Conclusion regarding the peer review of the pesticide risk assessment of the active substance

quinoclamine

finalized: 14 November 2007

(version of 7 December 2007 with a correction removing the fungicidal mode of action)

SUMMARY

Quinoclamine is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Sweden being the designated rapporteur Member State submitted the DAR on quinoclamine in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 15 June 2005. Following a quality check on the DAR, the peer review was initiated on 11 January 2006 by dispatching the DAR for consultation of the Member States and the sole notifier Agro-Kanesho Co. Ltd. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in October-November 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in March 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 25 September 2007 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide/algaecide on ornamentals, turf, lawns and nursery stock plants as proposed by the applicant, full details of the GAP can be found in the attached list of end points. The representative formulated product for the evaluation was "Mogeton", a wettable powder (WP) containing 250 g/kg of active substance.

Methods are not required for food of plant or animal origin as the use is on ornamentals, turf, lawns and nursery stock plants. Adequate methods are available to monitor quinoclamine in soil, drinking

[1] OJ No L 224, 21.08.2002, p. 25

water and air. A confirmatory method for surface water was identified as a data gap in the meeting of experts. A confirmatory method for surface water has been provided by the applicant but it has not been evaluated and therefore is not peer reviewed.
Some analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. However, a method of analysis for the relevant impurity dichlone (2,3-dichloro-1,4-naphthoquinone) is not available.

The acute oral toxicity of quinoclamine is moderate (R22 Harmful if swallowed) but the acute toxicity by inhalation or dermal application is low. The substance is irritating to the eyes (R36 Irritant to eyes) but not to the skin, and has sensitizing properties (R43 May cause sensitization by skin contact). Indications of haemolytic anaemia are observed in the short term studies in rats and dogs. Quinoclamine does not show a genotoxic or carcinogenic potential, but some teratogenic effects were observed and lead to the proposed classification Repro cat. 3, R63 Possible risk of harm to the unborn child. The acceptable daily intake (ADI) is 0.002 mg/kg bw/day, the acceptable operator exposure level (AOEL) is 0.03 mg/kg bw/day and the acute reference dose (ARfD) is 0.05 mg/kg bw. The dermal absorption values are 6.52% for the concentrate and the low dilution, and 10% for the high dilution. The operator exposure estimates in field or greenhouse are below the AOEL only when personal protective equipment is used. Preliminary estimates of children exposure show that the AOEL might be exceeded when the exposure occurs on the day of treatment.

Very high residue levels are present on grass directly after application of quinoclamine. A metabolism study demonstrated that parent compound is the main constituent of the residue on grass up to 2 weeks after application. Therefore only quinoclamine needs to be considered for risk assessment related to humans and terrestrial vertebrates in contact with treated lawn and turf.
One decline study demonstrated that residues decrease rapidly in favourable condition of grass growth. Also grass clipping results in low residues in regrown grass. Nevertheless it cannot be excluded that the decline of residues in grass may be significantly slower when growth rate of grass due to environmental conditions is weak. The need for further studies should therefore be considered at national level.
As a risk-mitigation measure related to human and wildlife exposure, label should give the user clear recommendations to apply the product in strong growing conditions of grass, and practical instructions to irrigate efficiently the treated area in case of low precipitation level, in accordance with the biological efficiency of the product.
Quinoclamine is moderately persistent in soil under dark aerobic conditions at 20 ºC and produces a number of minor metabolites (< 5 % AR). Quinoclamine ultimately degrades to non extractable residues and mineralizes to CO_2.
Under dark anaerobic conditions at 20 ºC, quinoclamine is low persistent and yields two main metabolites: AN and DHN.
Light may enhance the degradation of quinoclamine but its contribution to overall degradation in soil is deemed low due to the rapid microbiological degradation.

A field study is available where Mogeton 25WP (15 Kg /ha; 3.75 Kg a.s. / ha) was applied in four sites (two in spring and two in autumn) in Germany on bare soil. Only data from the spring trials was found relevant for the representative uses applied at EU level (spring application). PEC soil were calculated based on the field worst case spring application half life (DT_{50} = 29 d). The expert's meeting agreed that for uses in autumn longer dissipation pattern observed in autumn field trials would need to be considered. In that case, new kinetic analysis of the two autumn field studies would be necessary.

Quinoclamine may be considered low mobile in soil according the batch adsorption/desorption studies available.

According the available study quinoclamine is expected to be stable to hydrolysis under environmental conditions (pH 4 -9, 20 ºC).

According the aqueous photolysis study available in the original dossier quinoclamine has a short half life in water under irradiated conditions (2.2 d, corresponding to 4.2 d with 12 h irradiation per day in UK). A data gap was identified during the peer review for further information on non identified photolysis metabolites. In a new study, photolysis was slower. Two major photolysis metabolites were identified: phthalic acid and 2-carboxybenzaldehide. The two major photolysis metabolites were considered by the RMS in the updated risk assessment presented in the addendum.

According the available study quinoclamine is not ready biodegradable.

In dark water / sediment at 20 ºC, quinoclamine partitioned to the sediment and degraded in whole system with a first order half life of 14-15 d. Metabolite AN reached levels above 10 % AR in the sediment.

For the assessment of the representative use in lawns/turf, PEC_{SW} were calculated with the FOCUS SW scheme up to Step 3 using whole water /sediment degradation half lives. Only global maximum PEC_{SW} have been used in the risk assessment. Based on this PEC_{SW} calculation a risk for aquatic organisms was identified.

The FOCUS SW Step 4 calculations presented by the notifier were not found acceptable because input parameters employed deviated from those recommended by the RMS and agreed by the peer review and/or due to the implementation of additional mitigation by VFS or by spray shields. Also the experts in the meeting agreed that for uses on turf (particularly golf courses and other sport facilities) drainage should be considered a potential route of entry to surface water. However, the meeting agreed that available Step 4 calculations give an indication that significant mitigation regarding run off and spray drift will be necessary to mitigate risk to aquatic environment for the proposed representative use in turf / lawn. Applicant proposed that potential surface water contamination due to use in ornamental plants in pots may be managed in a way that contamination of surface water will be negligible. RMS calculated spray drift PEC_{SW} for the use on pots outdoor. During the experts meeting, it was indicated that in the case of pots standing in a hard surface high potential of surface water contamination as a consequence of run off is also possible. As there is not agreed way of dealing with run off from hard surfaces at EU level, it was agreed that this issue would have to be addressed a MS level.

Potential contamination of ground water for the use in turf was addressed following the FOCUS GW scheme with FOCUS PRZM (v 3.2.1.b). The resulting 80th percentile annual average concentrations of quinoclamine at 1m depth were below 0.001 µg / L in all the FOCUS GW scenarios.
Due to the low potential of volatilization and the estimated rapid photochemical transformation, the environmental concentrations in air and the transport through air are considered negligible.

The representative uses of quinoclamine are against algae and mosses in lawns/turf, ornamentals (outdoors) and nursery stock plants (out- and indoor). The risk assessment was focussed on the use in lawns and turf. Exposure of birds and mammals from the outdoor use in ornamentals was considered as negligible. The first-tier TERs for large herbivorous and small insectivorous birds were below the triggers of 10 and 5. The risk refinements based on residue decline in grass was accepted by the experts. However other suggested refinements were rejected and further data are required to refine the short-term risk to herbivorous birds, the short-term and long-term risk to insectivorous birds. The acute and long-term TERs for herbivorous mammals were below the triggers of 10 and 5. The refined long-term TER based on residue decline was calculated as 5.8. However the acute risk to mammals needs to be addressed further. Fish and daphnids were the most sensitive aquatic organisms triggering the acute and long-term risk assessment. No-spray buffer zones of up to 100 m are not sufficient as a risk mitigation measure to achieve TERs above the Annex VI triggers for the use in lawns/turf. The TER calculation of the RMS for the outdoor use in ornamentals and nursery stock plants indicated that a distance of 20m is not sufficient to mitigate the risk. However no agreed exposure scenario exists for the outdoor use in ornamentals and nursery stock plants. Therefore it was agreed that a risk assessment should be conducted at Member state level. The risk to bees, other non-target arthropods, earthworms, soil-micro organisms, non-target plants and biological methods of sewage treatment were assessed as low.

Key words: quinoclamine peer review, risk assessment, pesticide, herbicide, algaecide.

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Quinoclamine is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Sweden as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Sweden submitted the report of its initial evaluation of the dossier on quinoclamine, hereafter referred to as the draft assessment report, to the EFSA on 15 June 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 11 January 2006 to the Member States and the main notifier Agro-Kanesho Co. Ltd. as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives of the Member States identified and agreed during a written procedure in October-November 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised by EFSA in March 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 25 September 2007 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 19 December 2006)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 27 September 2007)

Given the importance of the draft assessment report including its addendum (compiled version of June 2007 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol. 3 B1-B2, B4-B6, B8-B9, Vol 4) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can basically be found in the original draft assessment report together with the peer review report which both is publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Quinoclamine is the ISO common name for 2-amino-3-chloro-1,4-naphthoquinone (IUPAC).

Quinoclamine, is a quinone herbicide/algaecide it is very similar to the quinone fungicide dichlone which is a relevant impurity in quinoclamine technical material. The mode of action is by binding to a protein involved in electron transfer in photosynthesis
(Hill-Reaction).

The representative formulated product for the evaluation was "Mogeton" a wettable powder formulation (WP).

The evaluated representative uses were as a herbicide/algaecide on ornamentals, turf, lawns and nursery stock plants as proposed by the applicant. Full details of the GAP can be found in the attached list of end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of quinoclamine as manufactured should not be less than 965 g/kg.
At the moment no FAO specification exists.

The technical material contains dichlone(2,3-dichloro-1,4-naphthoquinone, AKCN-01), which has to be regarded as a relevant impurity as it is more toxic to aquatic organisms than quinoclamine. The maximum content in the technical material should not be higher than 15 g/kg.

The content of quinoclamine in the representative formulation is 250 g/kg (pure).

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 quinoclamine or the respective formulation. However, as the meeting of experts ecotoxicology have confirmed that dichlone is a relevant impurity new data gaps have been identified for a method of analysis for dichlone in the formulation, spectra data and the content of the relevant impurity in the formulation before and after storage.

The main data regarding the identity of quinoclamine and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of quinoclamine in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible except that there is no method available for the relevant impurity as discussed above.

Methods are not required for food of plant or animal origin as the use is on ornamentals turf, lawns and nursery stock plants. Residues of quinoclamine in soil are analysed by GC-ECD with confirmation by HPLC-DAD with a limit of quantification of 0.02 mg/kg. Quinoclamine residues in drinking water can be analysed by GC-ECD with an LOQ of 0.01 µg/L with confirmation by GC-MS. For surface water the method is also GC-ECD with an LOQ of 2 µg/L however, a confirmatory method was identified as a data gap and the applicant has now submitted a method however it has not been evaluated and therefore has not been peer reviewed. The air method for quinoclamine is LC-MS/MS with an LOQ of 1.5 µg/m3.
An analytical method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicology

Quinoclamine was discussed by the experts in mammalian toxicology in March 2007 (PRAPeR 19, Round 4). It was agreed that the toxicological batches were compliant with the technical specification. The impurity dichlone was considered less toxic than quinoclamine and not toxicologically relevant.

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Quinoclamine was rapidly and extensively absorbed (>80% based on urinary and biliary excretion, plus the radioactivity remaining in the carcass after 48h). It was also widely distributed without evidence of accumulation. The metabolic pathway involved mainly conjugation, but also hydrolysis (with chlorine replacement). The conjugated products were larger molecules and generally polar in nature, that can be readily excreted from the body.

2.2. ACUTE TOXICITY

Quinoclamine had a moderate acute oral toxicity (200<LD_{50}<500 mg/kg bw) and no acute dermal toxicity (LD_{50}>2000 mg/kg bw). In the inhalation test, the highest technically attainable concentration was used (0.79 mg/L) with only slight toxic effects. Initially the classification with R20 (harmful by inhalation) was proposed, but the experts agreed not to classify in accordance with ECB's decision in November 2006. The substance was irritating to the eyes but not to the skin, and had sensitizing properties (Magnusson & Kligman test). Consequently, the proposed classification is: **Xn, R22 'Harmful if swallowed'; Xi, R36 'Irritant to eyes', R43 'May cause sensitization by skin contact'.**

2.3. SHORT TERM TOXICITY

The oral short term studies were performed in rats (28-day, old 90-day, new 90-day studies) and dogs (28-day and 90-day studies).

The target organs were the kidneys, the spleen and the liver in rats, and included also the urinary bladder and the bone marrow in dogs. Some findings were indicative of haemolytic anaemia (increased haemopoiesis, haematological changes) in both species. The experts discussed a possible classification with R48/22 ('Danger of serious damage to health by prolonged oral exposure') based on this effect, and decided to forward the question (**R48/22?**) to the competent authority for the final decision. The overall short term NOAEL was 3 mg/kg bw/day from the 90-day dog and the 90-d rat studies.

In a 28-day dermal study in the rat, the relevant systemic NOAEL was 100 mg/kg bw/day.

No studies were required for repeated inhalation since quinoclamine is not a volatile substance.

2.4. GENOTOXICITY

The genotoxic properties of quinoclamine were investigated with *in vitro* tests for gene mutations (Bacterial Reverse Mutation Test, Mouse lymphoma L5178Y cells/TK locus), for chromosomal aberrations (in human lymphocytes) and for DNA effects (Unscheduled DNA synthesis), and with an *in vivo* test for chromosomal aberration (Mouse Micronucleus Test).

All tests were negative except the *in vitro* cytogenetic assay in human lymphocytes that was positive in the presence of metabolic activation. Overall, the weight of evidence indicates that quinoclamine does not pose an *in vivo* mutagenic or genotoxic concern to humans.

2.5. LONG TERM TOXICITY

Long term studies were performed in rats (2-year), mice (80-week) and dogs (2-y).

In the rat study, the systemic NOAEL is 0.21 mg/kg bw/day based on increased kidney weight, epithelial hyperplasia throughout the urinary system and pancreatic acinar atrophy at the mid-dose. Effects were more pronounced at the high dose with renal papillary necrosis, cortical scarring, and slight increase in benign tumours of the urinary bladder.

In the mouse study, based on a decreased survival, urogenital findings, adrenal brown atrophy, stomach hyperkeratosis and chronic inflammation in females, the proposed systemic NOAEL was 0.38 mg/kg bw/day. Based on historical control data provided in an addendum (February 2007), the experts agreed that the incidence of tumours in the different groups were not dose-related or were within historical background.

In the dog study, the NOAEL proposed in the DAR was 1.5 mg/kg bw/day (50 ppm) based on decreased bodyweight gain or bodyweight losses, haematological changes due to anaemia, biochemical indications of liver toxicity, and histopathological changes in the adrenal gland, lung, spleen, liver and kidney. A re-evaluation of the study has been summarized in an addendum (February 2007) for the experts. The meeting agreed that the NOAEL had to be lowered to 0.31 mg/kg bw/day based on decreased erythrocytes in females, decreased bilirubin in females, pale mucosal membranes and brown granular pigment of urinary bladder mucosa, together with proliferation of bile duct and bile plugs of liver in females.

As a conclusion, based on the rat study, the overall long term NOAEL for systemic toxicity was 0.21 mg/kg bw/day and the overall long term NOAEL for tumour incidence was 2.82 mg/kg bw/day. The experts agreed that quinoclamine had no carcinogenic potential.

2.6. REPRODUCTIVE TOXICITY

The reproductive performance of rats exposed to quinoclamine was assessed in a 2-generation study. The parental and offspring NOAEL was 1.6 mg/kg bw/day, and the NOAEL for the reproductive parameters was 30.9 mg/kg bw/day. During the experts' meeting, a concern was raised with regard to the validity of the study (old study, from 1975, with limited description of parental effects) but the overall reproductive effects were considered as sufficiently investigated.

Four studies were performed for the developmental toxicity in rats and rabbits (1 with rats and 1 with rabbits in 1986, 1 with rats and 1 with rabbits in 2002), and historical background data were provided

in an addendum (February 2007) for the experts' meeting. The discussion was based on the occurrence of hydronephrosis (second rat study and second rabbit study) and effects on heart vessels (both rat studies and the first rabbit study).

The agreed maternal NOAEL for the **rat** studies was 5 mg/kg bw/day, based on decreased body weight gain and enlarged spleen; and the NOAEL for teratogenic effects was 20 mg/kg bw/day, based on major visceral abnormalities (inominate artery absent and interrupted aortic arch in the first study, hydronephrosis in the second study).

The agreed maternal NOAEL for the **rabbit** studies was 30 mg/kg bw/day (the highest dose tested), and the NOAEL for developmental effects was 17.5 mg/kg bw/day based on the occurrence of hydronephrosis together with increased renal pelvic cavitation in the recent rabbit study.

According to these results, the experts agreed to forward the proposal for classification **Repro cat.3 R63 Possible risk of harm to the unborn child** to the competent authority.

2.7. NEUROTOXICITY

From the overall toxicological profile and taking into account the chemical structure of quinoclamine, no specific neurotoxicity studies were performed or required.

2.8. FURTHER STUDIES

In a dermal embryo-foetal development study with rats, slight maternal toxicity was elicited at 600 mg/kg bw/day but no embryotoxicity and no teratogenicity. The maternal NOAEL was 100 mg/kg bw/day and the NOAEL for teratogenic effects was 600 mg/kg bw/day.

2.9. MEDICAL DATA

No hazardous incidents had occurred with workers in the production facilities of quinoclamine. No information was available about clinical cases or poisoning accidents.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

The agreed **ADI** was 0.002 mg/kg bw/day, based on the 2-year rat study, with a use of a safety factor of 100. With respect to the dose levels where tumours in the bladder were found there is a margin of safety of 1000.

The agreed **AOEL** was 0.03 mg/kg bw/day, based on the 90-day dog study, with the use of a safety factor of 100. With respect to the lowest dose levels where teratogenic effects were observed in the rabbit study, there is a margin of safety of 1000.

The agreed **ARfD** was 0.05 mg/kg bw, based on the 28-day rat study supported by the developmental rat study, with the use of a safety factor of 100.

2.11. DERMAL ABSORPTION

An *in vitro* test for dermal absorption, using human and rat skin, was performed with Mogeton WP (26.6%) and presented in the DAR. Revised results with inclusion of skin depot were presented in the

addendum and discussed by the experts. The highest dilution had not been tested, but the meeting agreed on a default value of 10% for the watering can use (1:10,000). Due to uncertainties in the study design for the concentrate (powder), it was also agreed to allocate the higher value of 6.52% as a worst case, since this is the value for the spray dilution (1:1000).

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Mogeton WP is a wettable powder containing 250 g quinoclamine/kg for which three representative uses are described: turfs and lawns, ornamentals (in field or potted plants), and nursery stock plants in field or greenhouse. The application rate is 3.75 kg as/ha, in 1000 L of water for spray application in fields (tractor or hand held), and in 10,000 L of water for watering can in ornamentals (potted) and nursery stock plant in field or greenhouse.

The **amateur use** for home gardens has not been considered by the experts. Preliminary calculations provided in the DAR and the addendum to the DAR, February 2007, indicates that the exposure for amateur home garden use of a handheld sprayer is below the AOEL without use of PPE in the German model only. Amateur use of can is below AOEL, without PPE, in both models. However it should be noted that these calculations include modifications of the models that have not been discussed by the experts. This has to be considered at Member State level.

Operator exposure during field use

The mode of application in field is spraying or watering cans. For the spray application, the adjustments of the input parameters of the German and UK models were discussed by the experts. It was agreed that the models should be used with standard assumptions in a first step, and that refinements could be used in a second step, if supportive information was provided by the applicant.

For the use of watering can, no model exists or has been agreed upon within EU. As worst cases, the UK and the German models for hand held professional sprayer are used.

Revised estimated exposure values were provided in an addendum (June 2007) and can be found in the following table.

Estimated exposure presented as % of AOEL (0.03 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Model	No PPE	PPE	Level of PPE*
	Spraying in turf or potted plants		
German – tractor	2120	63	M/L: gloves and RPE A: gloves, coverall and sturdy boots
German – hand held	1246	76	M/L: gloves and RPE A: gloves, RPE and coverall
UK POEM – tractor	16648	878	M/L: gloves and RPE A: gloves

Model	No PPE	PPE	Level of PPE*
UK POEM – hand held	4047	334	M/L: gloves and RPE A: gloves and coverall
	Watering can in potted plants		
UK POEM – hand held	2856	97	M/L: gloves and RPE A: gloves and coverall
German – hand held	1498	74	M/L: gloves, RPE, broad brimmed head wear A: gloves, RPE, coverall and sturdy boots

PPE*: personal protective equipment; RPE: respiratory protective equipment; M/L: mixing and loading ; A: application

Operator exposure during greenhouse use

The mode of application in greenhouse is spraying or watering can. Both NL model (Van Hemmen J.J., 1993) and German data (IVA - Mich, 1996) were used for the exposure assessment by spraying. Exposure by use of watering can was estimated with the NL model and with the UK POEM model for hand held professional sprayer as a worst case. Revised calculations were provided in an addendum (June 2007) and are presented in the following table.

Estimated exposure presented as % of AOEL (0.03 mg/kg bw/day), according to calculations with the NL model and the German data.

Model	No PPE	PPE	Level of PPE*
	Spraying		
NL – hand held	12964	808	M/L/A: gloves, coverall and RPE
German data – geometric mean	1066	34	M/L/A: RPE + coverall and gloves
German data – 75th percentile	1843	75	M/L/A: RPE + coverall and gloves
German data – maximum values	4051	126	M/L/A: RPE + coverall and gloves
	Watering can		
NL – hand held	2500	391	M/L/A: gloves, coverall and RPE
UK POEM – hand held	2856	97	M/L: gloves and RPE; A: gloves and coverall

PPE*: personal protective equipment; RPE: respiratory protective equipment; M/L: mixing and loading; A: application

The exposure estimates for the different applications (field or greenhouse, spraying or watering can) are below the AOEL only when PPE are used. It should be noted that these calculations are considered in the addendum to be an overestimation of exposure since the work rate is considered to be much lower for spraying or using watering cans on moss in turf and pots in fields.

Bystander exposure

Estimated exposure to bystanders was revised in the addendum 1 (February 2007) based on a dermal absorption value of 6.52% and gave a value of 13% of the AOEL. A new calculation based on the agreed dermal absorption value (10%) is not expected to increase the level of exposure above the AOEL. In addition, little wind drift is expected with use of a watering can.

Worker exposure

The main exposure route for the worker is dermal during potting of plants.

In the addendum 2 (June 2007), revised worker exposure estimates are given with the agreed dermal absorption value (10%). The resulting values are below the AOEL when exposure occurs on day of application only when coverall and gloves are worn by the worker.

Children exposure

There is no agreed model to evaluate the exposure of children since they are not typical re-entry workers. Very conservative calculations (addendum 1, February 2007) show that the AOEL may be exceeded at the day of treatment.

The experts agreed to ask the applicant to provide an exposure estimate of children entering a treated area, using the US EPA model with a hand to mouth scenario. This has been included in the addendum 2 (June 2007) but not peer-reviewed (provided after the expert meeting). According to the available data, the exposure estimates might exceed the AOEL on the day of treatment. Therefore children should not be allowed to re-enter public areas on the day of treatment. Based on the available information (see section 3.1.1) no exclusion period can be identified for the re-entry of children where exposure is below the AOEL.

3. Residues

Representative uses of quinoclamine do not result in any consumer exposure.

Nevertheless, a metabolism study and a residue trial in grass were submitted by the applicant in order to provide basis for exposure assessment of humans and non target organisms in contact with treated area.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. Primary crops

A metabolism study in grass (evaluated in the original DAR) has been submitted with radiolabelled quinoclamine applied at normal use rate. Total radioactive residues continuously decreased from 608 mg/kg fresh weight 2 days after application to 13 mg/kg fresh weight 28 days after application. Quinoclamine represented 94-63% of the extractable radioactivity within 14 days after application and 28% at the last sampling (28 days after application). The remaining extracted radioactivity was not identified but consisted of different polar and non polar compounds. A metabolic pathway in plant is therefore not possible to determine. Nevertheless, the study shows that quinoclamine is the most

important constituent of the residue within 14 days after application and contribution of metabolites to the risk is minor within this time interval. Therefore it is agreed that risk assessment for humans and terrestrial vertebrates in contact with treated grass can be based on the exposure to parent compound only.

One residue decline study on grass was conducted in Germany in June-July 2005 (evaluated in Addendum, February and revised in May 2007). Initial residues at day 0 after application were 406 mg quinoclamine/kg fresh grass. The study showed that favourable growth conditions for grass, with summer temperature, normal precipitation level and additional irrigations (10 and 5 mm on days 6 and 13, respectively), drastically decrease the residue levels (8 mg/kg fresh grass after 14 days and less than 1 mg/kg fresh grass after 28 days).

A separate part of the study indicated that intermediate grass clippings reduced the residue levels on regrown grass even more efficiently.

Nevertheless, only this single study is available and, although scientifically reliable, cannot be considered as representative of all possible conditions. In the opinion of EFSA it cannot be excluded that other growing conditions may result in a significantly longer persistence of the compound on grass. Even if the metabolism study shows comparable rate in residue decline, residues at day 2 in the metabolism study were ten times higher than in the field study (555 mg/kg versus 57 mg/kg). The need for further studies should therefore be considered to cover a representative range of grass and environmental conditions.

As a risk-mitigation measure related to human and wildlife exposure, label should recommend the user to irrigate the treated area in case of low precipitation level following a programme to be determined, in accordance with the biological efficiency of the product.

3.1.2. Succeeding and rotational crops

No data were submitted related to potential transfer of soil residues to rotational crops. The eventual conversion of turf, lawn, ornamental fields or nurseries to edible plant production is therefore not covered.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

No livestock exposure resulting form the representative uses is expected.

3.3. CONSUMER RISK ASSESSMENT

Consumer exposure and risk assessments are not relevant for the representative uses of quinoclamine.

3.4. PROPOSED MRLS

MRL setting is not relevant for the representative uses of quinoclamine.

4. Environmental fate and behaviour

Quinoclamine fate and behaviour in the environment was discussed in Parma at the meeting of experts PRAPeR 17 in March 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. Route of degradation in soil

The metabolism of quinoclamine in soil under dark aerobic conditions at 20 ºC was investigated in one study with two soils (pH 5.5-7.3; OM 1.6 – 2.3 %; clay 5.1 – 26.4 %) adjusted to 40 % MWHC. In two additional soils (pH 5.2 -7.5; OM 1.9 – 4.0 %; clay 2.9 – 11.8 %) only the extractable radioactivity and the remaining quinoclamine were determined.

A number of minor metabolites (< 5 % AR) were identified as transformation products of quinoclamine through, substitution or elimination of chlorine, elimination of amine moiety and reduction of the quinone, and possible formation of acetamide. Non extractable residue amounted up to 43.5 % AR after 100 d. Mineralization reached a maximum of 43.4 % AR after 100d.

Degradation of quinoclamine was investigated under dark anaerobic at 20 ºC in a separated study with one soil (pH 6.8; OM = 4 %; clay = 14 %). Under these conditions the degradation of quinoclamine was faster and two metabolites were identified above 5 % AR: **AN** (2-amino-1,4-naphthalenedione, max 14.6 % AR after 14 d) and **DHN** (1,4 dihydronaphthalenedione, max 5.4 - 6 % AR after 7-14 d).

Photodegradation in soil of quinoclamine was investigated in a study. Light accelerates the degradation of quinoclamine and a photolysis metabolite **S7** was identified at levels above 5 % AR at the end of the study. However, based on the slow photolysis rate (DT_{50} = 52 d continuous irradiation) compared to the rate of the microbial degradation no further data was considered necessary by the RMS.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

Rate of degradation of quinoclamine in soil was investigated in the same studies employed to establish the route of degradation. Quinoclamine is moderately persistent in soil ($DT_{50\ aerobic\ 20\ ºC}$ = 20 – 39 d) under aerobic conditions but low persistent ($DT_{50\ anaerobic\ 20\ ºC}$ = 4 d) under anaerobic ones.

A field study is available where Mogeton 25WP (15 Kg /ha; 3.75 Kg a.s. / ha) was applied in four sites in Germany on bare soil. In two of the sites it was applied in spring (Gnaschwitz and Rostock) whereas in the other two sites it was applied in autumn (Koetschau and Stutensee). Degradation data could be fitted reasonable well with first order kinetics for Gnaschwitz and Rostock (DT_{50} = 12.4 d and 29 d respectively) but not for the other two sites.

PEC soil were calculated based on the field worst case spring application half life (DT_{50} = 29 d). The expert's meeting agreed that this value was adequate for the representative uses proposed, but for uses in autumn longer dissipation pattern observed in autumn applications would need to be considered. In that case, new kinetic analysis of the two autumn field studies would be necessary. RMS fitted Stutensee to hockey-stick model (bi-phasic) ($DT_{50\ (overall)}$ = 42 d [$DT_{50\ first\ phase}$ = 25 d, $DT_{50\ second\ phase}$ =

134 d]; $DT_{90\ (overall)}$ = 358 d) however no reasonable fitting was possible for the Kötschau site. The dissipation end points for these two field trials may not be considered peer reviewed, but the experts' meeting agreed that at least for one of the autumn trials the biphasic pattern is apparent.
New PEC soil presented by the RMS in addendum of February 2007 for the use in ornamentals was also agreed by the meeting.

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

Two batch adsorption/desorption studies with a total of six diferents soils are available for quinoclamine. This substance may be considered to be low mobile in soil (K_{foc} = 552 – 1592 mL / g).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. Surface water and sediment

According the available study quinoclamine is expected to be stable to hydrolysis under environmental conditions (pH 4 -9, 20 ºC). According the aqueous photolysis study available in the original dossier quinoclamine has a short half life in water (pH 5) under irradiated conditions (DT_{50} = 2.2 d, corresponding to 4.2 d (12 h) in UK). Seven unknown degradation products were found but not identified. However, it was possible to conclude that none of the compounds was identical to any of the transformation products already known for quinoclamine. Therefore, a data gap was identified during the peer review. A new aqueous photolysis study was provided by the applicant and summarized by the RMS in the Addendum from February 2007. In this study, photolysis was slower than in the previous study (DT_{50} = 11.9 – 14.1 d under continuous irradiation). Two major photolysis metabolites were identified: **phthalic acid** (max 10.8 % AR after 11 d continuous irradiation) and **2-carboxybenzaldehide** (max. 19.5 % AR after 11 d continuous irradiation). Other four photolysis metabolites were found in this study at levels below 10 % AR. The two major photolysis metabolites were considered by the RMS in the updated risk assessment presented in the addendum. The FOCUS Step 3 PEC_{SW} calculations presented by the RMS in the addendum were considered adequate for the risk assessment by the experts in the meeting.
According the available study quinoclamine is not ready biodegradable.
Degradation in dark water / sediment at 20 ºC was investigated in a study with two systems (pH_{water} 8.0 – 8.6; $pH_{sediment}$ 7.5 – 7.6; $OM_{sediment}$ 2.1 – 7.7 %). In these experiments, quinoclamine partitioned to the sediment (max. 27-35 % AR after 2 d, $DT_{50\ water}$ = 4 – 5 d) and degraded in whole system with a first order half life of 14-15 d. The sediment in these systems had anaerobic conditions were the degradation of quinoclamine is expected to be faster than in aerobic ones. Metabolite AN reached levels above 10 % AR in the sediment. This metabolite degraded with a half life of 25-26 d in the whole system.
For the assessment of the representative use in lawns/turf, PEC_{SW} were calculated with the FOCUS SW scheme up to Step 3 by the RMS using whole water /sediment system degradation half lives. Only global maximum PEC_{SW} have been used in the risk assessment. Based on this PEC_{SW} calculation a risk for aquatic organisms was identified.

In the original dossier, the applicant presented a proposal of FOCUS SW Step 4 calculations considering a buffer zone of 20 m as risk mitigation measure. Standard spray drift reduction and a reduction of run-off of 97.5 % were assumed. Implementation of run off mitigation measures to FOCUS SW calculations was not agreed at the time of the peer review. Therefore, a data gap was identified for new FOCUS SW water calculations up to Step 4 incorporating only spray drift buffer strip mitigation. The calculations presented by the notifier were summarized and evaluated in the addendum by the RMS. However, they were not found acceptable because input parameters employed deviated from those recommended by the RMS and agreed by the peer review and/or because of the implementation of additional spray drift mitigation by spray shields in the calculation. Therefore, only FOCUS SW Step 3 calculations are considered with respect to the EU risk assessment. However, the meeting agreed that available Step 4 calculations give an indication that significant mitigation regarding run off and spray drift will be necessary to mitigate risk to aquatic environment for the proposed representative use in turf / lawn. Also the experts in the meeting agreed that for uses on turf (particularly golf courses and other sport facilities drainage should be considered a potential route of entry to surface water).

Applicant proposed that potential surface water contamination due to use in ornamental plants in pots may be managed in a way that contamination of surface water will be negligible. RMS calculated spray drift PEC SW for the use on pots standing outdoor. During the experts meeting it was indicated that in the case of pots standing in a hard surface high potential of surface water contamination as a consequence of run off is also possible. As there is no agreed way of dealing with run off form hard surfaces at EU level, it was agreed that this issue would have to be addressed a MS level.

4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products

Potential contamination of ground water for the use in turf was addressed following the FOCUS GW scheme with FOCUS PRZM (v 3.2.1.b). The resulting 80th percentile annual average concentrations of quinoclamine at 1m depth were below 0.001 µg / L in all the FOCUS scenarios.

4.3. FATE AND BEHAVIOUR IN AIR

Due to the low potential of volatilization and the estimated rapid photochemical transformation, the environmental concentrations in air and the transport through air are considered negligible.

5. Ecotoxicology

Quinoclamine was discussed at the PRAPeR experts`meeting for ecotoxicology (PRAPeR 18) in March 2007. The risk assessment was conducted for the use in lawns/turf. No full risk assessment was conducted for the use in ornamentals and nursery stock plants. The RMS informed during the peer-review that the risk assessment done for outdoor use in ornamentals and nursery stock relates to plants placed in pots or containers. The experts considered impurity AKCN-01 (dichlone) as ecotoxicologically relevant since it is more toxic to daphnids compared to quinoclamine. However the

risk to aquatic organisms is considered to be low because of the low concentrations expected in the environment.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Toxicity data were available only for one bird species (*Colinus virginianus*). The acute toxicity study with pigeon (*Columba livia*) was assessed as not valid. A new short-term (dietary) study with mallard duck (*Anas platyrhynchos*) was submitted and evaluated in an addendum. The observed endpoint was higher compared to the endpoint for *C. virginianus* suggesting that bobwhite quail was more sensitive and no further studies (acute and long-term) with mallard duck were considered necessary.

The representative uses of quinoclamine are against algae and mosses in lawns/turf, ornamentals (outdoors) and nursery stock plants (out- and indoor). The risk assessment was conducted for the use in lawns and turf only. Exposure of birds and mammals from the outdoor use in ornamentals was considered as negligible by the RMS. During the peer-review process it was explained by the RMS that the use in ornamentals is on potted flowers and the product is applied by direct spraying or watering of the soil surface of the pots. Hence birds potentially feeding on the leafy parts or taking insects from leafs would not be exposed significantly. The experts in the meeting accepted this explanation and agreed that no risk assessment for birds and mammals is required for the outdoor use in potted ornamentals and nursery stock plants.

The first-tier TERs for large herbivorous and small insectivorous birds were below the triggers of 10 and 5. A new refined risk assessment was presented in an addendum to the DAR. Residue decline in treated lawns and insects was suggested to refine the risk to herbivorous and insectivorous birds. The acute and long-term TERs were >11 and 6.8 for herbivorous birds. However the short-term TER of 2.2 was still significantly below the trigger of 10. It was argued that herbivorous birds would be scared away from lawns/turf by human activities. The meeting agreed that this argumentation is not sufficient to address the potential high risk to herbivorous birds since geese are observed regularly on lawns/turf. The experts identified a data gap to refine the short-term risk to herbivorous birds further.
The applicant suggested using the residue decline over an exposure window of 5 days to refine the short-term risk. The experts agreed that it may be justified to use residue decline in the risk refinement because of the very rapid dissipation. Dead birds were observed from day 3 on in the dietary study. Therefore it was suggested to use a 3 day exposure window. The RMS recalculated the short-term TER according to the recommendations of the meeting to be 9.3 which is still below the trigger of 10. One residue study on grass was conducted in Germany in June 2005. Initial residues at day 0 after application were 405.5 mg quinoclamine/kg fresh grass. The study showed that favourable growth conditions for grass, with summer temperature (16-18 °C), normal precipitation levels (66 mm in June and 119 mm in July) and additional irrigations (10+5 mm), drastically decrease the residue levels (8 mg/kg fresh grass after 14 days and less than 1 mg/kg fresh grass after 28 days). A separate part of the study indicated that intermediate grass clippings reduced the residue levels on regrown grass even more efficiently. However the residue decline data are from one study only. It is uncertain if the residue decline data are representative also for other situations with less precipitation

and slower growth of grass. However the suggested labelling will ensure good growth conditions for the grass during application (see section on residues point 3.1.1.). Although the long-term TERs are below the trigger the risk to birds may be acceptable if risk mitigation measures (e.g. scaring birds away from treated areas) are applied.

The acute TER for insectivorous birds was >9.9. Since it was close to the trigger of 10 the meeting considered the acute risk as addressed. The short-term TER was 3.5. The refined risk assessment was not accepted because the use of a RUD of 5.1 (only large insects) was rejected by the experts since no data were submitted confirming that only large insects would be taken up by small insectivorous birds feeding in lawn/turf. The applicant proposed a DT_{50} for residue decline in insects based on life span, generation cycles and number of eggs laid. This approach was not agreed by the experts. The suggested DT_{50} for residues in insects was considered as not robust enough to be used in a quantitative manner considering that different insect species reproduce at different rates and have different durations of life cycles. The applicant submitted TER calculations for 36 different bird species. The experts in the PRAPeR meeting identified the yellow wagtail (*Motacilla flava*) and starling (*Sturnus vulgaris*) as focal species. It was recommended that the risk assessment should be revisited based on the RUD value of 29. A data requirement remains to refine the short-term and long-term risk to small insectivorous birds for the use in lawn/turf. A new refined short- and long-term risk assessment based on yellow wagtail (*Motacilla flava* and skylark (*Alauda arvensis*) was submitted and included by the RMS in an updated addendum (May 2007). The new risk assessment is not peer-reviewed.

The first-tier and the refined risk assessment for herbivorous mammals resulted in TERs below the triggers of 10 and 5. A new refined risk assessment based on residue decline in grass was presented in the addendum to the DAR. The endpoints used in the risk assessment were discussed in the expert meeting. The experts recommended using the LD_{50} of 500 mg quinoclamine/kg and the NOAEL of 17.5 mg quinoclamine/kg bw/d for the acute and long-term risk assessment. The choice of a medium herbivorous mammal (rabbit) as a focal species was agreed but not the reduction of PT to 0.5. A long-term TER of 5.8 was calculated including residue decline in grass which was agreed on by the experts. However the acute TER of 4.8 needed further refinement and the meeting agreed on the data requirement to refine the acute risk to mammals. A new refined acute risk assessment was submitted and included by the RMS in an updated addendum (May 2007). The new risk assessment is not peer-reviewed. As for herbivorous birds the risk refinement based on rapid residue decline is uncertain with regard to representativeness for conditions less favourable to residue decline. However this uncertainty would be covered if the product is only applied during favourable growth conditions (see above).

No major metabolites have been identified in residue studies with grass and in aerobic soil degradation studies and hence the risk from metabolites was considered to be low. However uncertainty remained with regard to unidentified residues and the experts asked for further clarification regarding the analytical methods used to identify metabolites in the plant residue studies.

In the updated addendum of May 2007 the RMS listed the percentages of unknown metabolites and non-extractable residues. Polar and medium polar unknown metabolites reached percentages of >10% after 28 d in terms of total recovered radioactivity. However the risk from these metabolites is expected to be low since the total amounts of the metabolites in terms of applied radioactivity are very low (0.09-0.76%).

The risk to birds and mammals from uptake of contaminated drinking water was assessed in an addendum. The acute TERs were >9.9 for birds. The new agreed acute endpoint of 500 mg quinoclamine/kg was used to achieve a TER of 4.6 for mammals. It was agreed by the experts that the risk is sufficiently addressed considering that the formation of puddles would be infrequent and with higher application volumes the TER would also be higher.

No risk assessment for secondary poisoning is triggered since the log P_{ow} is <3.

5.2. RISK TO AQUATIC ORGANISMS

Studies with technical quinoclamnine and formulated as Mogeton 25 WP were available. The toxicity of quinoclamnine to aquatic organisms was not enhanced if formulated as Mogeton 25 WP. The acute risk assessment is driven by the endpoint observed for fish (63 µg quinoclamine/L) and the chronic risk assessment is driven by the endpoint observed for daphnids (NOEC = 2.1 µg quinoclamne/L). The risk assessment based on FOCUS step3 PECsw resulted in TER values below the Annex VI trigger of 100 and 10 respectively for most scenarios. The refined risk assessment was based on PECsw calculations according to FOCUS step 4 taking a no-spray buffer zone of 10 and 20 m, run-off mitigation via a vegetated buffer strip and/or use of a drift reducing spray shield into account. The calculated PECsw values were not agreed in the expert meeting on fate and behaviour.

Without mitigation of run-off and without application of a spray shield a no-spray buffer zone of 60 m is required to achieve acute TERs above the trigger of 100 for fish (except for scenario R2 stream where the TER is still below the trigger). No full scenario resulted in long-term TERs for daphnids above the trigger of 10 even if a no-spray buffer zone of 100 m is applied. Overall it is concluded that a high risk to aquatic organisms cannot be excluded for the use in lawn/turf. No-spray buffer zones of up to 100 m are not sufficient to mitigate the risk to aquatic organisms and significant mitigation measures regarding run-off and spray drift will be necessary. New PECsw calculations are required, however it is not expected that the new PECsw values will significantly change the outcome of the risk assessment (see chapter on fate and behaviour, point 4.2)

The risk from the photolysis metabolites phthalic acid and 2-carboxy-benzaldehyde was assessed as low. The risk of bioaccumulation in aquatic food chains was considered to be low since the log P_{ow} is <3.

The metabolite AN reached levels above 10 % of applied radioactivity in the water sediment study under anaerobic conditions. The metabolite was considered as relevant for sediment by the experts on

fate and behaviour (see point 4.2.1). No studies with metabolite AN and sediment dwelling organisms was conducted. The RMS suggested that the risk to sediment dwelling organisms is covered by the test with quinoclamine. However the metabolites potentially formed in the study were not measured. No measurement of oxygen or redox potential in sediment was conducted to verify anaerobic conditions. The sediment used in the test system is artificial and therefore it is expected that the biological activity is different from natural sediment. No conclusion can be drawn whether AN was formed in the test with quinoclamine. Therefore a data gap is suggested by EFSA to address the risk from metabolite AN to sediment dwelling organisms.

The RMS calculated the PECsw for the use in ornamentals and nursery stock plants based on spray drift. The acute and chronic TERs are below the triggers of 100 and 10 at a distance of 20 m. Further risk mitigation measures would be required for the outdoor use in ornamentals and nursery stock plants. Since there is no agreed way of calculating entry into surface water it was concluded by the experts in the meeting on fate and behaviour that the risk for those uses should be assessed at MSs level.

5.3. RISK TO BEES

Honey bees (*Apis mellifera*) were exposed to quinoclamine via inhalation, oral, contact (filter paper test) and direct overspray at a rate of about two times the recommended application rate. The mortality was less than 30% in all tests. The HQ values for acute oral exposure were calculated as <134 and <87. Since the mortalities were low at the highest dose (3% 24 h; 12% 72 h) the risk to honey bees from the representative uses considered as low. As agreed at expert meeting no HQ is calculated for contact exposure due to non-standard nature of test. However, data suggests that 5 times overspray at twice the recommended dose do not produce an increase in mortality. The experts agreed that the risk to bees is low for the representative uses.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The toxicity of quinoclamine formulated as Mogeton 25 WP was tested with *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Poecilus cupreus* and *Aleochara bilineata*. No effects of >30 % were observed at the tested dose of 3.8 kg quinoclamine/ha except for *A. bilineata*. Given that the LR_{50} is >3.8 kg quinoclamine/ha the resulting in-field HQ values for *T. pyri* and *A. rhopalosiphi* are < 0.98 suggesting a low in-field risk to non-target arthropods. However the parasitation rate was reduced by 66% in the test with *A. bilineata*. An extended laboratory test with *Pardosa sp*. showed no effects on mortality and feeding rate at a dose of 3.8 kg quinoclamine/ha (formulated as Mogeton 25WP). A new study with *A. bilineata* and the formulation Mogeton 50WDG did not result in effects of >30% at a dose rate up to 15 kg quinoclamine/ha. During the peer-review it was questioned whether the results of the new study should overrule the endpoint from the old taking into account that the new study was conducted with a different formulation type than the lead formulation. The RMS explained that the formulation Mogeton 50 WDG was only slightly different from Mogeton 25 WG and that the new study was more reliable since in the old study no toxic standard was used. An open point was set during the expert meeting for the RMS to check whether the first study is valid as there was no

positive control. The RMS considers the first study as valid but the test results from the second study are assumed to be more accurate since two dose rates were tested and a dose-response relationship was observed.

Overall it is concluded that the risk to non-target arthropod species is low for the representative uses evaluated.

5.5. RISK TO EARTHWORMS

The acute risk to earthworms was assessed as low for the use in turf (TER = 250). No long-term studies with earthworms are triggered since the field DT_{90} was < 100 days and the acute risk was assessed as low.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

No risk assessment is triggered since the effects on *Typhlodromus pyri* and *Aphidius rhopalosiphi* were < 30% at a dose of 3.8 kg quinoclamine/ha (assuming that the standard HQ would be below 2) and the soil DT_{90} is <100 days.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

Effects of >25 % on soil nitrification were observed at a concentration of 25 mg quinoclamine/kg soil. The effect was decreasing to 22 % at the end of the test after 57 days. No effects ± 25% on soil respiration and nitrification were observed at a concentration of 5 mg quinoclamine/kg soil (about 10 times the maximum PECsoil for the use in turf and equal to the maximum PECsoil for the use in ornamentals). No effects on soil nitrification and dehydrogenase activity were observed in tests with the formulation Mogeton 25WP when applied at the recommended dose of 3.75 kg quinoclamine/ha. The dehydrogenase activity was affected by 39% in the loamy soil at a dose equivalent 5 times the recommended application rate. However no effect was observed after 56 days. Therefore it is concluded that the representative uses do not pose a high risk to soil non-target micro-organisms.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Phytotoxic effects of quinoclamine were tested with three monocotyledon and three dicotyledon plant species. No studies with the formulated product were conducted. However based on results from studies with other organisms it is assumed that the toxicity of quinoclamine is not much enhanced if formulated as Mogeton 25WP. No effects on shoot height and biomass were observed at a rate of 3.485 kg quinoclamine/ha. Necrosis and chlorosis spots were observed at a concentration of 0.872 and higher. Oilseed rape (*Brassica napus*) was considered to be the most sensitive plant species tested. The EC_{50} was estimated to be 0.87 kg quinoclamine/ha. The TER value was calculated as 8.4 at a distance of 1m from the treated area. Therefore the risk to non-target plants is considered to be low.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Inhibitory effects were observed at all tested concentrations from 10 mg quinoclamine/L up to 1000 mg quinoclamine/L. However the effects were less than 50 % even at the highest concentration. Therefore no EC_{50} and no NOEC value was determined. It is expected that the concentration of 10 mg quinoclamine/L at which 11-17% inhibition of respiration was observed would not be reached if the product is applied according to the GAP list. Therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: quinoclamine, AN (anaerobic conditions only).
Definitions for monitoring: quinoclamine

Water

Ground water

Definitions for risk assessment: quinoclamine, AN and DHN (both anaerobic conditions only).
Definitions for monitoring: quinoclamine

Surface water

Definitions for risk assessment: quinocalmine, phthalic acid (from aqueous photolysis), 2-carboxybenzaldehyde (from aqueous photolysis).
Definitions for monitoring: quinoclamine

Air

Definitions for risk assessment: quinoclamine.
Definitions for monitoring: quinoclamine.

Food of plant origin

Definitions for risk assessment: none as there is no representative use on edible commodities.
Definitions for monitoring: none as there is no representative use on edible commodities.

Food of animal origin

Definitions for risk assessment: none as there is no representative use on edible commodities.
Definitions for monitoring: none as there is no representative use on edible commodities.

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Quinoclamine	Aerobic conditions: moderately persistent ($DT_{50\ aerobic\ 20\ °C}$ = 20 – 39 d) Anaerobic conditions: low persistent ($DT_{50\ anaerobic\ 20\ °C}$ = 4 d)	The risk to earthworms was assessed as low (TERs >10)
AN (anaerobic conditions only, therefore not considered further)	No data available, not required for the EU representative uses.	No data available, no data required for the representative uses evaluated.

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 activity	Ecotoxicological activity
Quinoclamine	low mobile in soil K_{foc} = 552 – 1592 mL / g	FOCUS GW: trigger of 0.1 µg / L not exceeded.	Yes	Yes	Quinoclamine is very toxic to aquatic organisms. (acute LD50 for fish = 63 µg/L)
AN (anaerobic conditions only)[1]	No data available, not required for representative uses.	No data available, not required for representative uses	No data available, not required.	No data available, not required.	No data available, not required

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 activity	Ecotoxicological activity
DHN (1,4 dihydronaphthalenedione), (anaerobic conditions only)	No data available, not required for representative uses.	No data available, not required for representative uses	No data available, not required.	No data available, not required.	No data available, not required

1) The meeting agreed that in soil anaerobic conditions would not be envisaged for the representative use (spring uses, turf potentially efficiently drained). Therefore a groundwater assessment for AN and DHN was not pertinent in this case.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Quinoclamine (water and sediment)	See 5.2.
AN (sediment only)	No endpoints available, no risk assessment provided,
Phthalic acid (water only, aqueous photolysis)	Less toxic to aquatic invertebrates and algae compared to quinoclamine, the risk to aquatic organisms was assessed as low
2-Carboxybenzaldehyde (water only, aqueous photolysis)	Less toxic to aquatic invertebrates and algae compared to quinoclamine, the risk to aquatic organisms was assessed as low

Air

Compound (name and/or code)	**Toxicology**
Quinoclamine	Not acutely toxic by inhalation.

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

- Spectra for the relevant impurity dichlone (relevant for all uses, data gap identified by EFSA June 2007, date of submission unknown, refer to chapter 1).
- Storage stability data where the relevant impurity dichlone is analysed for before and after storage (relevant for all uses, data gap identified by EFSA June 2007, date of submission unknown, refer to chapter 1).
- Confirmatory method for surface water is required (relevant for all uses, data gap identified by the meeting of experts March 2007, data have been made available to the rapporteur but they have not been evaluated and have not been peer reviewed, refer to chapter 1).
- An analytical method for the relevant impurity dichlone in the formulation is required (relevant for all uses, data gap identified by EFSA June 2007, date of submission unknown, refer to chapter 1).
- Further supervised decline residue studies in grass under a range of possible conditions of use of quinoclamine, depending of national conditions and covering at least the less favourable conditions for residue decline (relevant for the use on turf and lawns, data gap identified by EFSA June 2007, date of submission unknown, refer to point 3.1.1).
- New kinetic analysis of the two autumn field studies will be needed to address uses in autumn if these are applied for at MS level (not essential for EU representative uses; refer to point 4.1.2).
- Kinetic formation and degradation parameters will be needed for anaerobic soil metabolites AN and DHN to address uses were anaerobic soil conditions may occur (not essential for EU representative uses; refer to point 4.1.2).
- Soil adsorption / desorption parameters will be needed for anaerobic soil metabolites AN and DHN to address uses were anaerobic soil conditions may occur (not essential for EU representative uses; refer to point 4.1.2).
- New FOCUS SW calculations for turf and lawn were realistic use and mitigation measures are incorporated are necessary for turf and lawn (relevant for the use in turf/lawns; data requirement identified during the Evaluation meeting in September 2007; refer to point 4.2).
- The short-term risk to herbivorous birds needs further refinement (relevant for the use in turf/lawns; data requirement identified in the DAR, data gap confirmed in PRAPeR 18 (March 2007); new calculations presented in an updated addendum after the expert meeting; refer to point 5.1).
- The short-term and long-term risk to insectivorous birds needs further refinement. (relevant for the use in turf/lawns; data requirement identified in the DAR, confirmed in PRAPeR 18 (March 2007); submitted in May 2007; refer to point 5.1).
- A refined acute risk assessment for herbivorous mammals (relevant for the use in turf/lawns; data requirement identified in the DAR, confirmed in PRAPeR 18 (March 2007); submitted in May 2007; refer to point 5.1).

- The risk to aquatic organisms needs to be addressed further. (relevant for the use in turf/lawns; data requirement identified in the DAR; confirmed in PRAPeR 18 (March 2007); no submission date proposed; refer to point 5.2).
- The risk from the metabolite AN to sediment dwelling organism needs to be addressed. (relevant for all representative uses; data gap identified by EFSA following the outcome of the meeting of experts on fate and behaviour (PRAPeR 17, March 2007); no submission date proposed; refer to point 5.2).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide/algaecide on ornamentals turf, lawns and nursery stock plants as proposed by the applicant, full details of the GAP can be found in the attached list of end points. The representative formulated product for the evaluation was "Mogeton", a wettable powder (WP) containing 250 g/kg of active substance.

Methods are not required for food of plant or animal origin as the use is on ornamentals turf, lawns and nursery stock plants. Adequate methods are available to monitor quinoclamine in soil, drinking water and air. A confirmatory method for surface water was identified as a data gap in the meeting of experts. A confirmatory method for surface water has been provided by the applicant but it has not been evaluated and therefore is not peer reviewed.
Some analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. However, a method of analysis for the relevant impurity dichlone (2,3-dichloro-1,4-naphthoquinone) is not available.

The acute oral toxicity of quinoclamine is moderate (**R22 Harmful if swallowed**) but the acute toxicity by inhalation or dermal application is low. The substance is irritating to the eyes (**R36 Irritant to eyes**) but not to the skin, and has sensitizing properties (**R43 May cause sensitization by skin contact**). Indications of haemolytic anaemia are observed in the short term studies in rats and dogs. Quinoclamine does not show a genotoxic or carcinogenic potential, but some teratogenic effects were observed and lead to the proposed classification **Repro cat. 3, R63 Possible risk of harm to the unborn child**. The ADI is 0.002 mg/kg bw/day, the AOEL is 0.03 mg/kg bw/day and the ARfD is 0.05 mg/kg bw. The dermal absorption values are 6.52% for the concentrate and the low dilution, and 10% for the high dilution. The operator exposure estimates in field or greenhouse are below the AOEL only when personal protective equipment (including respiratory protective equipment) is used. On the day of application, the worker exposure estimates are below the AOEL only when coverall and gloves are worn. Preliminary estimates of children exposure show that the AOEL might be exceeded when the exposure occurs on the day of treatment.

Very high residue levels are present on grass directly after application of quinoclamine. A metabolism study demonstrated that parent compound is the main constituent of the residue on grass up to 2 weeks after application. Therefore only quinoclamine needs to be considered for risk assessment related to humans and terrestrial vertebrates in contact with treated lawn and turf.
One decline study demonstrated that residues decrease rapidly in favourable condition of grass growth. Also grass clipping results in low residues in regrown grass. Nevertheless it cannot be excluded that the decline of residues in grass may be significantly slower when growth rate of grass due to environmental conditions is weak. The need for further studies should therefore be considered at national level.
As a risk-mitigation measure related to human and wildlife exposure, label should give the user clear recommendations to apply the product in strong growing conditions of grass, and practical instructions to irrigate efficiently the treated area in case of low precipitation level, in accordance with the biological efficiency of the product.

Quinoclamine is moderately persistent in soil under dark aerobic conditions at 20 ºC ($DT_{50\ aerobic\ 20\ ºC}$ = 20 – 39 d) and produces a number of minor metabolites (< 5 % AR). The degradation of quinoclamine also produces non extractable residue (43.5 % AR after 100 d) and mineralization to CO_2 (43.4 % AR after 100d).
Under dark anaerobic conditions at 20 ºC, quinoclamine is low persistent ($DT_{50\ anaerobic\ 20\ ºC}$ = 4 d) and yields two main metabolites: **AN** (max 14.6 % AR after 14 d) and **DHN** (max 5.4 - 6 % AR after 7-14 d).
Light may enhance the degradation of quinoclamine but its contribution to overall degradation in soil is deemed low due to the rapid microbiological degradation.
A field study is available where Mogeton 25WP (15 Kg /ha; 3.75 Kg a.s. / ha) was applied in four sites (two in spring and two in autumn) in Germany on bare soil. Only data from the spring trials was found relevant for the representative uses applied at EU level (spring application). PEC soil were calculated based on the field worst case spring application half life (DT_{50} = 29 d). The expert's meeting agreed that for uses in autumn longer dissipation pattern observed in autumn field trials would need to be considered. In that case, new kinetic analysis of the two autumn field studies would be necessary.
Quinoclamine may be considered low mobile in soil (K_{foc} = 552 – 1592 mL / g) according the batch adsorption/desorption studies available.
According the available study quinoclamine is expected to be stable to hydrolysis under environmental conditions (pH 4 -9, 20 ºC).
According the aqueous photolysis study available in the original dossier quinoclamine has a short half life in water under irradiated conditions is 2.2 d (corresponding to 4.2 d (12 h irradiation) in UK). A data gap was identified during the peer review for further information on non identified photolysis metabolites. In a new study, photolysis was slower (DT_{50} = 11.9 – 14.1 d). Two major photolysis metabolites were identified: phthalic acid (max 10.8 % AR after 11 d continuous irradiation) and 2-carboxybenzaldehide (max. 19.5 % AR after 11 d continuous irradiation). The two major photolysis metabolites were considered by the RMS in the updated risk assessment presented in the addendum.

According the available study quinoclamine is not ready biodegradable.
In dark water / sediment at 20 ºC, quinoclamine partitioned to the sediment (max. 27-35 % AR after 2 d, $DT_{50\ water}$ = 4 – 5 d) and degraded in whole system with a first order half life of 14-15 d. Metabolite AN reached levels above 10 % AR in the sediment. This metabolite degraded with a half life of 25-26 d in the whole system.
For the assessment of the representative use in lawns/turf, PEC_{SW} were calculated with the FOCUS SW scheme up to Step 3 using whole water /sediment degradation half lives. Only global maximum PEC_{SW} have been used in the risk assessment. Based on this PEC_{SW} calculation a risk for aquatic organisms was identified.
The FOCUS SW Step 4 calculations presented by the notifier were not found acceptable because input parameters employed deviated from those recommended by the RMS and agreed by the peer review and/or due to the implementation of additional mitigation by VFS or spray shields. Also the experts in the meeting agreed that for uses on turf (particularly golf courses and other sport facilities drainage should be considered a potential route of entry to surface water). However, the meeting agreed that available Step 4 calculations give an indication that significant mitigation regarding run off and spray drift will be necessary to mitigate risk to aquatic environment for the proposed representative use in turf / lawn.
Applicant proposed that potential surface water contamination due to use in ornamental plants in pots may be managed in a way that contamination of surface water will be negligible. RMS calculated spray drift PEC_{SW} for the use on pots outdoor. During the experts meeting, it was indicated that in the case of pots standing in a hard surface high potential of surface water contamination as a consequence of run off is also possible. As there is not agreed way of dealing with run off from hard surfaces at EU level, it was agreed that this issue would have to be addressed at MS level.
Potential contamination of ground water for the use in turf was addressed following the FOCUS GW scheme with FOCUS PRZM (v 3.2.1.b). The resulting 80th percentile annual average concentrations of quinoclamine at 1m depth were below 0.001 µg / L in all the FOCUS GW scenarios.
Due to the low potential of volatilization and the estimated rapid photochemical transformation, the environmental concentrations in air and the transport through air are considered negligible.

The risk assessment was focussed on the use in lawns and turf. Exposure of birds and mammals from the outdoor use in ornamentals was considered as negligible. The first-tier TERs for large herbivorous and small insectivorous birds were below the triggers of 10 and 5. The risk refinements based on residue decline in grass was accepted by the experts. However other suggested refinements were rejected and further data are required to refine the short-term risk to herbivorous birds, the short-term and long-term risk to insectivorous birds. The acute and long-term TERs for herbivorous mammals were below the triggers of 10 and 5. The refined long-term TER based on residue decline was calculated as 5.8. However the acute risk to mammals needs to be addressed further. Fish and daphnids were the most sensitive aquatic organisms triggering the acute and long-term risk assessment. No-spray buffer zones of up to 100 m are not sufficient as a risk mitigation measure to achieve TERs above the Annex VI triggers for the use in lawns/turf. The TER calculation of the RMS for the outdoor use in ornamentals and nursery stock plants indicated that a distance of 20m is not

sufficient to mitigate the risk. However no agreed exposure scenario exists for the outdoor use in ornamentals and nursery stock plants. Therefore it was agreed that a risk assessment should be conducted at Member state level. The risk to bees, other non-target arthropods, earthworms, soil-micro organisms, non-target plants and biological methods of sewage treatment were assessed as low.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- Appropriate PPE as well as RPE (respiratory protective equipment) is needed in order to have an estimated operator exposure below the AOEL (refer to 2.12).
- Label should give the user clear recommendations to apply the product in strong growing conditions of grass, and practical instructions to irrigate efficiently the treated area in case of low precipitation level, in accordance with the biological efficiency of the product.
- Only uses in spring where anaerobic conditions are assumed not to occur have been evaluated. Further data would be necessary to assess uses in autumn or when anaerobic soil conditions may occur.
- Risk assessment for uses in ornamentals assumes that use in pots may be managed in a way that contamination of surface water will be negligible. This may not be the case when pots are treated outside or when are standing on hard surface where run off to SW may occur. MSs should pay special attention to these cases to mitigate surface water contamination.
- The Annex VI trigger for aquatic organisms is not met for the use in lawns/turf. Both run-off and spray drift would need to be mitigated substantially.

Critical areas of concern

- Re-entry exposure of children might exceed the AOEL for a period which cannot be determined on the basis of available data.
- The risk to birds and mammals from the use in lawns/turf.
- A high risk to aquatic organisms.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

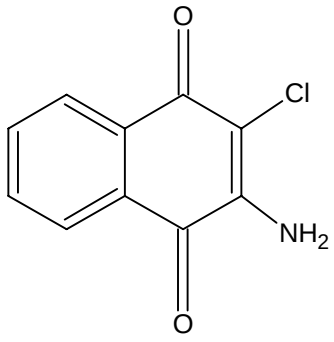
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	Quinoclamine
Function	Herbicide, algaecide.

Rapporteur Member State	Sweden
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	2-amino-3-chloro-1,4-naphthoquinone
Chemical name (CA)	2-amino-3-chloro-1,4-naphthalenedione
CIPAC No	648
CAS No	2797-51-5
EEC No (EINECS or ELINCS)	220-529-2
FAO Specification (including year of publication)	No FAO specification available
Minimum purity of the active substance as manufactured (g/kg)	965 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Dichlone (2,3-dichloro-1,4-naphthoquinone) max. content 15 g/kg.
Molecular formula	$C_{10}H_6ClNO_2$
Molecular mass	207.6
Structural formula	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity)	200-202 °C, purity 99%
Boiling point (state purity)	348 °C-350 °C, purity 99%
Temperature of decomposition	Decomposition during boiling at 348 °C-350 °C
Appearance (state purity)	Orange odourless solid, purity 99%
Vapour pressure (in Pa, state temperature)	7×10^{-6} Pa at 25 °C (purity 99.0%) 3×10^{-6} Pa at 20 °C (purity 99.0 %)
Henry's law constant (Pa m^3 mol^{-1})	3.05×10^{-5}
Solubility in water (g/L or mg/L, state temperature)	pH 4: 20.7 mg/L ± 1.0 mg/L at 20 °C pH 8.5 (unbuffered): 19.8 mg/L ± 0.4 mg/L at 20 °C pH 9: 20.7 mg/L ± 0.7 mg/L at 20 °C
Solubility in organic solvents (in g/L or mg/L, state temperature)	At 20 °C: acetone: 12.2-12.8 g/L 1,2-dichloroethane: < 10 g/L ethyl acetate: < 10 g/L n-heptane: < 10 g/L methanol: < 10 g/L p-xylene: < 10 g/L
Partition co-efficient ‡ (state temperature, pH and purity)	pH 11: 1.58 at 30 °C
Dissociation constant	Does not dissociate between pH 2 and pH 11
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Acidic conditions (pH 2.5) λ_{max}(nm) — ε (l x cm^{-1} x mol^{-1}) 219 — 14100 266 — 21500 339 — 2410 460 — 2570 Unadjusted conditions (pH 6.3) λ_{max}(nm) — ε (l x cm^{-1} x mol^{-1}) 219 — 14100 266 — 22500 338 — 2370 458 — 2550 Alkaline conditions (pH 11) λ_{max}(nm) — ε (l x cm^{-1} x mol^{-1}) 218 — 13900 267 — 22200 339 — 2230 460 — 2560
Flammability ‡ (state purity)	Not flammable (purity 99.0 %)

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

Explosive properties ‡ (state purity)	Not explosive (based on theoretical considerations)
Oxidising properties ‡ (state purity)	Not oxidizing (purity 99%)

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

Summary of representative uses evaluated *

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Turf, lawn	Northern and Southern EU	Mogeton	F	Mosses, Algae	WP	250 g/kg	spraying with spraying shield	Spring	1 per year	--	0.375	1000	3.75	--	[1] [2] [3]
Orna-mentals	Northern and Southern EU	Mogeton	F	Mosses, Algae	WP	250 g/kg	spraying with spraying shield	Spring	1 per year	--	0.375	1000	3.75	--	[3]
Orna-mentals	Northern and Southern EU	Mogeton	F	Mosses, Algae	WP	250 g/kg	watering by hand	Spring	1 per year	--	0.0375	10000	3.75	--	
Nursery stock plants	Northern and Southern EU	Mogeton	F	Liverwort	WP	250 g/kg	spraying with spraying shield	not relevant	1 per year	--	0.375	1000	3.75	--	[3]
Nursery stock plants	Northern and Southern EU	Mogeton	G	Liverwort	WP	250 g/kg	spraying with spraying shield	not relevant	1 per year	--	0.375	1000	3.75	--	
Nursery stock plants	Northern and Southern EU	Mogeton	F, G	Liverwort	WP	250 g/kg	watering by hand	not relevant	1 per year	--	0.0375	10000	3.75	--	

[1] The risk assessment has revealed a risk for bystanders (AOEL exceeded for children exposed on the day of treatment);

[2] High short and long term risk to insectivorous birds; high short term risk to herbivorous birds, high acute risk for herbivorous mammals needs further refinement;

[3] The risk assessment has revealed a high risk-for aquatic organisms. Further assessments of risk mitigation are necessary. Assessment of mitigation measures proposed by the applicant (spraying shields) was considered uncertain and ecotoxicological risk assessment presented in the conclusion assumes that such mitigation is not used.

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

Remarks:

(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 plants - type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No edible crop uses
Food of animal origin		No edible crop uses
Soil		Quinoclamine
Water	surface	Quinoclamine
	drinking/ground	Quinoclamine
Air		Quinoclamine

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required.
Soil (analytical technique and LOQ)	GC-ECD 0.02 mg/kg HPLC-UV/DAD 0.02 mg/kg
Water (analytical technique and LOQ)	GC-ECD 0.01 µg/L (drinking water). Confirmatory method (drinking water): GC-MS DFG-S8 GC/ECD 2 µg/L (surface water). Confirmatory method (surface water): Not available (data gap)
Air (analytical technique and LOQ)	HPLC-MS/MS 1.5 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not required

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption	>80% based on urinary and biliary excretion, and carcass recovery.
Distribution	Uniformly distributed
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Almost completely eliminated (20% bile, 54% urine and 4% faeces) within 24h
Metabolism in animals	Extensively metabolised to several glucuronide and sulphate conjugates.
Toxicologically relevant compounds ‡ (animals and plants)	Quinoclamine
Toxicologically relevant compounds ‡ (environment)	Quinoclamine

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	200 < LD_{50} < 500 mg/kg bw	**R22**
Rat LD_{50} dermal	> 2 000 mg/kg bw	
Rat LC_{50} inhalation	> 0.79 mg/L (4 hrs, whole body, highest attainable concentration)	
Skin irritation	Non-irritant	
Eye irritation	Irritant	**R36**
Skin sensitization (test method used and result)	Sensitizer (Magnusson & Kligman)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Kidney, blood, spleen (haemosiderin deposition indicated increased haemopoiesis).	**R48/ 22?**
Relevant oral NOAEL	3 mg/kg bw/day (90d dog)	
Relevant dermal NOAEL	100 mg/kg bw/day (NOEL, 28d rat)	
Relevant inhalation NOAEL	No study submitted, not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

…….……..	Not genotoxic	

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

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

Target/critical effect ‡	Rat: Increased kidney and spleen weights, epithelial hyperplasia in the urinary system. Several indications of haemolytic anaemia. Dog: Increased kidney and spleen weights. Haematology findings indicative of haemolytic anaemia.	**R48/ 22?**
Relevant NOAEL ‡	0.21 mg/kg bw/day (rat) 0.38 mg/kg bw/day (mouse) 0.31 mg/kg bw/day (dog)	
Carcinogenicity ‡	Mouse: Negative. Rat: Urinary bladder papilloma	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parents: clinical signs and decreased body weight Offspring: grey cysts in the lung Reproduction: decreased litter size	
Relevant parental NOAEL ‡	>30.9 mg/kg bw/day	
Relevant reproductive NOAEL ‡	1.6 mg/kg bw/day	
Relevant offspring NOAEL ‡	1.6 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Increased intrauterine deaths, hydronephrosis, blood vessels abnormalities (rat) Post implantation loss and hydronephrosis at maternally toxic doses (rabbit)	**Repro Cat.3, R63**
Relevant maternal NOAEL ‡	≥ 30 mg/kg bw/day (rabbit) 5 mg/kg bw/day (rat)	
Relevant developmental NOAEL ‡	17.5 mg/kg bw/day (rabbit) 20 mg/kg bw/day (rat)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data submitted, not required.	
Repeated neurotoxicity ‡	No data submitted, not required.	
Delayed neurotoxicity ‡	No data submitted, not required.	

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

Other studies	No data submitted, not required.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	No data submitted.
Studies performed on metabolites or impurities	**Impurity AKCN-01**: LD_{50} dermal: 5000 mg/kg bw (rabbit) LD_{50} oral: 1300 mg/kg bw (rat)
Dermal developmental study (rat)	Maternal NOAEL: 100 mg/kg bw/day NOAEL for teratogenicity: 600 mg/kg bw/day

Medical data ‡ (Annex IIA, point 5.9)

……..	No evidence of adverse effects to manufacturing or agricultural workers.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.002 mg/kg bw/day	2-yr rat	100
AOEL ‡	0.03 mg/kg bw/day	90 day dog	100
ARfD ‡	0.05 mg/kg bw/day	28 day rat, dev. tox rat	100

Dermal absorption (Annex IIIA, point 7.3)

Mogeton WP (powder)	6.52%
Mogeton WP spray dilutions	6.52%
can dilutions	10%

Exposure scenarios (including method of calculation)

Operator

Exposure values in % of AOEL		
Field use: tractor mounted equipment		
	without PPE	with PPE
UK POEM	16648	878
German model	2120	63
Field use: hand held sprayer 15L		
UK POEM	4047	334
German model	1246	76

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

	Field use: watering can (UK POEM for hand held 15L)		
	UK POEM	2856	97
	Glass house use		
	NL model	2500	391
	German study - geometric mean - 75th percentile - maximum values	 1066 1843 4051	 34 75 126
	Watering can (UK POEM)	2856	97
Workers	After field spraying (dermal absorption 6.52%)		
	without PPE	with gloves	
	379	76	
	After watering can (dermal absorption 10%)		
	without PPE	with gloves	with gloves + coverall
	583	117	58
Bystanders	Exposure via spray drift during field use: 13% of AOEL Exposure of children on treated grass can exceed the AOEL at the day of treatment.		

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

	RMS/EPCO proposal	ECB decision
Active substance	R22: Harmful if swallowed. R36: Irritating to eyes. R43: May cause sensitisation by skin contact. R48: Danger of serious damage to health by prolonged exposure. R63: Possible risk of harm to the unborn child	not yet included in Annex 1 of Directive 67/548/EC.
Preparation	R43: May cause skin sensitization by skin contact R48/22: Danger of serious damage to health by prolonged exposure if swallowed.	

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

Appendix 1.4: Residues

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

Plant groups covered	Grass
Rotational crops	Not relevant due to intended use
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant due to intended use
Processed commodities	Not relevant due to intended use
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant due to intended use
Plant residue definition for monitoring	Not relevant due to intended use
Plant residue definition for risk assessment	Not relevant due to intended use
Conversion factor (monitoring to risk assessment)	None

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

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

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

…….……..	Not required

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

……..……..	Not required

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

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)	Not required	Not required	Not required
Potential for accumulation (yes/no):	Not required	Not required	Not required
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not required	Not required	Not required
	Feeding studies Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Grass	Northern region	One decline residue study with following results (mg quinoclamine/kg fresh grass) : 406 (0 day); 80 (1 day); 57 (2 days); 7.7 (7 days); 8.1 (14 days); 0.13 (28 days)		Not relevant		Not calculated as only one study is available

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

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

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

ADI	Not required
TMDI (% ADI) according to WHO European diet	Not required
TMDI (% ADI) according to national (to be specified) diets	Not required
IEDI (WHO European Diet) (% ADI)	Not required
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI and NEDI	Not required
ARfD	Not required
IESTI (% ARfD)	Not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required
Factors included in IESTI and NESTI	Not required
Acute exposure (% ARfD)	Not required

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

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

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

Not required

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

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	36 – 43% $^{14}CO_2$ at 100 days from ^{14}C-ringlabelled (n=2)
Non-extractable residues after 100 days ‡	34 – 44% at 100 days from ^{14}C-ringlabelled (n=2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	None (5 minor metabolites, max. 4% of single metabolite)

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

Anaerobic degradation

Mineralization after 100 days	Mineralisation 0.7% after 120 days.
Non-extractable residues after 100 days	Bound residue fractionation 80 % after 120 days. Sandy loam
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	AN (2-amino-1,4-naphthoquinone) max 15% at 14 days DHN (1,4-dihydrohaphthoquinone) max 6.0% 14 days 2 further minor metabolites < 2 % Unknowns: max 4.5% total
Soil photolysis	20°C, n = 1, DT_{50}: 52 days (bi-phasic 1st order, r^2 0.99, DT_{50} corresponding to 101 days sunlight) DT_{50}: 135 days (dark control, 1st order, r^2 0.89)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Three main metabolites at sunlight conditions remained unidentified: SP3: < 2 % SP6: max 2.1% (at last sampling) SP7: max 5.3% (at last sampling)

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	Org mtr (%)	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1.3	5.5	20 °C/40 %	28/93	28	0.99	SFO
Loam soil	0.93	7.3	20 °C/40 %	39/130	35	0.97	SFO
Humic sand	2.3	5.2	20 °C/40 %	35/120	35	0.99	SFO

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

Sandy loam	1.1	7.5	20 °C/40 %	20/68	19	0.99	SFO
Geometric mean					28		

Field studies

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location	Appl rate (kg/ha)	pH	Depth (cm)	DT_{50} (d)	DT_{90}(d)	St. (r^2)	Method of calculation
Loamy sand (bare soil, autumn)[b]	Germany, Stutensee	3.75	5.4	0-20	- [a]	- [a]	- [a]	- [a]
Loam (bare soil, autumn) [b]	Germany, Kötschau	3.75	6.4	0-20	- [a]	- [a]	- [a]	- [a]
Loam (bare soil, spring) [b]	Germany Gnaschwitz	3.75	5.4	0-20	12	41	0.85	SFO, log-transformed data
Loamy sand (bare soil, spring) [b]	Germany, Rostock	3.75	5.9	0-20	29	98	0.93	SFO, log-transformed data

[a] Reliable kinetic endpoints have not been calculated; attempts to use "hockey-stick" kinetics shown in the DAR.
[b] Only spring trials were considered for the EU assessment.

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	No data, not relevant.

Parent	Anaerobic conditions							
Soil type	Org mtr (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. kdp/ kf	DT_{50} (d) 20°C pF2/10kPa	St. (r2)	Method of calculation
Sandy loam	4.0	6.8	20 °C/52.5%	4/13	-	0.99	SFO	Sandy loam

Metabolite AN	Anaerobic conditions							
Soil type	Org mtr (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. kdp/ kf	DT_{50} (d) 20°C pF2/10kPa	St. (r2)	Method of calculation
Sandy loam	4.0	6.8	20oC/53%	55/181	0.15	-	0.99	SFO

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	Org. C %	soil pH	Kd	Kf	Kdoc	Kfoc	1/n
Sandy loam	0.87	6.4	14	11	1592*	1264	0.69
Loamy sand	0.59	6.0	4.2	4.8	716*	814	0.81
Sandy silt loam	2.8	6.7	-	16.6	-	594*	0.81
Clay loam	4.7	7.6	-	26.0	-	552*	0.84
Sand	0.4	5.2	-	3.72	-	931*	0.73
Sandy loam	0.8	4.0	-	7.92	-	990*	0.76
Arithmetic mean						896	0.77
pH dependence, Yes or No			No				

*values used for the calculation of mean

Metabolite AN							
Soil Type	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n
No data, estimated by QSAR	-	-	-	-	588	-	-

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

Column leaching ‡	No relevant data available. Not required.
Aged residues leaching ‡	No relevant data available. Not required.
Lysimeter/ field leaching studies ‡	No data available. Not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): 29 days
Method of calculation	Kinetics: SFO Field or Lab: representative worst case from field studies at spring application.
Application data	Crop: turf; ornamentals and nursery stock plants Depth of soil layer: 5 cm % plant interception: 90% (turf); 0% (ornamentals, nursery stock plants) Number of applications: 1 Interval (d): not relevant Application rate(s): 3750 g as/ha

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

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Singe application Actual	Single application Time weighted average
Area of use:		Turf		Ornamentals and nursery stock plants	
Initial		0.50	-	5.0	-
Short term	24h	0.49	0.49	4.9	4.9
	2d	0.48	0.49	4.8	4.9
	4d	0.45	0.48	4.5	4.8
Long term	7d	0.42	0.46	4.2	4.6
	28d	0.26	0.36	2.6	3.6
	50d	0.15	0.29	1.5	2.9
	100d	0.05	0.19	0.5	1.9
Plateau concentration		Not relevant			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5 - 9: stable at environmentally relevant temperatures.
Photolytic degradation of active substance and metabolites above 10 % ‡	Study 1: DT_{50} : 2.2 days (continuous irradiation) Natural light, 40°N; DT_{50} 4.2 days Seven unknown products >4%, of which two were >10% and could be regarded as major. Study 2: DT_{50}: 11.9 (natural water), 14.1 d (pH 5 buffer) (continuous irradiation) Products: Phthalic acid, max 10.8%, 2-Caboxybenzaldehyde, max 19.5%. At least 5 additional minor unidentified products.
Quantum yield of direct phototransformation in water at Σ > 290 nm	3.55×10^{-5} mol · Einstein
Readily biodegradable ‡ (yes/no)	No

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

Degradation in water / sediment

Parent	Distribution (max. in sediment 35% after *2* d)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}/DT_{90} whole	St. (r^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
TNO loamy sand	8.6	7.5	20	14.5/48	0.81	4.8/16	0.90	not reported	-	SFO
Kromme Rijn sand	8.0	7.6	20	14.8/49	0.68	4.4/14.8	0.98	not reported	-	SFO
Geometric mean				15/49		4.6/15				

Metabolite AN	Distribution (max in water *6%* after *7* d. Max. sed 12% after *7* d)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}/DT_{90} whole	St. (r^2)	DT_{50}/DT_{90} water	r^2	DT_{50}/ DT_{90} sed	St. (r^2)	Method of calculation
TNO loamy sand	8.6	7.5	20	26/86	0.86	not reported	-	30/99	0.91	SFO
Kromme Rijn sand	8.0	7.6	20	25/82	0.74	not reported	-	27/90	0.76	SFO
Geometric mean				26/84				28/94		

Mineralization and non extractable residues (study with parent)					
Water / sediment system	pH w	pH sed	Mineralization	Non-extractable residues in sed.	Non-extractable residues in sed. (end of the study)
TNO loamy sand	8.6	7.5	15.6% after 105 d	81% after 105 d (end of study)	81% after 105 d (end of study)
Kromme Rijn sand	8.0	7.6	30.9% after 105 d	67% after 105 d (end of study)	67% after 105 d (end of study)

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

Parent	Not relevant since higher steps were used ofr the risk assessment.
Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	Molecular weight (g/mol): 207 Water solubility (mg/L): 19.8 Koc (L/kg): 896 (mean) DT_{50} soil (d): 29 days (SFO) DT_{50} water (d): 14.8 d DT_{50} sediment (d): 14.8 days

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

	Crop interception (%): default Vapour pressure: 3.0 x 10^{-6} Pa 1/n: 0.77
Application rate	Crop: grass/alfalfa Number of applications: 1 Interval (d): not relevant Application rate(s): 3.75 kg as/ha

Metabolite AN Parameters used in FOCUSsw step 1 and 2	Not relevant since higher steps were used ofr the risk assessment.
Parameters used in FOCUSsw step 3 (if performed)	Molecular weight (g/mol): 173 Water solubility (mg/L): 19.8 (assumed equal as for parent) Koc (L/kg): 588 (estimated value) DT_{50} soil (d): 29 days (assumed equal as for parent) DT_{50} water (d): 29 d DT_{50} sediment (d): 30 days Crop interception (%): default Vapour pressure: 3.0 x 10^{-6} Pa (assumed equal as for parent) 1/n: 0.9 (default)
Application rate	Crop: grass/alfalfa Number of applications: 1 Interval (d): not relevant Application rate(s): 3.75 kg a.s./ha
Main routes of entry	Spray drift, drainage and run off.

Calculation Method	Water body	Region / Scenario		Quinoclamine, global maximum		Metabolite AN	
				PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
FOCUS (STEP 3) Grass/Alfalfa	Stream	D1	Lanna	21.0	10.1	1.7	7.7
		D2	Brimstone	21.4	32.5	1.8	2.9
		D4	Skousbo	20.5	3.44	0.04	0.078
		D5	La Jailliere	22.1	4.8	0.28	0.26
		R2	Porto	21.1	4.2	3.7	2.3
		R3	Bologna	22.1	5.1	0.23	0.09

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

Calculation Method	Water body	Region / Scenario		Quinoclamine, global maximum		Metabolite AN	
				PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
cont. FOCUS (STEP 3) Grass/Alfalfa	Ditch	D1	Lanna	24.1	42.8	2.7	11.1
		D2	Brimstone	24.1	36.6	2.9	5.2
		D3	Vredepeel	23.8	14.6	0.000	0.000
	Pond	D4	Skousbo	0.82	1.8	0.01	0.05
		D5	La Jailliere	0.82	1.8	0.1	0.41

Parent: Ornamental pot plants, 3.75 kg as/ha, outdoor spraying, drift loading only (Rautmann) to 30 cm deep, static water body.

Calculation Method	Water body	Scenario	Maximum PEC_{SW} (µg/L)
Spray drift only, estimated based on Rautmann et al.	Static, 30 cm deep	1 m distance (2.77% drift)	34.5
		20 m distance (0.1% drift)	1.28

Photochemical degradation products
Phthalic acid and 2-Carboxybenzaldehyde
Parameters used in FOCUSsw step 3

Based on Step 3 results for parent, and calculated as:
PECsw,met = (PECsw,a.s.) x (mw/207.6) x 50%.
Assuming a 50% formation of each product.
Mol weight: 166.13 (Phthalic acid); 150.13 (2-Carboxybenzaldehyde)

Calculation Method	Water body	Region / Scenario		Maximum PEC_{SW} (µg/L) **Phthalic acid**	Maximum PEC_{SW} (µg/L) **2-Carboxybenzaldehyde**
FOCUS (STEP 3) Grass/Alfalfa	Stream	D1	Lanna	8.4	7.6
		D2	Brimstone	8.6	7.7
		D4	Skousbo	8.2	7.4
		D5	La Jailliere	8.8	8.0
		R2	Porto	8.4	7.6
		R3	Bologna	8.8	8.0
	Ditch	D1	Lanna	9.6	8.7
		D2	Brimstone	9.6	8.7
		D3	Vredepeel	9.5	8.6
	Pond	D4	Skousbo	0.33	0.30
		D5	La Jailliere	0.33	0.30

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

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

Method of calculation and type of study	For FOCUS gw modelling, values used – Modelling using FOCUS model, with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model used: PRZM v 2.4.1 Molecular mass; 207.62 Vapour pressure; 3 x 10^{-6} Pa Water solubility; 19.8 mg / l Kf_{oc}; 552 (lowest value) Freundlich 1/n ; 0.805 Plant uptake (default); 0.5 DT_{50}; 28 d (geometric mean of normalised values, n=4) Temp. Corr. Factor (Q10) (default); 2.2 Application time and rate; 3.75 kg a.i./ha on 1st May Crop; grass/alfalfa Crop-specific values; default Crop interception: None (ground application assumed)
Application rate	Application rate: 3.75 kg/ha. No. of applications: 1 Time of application: spring

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)
			AN (anaerobic soil met.)
PRZM/Grass, alfalfa, / soil application	Châteaudun	<0.001	Not reported, not required
	Hamburg	<0.001	
	Jokioinen	<0.001	
	Kremsmunster	<0.001	
	Okehampton	<0.001	
	Piacenza	<0.001	
	Porto	<0.001	
	Sevilla	<0.001	
	Thiva	<0.001	

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

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	Not required.		

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	3.55×10^{-5}
Photochemical oxidative degradation in air ‡	DT_{50} of 5.5 hours derived by the Atkinson method of calculation (overall OH rate constant was 23.4×10^{-12} cm^3/molecule-sec; 12-hr day; 1.5×10^6 OH radicals per cm^3)
Volatilisation ‡	From plant surfaces (BBA guideline): 5% after 24 hours
	from soil (BBA guideline): negligible after 24 hours
Metabolites	Not relevant.

PEC (air)

Method of calculation	Not relevant.

$PEC_{(a)}$

Maximum concentration	Negligible due to low volatilisation and rapid photolytical degradation.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Quinoclamine, AN (anaerobic conditions only therefore not considered further) Surface Water: Quinoclamine, Phthalic acid (aqueous photolysis), 2-Carboxybenzaldehyde (aqueous photolysis) Sediment: Quinoclamine, AN Ground water: Quinoclamine, AN and DHN (both metabolites under anaerobic conditions only) Air: Quinoclamine.

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

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

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

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

R53 (not readily biodegradable)

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

Appendix 1.6: Effects on non-target Species

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

Species	Test substance	Time scale	Endpoint (mg as/kg bw/d)	Endpoint (ppm)
Birds				
	a.s.	Acute	LD^{50} >2000	Not relevant
	Mogeton 25WP	Acute	LD^{50} >500	Not relevant
	a.s.	Short-term	LD^{50} 394	Not relevant
	Mogeton 25WP	Short-term	LD^{50} >206	Not relevant
	a.s.	Long-term	NOAEL 36.2	Not relevant
Mammals				
	a.s.	Acute	LD^{50} 500	Not relevant
	Mogeton 25WP	Acute	LD^{50} >1250	Not relevant
	a.s.	Long-term	NOAEL 17.5	Not relevant
Additional higher tier studies				
No additional higher tier studies submitted				

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

Crop and Application rate (kg as/ha)	Category (*e.g.* insectivorous bird)	Time-scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)					
Turf, 3.75 kg as/ha	large herbivorous bird	acute	235	**>8.5**	10
	insectivorous bird	acute	203	**>9.9**	10
	large herbivorous bird	short term	125	**3.2**	10
	insectivorous bird	short term	113	**3.5**	10
	large herbivorous bird	long term	66	**0.55**	5
	insectivorous bird	long term	113	**0.32**	5
Drinking water (leaf axis/puddles)	small bird	acute	202.5	**>9.9**	10
Drinking water (surface water)	small bird	long-term	0.21	173	5
Ornamental pot plants, 3.75 kg as/ha	not relevant	acute and short term	negligible	>>10	10
	not relevant	long term	negligible	>>5	5

Crop and Application rate (kg as/ha)	Category (*e.g.* insectivorous bird)	Time-scale	ETE	TER	Annex VI Trigger
Refined 2 (Birds)[b]					
Turf, 3.75 kg as/ha	large herbivorous bird	acute	182	>11	10
	large herbivorous bird	short term	42.23	**9.3**[c]	10
	large herbivorous bird	long term	5.35	6.8	5
	insectivorous bird	short term	data gap	data gap	10
	insectivorous bird	long term	data gap	data gap	5
Tier 1 (Mammals)					
Turf, 3.75 kg as/ha	small herbivorous mammal	acute	741	**0.67**	10
	medium herbiv. mammal	acute	149	**3.4**	10
	small herbivorous mammal	long term	261	**0.067**	5
	medium herbiv. mammal	long term	53	**0.33**	5
Drinking water (leaf axis/puddles)	small mammal	acute	108	**4.6**	10
Drinking water (surface water)	small mammal	long-term	0.011	1590	5
Ornamental pot plants, 3.75 kg as/ha	not relevant	acute and short term	negligible	>>10	10
	not relevant	long term	negligible	>>5	5
Refined 2 (Mammals)[f]					
	medium herbiv. mammal	acute	116	**4.3**	10
	medium herbiv. mammal	long term	3.4	**5.1**	5
Refined 3 (Mammals)[g]					
	medium herbiv. mammal	acute	103	4.8	10
	medium herbiv. mammal	long term	3.04	5.8	5

[b] Refinement for herbivorous birds based on highest value of initial measured residues in grass (acute RA) or the average of initial measured residues in grass (short- and long-term RA), and DT_{50} 0.5 d for decline of residues in grass (long-term RA), see Addendum B.9.
[c] TER based on measured residues and DT_{50} of 0.5 days, and an expected 3-days window of exposure (first mortality occurred on day 3) hence TWA over 3 days calculated. See Addendum B.9.
[f] Refinement based on highest value of initial measured residues in grass (acute RA) or the average of initial measured residues in grass (short- and long-term RA), and DT_{50} 0.5 d for decline of residues in grass (long-term RA), see Addendum B.9.
[g] Refinement based on rabbit as focal species.

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	Endpoint	Toxicity (mg as/L)
Laboratory tests				
Fish				
Oncorhyncus mykiss	a.s.	96 hours	mortality	LC_{50} 0.063
Oncorhyncus mykiss	Mogeton 25WP	96 hours	mortality	LC_{50} 0.12 (0.50 formulation)
Oncorhyncus mykiss	a.s.	21 days	behaviour	NOEC 0.02
Oryzias latipes	phthalic acid	48 h	mortality	>1000
Invertebrates				
Daphnia magna	a.s.	48 hours	immobilisation	EC_{50} 2.15
Daphnia magna	Mogeton 25WP	48 hours	immobilisation	EC_{50} 0.93 (3.7 formulation)
Daphnia magna	a.s.	21 days	reproduction	NOEC 0.0021
Daphnia magna	phthalic acid	48 h	immobilisation	103
Thamnocephalus platyurus	2-carboxybenzaldehyde	24 h	immobilisation	7.5
Sediment organisms				
Chironomus riparius [a]	a.s.	24 days	reproduction	NOEC 0.063
Chironomus plumosus	phthalic acid	48 h	immobilisation	>72
Algae				
Scenedesmus subspicatus	as	72 hours	biomass/growth rate	EC_{50} 0.022 NOEC 0.0025
Scenedesmus subspicatus	Mogeton 25WP	72 hours	biomass/growth rate	EC_{50} 0.022/0.014 (0.086/0.054 formulation NOEC 0.01)
Scenedesmus subspicatus	phthalic acid	7 days	biomass/growth rate	506/258
Scenedesmus subspicatus	2-carboxybenzaldehyde	7 days	biomass/growth rate	598/409
Higher aquatic plants				
Lemna minor	a.s.	7 days	biomass/growth rate	EC_{50} 0.11/0.09

[a] Long-term test on chironomids considered to cover also potential toxicity of metabolite AN (2-amino-1,4-naphthoquinone) identified in sediment of water/sediment study; max 12% in sediment on day 7.

Microcosm or mesocosm tests
No data available, not required.

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

FOCUS Step 2, short and long term assessment

Turf, 3.75 kg as/ha

Test substance	N/S	Organism	Toxicity endpoint (µg/L)	Time-scale	PEC (µg/L)	TER	Annex VI Trigger
a.s.	S	fish	LC_{50} 63	96 hours	84.6	**0.74**	100
a.s.	S	fish	NOEC 20	21 days	84.6	**0.24**	10
Mogeton	S	invertebrate	EC_{50} 930	48 hours	84.6	**11**	100
a.s.	S	invertebrate	NOEC 2.1	21 days	84.6	**0.025**	10
Mogeton	S	algae	EC_{50} 14	72 hours	84.6	**0.17**	10
a.s.	S	sediment organism	NOEC 63	24 days	84.6	**0.74**	10

Refined aquatic risk assessment

FOCUS Step 3, Short term

Turf, 3.75 kg as/ha

Calculation Method	Water body	Region / Scenario		Maximum PEC_{SW} (µg/L)	Taxonomic group	Toxicity LC/EC_{50} (µg/L)	TERst	Annex VI Trigger
FOCUS (STEP 3) Grass/Alfalfa	Stream	D1	Lanna	21.032	fish	63	3.0	100
					algae	14	**0.67**	10
					daphnids	930	**44.3**	100
		D2	Brimstone	21.466	fish	63	**2.9**	100
					algae	14	**0.65**	10
					daphnids	930	**43.3**	100
		D4	Skousbo	20.460	fish	63	**3.1**	100
					algae	14	**0.68**	10
					daphnids	930	**45.5**	100
		D5	LaJailliere	22.108	fish	63	**2.9**	100
					algae	14	**0.63**	10
					daphnids	930	**42.1**	100

Calculation Method	Water body	Region / Scenario		Maximum PEC_{SW} (µg/L)	Taxonomic group	Toxicity LC/EC_{50} (µg/L)	TERst	Annex VI Trigger
cont. FOCUS (STEP 3) Grass/Alfalfa	Stream	R2	Porto	21.072	fish	63	**3.0**	100
					algae	14	**0.66**	10
					daphnids	930	**44.1**	100
		R3	Bologna	22.148	fish	63	**2.9**	100
					algae	14	**0.63**	10
					daphnids	930	**42.0**	100
	Ditch	D1	Lanna	24.308	fish	63	**2.6**	100
					algae	14	**0.58**	10
					daphnids	930	**38.2**	100
		D2	Brimstone	24.148	fish	63	**2.6**	100
					algae	14	**0.58**	10
					daphnids	930	**38.5**	100
		D3	Vredepeel	23.847	fish	63	**2.6**	100
					algae	14	**0.59**	10
					daphnids	930	**39**	100
	Pond	D4	Skousbo	0.819	fish	63	**78**	100
					algae	14	17	10
					daphnids	930	1136	100
		D5	LaJailliere	0.820	fish	63	**78**	100
					algae	14	17	10
					daphnids	930	1134	100

FOCUS Step 3, Long term

Turf, 3.75 kg as/ha

Calculation Method	Water body	Region / Scenario		Maximum PEC_{SW} (µg/L)	Taxonomic group	Toxicity NOEC (µg/L)	TER_{lt}	Annex VI Trigger
FOCUS (STEP 3) Grass/Alfalfa	Stream	D1	Lanna	21.032	*Daphnia*	2	**0.10**	10
					fish	20	**0.95**	10
					chironomids	63	**3.0**	10

Calculation Method	Water body	Region / Scenario		Maximum PEC_{SW} (µg/L)	Taxonomic group	Toxicity NOEC (µg/L)	TER_{lt}	Annex VI Trigger
cont. FOCUS (STEP 3) Grass/Alfalfa	Stream	D2	Brimstone	21.466	*Daphnia*	2	**0.09**	10
					fish	20	**0.93**	10
					chironomids	63	**2.9**	10
		D4	Skousbo	20.460	*Daphnia*	2	**0.10**	10
					fish	20	**0.98**	10
					chironomids	63	**3.1**	10
		D5	LaJailliere	22.108	*Daphnia*	2	**0.09**	10
					fish	20	**0.90**	10
					chironomids	63	**2.8**	10
		R2	Porto	21.072	*Daphnia*	2	**0.09**	10
					fish	20	**0.95**	10
					chironomids	63	**3.0**	10
		R3	Bologna	22.148	*Daphnia*	2	**0.09**	10
					fish	20	**0.90**	10
					chironomids	63	**2.8**	10
	Ditch	D1	Lanna	24.308	*Daphnia*	2	**0.08**	10
					fish	20	**0.82**	10
					chironomids	63	**2.6**	10
		D2	Brimstone	24.148	*Daphnia*	2	**0.08**	10
					fish	20	**0.83**	10
					chironomids	63	**2.6**	10
		D3	Vredepeel	23.847	*Daphnia*	2	**0.08**	10
					fish	20	**0.84**	10
					chironomids	63	**2.6**	10
	Pond	D4	Skousbo	0.819	*Daphnia*	2	**2.4**	10
					fish	20	24	10
					chironomids	63	77	10
		D5	LaJailliere	0.820	*Daphnia*	2	**2.4**	10
					fish	20	24	10
					chironomids	63	77	10

Ornamental pot plants, 3.75 kg as/ha, outdoor spraying (no spraying shield), drift loading only (Rautmann) to 30 cm deep, static water body.

Test substance	Organism	Toxicity endpoint (µg as/L)	Time-scale	PEC (µg/L)[a]	TER	Annex VI Trigger
a.s.	fish	LC_{50} 63	96 hours	34.5 1.28	**1.8** **49**	100
a.s.	fish	NOEC 20	21 days	34.5 1.28	**0.58** 16	10
Mogeton	invertebrate	EC_{50} 930	48 hours	34.5 1.28	**27** 727	100
a.s.	invertebrate	NOEC 2.1	21 days	34.5 1.28	**0.06** **1.6**	10
Mogeton	algae	EC_{50} 14	72 hours	34.5 1.28	**0.41** 11	10
a.s.	sediment organism	NOEC 63	24 days	34.5 1.28	**1.8** 49	10

[a] PECsw for 1 m (34.5 µg/L) and 20 m (1.28 µg/L) distance

Photodegradation products: Phthalic acid and 2-Carboxybenzaldehyde

FOCUS Step 3, Short term

Turf, 3.75 kg as/ha, assumed formation of each product; 50%.

Water body	Scenario	Phthalic acid			2-Carboxybenz-aldehyde		
		PEC_{SW} (µg/L)	48 h EC_{50}, (mg/L)	TER	PEC_{SW} (µg/L)	24 h EC_{50}, (mg/L)	TER
Stream	D1	8.4	> 72	>8571	7.6	7.5	987
	D2	8.6	> 72	>8372	7.7	7.5	974
	D4	8.2	> 72	>8780	7.4	7.5	1014
	D5	8.8	> 72	>8182	8.0	7.5	938
	R2	8.4	> 72	>8571	7.6	7.5	987
	R3	8.8	> 72	>8182	8.0	7.5	938
Ditch	D1	9.6	> 72	>7500	8.7	7.5	862
	D2	9.6	> 72	>7500	8.7	7.5	862
	D3	9.5	> 72	>7579	8.6	7.5	872
Pond	D4	0.33	> 72	>218182	0.30	7.5	25000
	D5	0.33	> 72	>218182	0.30	7.5	25000

Bioconcentration

	Active substance
log P_{ow}	1.58 at pH 11 and 30°C
Bioconcentration factor (BCF)	No data available, not required.
Annex VI Trigger:for the bioconcentration factor	Not relevant.
Clearance time (CT_{50}) (CT_{90})	Not relevant.
Level of residues (%) in organisms after the 14 day depuration phase	Not relevant.

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	-	-
Mogeton 25WP	>28/>43 µg as/bee	- [a]
Field or semi-field tests Not available, not required.		

[a] Result from contact test not included because of non-standard nature of test conditions (filter paper test). However, additional test with 5 times overspray at twice the recommended appl. rate id not produce an increased mortality. Therefore no need for additional data on contact toxicity to bees.

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

Test substance	Route	Hazard quotient	Annex VI Trigger
Mogeton 25WP	Contact	-[a]	50
Mogeton 25WP	Oral	<134/<87[b]	50

[a] HQ not calculated for contact exposure due to non-standard nature of test. However, data suggests 5 times overspray at twice the recommended appl. rate do not produce increased mortality.
[b] HQ values suggest that risk may be indicated, however, this is due to the exposure conditions during the test. Mortality was max. 12% after 72 hours, or max. 3% after 24 hours indicating acceptable risk.

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

Laboratory tests with standard sensitive species

Species	Life stage	Test Substance	Dose (g as/ha)	Endpoint	% effect	Trigger value
Typhlodromus pyri	1 d proto-nymphs	Mogeton 25WP	3810	Mortality and fecundity	16% 16%	50%
Aphidius rhopalosiphi	juveniles	Mogeton 25WP	3810	Mortality and parasitation rate	3% 8%	50%
Poecilus cupreus	adults	Mogeton 25WP	3810	Mortality and feeding rate in pupae	0% 2%	50%
Aleochara bilineata[a]	juveniles	Mogeton 25WP	3810	Live parasitism and total parasitism	70% 66%	50%
Aleochara bilineata[b]	juveniles	Mogeton 50WDG	3750 15000	Reproduction rate (parasitism)	5.3% 19%	50%

[a] No toxic standard was included in the study.
[b] Toxic standard included.

Turf, 3.75 kg as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
Mogeton 25WP	*Typhlodromus pyri*	>3810	<0.98	low risk[1]	2
Mogeton 25WP	*Aphidius rhopalosiphi*	>3810	<0.98	low risk [1]	2

[1] low risk since already the in-field HQ was < the trigger value.

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% effect	Trigger value
Pardosa sp.	adults	Mogeton 25WP, moist sand, 14 days	3810, initial rate	Mortality and feeding capacity	0%	50%

Field or semi-field tests
No data, not required.

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

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
Eisenia foetida	a.s.	Acute 14 days	LC_{50} 125 – 250 mg a.s./kg d.w.soil
	Mogeton 25WP	Acute 14 days	LC_{50} 230 mg a.s./kg d.w.soil
Other soil macro-organisms			
	No data, not required		
Soil micro-organisms			
Nitrogen mineralisation	a.s.	57 days	22% effect at 25 mg a.s./kg d.w.soil (37.5 kg a.s/ha)
	Mogeton 25WP	28 days	0% effect at 18.8 kg a.s/ha
Carbon mineralisation	a.s.	28 days	13% effect at 25 mg a.s./kg d.w.soil (37.5 kg a.s/ha)
	Mogeton 25WP	56 days	0% effect at 18.8 kg a.s/ha
Field studies No data, not required.			

[1] not corrected since log Pow <2.0

Toxicity/exposure ratios for soil organisms

Turf, 3.75 kg as/ha

Test organism	Test substance	Endpoint (mg a.s./kg d.w.soil)	Soil PEC initial (mg a.s./kg d.w.soil)	Soil PEC twa	TER	Trigger
Earthworms						
	a.s.	Acute LD_{50} 125	0.5	-	250	10
	Mogeton 25WP	Acute LD_{50} 230	0.5	-	460	10
Other soil macro-organisms No data, not required						

Ornamentals and Nursery stock plants, 3.75 kg as/ha

Test organism	Test substance	Endpoint (mg a.s./kg d.w.soil)	Soil PEC initial (mg a.s./kg d.w.soil)	Soil PEC twa	TER	Trigger
Earthworms						
	a.s.	Acute LD_{50} 125	5.0	-	25	10
	Mogeton 25WP	Acute LD_{50} 230	5.0	-	46	10
Other soil macro-organisms No data, not required						

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

Preliminary screening data

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} g as/ha vegetative vigour	ER_{50} g/ha emergence	Exposure[1]	TER	Trigger
Brassica napus	a.s.	870	no data	2.77% drift (1 m)	**8.4**	5
				0.6% drift (5 m)	39	5

[1] based on Ganzelmeier drift data.

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

No data submitted, no data required

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

Test type/organism	Endpoint
Activated sludge	11 – 17% reduction at lowest test concentration (10 mg/L

Ecotoxicologically relevant compounds

Compartment	
soil	a.s.
water	a.s.
sediment	a.s
groundwater	None
air	a.s.

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

	RMS/peer review proposal
Quinoclamine	R50/53: Very toxic to aquatic organisms, may cause long –term adverse effects in the aquatic environment

	RMS/peer review proposal
Mogeton	R50/53: Very toxic to aquatic organisms, may cause long –term adverse effects in the aquatic environment

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
kg	kilogram
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry

LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mg	milligram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year