of the study)
Pond	7.55	7.33	39.9% after 106 d. (end of the study).	Max 30.7 at 63 d.	28.9% at 106 d. (end of the study)

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: v.1.1 Molecular weight (g/mol): 350 Water solubility (mg/L): 0.215 Kf_{OC} (mg/l): 30538 DT_{50} soil (d): 72.4 (mean lab at pF2, 20°C) DT_{50} water/sediment system (d): 25.3 DT_{50} water (d): 10.6 DT_{50} sediment (d): 25.8 Crop interception (%): 70% (each crop) These DT_{50} all differ slightly from the final correct endpoints. These minor differences were accepted as close enough to not require any recalculations.
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: v.1.1 Vapour pressure: 4.04 x 10^{-5} Pa at 20°C Kfoc (mg/l): 30538 1/n: 1.05
Application rate	Crop: grapes/tomatoes Crop interception: set by the FOCUS surface water models Number of applications: 1 Interval (d): - Application rate(s): 855 g as/ha Application window: at maturity (summer), late spray drift values used for vines.

FOCUS STEP 1 Scenario	**Grapes**				**Tomatoes**			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	29.71	-	2090		14.69	-	2090	
24 h	7.18	18.45	2190	2140	6.83	10.76	2090	2090
2 d	6.99	12.76	2130	2150	6.65	8.75	2030	2070
4 d	6.61	9.78	2020	2110	6.29	7.61	1920	2020
7 d	6.09	8.31	1860	2040	5.80	6.94	1770	1950
14 d	5.03	6.93	1540	1870	4.78	6.10	1460	1780
21 d	4.15	6.14	1270	1710	3.95	5.52	1210	1630
28 d	3.43	5.55	1050	1570	3.26	5.04	995	1500
42 d	2.34	4.65	713	1340	2.22	4.26	678	1270

FOCUS STEP 2 Scenario	**Grapes** Northern EU				**Tomatoes** Northern EU			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	22.88	---	264	---	7.86	---	169	---
24 h	7.49	15.18	260	262	2.57	5.22	166	167
2 d	2.78	10.16	253	259	0.95	3.49	161	165
4 d	1.26	5.91	239	252	0.69	2.06	152	161
7 d	0.77	3.76	220	242	0.49	1.41	140	155
14 d	0.64	2.23	181	221	0.41	0.93	115	141
21 d	0.52	1.68	149	202	0.33	0.74	95	129
28 d	0.43	1.38	123	186	0.28	0.63	78	118
42 d	0.29	1.04	83	158	0.19	0.50	53	101

FOCUS STEP 2 Scenario	**Grapes** Southern EU				**Tomatoes** Southern EU			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	22.88	---	324	---	7.86	---	229	---
24 h	7.49	15.18	318	321	2.57	5.22	224	226
2 d	2.78	10.16	309	317	0.95	3.49	218	224
4 d	1.46	5.94	292	309	0.89	2.09	206	218
7 d	0.95	3.85	269	297	0.67	1.50	190	209
14 d	0.78	2.35	222	271	0.55	1.06	156	191
21 d	0.64	1.81	182	248	0.45	0.87	129	174
28 d	0.53	1.50	150	227	0.37	0.76	106	160
42 d	0.36	1.15	102	193	0.25	0.61	72	136

Tomato	**Water-body**	**Loca-tion**	**Step 3**	**PECsw (µg/l) at buffer zone (m)**			
				20*	**20****	**30***	**30****
PECsw (µg/l)	ditch	D6	5.320	0.398	0.398	0.270	0.270
	stream	R2	4.722	0.476	0.486	0.323	0.332
	stream	R3	4.965	0.501	0.502	0.453	0.341
	stream	R4	3.524	0.817	0.360	0.817	0.247
PECsed (µg/kg)	ditch	D6	3.368	0.251	0.276	0.170	0.195
	stream	R2	258.89	258.88	12.96	258.88	12.96
	stream	R3	34.284	33.890	1.815	33.876	1.802
	stream	R4	17.401	17.400	0.959	17.400	0.959

* only spray drift was considered (without run-off or dry deposition mitigation)
** also run-off (solute flux input by 80% and eroded soil input by 95%) and dry deposition mitigations were considered

Vines	**Water-body**	**Loca-tion**	**Step 3**	**PECsw (µg/l) at buffer zone (m)**					
				20*	**20****	**30***	**30****	**100***	**100****
PECsw (µg/l)	ditch	D6	14.398	1.108	1.108	-	-	-	-
	pond	R1	0.520	0.172	0.167	0.112	0.108	0.029	0.028
	stream	R1	10.276	0.953	0.960	0.512	0.519	-	-
	stream	R2	14.156	1.313	1.322	0.705	0.715	-	-
	stream	R3	14.885	1.381	1.382	0.742	0.743	-	-
	stream	R4	10.562	0.983	0.983	0.549	0.530	-	-

PECsed (µg/kg)	ditch	D6	29.142	2.212	2.296	-	-	-	-
	pond	R1	2.119	0.712	0.690	0.473	0.451	0.144	0.122
	stream	R1	1.256	0.733	0.113	0.713	0.085	-	-
	stream	R2	8.507	8.501	0.449	8.501	0.449	-	-
	stream	R3	9.499	9.392	0.556	9.387	0.551	-	-
	stream	R4	3.262	0.259	0.259	3.212	0.257	-	-

* only spray drift was considered (without run-off or dry deposition mitigation)
** also run-off (solute flux input by 80% and eroded soil input by 95%) and dry deposition mitigations were considered

Metabolite TBPC Parameters used in FOCUSsw step 1 and 2	Molecular weight: 248 Water solubility (mg/L): 3.47 Soil and water metabolite Koc (mg/l): 320 DT_{50} soil (d): 7.2* at pF 2 and 20°C DT_{50} water/sediment system (d): 18.4* DT_{50} water (d): 14.3 DT_{50} sediment (d): 20.1* Crop interception (%):set by the FOCUS surface water models Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment system: 38% *These DT_{50} (correct value for soil of 19.6 days is the largest difference) differ from the final correct endpoints. These differences were accepted as close enough to not require any recalculations.
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Koc (mg/l): 320 1/n: 0.91 Metabolite kinetically generated in simulation (yes): Formation fraction in soil (k_{dp}/k_f): 100%
Application rate	Crop: grapes/tomatoes Number of applications: 1 Interval (d): - Application rate(s): 855 g as/ha Depth of water body: 30 cm Application window: at maturity (summer)
Main routes of entry	Drift

FOCUS STEP 1 Scenario	**Grapes**				**Tomatoes**			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	20.32		45.30		16.27		45.30	
24 h	17.79	19.05	56.93	51.11	15.06	15.67	48.19	46.75
2 d	17.13	18.26	54.82	53.49	14.50	15.22	46.41	47.02
4 d	15.89	17.38	50.84	53.15	13.45	14.60	43.04	45.86
7 d	14.19	16.37	45.41	50.98	12.01	13.79	38.44	43.65
14 d	10.90	14.42	34.89	45.45	9.23	12.18	29.53	38.72
21 d	8.37	12.81	26.80	40.52	7.09	10.82	22.69	34.47
28 d	6.43	11.45	20.59	36.28	5.45	9.67	17.43	30.84
42 d	3.80	9.30	12.15	29.52	3.21	7.86	10.29	25.07

FOCUS STEP 2 Scenario	**Grapes** Northern EU				**Tomatoes** Northern EU			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	6.16	---	12.92	---	2.12	---	5.61	---
24 h	4.70	5.43	12.36	12.64	1.61	1.87	5.37	5.49
2 d	4.38	4.98	11.82	12.36	1.50	1.71	5.14	5.37
4 d	4.56	4.65	10.82	11.84	1.95	1.65	4.70	5.14
7 d	3.64	4.36	9.48	11.11	1.58	1.68	4.12	4.83
14 d	2.67	3.75	6.95	9.63	1.16	1.52	3.02	4.18
21 d	1.96	3.26	5.10	8.41	0.85	1.35	2.22	3.65
28 d	1.44	2.87	3.74	7.41	0.62	1.19	1.62	3.22
42 d	0.77	2.27	2.01	5.87	0.34	0.95	0.87	2.55

FOCUS STEP 2 Scenario	**Grapes** Southern EU				**Tomatoes** Southern EU			
Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)		PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0 h	6.16	---	13.81	---	2.12	---	5.61	---
24 h	4.70	5.43	13.21	13.51	1.61	1.87	5.37	5.49
2 d	4.38	4.98	12.64	13.22	1.50	1.71	5.14	5.37
4 d	4.85	4.69	11.57	12.66	1.95	1.65	4.70	5.14
7 d	3.90	4.49	10.13	11.88	1.58	1.68	4.12	4.83
14 d	2.86	3.92	7.43	10.30	1.16	1.52	3.02	4.18
21 d	2.10	3.43	5.45	8.99	0.85	1.35	2.22	3.65
28 d	1.54	3.03	4.00	7.92	0.62	1.19	1.62	3.22
42 d	0.83	2.40	2.15	6.27	0.34	0.95	0.87	2.55

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using all FOCUS groundwater scenarios and model, according to FOCUS 2000 and 2002 guidance. Model(s) used: Pearl 3.3.3. Crop: Grapes and tomatoes Geometric mean parent $DT_{50lab/field}$ 72.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: parent - 30538, $^1/_n$= 1.05. Metabolites: TBPC Geometric mean TBPC $DT_{50lab/field}$ 6.9 d* (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58) kinetic formation fraction from propargite 1.0. *note the correct value that should be used for modelling is longer at 19.63 days. K_{OC}: TBPC 320, $^1/_n$ = 0.91
Application rate	Application rate: 855 g/ha. No. of applications: One Time of application: 15 September grapes, 15 days before harvest tomatoes Crop interception 85% grapes, 50% tomatoes

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

	Scenario	Parent (µg/L)	TBPC (µg/L)
Model /Grapes & tomatoes	Chateaudun	< 0.001	< 0.001
	Hamburg	< 0.001*	< 0.001*
	Jokioinen	crops not present	crops not present
	Kremsmunster	< 0.001*	< 0.001*
	Okehampton	crops not present	crops not present
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

*Vines only

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, not required
Quantum yield of direct phototransformation	3.11 x 10^{-5} mol · Einstein $^{-1}$
Photochemical oxidative degradation in air ‡	DT_{50} of 2.155 hours derived by the Atkinson model (12 h)
Volatilisation ‡	vapour pressure : <4.04 x 10-5 Pa at 20°C
	Henry's Law constant: 6.4 x 10-7 atm m^3/mol
Metabolites	-

PEC (air)

Method of calculation	-

PEC(a)

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines	Soil: Propargite, TBPC,

(toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Surface Water: Propargite, TBPC Sediment: Propargite, TBPC Ground water: Propargite, TBPC, TBPC-sulfate, Unk 1 Air: Propargite Data gaps need to be filled before all these definitions except for air can be finalised.

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

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

Candidate for R53

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds				
Anas platyrhynchos	Propargite	Acute	8dLD50 =>4640 mg/kg bw	
Colinus virginianus	Propargite	Short-term	Not accepted	
Anas platyrhynchos	Propargite	Short-term	Not accepted	
Anas platyrhynchos	Propargite	Long-term	13.5	100
Colinus virginianus	Propargite	Long-term	142	
Mammals				
Rat	Propargite	Acute	2639	
Rat	Omite 570 EW	Acute	1650	
Rat	Propargite	Long-term	6.3	80
Additional higher tier studies				
No studies				

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

Tomatoes, 0.855 kg a.s./ha

Indicator species/Category[2]	Time scale	ETE (mg as/kg bw/day)	TER[1]	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
Insectivorous	Acute	46.0	>100	10
Insectivorous	Short-term	Data gap.	------	10
Insectivorous	Long-term	25.8	**0.52**	5

Indicator species/Category[2]	Time scale	ETE (mg as/kg bw/day)	TER[1]	Annex VI Trigger[3]
Frugivoruous	Long-term	17.7	**0.8**	5
Higher tier refinement – uptake via diet (Birds)				
Frugivoruous bird [1]	Long-term	1.67	8.1	5
Tier 1– uptake via drinking water (Birds)				
Mallard duck	Acute	393.3	>11.8	10
Tier 1 – secondary poisoning (Birds) [2]				
Earthworm-eating bird	Long-term	5.05	**2.7**	5
Fish-eating bird	Long-term	7.95	**1.7**	5
Tier 1– uptake via diet (Mammals)				
Small herbivorous	Acute	101	16.3	10
Small herbivorous	Long-term	29	**0.2**	5
Higher tier refinement – uptake via diet (Mammals)				
	Long-term	Data gap		5
Tier 1– uptake via contaminatedwater (Mammals)				
	Acute	205	**8.0**	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term	6.4	**1.0**	5
Fish-eating mammals	Long-term	0.4	15.7	5

[1] In higher tier refinement, a frugivorous bird was used as generic focal species (EFSA 2009), for the DDD (ETE) calculation, the concentration was set as C = 1.03 mg/kg, corresponding to the highest residue at day 0 out of 8 studies with tomatoes, PD=1, PT=1

[2] Calculation made according to SANCO/4145/2000. According to EFSA 2009, the TER for earthworm-eating bird is 4.3 and the TER for fish-eating bird is 1.7.

Grapes, 0.855 kg a.s./ha

Indicator species/Category[2]	Time scale	ETE (mg as/kg bw/day)	TER[1]	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
Insectivorous	Acute	46.0	>100	10
Insectivorous	Short-term	Data gap.	-----	10
Insectivorous	Long-term	25.8	**0.52**	5
Frugivoruous	Long-term	12.3	**1.1**	5
Higher tier refinement – uptake via diet (Birds)				
Frugivoruous bird [1]	Long-term	2.49	5.4*	5
Tier 1– uptake via drinking water (Birds)				
Mallard duck	Acute	393.3	>11.8	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Long-term	1.53	8.8	5
Fish-eating bird	Long-term	7.95	**1.7**	5
Tier 1– uptake via diet(Mammals)				
Small herbivorous mammal	Acute	101	16.3	10
Small herbivorous mammal	Long-term	29	**0.2**	5
Higher tier refinement – uptake via diet (Mammals)				
	Long-term	Data gap		5
Tier 1– uptake via drinking water (Mammals)				
	Acute	205	**8.0**	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term	2.0	**3.2**	5
Fish-eating mammals	Long-term	5.04	**1.3**	5

[1] In higher tier refinement, a frugivorous bird was used as generic focal species (EFSA 2009), for the DDD (ETE) calculation, the concentration was set as C=1.44 mg/kg, corresponding to the 95th percentile residue in grapes on day 0 from 15 studies with grapes, PD=1, PT=1

[*] The long-term risk to birds was assessed as low, for the representative use on grapes (post flowering application.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (µg a.s./L)
Laboratory tests				
Fish				
O. mykiss	Propargite	96 hr (flow-through)	Mortality, LC_{50}	43 (mm)
C. variegatus	Propargite	96 hr (static)	Mortality, LC_{50}	55 (mm)
L. macrochirus	Propargite	96 hr (flow through)	Mortality, LC_{50}	81 (mm)
P. promelas	Propargite	272 d (flow-through)	Growth NOEC	5.7 (mm)
O. mykiss	Omite 570 EW	96 hr (flow-through)	Mortality, EC_{50}	47 (mm)
O. mykiss	Omite 570 EW	96 hr (static plus sediment)	Mortality, LC_{50}	160 (mm)
O. mykiss	TBPC	96 hr (semi-static)	Mortality, EC_{50}	1490
Aquatic invertebrate				
D. magna	Propargite	48 h (flow-through)	Mortality, EC_{50}	14 (mm)
D. magna	Propargite	21 d (flow-through)	Reproduction, NOEC	9 (mm)
D. magna	Omite 570 EW	48 h (flow-through)	Mortality, EC_{50}	74 (mm)
D. magna	Omite 570 EW	48 h (static plus sediment)	Mortality, EC_{50}	70 (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (µg a.s./L)
D. magna	TBPC	48 h (static)	Mortality, EC_{50}	3350 (mm)
Sediment dwelling organisms				
C. riparius	Propargite	28 d (static, spiked water)	NOEC	320 (nom)
Algae				
S. capricornutum	Propargite	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 1080 (mm) > 1080 (mm)
Higher plant				
No studies				
Microcosm or mesocosm tests: no study				

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

Maximum PEC_{sw} values and TER values for Propargite – application to tomatoes at 0.855 kg a.s./ha[1]

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***S. capricornutum***	***C. riparius***	
			96h LC_{50}	272d NOEC	48h EC_{50}	21d NOEC	72h ErC_{50}	28d NOEC	NOEC
			43 µg/L	5.7 µg/L	14 µg/L	9 µg/L	>1080 µg/L	320 µg/L	x.xx µg/L
FOCUS Step 1	14.69		**2.9**	**0.38**	**1.0**	**0.6**	73.5	21.8	
FOCUS Step 2									
North Europe	7.86		**5.5**	**0.7**	**1.78**	**1.1**			
South Europe	7.86		**5.5**	**0.7**	**1.78**	**1.1**			
FOCUS Step 3									
D6 / ditch	5.320		**8.7**	**1.2**	**2.8**	**1.8**			
R3 / stream	4.965		**8.1**	**1.1**	**2.6**	**1.7**			
Annex VI Trigger**			100	10	100	10	10	10	5

[1] for each body type, only the scenario providing the worst case exposure is included, i.e. R3 for stream and D6 for ditch. For pond, PEC is not calculated.

$FOCUS_{sw}$ step 4

TER calculation for the most critical endpoint including different mitigation options for FOCUS Step 4 Scenario – application to tomatoes at 0.855 kg a.s./ha

Mitigation options	30 m non-spray buffer zone		Xx % input reduction required – all scenarios.		Max drift reduction (95 %)		Max run-off reduction (90%)		Max drainage reduction (90%)	
	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER
FOCUS Step 4										
D6 / ditch	0.270	**51.9**								
R2 / stream	0.323	**43.3**								
R3 / stream	0.453	**30.9**								
R4 / stream	0.817	**17.1**								

[1] The TER are calculated using the *Daphnia magna* L48h EC_{50}14 µg/L. This is not the most sensitive endpoint but leads to the worst case risk conclusions taking into account the trigger of 100.

Maximum PEC_{sw} values and TER values for Propargite – application to grapes at 0.855 kg a.s./ha [1]

Scenario	PEC global max (µg L)	PEC twa, 28d (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***S. capricornutum***	***C. riparius***	
			96h LC_{50}	272d NOEC	48h EC_{50}	21d NOEC	72h ErC_{50}	28d NOEC	NOEC
			43 µg/L	5.7 µg/L	14 µg/L	9 µg/L	>1080 µg/L	320 µg/L	x.xx µg/L
FOCUS Step 1	29.71		**1.45**	**0.19**	**0.47**	**0.3**	>36.35	10.78	
FOCUS Step 2									
North Europe	22.88		**1.9**	**0.25**	**0.61**	**0.4**			
South Europe	22.88		**1.9**	**0.25**	**0.61**	**0.4**			
FOCUS Step									

3								
D6 / ditch	14.396	**3.0**	**0.4**	**1.0**	**0.6**			
R1 / pond	0.520	**82.7**	**11.0**	**26.9**	17.3			
R3 / stream	14.885	**2.9**	**0.4**	**0.9**	**0.6**			
R4 / stream								
Annex VI Trigger**		100	10	100	10	10	10	5

[1] for each body type, only the scenario providing the worst case exposure is included, i.e. R1 for pond, R3 for stream and D6 for ditch.

$FOCUS_{sw}$ step 4

TER calculation for the most critical endpoint including different mitigation options for FOCUS Step 4 Scenario – application to grapes at 0.855 kg a.s./ha [1]

Mitigation options	30 m non-spray buffer zone		Xx % input reduction required – all scenarios.		Max drift reduction (95 %)		Max run-off reduction (90%)		Max drainage reduction (90%)	
	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER	PECsw	TER
FOCUS Step 4										
D6 / ditch	-	-								
R1 / pond	0.112	125.0								
R1 / stream	0.512	**27.3**								
R2 / stream	0.705	**19.9**								
R3 / stream	0.742	**18.87**								
R4 / stream	0.549	**25.5**								

[1] The TER are calculated using the *Daphnia magna* L48h EC_{50}14 µg/L. This is not the most sensitive endpoint but leads to the worst case risk conclusions taking into account the trigger of 100.

Maximum PEC_{sw} values and TER values for the metabolite TBPC – application to grapes [1]

Scenario	PEC global max (µg L)	PEC twa, 28d (µg L)	fish acute	Daphnia acute
			O. mykiss	***Daphnia magna***
			96h LC_{50}	48h EC_{50}
			1490	3350
FOCUS Step 1	20.32		**73.3**	164.9
FOCUS Step 2				
North Europe	6.16		242	543.8
South Europe	6.16		242	543.8
Annex VI Trigger**			100	100

[1] The application to grapes provides the worst case scenario.

Bioconcentration				
	Active substance	TBPC		
$logP_{O/W}$	5.7	4.71 (estimated by QSAR)		
Bioconcentration factor (BCF)[1] ‡	13964 (estimated value)			
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

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

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Propargite	> 100	47.92
Omite 570EW	> 53.3 (> 100 µg Omite/bee)	31.5 (59.1 µg Omite/bee)
Field or semi-field tests		

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Not required		

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

(Grapes and tomatoes, 0.855 kg a.s./ha)

Test substance	Route	Hazard quotient	Annex VI Trigger
Propargite	Contact	17.8	50
	Oral	<8.6	50
Omite 570EW	Contact	27.1	50
	Oral	<16.1	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri	Omite 570 EW	Mortality	4.5
Aphidius rhopalosiphi	Omite 570 EW	Mortality	7.2

(Grapes and tomato, 0.855 kg a.s./ha)

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field (3m, drift rate 90%)	Trigger
Omite 570 EW	*Typhlodromus pyri*	4.5	190	15,2	2
Omite 570 EW	*Aphidius rhopalosiphi*	7.2	119	9.5	2

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g a.s/ha)[1, 2]	End point	% effect	Trigger value
Chrysoperla carnea	Larvae	Omite 570EW, glass plates, 17 d Lab study	1282.5 Fresh residues	Mortality	100 (9DAT)	50 %
Orius laevigatus	Nymph	Omite 570EW, glass plates, 9 d Lab study	1282.5 Fresh residues	Mortality	100 (3DAT)	50 %

Species	Life stage	Test substance, substrate and duration	Dose (g a.s/ha)[1, 2]	End point	% effect	Trigger value
Aphidius rhopalosiphi	Adult	Omite 570EW, barley seedlings, 13 d Extended Lab study	1282.5/ 51.3 Fresh residues	Mortality Reproduction	100/0 (2DAT) 0/74 (reduction in fecundity at 13 DAT)	50 %
Typhlodromus pyri	Protonymph	Omite 570EW, barley seedlings, 7 d Extended Lab study	1282.5 / 51.3 Fresh residues	Mortality Reproduction	100 (1DAT) /100 (7DAT) Not evaluated	50 %
Chrysoperla carnea	Larvae	Omite 570EW, barley seedlings, 18 d Extended Lab study	1282.5 / 51.3 Fresh residues	Mortality Reproduction	14.3/0 (pupae and larvae mortality) 10/14.6 (reduction in eggs number)	50%
Orius laevigatus	Nymph	Omite 570EW, barley seedlings, 19 d Extended Lab study	1282.5/ 51.3 Fresh residues	Mortality Reproduction	66.7/4.8 (9DAT) 47/0 (19DAT)	50%
Amblyseius andersoni, Trichogramma cacoeciae and Orius laevigatus	Protonymphs Newly emerged adults 2nd instar nymphs	Omite 570EW, apples leaves treated in field, 12 wk Extended Lab study	1282.5/ 51.3 Fresh and aged residues	Mortality Reproduction	*Amblyseius Andersoni*: all effects below 25% after 1 wk aged residues at both rates, *Trichogramma cacoeciae*: all effects below 25% after 4 wk aged residues at both rates, *Orius laevigatus*: all effects below 25% after 1 d at both rates	50%

indicate whether initial or aged residues

Field or semi-field tests
No study.

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

Test organism	Test substance	Time scale	End point
Earthworms			
E. foetida	Propargite	Acute 14 days	LC_{50} 378 mg a.s./kg d.w. soil *
E. foetida	Omite 570EW	Acute	LC_{50} 210 mg a.s./kg d.w. soil. *
	Metabolite TBPC	Acute	No data. Assumed 21 mg a.s./kg d.w. soil. (1/10 of the parent)*
Other soil macro-organisms			
Litter bag study	Omite 570 EW	12 months	No effect at 428 g a.s./ha
Soil micro-organisms			
Nitrogen mineralisation	Omite 570 EW		<25% deviation after 28 d at 6.4 kg a.s./ha
Carbon mineralisation	Omite 570 EW		<25% deviation after 28 d at 6.4 kg a.s./ha
Field studies			
Not required			

* The LC50 values have to be divided by 2 for the risk assessment.

Toxicity/exposure ratios for soil organisms

Tomatoes, 0.855 kg a.s./ha (worst case)

Test organism	Test substance	Time scale	Soil PEC mg a.s./kg	TER	Trigger
Earthworms					
E. foetida	Propargite	Acute	0.57	331.6	10
E. foetida	Omite 570EW	Acute	0.57	184	10
E. foetida	Metabolite TBPC	Acute	0.052	201.9	10
Other soil macro-organisms					
No data					

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

Preliminary screening data

The effects of Propargite on flora and fauna was evaluated through screening data for its acaricidal, insecticidal, fungicidal, and herbicidal activity. The results of the screening studies carried out during the development of propargite indicate that this compound only has significant activity against mite species.

Where effects in other groups of organisms were observed, these were observed at spray concentrations/application rates tested being greater that the (0.855 kg a.s./ha) recommended under GAP except for the mosquito (*Aedes aegypti*) for which propargite gave 75% and 100% mortality at the high spray concentrations of 10 and 100 ppm, respectively, mildew (98% effect at a spray concentration of 125 ppm).

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure (g/ha)[2]	TER
Tomato, cucumber, lettuce, soybean, radish, carrot, maize, sorghum, ryegrass and onion	Omite 570 EW	> 2750	> 2750	1280	> 2.14

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

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

No study

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

Data gap.

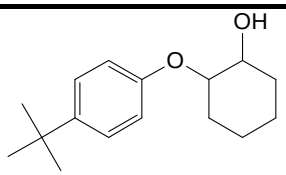
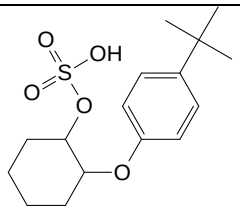
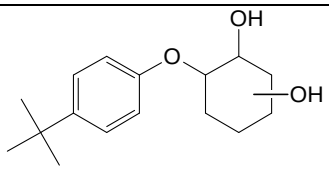
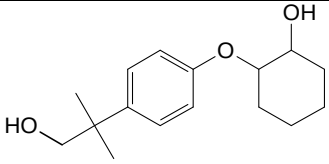
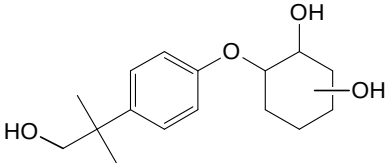
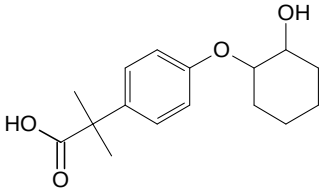
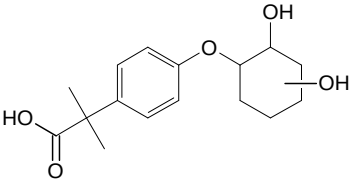
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

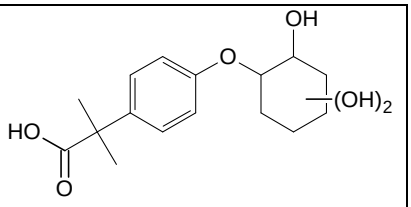
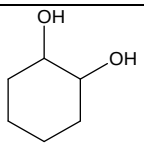
Compartment	
Soil	Propargite, TBPC
Water	Propargite, TBPC
Sediment	Propargite, TBPC
Groundwater	Propargite, TBPC

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

	RMS/peer review proposal
Active substance	R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
TBPC	(1*RS*,2*RS*;1*RS*,2*SR*)-2-[4-(2-methyl-2-propanyl)phenoxy]cyclohexanol **or** (1*RS*,2*RS*;1*RS*,2*SR*)-2-[4-(*tert*-butyl)phenoxy]cyclohexanol	
TBPC sulfate	(1*RS*,2*RS*;1*RS*,2*SR*)-2-[4-(2-methyl-2-propanyl)phenoxy]cyclohexyl hydrogen sulfate or (1*RS*,2*RS*;1*RS*,2*SR*)-2-(4-*tert*-butylphenoxy)cyclohexyl hydrogen sulfate	
TBPC diol	4-[4-(2-methyl-2-propanyl)phenoxy]-1,**x**-cyclohexanediol or 4-[4-(*tert*-butyl)phenoxy]-1,**x**-cyclohexanediol Unstated stereochemistry	
HOMe TBPC	(1*RS*,2*RS*;1*RS*,2*SR*)-2-[4-(1-hydroxy-2-methyl-2-propanyl)phenoxy]cyclohexanol	
HOMeTBPC diol	4-[4-(1-hydroxy-2-methyl-2-propanyl)phenoxy]-1,**x**-cyclohexanediol Unstated stereochemistry	
carboxy TBPC	2-(4-{[(1*RS*,2*RS*;1*RS*,2*SR*)-2-hydroxycyclohexyl]oxy}phenyl)-2-methylpropanoic acid	
carboxy TBPC diol	2-{4-[(2,**x**-dihydroxycyclohexyl)oxy]phenyl}-2-methylpropanoic acid Unstated stereochemistry	

carboxy TBPC triol	2-methyl-2-{4-[(2,**x,y**-trihydroxycyclohexyl)oxy]phenyl}propanoic acid Unstated stereochemistry	
1,2-cyclohexanediol	(1*RS*,2*RS*; 1*R*,2*S*)-cyclohexane-1,2-diol	

* The metabolite name in bold is the name used in the conclusion.

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
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
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
EW	emulsion oil in water formulation
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
FTIR	Fourier transform infrared spectroscopy

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

ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
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