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

dimethomorph

finalised: 23 June 2006

SUMMARY

Dimethomorph is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. 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.

Germany being the designated rapporteur Member State submitted the DAR on dimethomorph in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 11 June 2004. Following a quality check on the DAR, the peer review was initiated on 23 July 2004 by dispatching the DAR for consultation of the Member States and the sole applicant BASF. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in 7 March 2005. 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 June and July 2005.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 7 June 2006 leading to the conclusions as laid down in this report.

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide as proposed by the applicant which comprises application via tractor mounted hydraulic sprayer to hops, grapes and potatoes. The total maximum dose to hops is 3 kg dimethomorph per hectare, 1.5 kg dimethomorph per hectare for grapes and for potatoes 1.44 kg/ha (number of applications: 8) in Northern Europe and 0.9 kg/ha (number of applications: 5) in Southern Europe.
The representative formulated product for the evaluation was "Forum", a dispersible concentrate formulation (DC).

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Adequate methods are available to monitor for dimethomorph. Residues in food of plant origin products of animal origin and soil can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine residues of dimethomorph.
Sufficient 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.

The toxicological studies are performed with batches where the ratio E/Z isomer is between 43/57 to 45/55. Dimethomorph is rapidly and completely absorbed, more than 90% is eliminated via the bile within 24 hours. Dimethomorph is widely distributed and it is extensively metabolized. It is of low acute toxicity i.e. oral LD_{50} 3900 mg/kg bw, dermal LD_{50} > 2000 mg/kg bw and inhalation LC_{50} > 4.24 mg/L. It is neither a skin or an eye irritant nor a skin sensitizer. The target organs are the liver, testes and prostate (dog only). The dog was the most sensitive species with a short term NOAEL of 4.9 mg/kg bw/day (one year). There is no mutagenic or genotoxic or carcinogenic potential of dimethomorph. The long term NOAEL is 9 mg/kg bw/day in the rat based on decreased body weight gain and cellular alterations in the liver (females). There was no effect on the reproductive performance. The NOAEL for offspring, as well as reproduction, was 67 mg/kg bw/day. There are developmental effects observed in the rat and rabbit in conjunction to only mild maternal toxicity. The NOAEL for maternal and developmental toxicity is 60 mg/kg bw/day. The acceptable daily intake (ADI) is 0.05 mg/kg bw/day and the acceptable operator exposure level (AOEL) is 0.15 mg/kg bw/day, with a safety factor of 100 applied. The acute reference dose (ARfD) is based on the NOAEL 60 mg/kg bw/day from the rat developmental study rat where embryolethality as well as death of dams was observed at 160 mg/kg bw/day, with safety factor of 100. The dermal absorption value for the representative formulation Forum 15 DC is 20%.
The estimated exposure according to the German model is below the AOEL without any personal protective equipment (PPE) for potatoes (31%) but PPE is needed for hops and grapes in order to be below the AOEL. If PPE is not considered, the exposure is 128% and 282% of the AOEL for hops and wines, respectively. Estimated exposure for workers and bystanders are also below the AOEL.

The metabolism of dimethomorph in plants when applied as foliar spray is fully elucidated. It proceeds through hydrolysis of the 2 methoxy groups of the dimethoxyphenyl ring, hydrolysis and oxidation of the morpholine ring. None of the metabolites identified is expected to contribute significantly to the toxicological burden the consumer may be exposed to and therefore the residue definition in plant products for monitoring and risk assessment is proposed to be limited to the parent compound. Sufficient information from field studies is present in order to set MRLs and adequately assess the chronic and acute exposures of the consumer.
Processing does not affect the nature of the residue and processing factor can be established for wine and beer.
No residue of dimethomorph or its metabolites is expected to be present at measurable level in animal commodities as the potential livestock exposure resulting from the consumption of potatoes is very

limited. The residue definition for animal commodities is proposed to be restricted to the parent compound. However this definition should be reconsidered for milk and poultry products for which dimethomorph cannot be considered as an appropriate indicator compound, if on the basis of additional uses, beyond the scope of this peer review, animal exposure would be higher.
In following crops the presence of low amounts of dimethomorph is possible in some rare occasions. This however does not represent a concern in terms of consumer safety.
Proposed MRLs are 2 mg/kg, 50 mg/kg and 0.05 mg/kg for wine and table grapes, dried hops and potatoes respectively. The supported representative use of dimethomorph on those crops does not represent a risk for the safety of the consumer, at short or long term.

The available data demonstrated that in soil dimethomorph is moderately persistent, with aerobic soil metabolism DT_{50lab} ranging from 41 to 96 days in four soils. Microbial metabolism was the primary route of dissipation. No aerobic soil metabolism degradates were identified other than small amounts of $^{14}CO_2$ (maximum 31% AR after 120 days). As dimethomorph degraded, most of the radioactivity was not extracted from the soil (accounting for 18-52% AR after 120 days). During the aerobic degradation studies a shift in the E/Z isomers ratio was observed in the extractable dimethomorph; this was explained by a slower degradation of the Z-isomer rather than by isomerisation from E to Z under environmental conditions. A pair of isomers of mono-desmethyl dimethomorph were isolated and identified as primary (< 10% AR) intermediates for the anaerobic studies. Degradation under anaerobic conditions was faster than under aerobic conditions with DT_{50} values of about 26 days. Dimethomorph exhibited a low to medium mobility in soil and there was no evidence that adsorption changed with variation in soil pH.
Dimethomorph did not hydrolyze or photo degraded in the submitted studies.
In natural sediment water systems (dark laboratory studies) dimethomorph rapidly partitioned from the water phase into sediment and was fixed as unextractable residues (47-75% AR after 100 days). In sediment, dimethomorph was slowly metabolised to a certain amount to minor polar components. However, degradation appeared to be incomplete, with a mineralisation rate of 1.0-22% AR in around 100 days.
The available surface water exposure assessment via spray drift considered $PEC_{initial}$ values after the first application, PEC_{actual} values after the last application and PEC_{twa} values over various time-frames between 1 and 100 days after the last application for the minimum distances of 3 and 1 m for hops or grapevines and potatoes. Long-term risk assessment was based on PEC_{twa} values over a period of 46 days with specific moving time-window for each crop to ensure that worst-case values were obtained. Run-off route of exposure to surface water should be considered at Member State level and where pertinent additional aquatic risk assessment completed.
FOCUS groundwater modelling indicated a low potential for groundwater contamination in vulnerable situations over a wide range of geoclimatic conditions across the EU for the uses assessed in this conclusion (at all 9 FOCUS groundwater scenarios annual average leachate concentrations of dimethomorph leaving the to 1 m soil layer predicted to be below the parametric legal drinking water limit of 0.1 µg/L).

Based on the available volatilisation experiment and the calculated atmospheric half-life, contamination of the air compartment and long range transport through air are not expected.

A high first tier acute risk was identified for insectivorous birds in hops, medium herbivorous birds in potatoes, and small herbivorous mammals in hops and vine. The long-term risk to insectivorous birds in hops and to small herbivorous mammals in hops and vine cannot be concluded based on the available information and needs to be further addressed. Since potato leaves are considered unpalatable to birds, and weeds are not that frequent in potato field, it is the EFSA opinion that the acute risk to herbivorous birds in potato is probably low. However, further information is needed to conclude on the risk to insectivorous birds in hops and small herbivorous mammals in hops and vine where relevant decisions are to be based on the assessment according to SANCO/4145/2000.

The acute and long-term risk to aquatic organisms from the use in potato the is low, while for hops and grapevine risk mitigation measures comparable to buffer zones of 20 and 5 m respectively, are needed.

The risk to bees, other non-target arthropods, earthworms, other soil macro-organisms, soil micro-organisms, non-target plants and methods of sewage treatment is considered to be low.

Key words: dimethomorph, peer review, risk assessment, pesticide, fungicide.

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Dimethomorph is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Germany submitted the report of its initial evaluation of the dossier on dimethomorph, hereafter referred to as the draft assessment report, to the EFSA on 11 June 2004. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the draft assessment report was distributed for consultation on 23 July 2004 to the Member States and the sole applicant BASF 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 from Member States identified and agreed in an evaluation meeting on 7 March 2005 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

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 on behalf of the EFSA by the EPCO-Team at the Pesticide Safety Directorate (PSD) in York, United Kingdom in June and July 2005. 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 7 June 2006 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 8(7) of the amended Regulation (EC) No 451/2000, 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 16 March 2005)
- the consultation report

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 19 June 2006)

Given the importance of the draft assessment report including its addendum (compiled version of April 2006 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.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Dimethomorph is the ISO common name for (*E*,*Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine (IUPAC). Dimethomorph, belongs to the class of morpholine fungicides such as tridemorph and fenpropimorph. Dimethomorph is taken up via leaves and is locally systemic it inhibits the formation of the fungal cell wall. The representative formulated product for the evaluation was "Forum", a dispersible concentrate concentrate (DC).

The evaluated representative uses were as a fungicide with application via tractor mounted hydraulic sprayer to hops, grapes and potatoes. The total maximum dose to hops is 3 kg dimethomorph per hectare, 1.5 kg dimethomorph per hectare for grapes and for potatoes 1.44 kg/ha (number of applications: 8) in Northern Europe and 0.9 kg/ha (number of applications: 5) in Southern Europe.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of dimethomorph as manufactured should not be less than 965 g/kg. Currently there is no FAO specification for dimethomorph. A revised technical specification has recently been supplied which may resolve the issues with the technical specification raised by the meeting of experts at EPCO 30 July 2005. However, this specification has not been peer reviewed and therefore the related data requirements must remain. As a consequence the technical specification must be considered as provisional. The technical material contains no relevant impurities. The content of dimethomorph in the representative formulation is 150 g/L (pure).

Beside the specification, 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 dichlorvos or the respective formulation. However, the following data gaps were identified:

- confirm the identity of the impurities revealed by chemical analysis to address the requirement of the Directive on the specificity of the method(s).
- The applicant to provided data or a case to demonstrate if both of the isomers are biologically active.

The main data regarding the identity of dimethomorph 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 dimethomorph in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. However, there is still the outstanding requirement to address the specificity of the impurity method.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. dimethomorph.
Residues in food of plant origin, products of animal origin and soil can be determined with a multi-method (the German S19 method has been validated). The method of analysis for surface and drinking water is LC-MS/MS or HPLC-UV with a limit of quantification of 0.05 µg/L. Air is analysed by GC-PND with a limit of quantification of 10 µg/m^3.

A method of analysis for body fluids and tissues is not required as dimethomorph is not classified as either toxic or very toxic

2. Mammalian toxicology

Dimethomorph was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 33) in June, 2005.
Dimethomorph consists of a mixture of E and Z isomers. The ratio in the technical material ranges from 60/40 to 50/50. The toxicological studies are performed with batches where the ratio E/Z isomer is between 43/57 to 45/55.

2.1 Absorption, distribution, excretion and metabolism (Toxicokinetics)

Dimethomorph is rapidly and nearly completely absorbed based on excretion data. Urinary excretion is 6-15% and the fecal excretion is 85-90%. More than 90% is eliminated via the bile within 24 hours. No accumulation seems to occur after repeated oral exposure.
Dimethomorph is widely distributed and the highest level is found in the liver. It is extensively metabolized (methylation and further oxidation).

2.2 Acute toxicity

The acute toxicity is low i.e. oral LD_{50} 3900 mg/kg bw, dermal LD_{50} > 2000 mg/kg bw and inhalation LC_{50} > 4.24 mg/L. The batch used was the 50/50 ratio. It is neither a skin or an eye irritant nor a skin sensitizer. Thus, no classification for acute toxicity is proposed.

2.3 Short term toxicity

The short term effects of dimethomorph were studied in 10 studies (including range finding studies) in the rat, mouse and dog for 4 weeks up to 1 year. The studies are performed with dimethomorph technical (E/Z racemate) No studies on dermal or inhalation were submitted.

The target organs are the liver, testes and prostate (dog only). The dog was the most sensitive species with an NOAEL of 4.9 mg/kg bw/day based on increased liver weights (females) and testes in males. Although the effects are not statistically significant it was agreed at the experts´ meeting that it was possible to set the NOAEL since the effects were supported by similar findings in the 90-day dog study (NOAEL 15 mg/kg bw/day).

2.4 Genotoxicity

In the DAR the genotoxic properties of dimethomorph were studied in 7 *in vitro* studies (of which one Ames test) and one *in vivo* study. The purity was between 94.2% and 98.7% (ranging from 40/60 to 50/50 E/Z ratio).

Dimethomorph did not induce mutation, chromosome aberration, clastogenicity or cell transformation. The overall conclusion is that there is no mutagenic or genotoxic potential for dimethomorph.

2.5 Long term toxicity

Three long term studies (2-year) were evaluated two in the rat and one in the mouse. Liver effects were noted at high dose levels. There was an increased incidence of testicular tumours in both rat studies.
In the first chronic study in rats the number of animals bearing one or more testicular tumours is 6 at the highest dose (2000 ppm i.e. 98.9 mg/kg bw/day in males and 157.8 mg/kg bw/day in males and females, respectively) as compared to 2 in the control group. The increase is not statistically

significant. It should be noted that in this study the survival rate at the highest dose is 75% whereas the control is 45%.
There are tumours observed in the carcinogenicity study in rat as well. Testicular adenomas and hyperplasia was observed in 15 animals at the highest dose level (2000 ppm i.e. 94.5 mg/kg bw/day in males and 132.5 mg/kg bw/day in males and females, respectively) and 8 in the control group (i.e. 30%), only testicular interstitial cell adenomas is 10 (i.e. 20%). In this study the survival rate was similar between the groups.

There were no tumors observed in the mice.

The overall conclusion from the rapporteur Member State is that there was no evidence of carcinogenicity of dimethomorph in either rats or mice. This is based on evidence that there was no statistical significance or positive trend for the tumours observed in the rat. The higher survival rate in the highest dose group in the first study, although not evident in the second study may have an impact on the amount of tumours observed. According to historical control data the range for testicular interstitial cell adenomas (not including hyperplasia) is 4-20%. The combined no of animals bearing testicular interstitial cell adenomas is 16/70 i.e. 22.9% which is slightly above the historical control range. In addition, there is no progression from benign interstitial tumours to malignant carcinomas. Furthermore, there are no tumours evident in the mouse study.

EFSA notes: The carcinogenic potential was not raised during the scientific commenting period and but was highlighted at the experts meeting and discussed briefly, the meeting agreed with the conclusion of the rapporteur Member State. Finally the classification is concluded at ECB, the current classification is from 1993 where no classification was proposed for toxicology.

The NOAEL for chronic toxicity is 9 mg/kg bw/day in the rat based on decreased body weight gain and cellular alterations in the liver (females). Overall, there is no carcinogenic potential of dimethomorph.

2.6 REPRODUCTIVE TOXICITY

One multigeneration study in the rat in order to determine the reproductive effects of dimethomorph is presented in the DAR.
There was no effect on the reproductive performance. The NOAEL for parental toxicity was 20 mg/kg bw/day, based on reductions in pre-mating body weight gains. The NOAEL for offspring, as well as reproduction, was 67 mg/kg bw/day, the highest concentration tested.

The teratogenic or developmental effects of dimethomorph were studied in two rat and rabbit studies. There were no treatment related malformations or variations observed in the rat. The NOAEL for maternal toxicity was 60 mg/kg bw/day based on decreased body weights, body weight gains (around 2-7%), and food consumption at 160 mg/kg bw/day (23%). The NOAEL for developmental toxicity was also 60 mg/kg bw/day, based on of total litter losses in two animals at 160 mg/kg bw/day and increase post-implantation loss.

In the rabbit, the NOAEL for maternal toxicity was 300 mg/kg bw/day based on decreased body weight gains (5-7%) and food consumption (30%) at 650 mg/kg bw/day. The NOAEL for developmental toxicity was 300 mg/kg bw/day based on a slightly increased embryolethality (i.e. abortion of three dams).

EFSA notes: there are developmental effects observed in the rat and rabbit in conjunction to only mild maternal toxicity.
This was not raised as a concern during the scientific commenting period and thus not discussed at the experts meeting. However, the effects were discussed in relation to setting of the ARfD and the NOAEL from the rat developmental study was indeed used for the ARfD. Whether there is a need for classification is up to the ECB. The current classification is from 1993 where no classification was proposed for toxicology.

2.7 NEUROTOXICITY

Dimethomorph is not an organophosphate or carbamate and no neurotoxicological studies were conducted. No signs indicative of neurotoxic effects were observed in other toxicity studies.

2.8 FURTHER STUDIES

Metabolites
No studies available

Impurities
Ames mutagenicity tests are performed on three impurities Z86, Z87 and Z106 which were all negative; information is presented in the addendum (confidential part, May, 2005).

Studies on the pharmacologic responses
Several studies on the rat mouse as well as guinea pig are summarised in the DAR. The studies are on blood presure, body temperature, inflammatory responses, analgesic effects etc and generally no adverse effects were observed up to 100 mg/kg bw/day.

2.9 MEDICAL DATA

No adverse effects on health due to dimethomorph have been observed in a health surveillance programme for workers in a manufactoring plant, Cyanamid Resende Plant, Resende, Brazil. The annual medical examination included blood tests, tests of liver functions, kidney function, expirometry and audiometry.
No clinical cases and poisoning incidents related to dimethomorph are known. No observations regarding health effects after exposure of the general public are known.

2.10 Acceptable daily intake (ADI), Acceptable operator Exposure Level (AOEL) and Acute reference dose (ARfD)

ADI

The ADI is 0.05 mg/kg bw/day based on the NOAEL of 5 mg/kg bw/day from the 1-year study in dogs, with the safety factor of 100 applied.

AOEL

The AOEL is 0.15 mg/kg bw/day based on the NOAELs from the 90-day studies in the rat and dog, with a safety factor of 100. Correction for oral absorption is not needed.

ARfD

The ARfD is based on the NOAEL 60 mg/kg bw/day from the rat developmental study rat where embryolethality as well as death of dams was observed at 160 mg/kg bw/day.
The ARfD is 0.6 mg/kg bw/day, with the safety factor of 100 applied.

2.11 Dermal absorption

An *in vivo* study in the rat is available for the representative formulation Forum 15 DC based on dilutions of dimethomorph. Initially, in the DAR the rapporteur Member State proposed 5%.
However, it was agreed at the experts meeting to include the amount in skin (in accordance to the Guidance document on dermal absorption Sanco/222/2000, Nov 2002). As no in vitro studies are available no correction can be performed for interspecies variability, the agreed dermal absorption value of 20% should be seen as a worst case. Details are presented in the addendum (April, 2006)

2.12 Exposure to operators, workers and bystanders

The representative plant protection product Forum 15 DC is a dispersible concentrate containing 150 g dimethomorph/L. The application is performed using tractor mounted spray and the rate is 300 g/ha for grape wines, 600 g/ha for hops and 180 g/ha for potatoes. The exposure assessments were amended due to the changed dermal absorption value and are presented in the addendum (April 2006).

Operator exposure

The operator exposure was estimated using the UK-POEM and the German model. The calculations are based on the dermal absorption of 20%. With the German model, the assumed treated area for tractor application (600 g/ha) in field crop and high crop is 20 and 8 ha/day, respectively. For knapsack application in high crop (180 g/ha) 1 ha/day is used in the calculations.

For the UK-POEM, the treated area for tractor application in high crop is 30 ha/day (600 g/ha and 300 g/ha; the standard treated area in the UK POEM model for high crop is 15 ha) whereas in field crop it is 50 ha/day (180 g/ha).

The estimated exposure according to the German model is below the AOEL if personal protective equipment (PPE) and is used. According to the UK-POEM, the estimated exposure is higher than the AOEL for vines but below for hops and potatoes if PPE is used, see table below.

Estimated exposure presented as % of AOEL (0.15 mg/kg bw/day), according to calculations with the UK-POEM and German model. The default for body weight of operator is 70 kg for the German model and 60 kg for the UK-POEM. For UK-POEM, the 5 L container is used and the application is tractor mounted for all uses.

Model/scenario (treated area, application rate)	**No PPE**	**With PPE gloves m/l**	**With PPE (gloves m/l and appl. and garment appl. for German model; gloves during m/l and appl. for UK POEM)**
German model			
High crop (8 ha, 600 g/ha) hops	128%	106%	16%
High crop, handheld (1 ha, 600 g/ha) vines	282%	51%	11%
Field crop (20 ha, 180 g/ha) potatoes	31%	14%	1%
UK-POEM			
High crop (30 ha, 600 g/ha) hops	162%	86%	62%
High crop (30 ha, 300 g/ha) vines	244%	206%	147%
Field crop (50 ha, 180 g/ha) potatoes	207%	170%	29%

PPE: personal protective equipment, m/l: mixing and loading, appl: application

Worker exposure

Potential inhalation exposure during re-entry is assumed to be negligible and the predominant exposure would be via dermal exposure. Re-entry exposure may occur for vines and potatoes and the estimations are using transfer coefficients from Hoernicke et al., 1998 and EPA 1998. The assumed working period is 8 hours and the estimated exposure is 140% without PPE and 7% if PPE is used for grapes and field crop.

EFSA note: the worker exposure for re-entry in hops, which represents the maximum application rate for application of dimethomorph, was not assessed.

Bystander exposure

Assumption from the EUROPOEM II model is used in order to estimate bystander exposure. The estimated exposure is 22% for hops and 0.3% for potatoes.

3. Residues

Dimethomorph was discussed at EPCO experts' meeting for residues (EPCO 34) in June 2005.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of dimethomorph was investigated in grapes, potatoes and lettuce. The designs of these studies were representative of the proposed representative uses with sampling at maturity of the crop in the range of proposed PHIs. The degradation of dimethomorph is limited after foliar application and the parent compound was the major constituent of the residue in all investigated plant parts, including potato tubers.

Two degradation pathways were identified:

- Demethylation of the 2 methoxy groups of the dimethoxyphenyl ring to produce metabolites Z67[3] and Z69[4], resulting in a hydroxyl group that most likely forms the corresponding glucose conjugate.
- Hydrolysis of dimethomorph to form metabolite Z7[5]
- Oxydation of the morpholine ring to lead to metabolite Z37[6]

An additional metabolism study on tomatoes, although not representative of the supported representative uses (the product was applied in a nutrient solution) indicated that the compound is uptaken by the roots and translocated to the fruits. Some metabolites were present at levels similar to that of the parent compound and an additional degradation pathway based on a stepwise degradation of the morpholine ring was observed.

The residue definition proposed for monitoring and risk assessment is dimethomorph. No metabolite is included in the residue definition given that the residue pattern is largely dominated by the parent compound. These definitions are valid when the product is applied by foliar spray. Other methods of application involving uptake by the roots and acropetal translocation of the compound would necessitate a re-evaluation of the residue definition for risk assessment.

A sufficient number of supervised residue trials carried out in accordance with the supported representative uses are available to allow the setting of MRLs and to assess the exposure of the consumer. In grapes 19 trials are available for the Northern region and 8 for the Southern region with respective Supervised Trials Median Residues (STMR) at 0.62 and 0.37 mg/kg. The Highest Residue value (HR) in grapes was found in the Southern region (2.28 mg/kg). Ten trials are available for the use on hops with STMR and HR values at 25 and 42 mg/kg respectively. For potatoes a total of 58 trials are available carried out in Northern and Southern Europe with application rates up to 0.5 mg/kg. In most cases residues were below the Limit of Quantification (LOQ) of the method of analysis. Only in very few cases detectable residues were present (all below 0.05 mg/kg), probably due to soil contamination.

The results of supervised residue trials can be considered as reliable on the basis of storage stability studies indicating that dimethomorph residues are stable under deep freeze conditions in various plant commodities including potatoes, grapes and grapes products, hops and beer for periods of 18-24 months.

3 4-[(E)-and(Z)-beta-(p-chlorophenyl)-3-hydroxy-4-methoxycinnamoyl]morpholine
4 4-[(E)-and(Z)-beta-(p-chlorophenyl)-4-hydroxy-3-methoxycinnamoyl]morpholine
5 4-chloro-3',4'-dimethoxy-benzophenone
6 4-[3-(4-chlorophenyl)-3-3,4-dimethoxy-phenyl)-1-oxo-2-propenyl]-2-oxo-morpholine

The effects of processing on the nature of the residues were investigated through hydrolysis studies simulating sterilisation, baking, brewing, boiling and pasteurisation. These studies showed that dimethomorph is hydrolytically stable under these simulated processing conditions. The effect of processing on the residue level in processed commodities was investigated for grapes and hops. In wine processing balance studies indicated that residues are transferred into pomace and wine (40-60 % and 16-50 % of the initial residues in raw grapes respectively). Twenty-four follow-up studies are available demonstrating that the average transfer factor from grapes to wine is 0.34 and 0.23 for red and white wine respectively. In beer processing, about 70% of the initial residues in hops are transferred to beer. Processing factors from dried hops to beer were calculated in 4 processing studies and are ranging from <0.001 to 0.004.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

The metabolism of dimethomorph in succeeding and rotational crops has been investigated in 2 studies with radioactive material. Dimethomorph as well as its 2 metabolites Z67 and Z69 (free or conjugated to glucose) resulting from demethylation of the phenolic methoxy groups were identified in small amounts (at 0.01 to 0.04 mg/kg for application rates in the range of those proposed in representative uses), indicating that dimethomorph is uptaken by the roots and that the metabolic pathway in following crops is similar to that observed in primary crops. Four field trials carried out in 2 different years and using carrots, spinach and beans as following crops sowed within 30 days after last application of dimethomorph on potatoes indicate that residues of dimethomorph are generally below the LOQ (0.01 mg/kg), but also in some circumstances (for instance in dry beans or in case of early harvest of carrots or spinach) present at low but measurable levels in following crops. The highest residue found was 0.09 mg/kg in a spinach sample. These residue levels in following crops are not a concern as far as the safety of the consumer is concerned. Considering a contamination of 0.02 mg/kg of vegetables and a consumption of 1 kg vegetables per day by an adult of 60 kg, the dietary burden of dimethomorph would be lower than 1 % of the ADI of the compound. The necessity of plant-back restrictions for regulatory purpose needs to be examined at management level.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Metabolism studies were performed in lactating goats and laying hens.

Lactating goats were dosed at 1 mg/kg bw/d, corresponding to an approximate dietary burden of 25 mg/kg diet. Total Radioactive Residues (TRR) were readily and almost completely extractable in edible tissues and were the highest in liver (7 mg/kg). TRR in the other organs were ranging from 0.04 mg/kg (muscle) to 0.3 mg/kg (kidneys). No sign of accumulation was present. The major component of the extractable residue in kidney, liver, muscle and fat was the unchanged parent compound, representing 9, 72, 7 and 75 % of the TRR in these tissues, respectively. Metabolites Z67 and Z69 were also detected in liver, indicating that dimethomorph in the lactating goat is initially metabolised via demethylation of one of the phenolic methoxy-groups. Additional metabolic processes involve morpholine-ring cleavage and degradation, leading to metabolite CUR 7117[7] which is the only compound identified in milk, representing 48 % of the TRR.

Laying hens received a daily dose of 4 mg/kg bw, corresponding to dietary burden of 40 mg/kg diet. TRR in edible tissues ranged from 0.016 mg/kg (muscle) to 1.05 mg/kg (liver). Extractability of residues was high and parent compound was present in fat only. The metabolic pattern observed in tissues indicates that the degradation pathway in laying hens is similar to that observed in goat, being based on demethylation of the phenolic methoxy-groups and on degradation of the morpholine ring.

The residue definition for animal products was discussed in the expert meeting (EPCO 34). The parent compound is not a valid indicator for milk and poultry products, where metabolites CUR 7117 and the sum of metabolites Z67 and Z69, respectively, seem more appropriate. However, given the low exposure of livestock in practice resulting from the use of dimethomorph according to the supported representative uses, the expert meeting proposed dimethomorph as default residue definition for monitoring and risk assessment. It must however be kept in mind that this definition should be revised for milk and poultry product in case of animal exposure exceeding the trigger value of 0.1 mg/kg feed.

The maximum residue level in potatoes, which is the only relevant feeding stuff within the representative uses, is 0.05 mg/kg. Taking into account the nutrition practices of livestock, the animal exposure is below 0.1 mg/kg feed in cattle, pig and poultry. Therefore, in the absence of any sign of potential accumulation of dimethomorph residues by livestock, feeding studies are not required. A feeding study in dairy cows was however submitted. The lowest dose level in that study was 25 times higher than the potential highest estimated exposure level of ruminants based on the representative use in potatoes. Dimethomorph and its metabolites Z67/Z69 and CUR 7117 were found below the LOQ (0.02 mg/kg) in all matrices. Therefore, considering the large overdosage factor, it can be concluded that no residues are expected in milk and tissues from animals receiving feed treated with dimethomorph according to the supported representative uses. The setting of MRLs for animal products is not needed.

3.3. CONSUMER RISK ASSESSMENT

Chronic exposure

The chronic dietary exposure assessment has been based on the Theoretical Maximum Daily intake (TMDI) calculation model of WHO using the WHO typical European diet for adult consumers and the German national diet for the 4-6 year old girl. Residues in grapes, hops and potatoes were considered to be at the level of the respective proposed MRLs. Contribution from animal commodities and following crops were not included in the calculations, but as mentioned under points 3.1.2 and 3.2, their expected influence to the total dietary burden is not significant. Under these conditions the calculated TMDI were 16 and 5 % of the ADI for the European and German diets respectively.

[7] N-[3-(4-chlorophenyl)-3-3,4-dimethoxyphenyl)-1-oxo-2-propenyl-glycine

Acute exposure

The acute exposure of adult population, as the ARfD is based on developmental effects, to residues of dimethomorph in table grapes and potatoes has been assessed according to the WHO model for conducting National Estimates of Short Term Intakes (NESTI) calculations. Large portion consumption data for adults in UK were used. Calculations were carried out considering residues of dimethomorph in composite samples of treated grapes and potatoes at 1.70 mg/kg and 0.05 mg/kg respectively (in the case of table grapes the residue level used is slightly lower than the proposed MRL) as well as variability factors of 5 and 7 for table grapes and potatoes respectively. Under these conditions the calculated NESTI were 4 and less than 1 % of the ARfD for table grapes and potatoes respectively. In addition an acute exposure assessment through beer consumption was conducted during the expert meeting (EPCO 34). Using UK consumption data for hops and the proposed MRL (50 mg/kg) a NESTI calculation indicated that the intake of beer consumers is very low (1.5 % of the ARfD).

Based on chronic and acute exposure assessment, no risk for the health of the consumer has been identified resulting from the supported representative uses of dimethomorph.

3.4. PROPOSED MRLS

The results of supervised residue trials were analysed according to the statistical tools recommended for MRL setting by the current European guidelines (Doc 7039/VI/95). The proposed MRLs are:

Grapes	2 mg/kg
Hops (dried)	50 mg/kg
Potatoes	0.05 mg/kg

It must be noted that for grapes grown in Southern Europe, one of the statistical method suggested the MRL to be set at 1 mg/kg and the other method suggested a level of 3 mg/kg. This is due to the weight of an extreme value of 2.28 mg/kg present in the data base for Southern Europe, which is not taken into account in one method while it is in the other. As this value is the only result above 2 mg/kg, it was considered by the rapporteur Member State that a MRL of 2 mg/kg, also in accordance with the use on grape in Northern Europe was the most appropriate.

4. Environmental fate and behaviour

Dimethomorph was discussed at the EPCO experts' meeting for environmental fate and behaviour (EPCO 26) in June 2005.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Route of degradation of dimethomorph was investigated in soil experiments carried out under aerobic conditions in the laboratory (20 - 25ºC, 75% and 82% FC or 33% MWHC) in the dark with dimethomorph labelled in the chlorophenyl position or in the morpholine position. The five soils covered a wide range of pH (3.5-7.0), clay content (0-23.1%) and organic carbon content (0.9-2.9%). A rapid decrease of extractable dimethomorph was observed, with a corresponding increase in unextractable (bound) residues (max. 51.6% AR with the chlorophenyl-label and max. 47% AR with the morpholine-label after 119-120 days). Nature of non-extractable residues was not further investigated. Mineralisation from the chlorphenyl ring and morpholine ring was 22.6% and 30.9% AR, respectively, after approximately 120 days. A shift in the E/Z isomer ratio from E to Z was observed in the extractable dimethomorph (maximum shift: from approximately 48/52 at 0-time to approximately 29/71 at 180 days). The combined amounts of unidentified radioactivity detected in the solvent-extractable radioactivity never exceeded 10.2% AR.

In a study conducted under sterile conditions showed that dimethomorph was stable, with less than 10% AR dimethomorph degraded in 4 months. Under these conditions, the amount of bound residues also remained very low (≤ 5% AR) indicating that the degradation of dimethomorph and incorporation of residues in the soil matrix observed in the non-sterile soil degradation studies might be attributed to microbial activity.

Under anaerobic conditions (three studies in the dark at 22-25ºC with four soils) mineralisation to CO_2 was minimal (maximum 5.5% AR after 60d) and up to 73% AR were fixed in soil as bound residues after 60 days. Two isomers (mono-desmethyl compounds) formed from demethylation of the dimethoxyphenyl ring, with combined amounts ranging from 2.1 to 9.1% AR.

A soil photolysis study is available. Dimethomorph was slowly degraded by irradiation in the soil to give two minor unidentified photolysis products, each at < 4% AR after 15 days of continuous irradiation. A shift in the E/Z ratio of dimethomorph was observed in the irradiated samples during the study, changing from 42/58 at time 0 to 34/66 after 15 days, whereas in the dark control the initial ratio was maintained throughout the study. Therefore, the shift from E to Z observed in the irradiated samples can be attributed to photochemical reactions.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Degradation rate of dimethomorph was investigated in the same studies used to establish the route of degradation in soil. Dimethomorph (as mixture of E and Z isomers) is moderate to medium persistent in soil under aerobic conditions at 20 – 25ºC (DT_{50} = 41 – 96 d). The shift in the ratio of the E and Z isomer observed during the degradation studies resulted in DT_{50} values for the Z-isomer consistently longer (62 d, 58 d, 162 d) than for the E-isomer (47 d, 41 d, 38 d). The isomers' different rate of degradation with respect to the fate risk assessment was discussed at the meeting of experts. It was agreed that the worst-case DT_{50} value for the isomeric mixture from laboratory studies (= 90.2 d, corrected for temperature and moisture) is appropriate to calculate PECsoil. For reason of completeness, the isomeric DT_{50} values for the laboratory studies with individual isomers are also reported in the list of endpoints.

The rate of degradation of dimethomorph at 10ºC and 40-50% MWHC under aerobic conditions was investigated in a sandy loam (clay 5.6%, pH in KCl 5.7, organic carbon 1.3%). The first order DT_{50} value was 74 days.

Under anaerobic conditions dimethomorph degraded more rapidly than under aerobic conditions, with a first order DT_{50} value of approximately 26 days. A slight difference was observed in the rate of degradation of the individual E and Z isomers.

The photolysis DT_{50} for dimethomorph was estimated to be 75 days of continuous irradiation using a zero-order reaction model.

The rate of dissipation of dimethomorph was measured in soil field dissipation studies. Five trial sites in Germany were conducted on bare soil (sandy loam, clay and loamy sand soils), and three trials were conducted in UK, France and Spain (loamy sand, loamy sand and sand soil, respectively). Results indicated that dimethomorph is moderate to medium persistent with $DT_{50field}$ values ranging from 10 to 61 days and $DT_{90field}$ values between 33 and 203 days. Two mono desmethyl metabolites detected in laboratory soil studies primarily under anaerobic conditions, were found in the UK, France and Spain trials, but only in minor amounts (close to the limit of quantification of the soil method) and sporadically. Detectable residues of dimethomorph were found only in the 0-10 cm soil layer. Like in the aerobic degradation studies in the laboratory, the ratio of the two isomers of dimethomorph changed, with the dissipation of the E-isomer consistently faster (DT_{50} = 17-38 days) than for the Z-isomer (DT_{50} = 34-78 days).

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

In guideline laboratory batch adsorption studies on 7 soils, dimethomorph K_{foc} values were determined in the range 290-566 L/kg (mean 407.7 L/kg) with corresponding 1/n values in the range 0.81-0.92 (mean 0.857). Dimethomorph can be considered low to medium mobile in soil. There was no indication of adsorption being pH dependant. Results are available also for the sorption of the individual E and Z isomers of dimethomorph in four soils, indicating that the two isomers have very similar sorption behaviour. Taking into account the averages of the K_{foc} values (345-557 L/kg) calculated from the individual K_{foc} values for each E- and Z-isomer, the overall mean K_{foc} value (n = 11) for dimethomorph is 430 L/kg.

A column leaching study was conducted with an unlabelled dimethomorph/mancozeb formulation in four soils (OC 0.70-2.56 %, pH in $CaCl_2$ 4.9-7.7, 200 mm rainfall over 48 hours). The application rate approximately equals 10 times the maximum labelled use rate (i.e. 1.8 kg/ha of dimethomorph). No residues of dimethomorph were detected in the leachates, except for one replicate of one sand soil, where a peak was detected at a level below the limit of determination, corresponding to 0.67% of the applied dose.

The mobility of dimethomorph was further assessed in two aged residue column leaching studies, with ^{14}C-morpholine or ^{14}C-chlorophenyl dimethomorph. After ageing of 60-90 days the soils contained approximately 45.0-67% AR dimethomorph. The columns were leached with 200 mm (chlorophenyl label) and 510 mm (morpholine label) of water in two days. Following the leaching process, only 0.7-0.8% and 3.3-3.4% of column AR was found in the leachate. This leached radioactivity was composed of several compounds (up to seven compounds in the study with the chlorophenyl label dimethomorph), none of which accounted for greater than 0.5% of the dose. None of the products I the leachate chromatographed with dimethomorph or with a series of known or suspected degradation products.

Predicted environmental concentrations in soil were calculated for multiple applications in hops, representing the worst case of the all representative uses.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Dimethomorph was stable to aqueous hydrolysis in sterile buffers within the pH range of 4 to 9.

Photochemical degradation was investigated in two aqueous photolysis studies. In the first study, conducted with ^{14}C-chlorophenyl dimethomorph, the photodegradation in water was described using zero-order kinetics, with an estimated DT_{50} value of approximately 28 days of continuous irradiation (comparable to natural noon daylight at latitude 40º N in the summer). In the second study, both the ^{14}C-morpholine and ^{14}C-chlorophenyl label positions were investigated. Dimethomorph was slowly degraded by UV irradiation to a number of minor photolysis products, none of which exceeded 6.6% AR after 15 days of continuous irradiation. The aqueous photolysis first-order DT_{50} values of dimethomorph were 107 and 86 days for the chlorophenyl and morpholine label, respectively (comparable to a natural sunlight intensity in the spring at 40º N latitude). The average quantum yield of the direct photolysis of dimethomorph in buffered medium at pH 7 and 20ºC was 6.71 x 10^{-6}, indicating that photolysis in water would be slow under environmental conditions.

Based on the results of an OECD guideline test, dimethomorph can be classified as not readily biodegradable.

Two water/sediment studies were available. In the first study only the chlorophenyl-moiety of the molecule was labelled and the isomers were not determined separately. Two different systems (sediment OC: 1.84-5.0%, sediment pH: 7.3-7.5, water pH: 8.0-8.2) were investigated in this study. Dimethomorph quickly moved to the sediment and was fixed as bound residues (max. 57% AR at 105d study end, and 74% AR at 29d). The complete degradation was low (mineralisation rate: 14-22% AR at 105d study end). The first-order DT_{50} values calculated for the total water-sediment system were 2-3 days, and DT_{90} values $\leq$ 10 days. In the sediment phase, small amounts of de-methylated metabolites were observed in one system (7.8% AR after 1d) and an unknown polar fraction (max. 14-16% AR after 105d) consisted of several components. The second study was performed with both ^{14}C-morpholine and ^{14}C-chlorophenyl dimethomorph in two different systems (sediment OC: 1.3-4.5%, sediment pH: 7.8-8.0, water pH: 7.6-8.5). The dissipation of dimethomorph form water phase to sediment was slower, reaching a maximum of 41% AR after 7 days in both systems, and then declined to 7.8-9.6% AR at 100d study end. The majority of the applied radioactivity became associated with non-extractable sediment residues (max. 47-82% AR). The mineralisation rate was low, reaching a maximum of 8.6% AR after 100 days. First order DT_{50} values of 5 and 15 days were calculated for the water phase and 7 and 33 days for the sediment. The 1st order half-lives for the total systems were 16 and 59 days. Up to 17 different metabolite fractions were found, none exceeding 2.3% of the applied radioactivity.

The available surface water exposure assessment considered the spray drift as the only entry route to surface water. Standard values for $PEC_{initial}$ after the first application, PEC_{actual} after the last application and PEC_{twa} over various time-frames between 1 and 100 days after the last application for the minimum distances of 3 and 1 m for hops or grapevines and potatoes were provided in an addendum (May 2005). At the meetings of experts (EPCO 26 on fate and EPCO 27 on ecotoxicology, June 2005) concerns raised on the approach used by the rapporteur Member State to assess the long-term risk to aquatic organisms with a time-weighted average PEC from 0 to 60d. It was concluded that according to the relevant time period (exposure of most sensitive life-stage) in the fish ELS-test, a PEC_{twa} over 46 days is appropriate for the assessment. Therefore, PEC_{twa} values (46 d) with specific moving time-window for each crop to ensure that worst-case values were obtained, were provided by the rapporteur Member State in a new addendum (April 2006). The experts considered that run-off route of exposure to surface water should be considered at Member State level and where pertinent additional aquatic risk assessment completed. PEC values in sediment were calculated with the same multicompartment model as used for assessment of the water/sediment study, but amended by an external "event generator" for drift intakes. However, the PEC_{sed} values were not used in the risk assessment (refer to section 5.2) and should be considered as additional supportive data.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The predicted 80th percentile concentrations of dimethomorph in shallow groundwater (1-meter depth) were calculated with FOCUS PELMO (version 2.2.2) for all the relevant crop-location scenarios. The pesticide properties used as input to the modelling included an average laboratory half-life of 56.7 d (average first-order laboratory degradation DT_{50} values of dimethomorph corrected to the reference temperature and soil moisture conditions of 20ºC and pF2) and an average K_{OC} and 1/n values of 430 L/kg and 0.86, respectively, based on results from adsorption coefficients of the mixture of E/Z isomers as well as the K_{foc} values determined separately for each E- and Z-isomer. Results showed that PEC_{gw} were ≤ 0.001 µg/L in all crop-location scenarios modelled. It is the opinion of EFSA that the mean K_{foc} value of 408 L/kg as the average value derived only from adsorption coefficients of dimethomorph as a mixture of the two isomers would be more appropriated for the modelling. However, this slight difference it is not expected to have an impact on the final assessment.

4.3. FATE AND BEHAVIOUR IN AIR

The volatilisation of dimethomorph from potato plants and soil surfaces was investigated in the field within 24 hours after treatment. No chronological decrease of dimethomorph residues was observed in the course of the experiment, indicating that volatilisation losses from these substrates are likely to be relatively low. Another study, performed with ^{14}C-labelled dimethomorph in a wind tunnel, confirmed that dimethomorph is not expected to volatilise from soil/plant leaves.

The DT_{50} of dimethomorph in the atmosphere due to photochemical oxidative degradation in the presence of hydroxyl radicals was calculated using the method of Atkinson (AOP v1.90) to be 3.6 hours, assuming a 24-h day and an atmospheric hydroxyl radicals concentration of 5×10^{-5} /cm^3. Therefore, any dimethomorph that reaches the upper atmosphere would not be expected to subject to long range transport.

5. Ecotoxicology

Dimethomorph was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 27) in June 2005.

Technical dimethomorph is a mixture of two isomers, E and Z. No specific information on the isomeric composition of the test material used in the ecotoxicological studies are given in the study reports. For the assessment it was assumed that the composition was in accordance with the technical specification.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The representative evaluated uses of dimethomorph are as fungicide in grapevine (5×300 g a.s./ha), hops (5×600 g a.s./ha) and potato (8×180 g a.s./ha) with an interval of 7 to 10 days between applications for the different crops. Dimethomorph is a systemic compound.

The first tier risk to a generic insectivorous bird was calculated in the DAR with endpoints for short and long term based on concentration in food. Residue estimates were based on generic data according to Fisher and Bowers[8] assuming 21 mg/kg for 1 kg/ha. Consumption of fresh insects for a 10 g bird was based on data from Nagy[9] and equal to 94% of the body weight. All TER values (acute, short- and long-term) were well above the relevant Annex VI triggers indicating a low risk. In addendum 1 of May 2005, tier 1 TER values calculated according to SANCO/ 4145/2000 and based on endpoints as daily dose were presented for insectivorous birds in all representative crops and for herbivorous birds in potato. All TER values were still above the trigger, except the long-term TER for insectivorous birds in hops, where it was 3.2 using the NOAEL from the bobwhite quail study and 4.3 using the NOAEL from the mallard study. No data to refine the assessment are available since no request was done to the applicant. The rapporteur Member State is of the opinion that a refined assessment would lead to a TER value above the trigger. No parental or reproductive effects were observed in the two reproduction studies that are available even at the highest dose tested. However, the EFSA is of the opinion that the expected low risk should be verified with a refined long-term risk assessment where relevant decisions are to be based on the assessment according to SANCO//4145/2000.

As for birds, the first tier assessment for mammals presented in the DAR was based on endpoints for short and long term expressed as concentration in food. Residue data for insects were from Fisher and

[8] Fischer DL & Bowers LM (1997) Summary of field measurements of pesticide concentrations in invertebrate prey of birds. *18th Annual Meeting of the Society of Environmental Toxicology and Chemistry*. San Francisco (US)

[9] Nagy, K. A. (1987) Field metabolic rate and food requirement: scaling in mammals and birds. *Ecol. Monogr.* **57**:111-128

Bowers and from Hoerger and Kenaga[10] for vegetation. Food consumption equal to 100% of the body weight was used for a 10 g insectivorous mammal (shrew)[11], and equal to 28% of the body weight for a 300 g herbivorous mammal[12] All TER values (acute, short- and long-term) were well above the relevant Annex VI triggers indicating a low risk. In addendum 1 of May 2005, TER values calculated according to SANCO/4145/2000 and based on endpoints as daily dose were presented for standard mammalian species in all representative crops. The acute TER values were above the Annex VI trigger in all crops, while the long-term values were below the trigger in hops and vine (0.4 and 1.0 respectively). Hence the long-term risk to small herbivorous mammals in hops and vine needs to be further addressed where relevant decisions are to be based on the assessment according to SANCO//4145/2000.

Acute toxicity studies with the formulation 'FORUM 150 DC' showed that the formulation is more toxic to birds than expected based on the content of dimethomorph, and maybe also to mammals. Acute TER values were calculated with the endpoint from the formulation study in the DAR using daily intake estimates as described above. The derived TER values were still above the Annex trigger for all uses evaluated. However, if the ETE values from addendum 1 of May 2005 are used, which were calculated according to SANCO/4145/2000, TER values below the Annex VI trigger are obtained for insectivorous birds in hops (TER_a=5.7), medium herbivorous birds in potatoes (TER_a=7.3), and small herbivorous mammals in hops (TER_a=1.1), and vine (TER_a=2.4).

In addendum 1 of May 2005 a risk assessment for birds and mammals from consumption of contaminated drinking water was presented. A mistake in the calculations was corrected in addendum 6 of April 2006. The acute TER values for both birds and mammals are well above the trigger of 10 even assuming intake of undiluted spray solution and it can be concluded that the acute risk is low.

The $logP_{ow}$ for dimethomorph is <3 and hence the potential for bioaccumulation and secondary poisoning is considered to be low.

In summary a high first tier acute risk was identified for insectivorous birds in hops, medium herbivorous birds in potatoes, and small herbivorous mammals in hops and vine. The identified first tier high long-term risk to insectivorous birds in hops and to small herbivorous mammals in hops and vine needs to be further addressed where relevant decisions are to be based on the assessment according to SANCO//4145/2000. Regarding birds it could be noted that no effects were observed at the highest dose tested. Since potato leaves are considered unpalatable to birds, and weeds are not

[10] Hoerger FD & Kenaga EE (1972) Pesticide residues on plants, correlation of representative data as a basis for estimation of their magnitude in the environment. In: *Environmental Quality and Safety*, Vol. I, pp. 9–28. Academic Press, New York (US).
[11] Churchfield S., (1982), Food availability and the diet of the common shrew, *Sorex araneus*, in Britain, J Anim Ecol 51, 15-28.
[12] Nagy, K. A. (1987) Field metabolic rate and food requirement: scaling in mammals and birds. *Ecol. Monogr.* 57:111-128

normally frequent in potato field, it is the EFSA opinion that the acute risk to herbivorous birds in potato is probably low.

5.2. RISK TO AQUATIC ORGANISMS

Studies to cover the toxicity of the formulated product were conducted with the formulation CYD15107 (acute study with fish, reproduction study with Daphnia, algae study). The applicant was asked to address the comparability to the lead formulation 'FORUM'. Data has been submitted but are not included in an addendum and thus not peer reviewed.

Based on the available acute toxicity data, dimethomorph is classified as toxic to aquatic organisms, with an EC_{50} of 3.4 mg/L for rainbow trout, *Oncorhynchus mykiss,* the most sensitive species tested. The formulation 'FORUM' had similar toxicity to *O. mykiss* as expected based on the content of dimethomorph, while it was more toxic to algae (E_bC_{50}=3.7 mg a.s./L for the formulation compared to 24.4 mg/L for dimethomorph). In long-term tests dimethomorph was more toxic to both *O. mykiss* and *Daphnia magna* than in acute tests. The long-term risk assessment was based on a NOEC of 0.056 mg dimethomorph/L from an early life stage test with *O. mykiss*. In this study only effects on growth were detected, while no critical singular development steps were affected. The study was discussed in the experts' meeting and it was agreed that the long-term risk assessment should be based on this end point and that it should be compared to the time weight average PEC_{sw} for the post-swim up period of 46 days.

The TER values were calculated using on PEC_{sw} from spray drift of 5 applications in hops and grapevine, and 8 applications in potato. Actual PECs, i.e. the highest concentrations occurring after application of the product according to the GAPs, were used for the acute assessment. The 60 day time weight average PEC used by the rapporteur Member State for the long-term assessment is very similar to the worst case 46 day time weight average PEC and does not change the buffer zone distances. The TER calculations based on 46 days time weight average PEC_{sw} are presented in addendum 6 of April 2006. For the use in potatoes the TER_{lt} is above the Annex VI trigger with 1 m distance to the treated field (TER_{lt} = 24.9), while for hops and grapevine risk mitigation measures comparable to buffer zones of 20 (TER_{lt}=18.3) and 5 m (TER_{lt}=11.7) respectively are needed to meet the trigger. The same risk mitigation measures also cover the acute risk.

Dimethomorph were detected in sediment at amounts up to 66% one day after application. The effect on sediment dwelling organisms was addressed with a study on *Chironimus riparius*. No effects were observed at the highest test concentration, 4.4 mg/L and it can be concluded that *Chironimus* will be protected by risk mitigation measures needed to protect fish.

The log P_{ow} for dimethomorph has been determined to be 2.7. Since this is <3 no bioaccumulation study is considered necessary. No metabolites were detected in amounts >10% of applied in the water/sediment studies.

5.3. RISK TO BEES

The oral and contact toxicity studies are available using both technical dimethomorph and the formulation 'FORUM' or formulations that the rapporteur Member State considered fully comparable to this formulation. HQ values calculated based on the derived endpoints from these studies are clearly below the Annex VI trigger indicating a low risk to bees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The risk assessment for non-target arthropods is based on extended laboratory studies with *Typhlodromus pyri* and *Aphidius rhopalosiphi* conducted with the formulations BAS 550 02 F as presented in addendum 1 of May 2005. Like 'FORUM' the formulation BAS 550 02 F is a DC formulation containing 150 g/L dimethomorph and was considered comparable from an ecotoxicological point of view by the rapporteur Member State. No effects >50% compared to the control were observed for mortality or reproduction for either species at a test concentration covering the worst case exposure in-field and off-field as calculated according to ESCORT II. In addendum 1, the rapporteur Member State used a vegetation distribution factor of 5. The ESCORT II document recommends a factor of 10 for the time being, and it was therefore agreed in the expert's meeting to use a vegetation distribution factor of 10. However, this does not change the outcome of the assessment. Results from available laboratory studies with *Trichogramma cacoeciae* and *Pardosa* spp. and three field studies with *T. pyri* in grapes confirm the low risk to non-target arthropods.

5.5. RISK TO EARTHWORMS

Acute toxicity studies with earthworms are available for dimethomorph and the formulated product 'FORUM'. TER values calculated with a worst case initial PEC_{soil} based on 5 applications of 600 g a.s./ha with no interception and no degradation between applications are >125 for dimethomorph and 25 for the formulation. Hence the acute risk to earthworms is considered as low. The DT_{90} for dimethomorph in soil is >90 days and since multiple applications are proposed a long-term/reproduction study is required. Such a study is available with dimethomorph and the TER calculated from the study is 33, which is above the Annex VI trigger and thus indicating a low risk. However, since the acute toxicity of the formulated product was greater than expected on basis of the content of dimethomorph, a long-term/reproduction study with the formulation was considered necessary by the rapporteur Member State. Such a study is summarised in addendum 6 of April 2006 but has not been peer reviewed. No significant effects on reproduction or body weight were observed in the study. The NOEC was determined to be 92.2 mg formulation/kg soil dry weight, corresponding to 12.8 mg a.s./kg soil. No correction of the NOEC for log P_{ow} was done by the rapporteur Member State who argued that a log P_{ow} cannot be derived for a formulation. It is the view of the EFSA that a correction normally should be done, and that the TER value should be calculated on the basis of the content of the active substance. The $NOEC_{corr}$ would then be 6.4 mg a.s/kg soil and the corresponding TER_{lt} for the formulation 3.6, which is below the Annex VI trigger. However, since no indication of effects were observed neither in the study with technical dimethomorph nor with the formulation, the EFSA considerers that the risk is probably low.

No major metabolites were detected in the aerobic soil degradation studies.

5.6. Risk to other soil non-target macro-organisms

A litter bag study using 3 applications of 1.2 kg a.s./ha (recommended application rate in hops: max. 5×600 g a.s./ha) with 6 and 10 days interval did not reveal any significant effect on the break down of leaf material. Thus the risk to other soil non-target organisms is regarded as low.

5.7. Risk to soil non-target micro-organisms

The formulation 'FORUM' had no effect >25% compared to the control on soil respiration and nitrogen transformation in a 28-day study at a concentration equivalent to an application rate of 6 kg a.s./ha, which is equal to two times the maximum dose. The risk to soil non-target micro-organisms is therefore considered to be low.

5.8. Risk to other non-target-organisms (flora and fauna)

Effects on non-target plants were tested by means of seedling emergence and vegetative vigour studies following soil surface or foliar application of the formulation 'FORUM' to seven species (*Avena sativa, Allium cepa, Lactuca sativa, Raphanus sativus, Glycine max, Beta vulgaris, Zea mays*). Application rates of 0.6 and 1.8 kg dimethomorph/ha was used. Significant increases were observed on emergence rate and mean plant dry weight for some species. The rapporteur Member State attributed these effects to fungicidal action on plant pathogens. From the data available it was concluded that the risk to non-target plants is low.

5.9. Risk to biological methods of sewage treatment

Data from a test with technical dimethomorph on inhibition of respiratory activity of micro-organisms in sewage sludge indicate that dimethomorph will pose a low risk to biological methods of sewage treatment at concentration predicted for surface water.

6. Residue definitions

Soil

Definitions for risk assessment: dimethomorph

Definitions for monitoring: dimethomorph

Water

Ground water

Definitions for exposure assessment: dimethomorph

Definitions for monitoring: dimethomorph

Surface water

Definitions for risk assessment: dimethomorph

Definitions for monitoring: dimethomorph

Air

Definitions for risk assessment: dimethomorph

Definitions for monitoring: dimethomorph

Food of plant origin

Definitions for risk assessment: dimethomorph

Definitions for monitoring: dimethomorph (valid for application by foliar spray only)

Food of animal origin

Definitions for risk assessment: dimethomorph (for poultry and milk, this is to be considered as a default residue definition)

Definitions for monitoring: dimethomorph (for poultry and milk, this is to be considered as a default residue definition)

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Dimethomorph	Moderate to medium persistence (first-order DT50lab = 41-96 days, at 22-25ºC and 75-82% FC or 20ºC and 33% MWHC)	See sections 5.5-5.7

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
Dimethomorph	Low to medium mobility $K_f$oc = 290-566 L/kg	No for all 9 FOCUS groundwater scenarios	Yes	Yes	Relevant

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dimethomorph	See section 5.2

Air

Compound (name and/or code)	Toxicology
Dimethomorph	The toxicity during acute exposure is low i.e. LC_{50} > 4.2 mg/L. No repeated studies available.

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

- Justification for the specification for the impurities Z 69, Z 86, Z87 and Z106 or a new specification (relevant for all uses evaluated; data requirement identified by the RMS in the DAR and confirmed by expert meeting, July 2005; data available and evaluated in addendum 7 but it has not been peer reviewed, refer to chapter 1).
- Confirmation of the identity of the impurities revealed by chemical analysis to address the requirement of the Directive on the specificity of the method(s) (relevant for all uses evaluated; data gap identified by the EFSA and confirmed by the evaluation meeting March 2005; date of submission unknown; refer to chapter 1).
- The applicant to provided data or a case to demonstrate if both of the isomers are biologically active (relevant for all uses evaluated; data gap identified by the meeting of experts in July 2005; date of submission unknown, refer to chapter 1).
- Applicant to provide detailed information on the composition of the formulation CYD 15107 (used in acute study with fish, reproduction study with Daphnia and algae study) and to assess the comparability to ‘Forum’ (relevant for all uses evaluated; date of submission unknown; refer to point 5.2).
- The acute and long-term risk to insectivorous birds needs to be further addressed (relevant for the use in hops; data gap identified in EPCO meeting; date of submission unknown; refer to point 5.1).
- The acute and long-term risk to small herbivorous mammals needs to be further addressed (relevant for the use in hops and vine; data gap identified in EPCO meeting; date of submission unknown; refer to point 5.1).
- The long-term risk to earthworms from the use of the formulation ‘FORUM’ needs to be further addressed (relevant for all uses evaluated; a study was submitted and an evaluation was included in addendum 6 of April 2006 but has not been peer reviewed; refer to point 5.5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as a fungicide as proposed by the applicant which comprises application via tractor mounted hydraulic sprayer to hops, grapes and potatoes. The total maximum dose to hops is 3 kg dimethomorph per hectare, 1.5 kg dimethomorph per hectare for grapes and for potatoes 1.44 kg/ha (number of applications: 8) in Northern Europe and 0.9 kg/ha (number of applications: 5) in Southern Europe.
The representative formulated product for the evaluation was "Forum", a dispersible concentrate formulation (DC).

Adequate methods are available to monitor for dimethomorph. Residues in food of plant origin products of animal origin and soil can be determined with a multi-method (The German S19 method

has been validated). For the other matrices only single methods are available to determine residues of dimethomorph.
Sufficient 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.

The toxicological studies are performed with batches where the ratio E/Z isomer is between 43/57 to 45/55. Dimethomorph is rapidly and nearly completely absorbed based on excretion data. More than 90% is eliminated via the bile within 24 hours. No accumulation seems to occur after repeated oral exposure. Dimethomorph is widely distributed and highest liver and it is extensively metabolized. It is of low acute toxicity i.e. oral LD_{50} 3900 mg/kg bw, dermal LD_{50} > 2000 mg/kg bw and inhalation LC_{50} > 4.24 mg/L. It is neither a skin or an eye irritant nor a skin sensitizer. The target organs are the liver, testes and prostate (dog only). The dog was the most sensitive species with a short term NOAEL of 4.9 mg/kg bw/day for the one year dog. Although the effects are not statistically significant it was agreed at the experts´ meeting that it was possible to set the NOAEL since the effects were supported by similar findings in the 90-day dog study (NOAEL 15 mg/kg bw/day). There is no mutagenic or genotoxic or carcinogenic potential of dimethomorph. The long term NOAEL is 9 mg/kg bw/day in the rat based on decreased body weight gain and cellular alterations in the liver (females). There was no effect on the reproductive performance. The NOAEL for offspring, as well as reproduction, was 67 mg/kg bw/day. There are developmental effects observed in the rat and rabbit in conjunction to only mild maternal toxicity. The NOAEL for maternal and developmental toxicity is 60 mg/kg bw/day. The acceptable daily intake (ADI) is 0.05 mg/kg bw/day based on the NOAEL of 5 mg/kg bw/day from the 1-year study in dogs and the acceptable operator exposure level (AOEL) is 0.15 mg/kg bw/day based on the NOAELs from the 90-day studies in the rat and dog, with a safety factor of 100 applied. The acute reference dose (ARfD) is based on the NOAEL 60 mg/kg bw/day from the rat developmental study rat where embryolethality as well as death of dams was observed at 160 mg/kg bw/day, with safety factor of 100. The dermal absorption value for the representative formulation Forum 15 DC is 20%.
The estimated exposure according to the German model is below the AOEL without any personal protective equipment (PPE) for potatoes (31%) but PPE is needed for hops and grapes in order to be below the AOEL. If PPE is not considered, the exposure is 128% and 282% of the AOEL for hops and wines, respectively. Estimated exposure for workers and bystanders are also below the AOEL.

The metabolism of dimethomorph in plants when applied as foliar spray is fully elucidated. It proceeds through hydrolysis of the 2 methoxy groups of the dimethoxyphenyl ring, hydrolysis and oxidation of the morpholine ring. None of the metabolites identified is expected to contribute significantly to the toxicological burden the consumer may be exposed to and therefore the residue definition in plant products for monitoring and risk assessment is proposed to be limited to the parent compound. Sufficient information from field studies is present in order to set MRLs and adequately assess the chronic and acute exposures of the consumer.

Processing does not affect the nature of the residue and processing factor can be established for wine and beer.

No residue of dimethomorph or its metabolites is expected to be present at measurable level in animal commodities as the potential livestock exposure resulting from the consumption of potatoes is very limited. The residue definition for animal commodities is proposed to be restricted to the parent compound. However this definition should be reconsidered for milk and poultry products for which dimethomorph cannot be considered as an appropriate indicator compound, if on the basis of additional uses, beyond the scope of this peer review, animal exposure would be higher.

In following crops the presence of low amounts of dimethomorph is possible in some rare occasions. This however does not represent a concern in terms of consumer safety.

Proposed MRLs are 2 mg/kg, 50 mg/kg and 0.05 mg/kg for wine and table grapes, dried hops and potatoes respectively. The supported representative use of dimethomorph on those crops does not represent a risk for the safety of the consumer, at short or long term.

The environmental exposure assessment available are sufficient to complete the necessary EU level estimates of predicted Environmental Concentrations (PEC) for the representative uses applied for, for Annex I listing. Member States need to carry out aquatic exposure and risk assessments from runoff route of exposure to surface water, as this route of entry has not been considered in the EU level assessment completed and peer reviewed. For the notified intended uses, the potential for groundwater exposure by dimethomorph above the parametric drinking water limit of 0.1 µg/L is low.

A high first tier acute risk was identified for insectivorous birds in hops, medium herbivorous birds in potatoes, and small herbivorous mammals in hops and vine. The long-term risk to insectivorous birds in hops and to small herbivorous mammals in hops and vine can not be concluded based on the available information and needs to be further addressed. Since potato leaves are considered unpalatable to birds, and weeds are not that frequent in potato field, it is the EFSA opinion that the acute risk to herbivorous birds in potato is probably low. However, further information is needed to conclude on the risk to insectivorous birds in hops and small herbivorous mammals in hops and vine where relevant decisions are to be based on the assessment according to SANCO/4145/2000.

The acute and long-term risk to aquatic organisms from the use in potato the is low, while for hops and grapevine risk mitigation measures comparable to buffer zones of 20 and 5 m respectively, are needed.

The risk to bees, other non-target arthropods, earthworms, other soil macro-organisms, soil micro-organisms, non-target plants and methods of sewage treatment is considered to be low.

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

- Appropriate PPE is needed in order to have an estimated operator exposure below the AOEL except for use on potatoes, German model (refer 2.12).
- Risk mitigation comparable to 20 m in hops and 5 m in grapevine are required to protect fish.
- (refer to point 5.2)

Critical areas of concern

- An acceptable peer reviewed technical specification is not available.
- The worker exposure for re-entry in hops, which represents the maximum application rate for application of dimethomorph, was not assessed.
- A first tier high acute and long-term risk was identified for insectivorous birds in hops.
- A first tier high acute and long-term risk to small herbivorous mammals in hops and vine was identified and needs to be further addressed.
- Dimethomorph is toxic to fish and aquatic invertebrates. Risk mitigation comparable to 20 m in hops and 5 m in grapevine are required to protect fish.

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

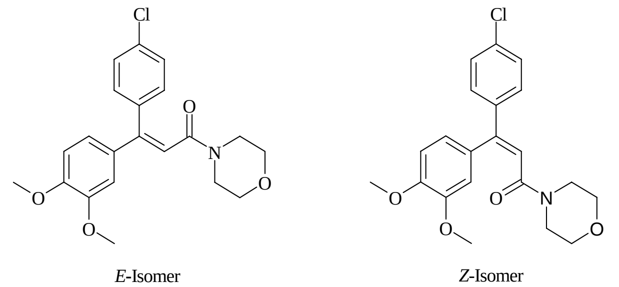
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Dimethomorph
Function (e.g. fungicide)	Fungicide

Rapporteur Member State	Germany
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(*E*,*Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine
Chemical name (CA) ‡	(*E*,*Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxy-phenyl)-1-oxo-2-propenyl]-morpholine
CIPAC No ‡	483
CAS No ‡	110488-70-5
EEC No (EINECS or ELINCS) ‡	404-200-2
FAO Specification ‡ (including year of publication)	–
Minimum purity of the active substance as manufactured ‡ (g/kg)	965 (*E*/*Z* isomer ratio 44/56)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula ‡	$C_{21}H_{22}ClNO_4$
Molecular mass ‡	387.9 g/mol
Structural formula ‡	

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

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	E/Z mixture: 125.2 – 149.2 °C (99.1 %, *E/Z* 48/52) *E* isomer: 136.8 - 138.3 °C (99.1 %) *Z* isomer: 166.3 - 168.5 °C (99.1 %)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition	*E* isomer: 280 °C (99.1 %) *Z* isomer: 280 °C (99.1 %)
Appearance (state purity) ‡	White crystalline solid (98.8%)
Relative density (state purity) ‡	1.3 (20 °C) (99.1%)
Surface tension	60.8 mN/m (20 °C, 90% saturated aqueous solution)
Vapour pressure (in Pa, state temperature) ‡	$9.7 \cdot 10^{-7}$ (*E*); $1 \cdot 10^{-6}$ (*Z*), 25 °C
Henry's law constant (Pa m^3 mol^{-1}) ‡	$5.4 \cdot 10^{-6}$ (*E*); $2.5 \cdot 10^{-5}$ (*Z*)
Solubility in water ‡ (g/L or mg/L, state temperature)	20 °C [g/L]. *E*-isomer: 0.0472 *Z*-isomer: 0.0107
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	Individual isomers *E*(*Z*) [g/L; 20 °C] CH_2Cl_2: 296 (165) Acetone: 84.1 (16.3) Ethyl acetate: 39.9 (8.4) Toluene: 39.0 (10.5) Methanol: 31.5 (7.5) *n*-Hexane: 0.076 (0.036) 1.2-Dichloroethane: 182.5 (92.5) Xylene: 22.2 (6.4) Heptane: 0.120 (0.053)
Partition co-efficient (log POW) ‡ (state pH and temperature)	2.63 (*E*) 2.73 (*Z*), 20 °C, Milli Q water
Hydrolytic stability (DT50) ‡ (state pH and temperature)	After 10 weeks at 70 °C and 90 °C less than 10 % degradation at pH 4, 7 and 9
Dissociation constant ‡	- 1.3 (calculation)

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

UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	λ_{max} [nm] — ε [L mol^{-1} cm^{-1}] 200 — $4.5 \cdot 10^4$ 205 — $3.0 \cdot 10^4$ 221 — $1.6 \cdot 10^4$ 242 — $2.0 \cdot 10^4$ 286 — $9.1 \cdot 10^3$ 312 — $4.5 \cdot 10^3$
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	DT_{50} 86 d and 107 d (22 °C, pH 5)
Quantum yield of direct phototransformation in water at λ > 290 nm ‡	$6.71 \cdot 10^{-6}$, pH 7, 20 °C
Flammability ‡	None
Explosive properties ‡	None

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

List 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 a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water L/ha min max	kg a.s./ha min max		
Grapevines	Northern and Southern Europe	Forum	F	*Plasmopara viticola*	DC	150 g/L	Tractor mounted spray	BBCH 53 – 79 May - end of August	5	10 days	30 - 75	400 – 1000	max 300	28	[1]
Hops	Northern Europe	Forum	F	*Pseudoperon-ospora humili*	DC	150 g/L	Tractor mounted spray	BBCH 39 – 69 end of May – 15th of August	5	8 days	15 - 30	2000 - 4000	max 600	10	[1]
Potatoes	Northern Europe Southern Europe	Forum	F	*Phytophthora infestans*	DC	150 g/L	Tractor mounted spray	BBCH 11-65 June – end of August March – end of April	8 5	7 days	18 - 45	100 – 400	max 180	7	Registered in co-formulation

[1] The risk assessment revealed a risk in section 5.

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

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(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)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(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 (principle of method)	HPLC-UV
Impurities in technical as (principle of method)	HPLC-UV GC-FID
Plant protection product (principle of method)	HPLC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Multi method DFG S19 (enforcement method) GC-PND 0.02mg/kg (grapes, potatoes, rapeseed) 0.2 mg/kg (hops, onions) Single methods (confirmatory methods) GC-PND 0.05 mg/kg (potato, grape) HPLC-UV 0.01 mg/kg (potato) LC-MS/MS 0.05 mg/kg (potato, grape)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Multi method DFG S19 GC-PND 0.01 mg/kg (muscle, fat, milk, eggs)
Soil (principle of method and LOQ)	Multi method DFG S19 GC-PND 0.01 mg/kg GC-MS 0.01 mg/kg LC-MS/MS 0.01 mg/kg
Water (principle of method and LOQ)	HPLC-UV 0.05 µg/L LC-MS/MS 0.05 µg/L Surface and drinking water
Air (principle of method and LOQ)	GC-PND 10 µg/m3
Body fluids and tissues (principle of method and LOQ)	No method submitted as dimethomorph is not classified as toxic or highly toxic

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	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 in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Rapid and almost complete (> 90 % based on biliary and renal excretion within 24 hours)
Distribution ‡	Initially widely distributed, highest residues in the liver
Potential for accumulation ‡	Low potential for accumulation ($T_{1/2:}$ 60 - 68 h)
Rate and extent of excretion ‡	Rapid 5.5/13 % via urine, 88/85 % via feces 48 hours after dosing (male/female)
Metabolism in animals ‡	Extensively metabolised by de methylation of the dimethoxyphenyl ring and to a smaller extend by oxidation of the morpholine ring
Toxicologically significant compounds ‡ (animals, plants and environment)	Dimethomorph

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	3900 mg/kg bw (racemate) > 5000 mg/kg bw (Z-isomer) 4472 mg/kg bw (E-isomer)
Rat LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC_{50} inhalation ‡	> 4.24 mg/L (4 hr, whole-body, dust)
Skin irritation ‡	Non-irritant
Eye irritation ‡	Non-irritant
Skin sensitization ‡ (test method used and result)	Not sensitising (Maximisation Test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver; testes and prostate (dog only)
Lowest relevant oral NOAEL / NOEL ‡	1yr dog: (5 mg/kg bw/d) 90d dog: (15 mg/kg bw/d) 90d rat: (16 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL ‡	No data - not required
Lowest relevant inhalation NOAEL / NOEL ‡	No data - not required

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

Genotoxicity ‡ (Annex IIA, point 5.4)

……………………………………………..	No genotoxic potential

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

Target/critical effect ‡	Liver, testes, decreased body weight
Lowest relevant NOAEL / NOEL ‡	2yr rat: (9 mg/kg bw/d)
Carcinogenicity ‡	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No reproductive toxicity at parental toxic dose level
Lowest relevant reproductive NOAEL / NOEL‡	(Reproductive: 67 mg/kg bw/day Parental and offspring: 20 mg/kg bw/day
Developmental target / critical effect ‡	Slightly increased early resorption rate at very slight maternal toxic doses in rat and rabbit.
Lowest relevant developmental NOAEL / NOEL ‡	Developmental and maternal: 60 mg/kg bw/day (rat) 300 mg/kg bw/day (rabbit)

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

……………………………………………..	No specific studies. No evidence for a neurotoxic potential was found in other studies

Other toxicological studies ‡ (Annex IIA, point 5.8)

Impurities	Ames mutagenicity tests with: Impurity Z 86: Negative Impurity Z 87: Negative Impurity Z 106: Negative

Medical data ‡ (Annex IIA, point 5.9)

……………………………………………..	No effects on health in manufacturing, no cases of poisoning are known.

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

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.05 mg/kg bw/day	1 yr dog study	100
AOEL systemic ‡	0.15 mg/kg bw/day	90d dog & rat	100
ARfD ‡ (acute reference dose)	0.6 mg/kg bw	Developmental toxicity study in rats	100

Dermal absorption (Annex IIIA, point 7.3)

Forum 15 DC	20 % (in vivo rat, 168 hours), worst case

Acceptable exposure scenarios (including method of calculation)

Operator

Estimated exposure (% of the AOEL) according to the **German model:**

Hops (0.6 kg a.s./ha, 8 ha/day):

	No PPE	With PPE (m/l + A)
Tractor mounted	128%	16%

Vines (0.6 kg/ha, 1 ha/day)

Handheld	282%	11%

Potatoes (0.18 kg/ha, 20 ha/day)

Tractor	31%	1%

according to **UK POEM:**

Hops (0.6 kg a.s./ha, 30* ha/day):

	No PPE	With PPE (m/l + A)
Tractor mounted	162%	62%

Vines (0.3 kg/ha, 30 ha/day)

Tractor	244%	147%

Potatoes (0.18 kg/ha, 50 ha/day)

Tractor	207%	29%

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

	*the standard rate for high crops in the UK POEM is 15 ha
Workers	Estimated exposure in vines and potatoes (% of the AOEL) according to calculation based on Hoernicke et al.: 0.3 kg a.s./ha; TF, worst case = 30000 cm^2/h x person: Exposure - no PPE = 137.1 % and exposure – with PPE = 6.9 % of the systemic AOEL) The estimated exposure in hops was not calculated
Bystanders	Estimated exposure (% of the AOEL). - hops (0.6 kg a.s./ha): exposure = 22 % of AOEL, syst., - potatoes (0.18 kg a.s./ha): exposure = 0.34 % of AOEL, syst.

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	None

‡ 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	Fruit (grapes, tomato); tuber (potato); leafy (lettuce)
Rotational crops	Lettuce, soybean, radish and wheat
Plant residue definition for monitoring	Dimethomorph
Plant residue definition for risk assessment	Dimethomorph (valid for application by foliar spray only)
Conversion factor (monitoring to risk assessment)	-

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

Animals covered	Lactating goat, laying hen
Animal residue definition for monitoring	Dimethomorph (for poultry and milk this is to be considered as a default residue definition)
Animal residue definition for risk assessment	Dimethomorph (for poultry and milk this is to be considered as a default residue definition)
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No (log $P_{o/w}$ 2.7)

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

……………………………………………..	Rotational crop studies with radioactive material as well as field trial with unlabeled parent compound show that residues of dimethomorph above 0.05 mg/kg in crops grown in rotation are highly unlikely. Crops grown in rotation: beans, carrots, lettuce, radish, soybean, spinach and wheat

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

……………………………………………..	Stable

‡ 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)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies		
	Residue levels in matrices : Mean (max) mg/kg		
Muscle	Although not required a feeding study in lactating cow performed with an overdosing factor of 25 is available demonstrating that no residues of dimethomorph and its metabolites Z67/Z69 and CUR 7117 were found below the LOQ (0.02 mg/kg) in all matrices	Not required	Not required
Liver		Not required	Not required
Kidney		Not required	Not required
Fat		Not required	Not required
Milk			
Eggs		Not required	

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

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (mg dimethomorph/kg) (a)	Recommendation/comments	MRL	STMR (b)
Grapes	Northern Europe	0.23, 0.25, 0.38, 0.38, 0.42, 0.5, 0.50, 0.51, 0.55, 0.62, 0.76, 0.95, 1.00, 1.0, 1.08, 1.10, 1.3, 1.65, 1.70		2 mg/kg	0.62 mg/kg
	Southern Europe	0.21, 0.24, 0.36, 0.36, 0.38, 0.42, 0.63, 2.28			0.37 mg/kg
Hops (dried cones)	Northern Europe	8.3, 8.7, 9.3, 21, 24, 26, 26, 28, 29, 42		50 mg/kg	25 ~~24~~ mg/kg
Potatoes	Northern and Southern Europe	altogether 58 trials with application rates up to 0.5 kg a.s./ha: no results above 0.05 mg/kg		0.05 mg/kg	0.05 mg/kg

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

‡ 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	0.05 mg/kg bw/day
TMDI (European Diet) (% ADI)	German model: 4 to 6 years old girl: 5 % + adult women (36 to 50 years old) 14.7 % WHO (European diet): 16 %
NEDI (% ADI)	Calculation not necessary
Factors included in NEDI	-
ARfD	0.6 mg/kg bw/day
Acute exposure (% ARfD)	According consumption data from UK: NESTI (grapes): 4 % for adults NESTI (potatoes): <1 % of ARfD for adults NESTI (beer): 1.5 % of ARfD for adults
Factors included in NESTI calculation	Variability factor of 5 and 7 for grapes and potatoes respectively; MRL proposed for potatoes and hops; HR for grapes.

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Grapes/wine	4 (2 red wine and 2 white wine) balance studies and 24 follow up studies (17 red wine and 7 white wine)	Red wine: 0.36, 0.67, 0.14, 0.17, 0.22, 0.24, 0.24, 0.25, 0.29, 0.30, 0.31, 0.31, 0.32, 0.34, 0.36, 0.47, 0.56, 0.58, 0.70 Mean : 0.36 White wine: 0.49, 0.60, 0.06, 0.11, 0.14, 0.15, 0.30, 0.34, 0.49 Mean : 0.30	16 – 50
Grapes/pomace	4 (2 red wine and 2 white wine) balance studies	Red wine: 2.9, 3.0 White wine: 1.2, 2.3	40 – 60
Hops (dried)/beer	1 balance and 3 follow up studies	<0.001, 0.001, 0.003, 0.004	Beer: 69 Brewers' yeast: 44 Spent hops: 12

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

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

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

Grapes	2 mg/kg
Hops	50 mg/kg
Potatoes	0.05 mg/kg

‡ 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 ‡	Chlorophenyl-label: 5.4 - 22.6 % at ≈120 days (3 soils) 17 % after 365 days Morpholine-label: 9.3 - 30.9 % at ≈120 days (2 soils) 28 % after 365 days
Non-extractable residues after 100 days ‡	Chlorophenyl-label: 18 - 51.6 % at ≈120 days (3 soils) 57 % after 365 days Morpholine-label: 35.5 - 47 % at ≈120 days (2 soils) 43 % after 365 days
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	None

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

Anaerobic degradation ‡	Chlorophenyl-label: Mineralisation: 0.3-5.5% AR after 60d (n=2) Non-extractable residues: 55.3-72.5% AR after 60d (n=2) Main metabolites were a mixture of mono-desmethyl dimethomorph. Morpholine-label: Mineralisation: 1.0-3.8% AR after 60d (n=2) Non-extractable residues: 58.8-69.5% AR after 60d (n=2) Main metabolites were a mixture of mono-desmethyl dimethomorph.
Soil photolysis ‡	Mineralisation 1.2% AR after 15 d (irradiated samples) Non extractable residues 6.4% AR after 15 d Two minor (3.6 and 3.9 % AR) metabolites. Mineralisation 0% AR after 15 d (dark samples) Metabolites: not identified

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

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

Method of calculation	First-order kinetics
Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50} (aerobic): 41 - 96 d, DT_{90}(aerobic): 137 - 319 d at 20 - 25 °C (4 soils, r^2: 0.92 - 0.99) E-isomer: DT_{50} (aerobic) = 38 - 47 days at 20 - 25 °C (2 soils) Z-isomer: DT_{50} (aerobic) = 58 - 162 days at 20 - 25 °C (2 soils) For FOCUS groundwater modelling: DT_{50lab} = 56.7 days (mean value, normalised to 20°C and pF 2).
	DT_{50lab} (study at 10ºC, aerobic): 74 days (n=1, r^2 = 0.93)
	DT_{50lab} (anaerobic) at 25ºC: chlorophenyl-label: 26.2 days (mixture of isomers, 1 soil), 28 days (E-isomer, 1 soil), 25 days (Z isomer, 1 soil). morpholine-label: 25.7 days (mixture of isomers, 1 soil), 27 days (E-isomer, 1 soil), 26 days (Z isomer, 1 soil).
	DT_{50lab} (22ºC, photolysis) = 75 days (estimated value for continuous irradiation, assuming zero-order kinetics).
	Degradation in the saturated zone: no data submitted and not required.
Field studies ‡ (state location, range or median with n value)	DT_{50} = 34 - 53.4 days, DT_{90}: 112 - 176 days (5 sites in DE) r^2 = 0.89 - 0.99 E-isomer: DT_{50} = 17 - 38 days (4 sites, r^2 = 0.974 - 1.0) Z-isomer: DT_{50} = 34 - 78 days (4 sites, r^2 = 0.93 - 0.98) DT_{50}: 10 - 61 days, DT_{90}: 33 - 203 days (3 trials in UK, F, ES, r^2 = 0.83 - 1.0)
Soil accumulation and plateau concentration ‡	Not available

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f / K_{foc} ‡	K_f : 2.09 - 11.67 L/kg (BAS 550 F, 7 soils) 4.30 - 21.1 L/kg (E-isomer, 4 soils) 3.92 - 17.9 L/kg (Z-isomer, 4 soils) K_{fOC}: 290 - 566 L/kg (BAS 550 F, 7 soils, mean: 407.7 L/kg) 346 - 574 L/kg (E-isomer, 4 soils) 344 - 540 L/kg (Z-isomer, 4 soils)
1/n ‡	1/n: 0.81 - 0.92 (BAS 550 F, 7 soils, mean: 0.86) 0.79 - 0.87 (E-isomer, 4 soils) 0.85 - 0.92 (Z-isomer, 4 soils)
pH dependence ‡ (yes / no) (if yes type of dependence)	No

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

Column leaching ‡	4 soils (OC 0.70-2.56%, pH in $CaCl_2$ 4.9-7.7), 200 mm rainfall over 2 days < 0.67 % of applied dose (1.8 kg/ha) was detected in leachate
Aged residues leaching ‡	Chlorophenyl-label: 3.4 % of applied dose was detected in leachate (sand soil after 60-day aging and equivalent of 20 cm rainfall. At least 7 metabolite products, each ≤ 0.5 % of applied dose. Morpholine-label: < 0.8 % of applied dose detected in leachate (silty clay loam after a 90-day aging and equivalent of 51 cm rainfall).
Lysimeter/ field leaching studies ‡	Not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	First-order kinetics with multiple application 5 cm soil horizon DT_{50} 90.2 d (worst-case from laboratory study, corrected for temperature and moisture)
Application rate	600 g a.s./ha on hops, corresponding to a soil load of 300 g a.s./ha after 50 % interception

‡ 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	Multiple application Actual	Multiple application Time weighted average
Initial	0.400	0.400	1.775	1.775
Short term 24h	0.397	0.398	1.762	1.769
2d	0.394	0.397	1.748	1.762
4d	0.388	0.394	1.722	1.748
Long term 7d	0.379	0.389	1.682	1.728
28d	0.323	0.360	1.432	1.683
50d	0.272	0.332	1.209	1.597
100d	0.185	0.279	0.823	1.474

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	Stable within pH range 4 to 9
Photolytic degradation of active substance and relevant metabolites ‡	Chlorophenyl-label: pH 5, 25 °C (continuous irradiation, mid summer day, 40° N latitude): DT_{50}: 28 days (zero-order kinetics) Chlorophenyl-label: pH 5, 22 °C (continuous irradiation, spring mid-day, 40° N latitude): DT_{50}: 107 days Morpholine-label: pH 5, 22 °C (continuous irradiation spring mid-day, 40° N latitude): DT_{50}: 86 days Multiple minor metabolite fractions < 6.6 % of applied radioactivity Quantum yield: 6.71 x 10^{-6} (20°C)
Readily biodegradable (yes/no)	No

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

Degradation in water/sediment	Two studies: ① (chlorophenyl label only) and ② (chlorophenyl and morpholine labels)
- DT_{50} water - DT_{90} water - DT_{50} total system - DT_{90} total system	② 5 - 15 days (2 systems) ② 16 - 51 days (2 systems) ② 16 - 59 days (2 systems), ① 2 - 3 days (2 systems) ② 52 - 195 days (2 systems), ① 7 - 10 days (2 systems)
Mineralization	Chlorophenyl-label: ① 14 - 22 % AR after 105 days (2 systems) ② 3.2 - 4.5 % AR after 100 days (2 systems) Morpholine-label: ② 1.0 - 8.6 % AR after 100 days (2 systems)
Non-extractable residues	Chlorophenyl-label: ① 57 - 69 % AR after 105 days (2 systems) ② 47 - 75 % AR after 100 days (2 systems) Morpholine-label: ② 62 - 68 % AR after 100 days (2 systems)
Distribution in water / sediment systems (active substance) ‡	Chlorophenyl-label: ① 24 - 37 % AR in water at day 0, not detected after 14 days. 53 - 68 % AR in sediment at day 0, not detected after 29 days (2 systems) ② 75 - 98 % AR in water at day 0, 2 - 9 % AR after 100 days. 9 - 12 % AR in sediment after 6 hours, max 42 - 48 % AR at 7 - 14 days, 8 - 30 % AR after 100 days (2 systems) Morpholine-label: ② 74 – 97 % AR in water at day 0, 1 - 5% AR after 100 days. 10 –1 3 % AR in sediment after 6 hours, max 47 – 51 % AR at 7 days, 10-17 % AR after 100 days (2 systems)
Distribution in water / sediment systems (metabolites) ‡	Chlorophenyl-label: ① Des-methyl metabolites in sediment, max 7.8 % AR at day 1, not detected after 29 days (1 system). Unknown polar fraction (several components) in sediment, max 14 - 16 % AR after 105 days (2 systems). ② Multiple minor metabolites, combined max of 3 – 5 % AR in water, 3 – 4 % AR in sediment. Morpholine-label: ② Multiple minor metabolites, combined max of 4 - 7% AR in water, 3 – 6 % AR in sediment.

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

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

Parent

Method of calculation	First-order kinetics in water phase from water-sediment studies with multiple applications and overall 90th percentile drift values DT_{50} water 15 d (worst-case from water/sediment-study)
Application rate	hops: 5 × 600 g a.s./ha grapevines: 5 × 300 g a.s./ha potatoes (NE): 8 × 180 g a.s./ha
Main routes of entry	Drift, calculated for various distances to static water body (late growth stage for vines)

PEC_{sw} based on spray drift for multiple application in hops, grapevines and potatoes

PEC_{sw} (µg/L)	hops 5 × 600 g a.s./ha, 8 d interval (72th perc.)		grapevines 5 × 300 g a.s./ha, 10 d interval (72th perc.)		potatoes (NE) 8 × 180 g a.s./ha, 7 d interval (67th perc.)	
	0 m	3 m	0 m	3 m	0 m	1 m
initial[a)]	200.000	30.240	100.000	6.590	60.000	0.912
actual [b)]	545.237	82.440	243.430	16.042	200.780	3.052
twa short term[b)]						
24 h	532.831	80.564	237.891	15.677	196.212	2.982
2 d	520.800	78.745	232.520	15.323	191.781	2.915
4 d	497.813	75.269	222.257	14.647	183.316	2.786
twa long term[b)]						
7 d	465.840	70.435	207.982	13.706	171.543	2.607
14 d	401.469	60.702	179.242	11.812	147.838	2.247
21 d	348.958	52.762	155.798	10.267	128.502	1.953
28 d	305.848	46.244	136.551	8.999	112.627	1.712
42 d	240.594	36.378	107.417	7.079	88.597	1.347
50 d	212.571	32.141	94.906	6.254	78.278	1.190
100 d	116.830	17.665	52.161	3.437	43.022	0.654

a) after first application, 90th drift percentile for single application
b) after last application

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

$PEC_{sw,act}$ and $PEC_{sw,twa}$ (46 d) as relevant for the aquatic risk assessment (multiple application)

distance [m]	hops 5 × 600 g a.s./ha, 8 d interval time window day 8 - 54 (72th perc.)		grapevines 5 × 300 g a.s./ha, 10 d interval time window day 10 - 56 (72th perc.)		potatoes (NE) 8 × 180 g a.s./ha, 7 d interval time window day 14 - 60 (67th perc.)	
	PEC_{act} [µg/L]	PEC_{twa} [µg/L]	PEC_{act} [µg/L]	PEC_{twa} [µg/L]	PEC_{act} [µg/L]	PEC_{twa} [µg/L]
0	545.24	348.56	243.43	163.14	200.78	147.75
1	-/-	-/-	-/-	-/-	3.05	2.25
3	82.44	52.70	16.04	10.75	-/-	-/-
5	43.56	27.85	7.13	4.78	-/-	-/-
10	18.32	11.71	-/-	-/-	-/-	-/-
15	11.07	7.08	-/-	-/-	-/-	-/-
20	4.80	3.07	-/-	-/-	-/-	-/-

PEC (sediment)

Parent

Method of calculation	Non-linear first-order kinetic multicompartment model (ModelMaker) as used for assessment of the water/sediment-study, amended by external "event generator" for drift intakes (overall 90th percentile). fastest transfer water → sediment, slowest transfer sediment → sink highest $PEC_{sed,ini}$ after last individual application calculation of maximum $PEC_{sed,twa}$ using moving time-window consideration of buffer zones according to the results of aquatic risk assessment[1]
Application rate	Hops: 5 × 600 g a.s./ha, 20 m buffer zone grapevines: 5 × 300 g a.s./ha, 5 m buffer zone potatoes (NE): 8 × 180 g a.s./ha, 1 m buffer zone
Main routes of entry and type of water body	Drift to static water body

1) It should be noted that for the minimum distance of 3 m, the PEC_{sed} values reported in the table should be multiplied by a factor of 2.3 for hops and a factor of 2.2 for grapevines.

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

PEC_{sed} based on spray drift for multiple applications in hops, grapevines and potatoes

PEC_{sed} (mg/kg wet sed)	hops 5 × 600 g a.s./ha, 20 m (72th perc.)		grapevines 5 × 300 g a.s./ha, 5 m (72th perc.)		potatoes (NE) 8 × 180 g a.s./ha, 1 m (67th perc.)	
	PEC_{ini}	$PEC_{twa,max}$	PEC_{ini}	$PEC_{twa,max}$	PEC_{ini}	$PEC_{twa,max}$
0 d	0.065	0.065	0.102	0.102	0.015	0.015
twa short term						
24 d	0.065	0.065	0.102	0.102	0.015	0.015
2 d	0.065	0.065	0.101	0.101	0.015	0.015
4 d	0.064	0.065	0.099	0.101	0.015	0.015
twa long term						
7 d	0.061	0.065	0.095	0.100	0.014	0.015
14 d	0.054	0.063	0.084	0.098	0.012	0.014
21 d	0.047	0.061	0.072	0.095	0.011	0.014
28 d	0.040	0.059	0.063	0.092	0.009	0.013
42 d	0.030	0.055	0.047	0.086	0.007	0.012
50 d	0.025	0.052	0.039	0.083	0.006	0.011
100 d	0.009	0.039	0.014	0.064	0.002	0.008

Compilation of $PEC_{sed,ini}$ values for different buffer zones (multiple application)

distance [m]	hops	grapevines	potatoes (NE)
	$PEC_{sed,ini}$ [mg/kg wet sed]	$PEC_{sed,ini}$ [mg/kg wet sed]	$PEC_{sed,ini}$ [mg/kg wet sed]
0	7.421	3.466	3.152
1	-/-	-/-	0.048
3	-/-	-/-	-/-
5	-/-	0.102	-/-
10	-/-	0.034	-/-
15	0.151	-/-	-/-
20	0.065	-/-	-/-

‡ 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 (*e.g.* modelling, monitoring, lysimeter)	Modelling with FOCUS_PELMO v2.2.2 K_{oc} = 430 L/kg (laboratory, mean) 1/n = 0.86 (laboratory, mean) DT_{50} = 56.7 d (mean from laboratory studies, separately corrected for temperature and moisture)
Application rate	Hops (using vine scenario): 5 × 600 g a.s./ha, 50 % interception, 8-d interval vines: 5 × 300 g a.s./ha, 70 % interception, 10-d interval potatoes: 8 × 180 g a.s./ha, 15 % interception (NE), 7-d interval 5 × 180 g a.s./ha, 15 % interception (SE), 7-d interval

PEC$_{(gw)}$

Maximum concentration	Not available and not required
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Not available
80th percentile concentration	≤ 0.001 µg/L (all locations)

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

Direct photolysis in air ‡	Not required
Quantum yield of direct phototransformation	Not required
Photochemical oxidative degradation in air ‡	3.6 h (Atkinson model, AOP v1.90, 24-h day, OH concentration 5 × 10^{-5}/cm^3).
Volatilization ‡	Not volatile, no volatilisation from soil and plant surfaces within 24 hours

PEC (air)

Method of calculation	Not required due to rapid degradation in air

PEC$_{(a)}$

Maximum concentration	Not required due to rapid degradation in air

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

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: dimethomorph Groundwater: dimethomorph Surface water: dimethomorph Sediment: dimethomorph Air: dimethomorph

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

Soil (indicate location and type of study)	None
Surface water (indicate location and type of study)	None
Ground water (indicate location and type of study)	None
Air (indicate location and type of study)	None

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	R53 May cause long-term adverse effects in the aquatic environment

‡ 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)

Acute toxicity to mammals ‡	LD_{50} 3900 mg/kg bw FORUM 150 DC CF 07460: 900 mg/kg bw (135 mg a.s./kg bw)
Long term toxicity to mammals ‡	Overall NOEL rat multi-gen study: 300 ppm (20 mg/kg bw/d)
Acute toxicity to birds ‡	Dimethomorph: LD_{50} > 2000 mg/kg (bobwhite quail and mallard) FORUM 150 DC; CF 07460: LD_{50} 1243 mg formulation/kg bw (bobwhite quail; 186 mg a.s./kg bw)
Dietary toxicity to birds ‡	Bobwhite quail: LC_{50} > 5200 ppm (LD_{50} > 728.3 mg/kg bw/d) mallard: LC_{50} > 5200 ppm (LD_{50} > 937.5 mg/kg bw/d)
Reproductive toxicity to birds ‡	Bobwhite quail: NOEL 800 ppm (58.4 mg/kg bw/d) mallard: NOEL 800 ppm (78.4 mg/kg bw/d)

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

Residue estimates:
Vegetation potato fields: Estimate according to Hoerger and Kenaga, category ”leafy crops”
Ground vegetation grapevine and hops: Estimate according to Hoerger and Kenaga, category ”short grass”, 50 % interception (grapevine) respectively 75 % (hops)
Insects: Estimate according to Fischer and Bowers (21 mg/kg for 1 kg/ha)
Indicator species and daily food intake:
Medium-sized herbivorous mammal (e.g. hare), 3000 g bw, 850 g food demand
Small insectivorous mammal (e.g. shrew), 10 g bw, 10 g food demand
Small insectivorous birds, 10 g bw, 9.4 g food demand

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.18	Potatoes	Insectivorous mammal	acute	1315	10
			long term	78	5
		Herbivorous mammal	acute	2430	10
			long term	53	5

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

Application rate (kg a.s./ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.18	Potatoes	Insectivorous bird	acute	> 555	10
			short term	> 1368	10
			long term	210	5
0.3	Grapevine	Insectivorous mammal	acute	619	10
			long term	47	5
		Herbivorous mammal	acute	829	10
			long term	17	5
		Insectivorous bird	acute	> 338	10
			short term	> 825	10
			long term	126	5
0.6	Hops	Insectivorous mammal	acute	109	10
			long term	23	5
		Herbivorous mammal	acute	829	10
			long term	17	5
		Insectivorous bird	acute	> 169	10
			short term	> 412	10
			long term	63	5

Risk assessment according to SANCO/4145/2000-final

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
8 x 0.18 7 d interval	Potatoes (N EU)	Medium herbivorous mammal	acute	418	10
			long-term	7.3	5
		Medium herbivorous bird	acute	> 79	10
			short-term	> 52	10
			long-term	≥ 7.9	5
		Insectivorous bird	acute	> 205	10
			short-term	> 134	10
			long-term	≥ 10.8	5

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

Application rate (kg a.s./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
5 x 0.3 10 d interval	Grapevine	Small herbivorous mammal	acute	69	10
			long-term	1.0	5
		Insectivorous bird	acute	> 123	10
			short-term	> 80	10
			long-term	≥ 6.5	5
5 x 0.6 8 d interval	Hops	Small herbivorous mammal	acute	31	10
			long-term	0.4	5
		Insectivorous bird	acute	> 61	10
			short-term	> 40	10
			long-term	3.2	5

Application rate (kg formul./ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
8 x 1.2 7 d interval	Potatoes (N EU)	Medium herbivorous mammal	acute	14.5	10
		Medium herbivorous bird	acute	**7.3**	10
		Insectivorous bird	acute	19.1	10
5 x 2.0 10 d interval	Grapevine	Small herbivorous mammal	acute	**2.4**	10
		Insectivorous bird	acute	11.5	10
5 x 4.0 8 d interval	Hops	Small herbivorous mammal	acute	**1.1**	10
		Insectivorous bird	acute	**5.7**	10

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/L)
Laboratory tests ‡				
Oncorhynchus mykiss	dimethomorph	Static – 96 h	LC_{50}	3.4 meas.
Oncorhynchus mykiss	dimethomorph	Flow-through – 60 d ELS	NOEC	0.056 nom.

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Oncorhynchus mykiss	Forum (CYD 15107)	Static – 96 h	LC_{50}	2.64 nom.
Oncorhynchus mykiss	Forum (CYD 15107)	Flow-through – 28 d	NOEC	0.07 meas.
Daphnia magna	dimethomorph	Static – 48 h	EC_{50}	> 10.6 meas.
Mysidopsis bahia	dimethomorph	Flow-through – 96 h	EC_{50}	7.9 meas.
Crassostrea virginica	dimethomorph	Flow-through – 96 h	EC_{50}	4.4 meas.

Microcosm or mesocosm tests
No study submitted.

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

Application rate (kg a.s./ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
dimethomorph						
5 × 600	Hops	Fish	Acute	10	186	100
			Chronic	20	18	10
5 × 300	Grapevines		Acute	3	212	100
			Chronic	5	12	10
8 × 180	Potatoes (NE)		Acute	1	1114	100
			Chronic	1	25	10
Forum						
5 × 600	Hops	Fish	Acute	10	144	100
5 × 300	Grapevines		Acute	3	165	100
8 × 180	Potatoes (NE)		Acute	1	865	100

Bioconcentration

Bioconcentration factor (BCF) ‡	Study not required, because log Po/w < 3
Annex VI Trigger:for the bioconcentration factor	-

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

Clearance time (CT_{50}) (CT_{90})	- -
Level of residues (%) in organisms after the 14 day depuration phase	-

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

Acute oral toxicity ‡	LD_{50} > 32,4 µg/bee (active substance) (9.4.1.1) LD_{50} > 100 µg/bee (active substance) (9.4.1.2a) LD_{50} > 74,4 µg/bee (formulation) (9.4.1.2c)
Acute contact toxicity ‡	LD_{50} > 102 µg/bee (active substance) (9.4.1.1) LD_{50} > 100 µg/bee (formulation) (9.4.1.2a) LD_{50} > 100 µg/bee (formulation) (9.4.1.2c)

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

Application rate (kg a.s./ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
9.4.1.1.		oral (48 h)	18.5	50
		cont (48 h)	5.9	50
9.4.1.2 a		cont (96 h)	6.0	50
Laboratory tests (formulation: Forum®)				
9.4.1.2 a		oral (96 h)	6.0	50
		cont (96 h)	6.0	50
9.4.1.2 b		cont (48 h)	1.6 (1. Run)	50
		cont (48 h)	2.2 (2. Run)	50
9.4.1.2 c		oral (48 h)	8.1	50
		cont (48 h)	6.0	50
9.4.1.2 d		oral	4.4	50
9.4.1.2 e		oral	4.0	50
9.4.1.2 f		oral	4.4	50

Field or semi-field tests
Not required

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

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

Species	Stage	Test Substance	Dose (kg a.s./ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests ‡						
Phytoseiulus persimilis	Protonymphs	CYA 15107	115	Mortality Fertility	0 0	30
Trichogramma cacoeciae	Imagines	CYA 15107	115	Mortality Parasitation capacity	0 8	30
Trichogramma cacoeciae	Imagines	SF 07460	360	Mortality Parasitation cap.	0 +14	30
Trichogramma cacoeciae	Imagines	SF 07460	3 x 360	Mortality Parasitation cap.	0 +4	30
Trichogramma cacoeciae	Imagines	SF 07460	6 x 360	Mortality Parasitation cap.	0 6	30
Pardosa spp.	Adult	CYA 15107	300	Mortality Food uptake	0 0	30
Pardosa spp.	Adult	CYA 15107	600	Mortality Food uptake	0 0	30
Pardosa spp.	Adult	SF 07460	6 x 72	Mortality Food uptake	3 0	30
Pardosa spp.	Adult	SF 07460	6 x 300	Mortality Food uptake	15 5	30
Extended laboratory tests						
Typhlodromus pyri	Protonymphs	CYA 15107	115	Mortality	23	50
Typhlodromus pyri	Protonymphs	BAS 550 02 F	150 – 1800	Mortality Reproduction	LR_{50} > 1800 ER_{50} > 1800	--- ---
Aphidius rhopalosiphi	Adult	BAS 550 02 F	150 – 1800	Mortality Reproduction	LR_{50} > 1800 ER_{50} > 1800	--- ---

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

Field or semi-field tests							
Test material	Species	Test	No. of appl.	Dosage L/ha		Final bonitur 1st / 2nd Effects (%) in comparison to	
				per appl.	total	untreated control	water treated control
Predatory mites							
CYA 15107	*T. pyri*	Field	6	0.46 – 1.96	7.7	25.6 / 14.9	-
CYA 15107	*T. pyri*	Field	6	0.94 - 2.37	10.9	14.8 / 2.3	-
CYA 15107	*T. pyri*	Field	6	0.72 - 1.92	8.6	26.7 / 47.0	9.8 / 7.0

Risk assessment according to Escort 2 (presentation based on template from EPCO Manual E4, rev3)

Crop and application rate

Test substance	Species	Effect (LR50 g/ha)	HQ in-field	HQ off-field[1]	Trigger
-/-*	*Typhlodromus pyri*	-/-*	-/-*	-/-*	2
-/-*	*Aphidius rhopalosiphi*	-/-*	-/-*	-/-*	2

[1] indicate distance assumed to calculate the drift rate
* no test data available

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% adverse effect[3]	Trigger value
Typhlodromus pyri	Proto-nymphs	BAS 550 02 F, initial residues	g a.s./ha 150 300 600 1200 1800 150 300 600 1200 1800	Mortality Reproduction	 -7* -7* -10* 6* 4* 11* 10* -2* 29* 35*	50%

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

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% adverse effect[3]	Trigger value
Aphidius rhopalosiphi	Adult	BAS 550 02 F, initial residues	g a.s./ha 150 300 600 1200 1800 150 300 600 1200 1800	Mortality Reproduction	 3 0 17 3 23 0 0 19 48 39	50%

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate when the effect is not adverse
[*] no statistically significant differences compared to the control (Fishers exact test for mortality, ANOVA for reproduction, $\alpha = 0.05$)

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	Dimethomorph: $LC_{50corr.}$: > 500 mg as /kg[*] BAS-15107-F-0-DC (Forum): LC_{50}: 1326 mg/kg, corresponding to 99.5 mg a.s./kg[*]
Reproductive toxicity ‡	Dimethomorph: NOEC: 60 mg a.s./kg* BAS 550 09 F (Forum): NOEC: 92.20 mg /kg (corresponding to 6.4 mg a.s./kg*)

* including a correction factor of 0.5 due to log P_{ow} > 2

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg a.s./ha)	Crop	Time-scale	TER	Annex VI Trigger
5 x 0.6 (a.s.)	hops	acute	> 125	10
		long-term	33	5
5 x 0.6 (Forum, expressed as a.s.)		acute	25	10
		long-term	**3.6***	5

* including a correction factor of 0.5 due to log P_{ow} > 2

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

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	No effects up to 40 L FORUM®/ha (equivalent to 6 kg a.s./ha)
Carbon mineralization ‡	No effects up to 40 L FORUM®/ha (equivalent to 6 kg a.s./ha)

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N;	Harmful to the environment
	R51/R53	Toxic to aquatic organisms, may cause long term-adverse effects in the aquatic environment

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

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
ER50	emergence rate, median
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
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
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
NOEC	no observed effect concentration
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