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

1-methylcyclopropene

finalized: 2 May 2005

SUMMARY

1-Methylcyclopropene is a new active substance for which in accordance with Article 6 (2) of Council Directive 91/414/EEC[1] the United Kingdom received an application from Rohm and Haas for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2003/35/EC[2].

Following the agreement between the EU-Commission and the EFSA for the EFSA to organise a peer review of those new active substances for which the decision on the completeness of the dossier had been published after June 2002, the designated rapporteur Member State United Kingdom made the report of its initial evaluation of the dossier on 1-methylcyclopropene, hereafter referred to as the draft assessment report (DAR), available on 22 March 2003. EFSA received this document on 7 August 2003.

The peer review was initiated on 14 August 2003 by dispatching the draft assessment report for consultation to the Member States and the notifier. Subsequently, the comments received on the draft assessment report were examined by the rapporteur Member State and discussed in an evaluation meeting on 15 January 2004. Remaining issues as well as further information made available by the notifier were evaluated in a scientific meeting with Member State experts in May 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 7 March 2005 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as plant growth regulator as proposed by the notifier which comprises room treatment via a gas supply generator used for the storage of apples at application rate up to 2.24 mg 1-methylcyclopropene per cubic meter or 0.009 mg per kg apple. The representative formulated product for the evaluation was "smart fresh", a water soluble powder, which release 1-MCP when dissolved in water (vapour releasing product, VP).

[1] OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19
[2] OJ No L 11, 16.1.2003, p. 52

For the purposes of this evaluation, 1-MCP is used as an abbreviation for 1-methylcyclopropene (IUPAC), but has no official status (not accepted by ISO). 1-MCP is a gas. At high concentrations, it is energetically self-reactive and becomes explosive if it is allowed to warm in a closed container. These properties present practical difficulties when conducting studies with 1-MCP. The active substance is never isolated in the manufacturing process for reasons of safety. Instead, 1-MCP is produced as an α-cyclodextrin complex, containing ≈3.3 % of 1-MCP.

Adequate methods are available to monitor all compounds given in the respective residue definition. No analytical methods for the determination of residues in soil and water have been required, since 1-methylcyclopropene is a gas and it is unlikely to reach these compartments.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

A limited toxicology data set was submitted since 1-MCP is a gas at room temperature and it was only tested in inhalation studies, no studies on neurotoxicity, long term studies or reproductive toxicity were submitted. Ten percent of 1-MCP inhaled into the lungs on each breath was absorbed. 1-MCP is not acutely toxic. Based on available data 1-MCP gave negative results in *in vitro* and *in vivo* genotoxicity assays. However, two impurities, 1-chloro-2-methylpropene (1-CMP) and 3-chloro-2-methylpropene (3-CMP), evident at a low concentration, are reported to give positive results in genotoxicity studies and are carcinogenic. Thus, a classification of 1-MCP as T; R46 is proposed. In the short-term toxicity studies, effects on red blood cells were observed. A developmental study was submitted and no effects were observed. The acceptable daily intake (ADI), the acceptable operator exposure level (AOEL) for inhalation as well as the systemic AOEL was derived from the 90 day study in rats (NOAEL of 9 mg/kg bw/day). For the ADI, a 100 fold assessment factor, with an additional assessment factor of 10 in extrapolating from a short-term study to lifetime exposure as well as adjustment for 10% inhalatory absorption gives a total assessment factor of 10 000 resulting in an ADI of 0.0009 mg/kg bw/day. The inhalation AOEL is 0.09 mg/kg bw/day with and the systemic AOEL is 0.009 mg/kg bw/day with adjustment for 10 % inhalatory absorption. The acute reference dose (ARfD) is 0.07 mg/kg bw/day. On the basis of field measurements, a treated store contains a maximum possible air concentration of 1-MCP (1.0 ppm). The maximum concentration of 1-MCP in air would contain a maximum combined concentration of <0.05 ppm of toxicologically significant impurities. The estimated operator exposure is < 1% of the systemic AOEL. Worker exposure is estimated to be < 2% of the inhalatory AOEL and bystander exposure is negligible.

The metabolism of 1-MCP following application on plant commodities was not investigated, as based on the representative GAP on apples a theoretical maximum residue level was calculated as 0.009 mg/kg from the amount of active ingredient applied to a given weight of apples at the maximum proposed concentration. From a residue study with radiolabelled 1-MCP it became evident that total residues on apples will in fact hardly ever exceed 50 % of the theoretical calculated level. Thus, the level of potential metabolites present is deemed insignificant. Moreover their nature would be not identifiable at these low levels. The dietary risk assessment for consumers demonstrated that

intakes are less than 1% of the ADI and the ARfD, respectively, for all considered population subgroups except for children of 1-4 years of age. For the latter group, the national estimate of daily intake calculated using the UK model was 14% of the ADI.

Use of 1-MCP will be restricted to indoor use in post-harvest storage. Therefore, contamination of natural soils, surface and ground waters may be precluded. Studies to investigate the fate of 1-MCP in these compartments are not required.
The active ingredient 1-MCP is a gas under environmental relevant conditions. Emission from a Controlled Atmosphere Facility (CAF) through ventilation after the treatment processes may not be precluded. However, concentrations expected in open air as a consequence venting storage facilities will be low and unlikely to persist.

The risk to birds, mammals, aquatic organisms, bees, non-target arthropods, soil micro- and macro-organisms, including earthworms, non-target plants and biological methods for sewage treatment is low with respect to 1-MCP as far as investigated.

Key words: 1-methylcyclopropene, 1-MCP, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

In accordance with Article 6 (2) of Council Directive 91/414/EEC the United Kingdom received an application from Rohm and Hass for inclusion of the active substance 1-methylcyclopropene in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 2003/35/EC.

Following the agreement between the EU-Commission and EFSA for EFSA to organise a peer review of those new active substances for which the completeness of the dossier had been officially confirmed after June 2002, the designated rapporteur Member State United Kingdom submitted the report of its initial evaluation of the dossier on 1-methylcyclopropene, hereafter referred to as the draft assessment report (DAR), to the ECCO team at the Federal Biological Research Center for Agriculture and Forestry (BBA) in Braunschweig on 22 March 2003. EFSA received this document on 7 August 2003.This draft assessment report was distributed for consultation to the Member States and the notifier on 14 August 2003.

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 15 January 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing issues identified for further consideration, a scientific discussion of the identified toxicological issues took place in an expert meeting organised on behalf of the EFSA by the EPCO-Team at the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig, Germany in May 2004. 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 March 2005 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).

Following the agreement between the EU-Commission and EFSA regarding the peer review of new active substances, 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. 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 4 February 2004)
- 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. 1-1 of 10 February 2005)

Given the importance of the draft assessment report including its addendum (compiled version of March 2005 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

1-MCP is the used abbreviation for 1-methylcyclopropene (IUPAC), but has no official status. Due to the fact that the chemical name is reasonably short and distinctive no ISO common name will be given to this compound.

1-MCP belongs to the class of ethylene inhibitor plant growth regulators. 1-MCP is used in the storage of apples to slow down fruit softening, senescence, drop in acidicity and development of superficial scald disorder.

The representative formulated product for the evaluation was "smart fresh", a water soluble powder, which release 1-MCP when dissolved in water (vapour releasing product, VP).

The representative uses evaluated comprises room treatment via a gas supply generator used for the storage of apples at application rate up 2.24 mg 1-MCP per cubic meter or 0.009 mg per kg apple.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of 1-MCP as manufactured should not be less than 960 g/kg, but such material is unavailable since its instability. At the moment no FAO/WHO specification exists. The technical material contains two impurities (1-CMP, 1-chloro-2-methylpropene and 3-CMP, 3-chloro-2-

methylpropene), which have to be regarded as relevant impurities. The maximum content in the technical material should not be higher than 0.8 g/kg (1-CMP) and 0.8 g/kg (3-CMP), respectively.
Due to the fact that 1-MCP is not isolated on its pure state, but produced as a powder formulation, the content of pure 1-MCP can not be given as for other formulations. However, the content of 1-MCP in the representative formulation "smart fresh" is nominal 33 g/kg (with a range of 30 – 36 g/kg).
The assessment of the data package revealed no particular area of concern in respect of the identity, physical, chemical and technical properties of 1-MCP or the respective formulation.
However, there are some uncertainties with respect to a possible classification. As a hydrocarbon gas 1-MCP would be classified, but it will only be produced in an encapsulated form. The free gas will neither be isolated nor transported. No classification was proposed during the risk assessment, but the issue is highlighted to drawn the attention of the ECB (European Chemicals Bureau) on it.
Furthermore, the results of the shelf-life study for the preparation that demonstrate the stability for 2 years are summarised in addendum 2 (June 2004) of the draft assessment report (DAR), due to the fact that the study was finalised after the preparation of the DAR. The conclusion of the RMS that this study fulfils the data gap is confirmed by EFSA.

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

Adequate analytical methods are available for the determination of 1-MCP in the technical material as well as for the determination of the respective impurities in the formulated product. It should be noted that the preparation and the technical material are identical.

Analytical methods for the determination of residues of 1-MCP in apples and air are available. No analytical methods for the determination of residues in soil and water have been required, since 1-MCP is a gas and therefore unlikely have any impact on these. It seems also not necessary to require analytical methods for these matrices to cover emergency measures in the event of an accident since the properties of 1-MCP and of the manufactured end-product (the 1-MCP/cyclodextrin complex releases 1-MCP, if the complex is in contact with water) indicate also that it is unlikely that these compartments will be contaminated.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

2. Mammalian toxicology

A limited toxicology data set was submitted. Since 1-MCP is a gas at room temperature it was only tested in inhalation studies. No chronic toxicity or carcinogenicity studies, or multigeneration studies were submitted, and short-term toxicity and teratology studies have only been submitted for one species, when two species would normally be required. The exposure to 1-MCP is very low, close to negligible.

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

1-MCP appeared rapidly in the blood stream when inhaled and it was cleared from the blood compartment at a modest rate. Less than 10% of available radioactivity was absorbed during 4 hours of exposure. At high dose (1000 ppm) exhalation was the main route of excretion. At low dose (100 ppm) urinary excretion and excretion via exhaled air were of equal prominence. Excretion via exhaled air is likely to be irrelevant at proposed in-use atmospheric concentrations. Bioaccumulation is not suspected, although some radioactivity may remain for the lifetime of biomolecules which may incorporate carbon from metabolism of 1-MCP.

2.2. ACUTE TOXICITY

Due to practical reasons (1-MCP is a gas at room temperature) it was only tested in inhalation studies, LC50 > 2.5 mg/L (the highest dose tested).

2.3. SHORT TERM TOXICITY

Three short term studies in rats were submitted and evaluated in the DAR, 2-weeks inhalation in females and 3-week and 90-day inhalation in males.

Repeated inhalation of 1-MCP resulted in destruction of red blood cells. Other target organs of 1-MCP toxicity were the liver and kidneys. The overall population of WBCs in males appeared to be increased in treated animals at the highest concentration used. The NOAELs were based on the kidney and RBC effects in all short-term studies and corresponds to the dose of the actual day.

The NOAEL in the 3 week inhalation study in male rats was 68 mg/kg bw/day (107 ppm atmospheric concentration) based on proteinuria.

The NOAEL in the 90 day inhalation study in rats was 9 mg/kg bw/day (23.5 ppm 1-MCP in atmosphere) based on proteinuria and splenic haemosiderosis in males.

2.4. GENOTOXICITY

Three *in vitro* studies and one *in vivo* assay were provided. There were no evidence of mutagenic activity for vapour concentrations of 1-MCP up to 1000 ppm.

However, the technical material contains two impurities, 1-chloro-2-methylpropene (1-CMP) and 3-chloro-2-methylpropene (3-CMP). These impurities are monohaloalkenes, which are structurally similar to vinyl chloride and are reported in the published literature to give positive results in certain genotoxicity studies, see also 2.8.

The maximum limit for each of these impurities in the technical material is 0.8 g/kg (0.08%).

The EPCO expert meeting (May 2004) discussed the presence of genotoxic impurities. A report from the UK Committee of Carcinogenicity (COC/03/S3-September 20033) concerning the carcinogenic properties and estimation of maximum predicted exposures for operators and consumers was discussed. The COC concluded that the maximum predicted exposures for operators and consumers will be below the proposed minimum by factors varying from 3 to 5311. The risk of carcinogenicity

[3] Carcinogenic impurities in the pesticide 1-methylcyclopropene (1-MCP)

to the impurities posed by exposure was considered to be negligible. The COC stated that there was always a need to control the exposure so that is "as low as reasonable practical" (ALARP) to genotoxic carcinogens. The EPCO expert meeting agreed with the COC conclusions however proposed that 1-MCP could be classified as T; R46 (May cause heritable genetic damage). The final decision is to be made by ECB.

2.5. LONG TERM TOXICITY

No studies submitted. The need for studies to be performed was discussed at the EPCO expert meeting. The meeting raised concerns regarding the limited data set available for this compound but concluded that such studies were not essential as consumer and operator exposures would be exceedingly low or non-existent, provided that Member States can accept the limited data set for 1-MCP.

2.6. REPRODUCTIVE TOXICITY

No multigeneration studies were submitted. The need for studies to be performed was discussed at the EPCO expert meeting. The meeting raised concerns regarding the limited data set available for this compound but concluded that the provision multigeneration studies were not essential as consumer and operator exposures would be exceedingly low or non-existent, provided that Member States can accept the limited data set for 1-MCP.

A developmental study was performed in the rat. The maternal NOAEL was 107 ppm i.e. 56 mg/kg bw/day based on darkened and enlarged spleens. No developmental effects were seen and the NOAEL is set to the highest dose tested 1029 ppm i.e. 543 mg/kg bw/day.

The need for studies to be performed in the rabbit was discussed at the EPCO expert meeting. The meeting agreed that a rabbit study would not be required.

2.7. NEUROTOXICITY

No studies submitted. In the short term study, there were no indications that 1-MCP required testing for neurotoxicity or delayed neurotoxicity.

2.8. FURTHER STUDIES

Binding of ethylene by plant and animal tissues

Comparative ethylene binding assays have been evaluated in the DAR. It was evident that binding by animal tissues was not greater than background whereas ethylene binding by plant tissues containing ethylene receptors was > 10 fold higher than background.

Toxicity of impurities

The following information, summarised by the RMS, regarding the genotoxicity and carcinogenicity of two impurities found in the literature (IARC monographs, vol. 63, pp315-333). Both compounds are carcinogenic in the mouse.

1-chloro-2-methylpropene (1-CMP)

Negative results in 9 out of 10 Ames tests. Positive results in a heritable translocation assay in Drosophila melanogaster, a sex-linked recessive lethal mutation assay, in an *in vitro* mammalian cell mutation assay in D. melanogaster, at the tk locus in L5178Y cells, and in an in vitro sister chromatid exchange assay in CHO cells. No *in vivo* genotoxicity assays were performed in mammals. It was carcinogenic in mice.

3-chloro-2-methylpropene (3-CMP)

Positive results in 5 out of 7 Ames assays, a 'genetic crossing over' or recombination assay in D. melanogaster, a sister chromatid exchange in CHO cells, and chromosomal aberration assay also in CHO cell. Positive result in an *in vivo* assay in mammals (mouse micro nucleus test). It was carcinogenic in mice.

2.9. MEDICAL DATA

No adverse effects have been reported in the United States by manufacturing workers, applicators, retailers or the general population.

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

The ADI was derived from the 90 day inhalation study in rats. The NOAEL from this study was 9.0 mg/kg bw/day (23.5 ppm 1-MCP in atmosphere) based on proteinuria and splenic haemosiderosis in males. A 100 fold assessment factor, with an additional assessment factor of 10 in extrapolating from a short-term study to lifetime exposure as well as adjustment for 10% inhalatory absorption gives a total assessment factor of 10 000.

The ADI is 0.0009 mg/kg bw/day.

The inhalation and systemic AOEL are derived from the NOAEL in the 90 day rat inhalation study of 9 mg/kg bw/day, with an assessment factor of 100.

The inhalation AOEL is 0.09 mg/kg bw/day.

In the toxicokinetic study it was estimated that 10% of 1-MCP inhaled into the lungs on each breath was absorbed, hence the actual systemic dose is one tenth of the material inhaled.

The systemic AOEL is 0.009 mg/kg bw/day.

An ARfD is needed since effects on the red blood cell may occur after a single dose. It may be set using the NOAEL from the 3 week inhalation study in male rats (the shortest duration study in the more sensitive sex), which accounted for all effects that might be encountered after a single exposure. This NOAEL (107 ppm atmospheric concentration equivalent 68 mg/kg bw/day) was based on proteinuria. The safety factor of 100 is adjusted for inhalation absorption which was 10%.

The acute reference dose is 0.07 mg/kg bw/day.

2.11. DERMAL ABSORPTION

The dermal route is not a significant route of exposure compared to the inhalation route. Therefore no studies of dermal absorption were submitted and none are required.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

On the basis of field measurements, a treated store containing the maximum possible air concentration of 1-MCP (1.0 ppm) would contain a maximum combined concentration of <0.05 ppm for all four impurities. On venting, atmospheric concentrations of 1-MCP fall to non-detectable levels. Therefore, it is assumed that operators, bystanders and workers will be exposed to negligible levels of 1-MCP and the toxicological significant impurities.

As a worst case, it can be assumed that the concentration of 1-MCP in treatment rooms after venting is 0.015 mg/m^3 (half the LOQ for the validated method of analysis for 1-MCP). A 60 kg operator with a typical breathing volume of 0.8 m^3/h exposed to this atmosphere for an 8 hour working day will receive an inhalation exposure to 1-MCP of 0.0016 mg/kg bw/day. This translates to a maximum total theoretical exposure to combined impurities 1-4 (at ≈5% of the technical specification) of <0.083 µg/kg bw/d. Given actual exposures will be <1 hour day, exposure to the impurities combined will be <0.01µg/kg bw/d.

On the basis of field measurements, a treated store contains a maximum possible air concentration of 1-MCP (1.0 ppm). The maximum concentration of 1-MCP in air would contain a maximum combined concentration of <0.05 ppm of toxicologically significant impurities. The estimated operator exposure is approximately < 1% of the systemic AOEL. Worker exposure is estimated to be < 2% of the inhalatory AOEL and bystander exposure is negligible.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

A metabolism study of 1-MCP in plant material was not submitted. Based on the representative GAP on apples it was estimated that the application rate on a mass to mass basis can not produce total residues greater than 0.009 mg/kg. There is no requirement for plant metabolism data as levels of metabolites would not be identifiable at this low total residue level, being less than 0.01 mg/kg.

The estimate was confirmed by a laboratory study conducted on apples with 1.2 ppm concentration (representative GAP is 1 ppm) of radiolabelled 1-MCP, applied once under conditions designed to replicate commercial practice. Apple samples were removed from the container at various time intervals after the vent and immediately analysed for total radioactive residues. The results clearly demonstrate that residues are in the main less than half the theoretical maximum residue calculated based on the study treatment rate. After a period of venting the residues stabilise and do not decline significantly up to the 14 day time point in the study. This is likely to be due to the 1-MCP binding to the ethylene receptor sites.

Thus, the residue of concern should be defined as 1-MCP for risk assessment and monitoring purposes.
Processing studies are not required as there are no significant residues in the raw commodity.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

As 1-MCP is due to its function only applied in food storage practice it is not expected getting to soil and producing residues in rotational crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Metabolism and feeding studies in livestock have not been conducted as based on the representative GAP the residue level in potential feeding stuff, i.e. apple pomace is expected to be insignificant. (<0.01 mg/kg)

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary exposure assessment for consumers is based on an estimated theoretical worst case residue level of 0.009 mg 1-MCP per kg apples and the UK consumption data for various consumer subgroups. The estimated chronic intake (NEDI, UK model) of 1-MCP residues via apples by young children (1-4 years of age) doesn't exceed 14% of the ADI. For all other considered population subgroups the contribution of the residue intake to the ADI is estimated as less than 1% of the ADI.

An acute risk due to intake of 1-MCP residues from apples is unlikely to occur as the acute exposure assessment indicates that intakes are less than 1% of the ARfD for all considered population subgroups.

3.4. PROPOSED MRLS

The proposed MRL for 1-MCP in apples is 0.01 mg/kg.
1-MCP is a new active substance and no CAC MRL's had been proposed yet and need to be taken into account.

4. Environmental fate and behaviour

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Use of 1-MCP will be restricted to indoor use in post-harvest storage. Therefore, contamination of natural soils due to the proposed use of 1-MCP may be precluded.
Studies to investigate the route of degradation in soil are not required.

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

Use of 1-MCP will be restricted to indoor use in post-harvest storage in Controlled Atmosphere Facilities (CAF). Therefore, contamination of natural soils due to the proposed use of 1-MCP may be precluded.

Studies to investigate the rate of degradation in soil are not required.

QSARs (EPIWIN Suite 3.04 package) estimates of soil half life were provided by the notifier in the context of the ground water risk assessment. The models employed to produce these estimates have not been peer reviewed at the EU level and the results should be taken as indicative. In general, QSAR estimates can be considered to have an approximate 95 % confidence interval of ± 10 fold. Therefore, these estimates would not be appropriate to perform the risk assessment of uses were soil contamination by 1-MCP was possible.

Estimates of the initial PEC in soil were produced based on a model that considers the limited exposure via ventilation of the CAF and subsequent deposition from the released air. The model has not been Peer Reviewed at EU level since EU models to calculate soil contamination through volatilization / deposition processes are expected to be provided by FOCUS air. However, it is considered that assumptions made in the calculation are conservative. The values obtained may be considered illustrative to confirm that no further data are needed to support the proposed uses.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Use of 1-MCP will be restricted to indoor use in post-harvest storage in Controlled Atmosphere Facilities (CAF). Therefore, contamination of natural soils due to the proposed use of 1-MCP may be precluded.

QSARs (EPIWIN Suite 3.04 package) estimates of adsorption coefficients to soil were provided by the notifier in the context of the ground water risk assessment. The models employed to produce this estimates have not been peer reviewed at EU level and the results should be taken as indicative. In general, QSAR estimates can be considered to have an approximate 95 % confidence interval of ± 10 fold. Therefore, these estimates would not be appropriate to perform the risk assessment of uses were soil contamination by 1-MCP was possible.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Results for the available hydrolysis study are not reliable since temperature (50 °C) seems to have produced the reaction of 1-MCP with itself. Under the more environmental relevant temperature of 20-22 °C used in the ready biodegradability test 1-MCP shows to be stable to hydrolysis.

1-MCP is not readily biodegradable.

Use of 1-MCP will be restricted to indoor use in post-harvest storage in Controled Atmosphere Facilities (CAF). Therefore, contamination of natural surface waters due to the proposed use of 1-MCP may be precluded. Consequently, water-sediment studies are not required.

Estimates of the initial PEC in surface water were produced based on a model that considers the limited exposure via ventilation of the CAF and subsequent deposition from the released air. The model has not been Peer Reviewed at EU level since EU models to calculate surface water contamination through volatilization / deposition processes are expected to be provided by FOCUS air. However, it is considered that assumptions made in the calculation are conservative. The values obtained may be considered illustrative to confirm that no further data are needed to support the proposed uses.

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

Ground water contamination by 1-MCP is not expected since soil contamination is precluded for the proposed uses. However, a PELMO 3.0 simulation with the Hamburg 1961 scenario has been provided. Input parameters are estimated by QSARs (EPIWIN Suite 3.04 package). This modelling exercise is not performed according FOCUS gw guidance and FOCUS scenarios are not simulated. Since this simulation is not needed for the risk assessment of the representative use proposed no further data has been required.

4.3. FATE AND BEHAVIOUR IN AIR

1-MCP is a gas under environmental relevant conditions. Emission from a CAF through ventilation after the treatment processes may not be precluded. The notifier provided an estimation of the discharge from apple stores using the Industrial Source complex dispersion model (ISCST3). This model was used to estimate the maximum concentration of 1-MCP in air following venting of a controlled treatment facility. Using a number of conservative assumptions, the maximum predicted concentration of 1-MCP in air is approximately 1.1 ppb v/v (first 80 min of venting at approximately 50 to 75 m downwind).

The actual rate coefficient for the reaction of 1-MCP with hydroxyl radicals was measured using laser induced fluorescence. From this experiment, a half life of 4.4 h may be deduced for the reaction of 1-MCP with tropospheric OH radicals. Due to the negligible absorbance at wavelengths above 290 nm direct photolysis is assumed to be negligible. However, other dissipation and degradation routes may contribute to further reduce the half life of 1-MCP in air.

It may be concluded that concentrations of 1-methylcyclopropene in air resulting form the proposed use will be low and unlikely to persist. Based on theoretical considerations ozone, formic acid, acetaldehyde and formaldehyde are likely the breakdown products in air. The quantities of these products produced by the expected maximum use of 1-MCP was compared to other anthropogenic sources of these compounds and was considered negligible and unlikely to impact the chemistry of the upper atmosphere globally or air quality nearer ground level at the local scale.

5. Ecotoxicology

5.1. RISK TO TERRESTRIAL VERTEBRATES

No studies were provided to address the risk to birds.

The representative use evaluated is an application in a Controlled Atmosphere Facility (CAF). The most likely exposure scenario for birds would be inhalation of 1-MCP after flying through a peak concentration of the gas released from a vented CAF. In the absence of data to address the inhalation toxicity to birds it has been assumed that the avian and mammalian toxicity are similar resulting in a TER value of > 1000. This value is considered to indicate a low acute toxicity to birds from inhalation given the uncertainties in both the toxicity and exposure estimates.

The dietary risk is calculated according to the EPPO decision scheme assuming a Tier II worst-case release from a CAF resulting in a deposition on short grass. Also no dietary studies with birds are available but it was calculated that the acute and dietary endpoint must be lower than 0.079 mg/kg bw for a small bird (approx. 20 g bw) or less than 0.026 mg/kg bw for a large bird (approx. 100 g bw) to breach the acute and short term Annex VI trigger value of 10. Assuming that the toxicity of 1-MCP is similar for birds and mammals the acute oral LD_{50} will be expected to be orders of magnitude higher than those estimated above. Therefore the acute and short term risk to birds can be considered as low.

As this risk was calculated according to EPPO, EFSA made a similar risk assessment available based on the "Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC" (Sanco/4145/2000 of 25. September 2002). According to this assessment (see addendum by EFSA) endpoints for birds have to be higher than 2.499 mg as/kg bw for the acute risk, higher than 1.338 mg as/kg bw for the short term risk and higher than 0.603 mg as/kg bw for the long term risk to birds to meet the Annex VI trigger value. If it is assumed that the toxicity of 1-MCP is similar for birds and mammals, as was done by the RMS, the acute oral LD_{50} is expected to be higher than these estimations. Therefore also according to SANCO/4145/2000, the acute and short term risk to birds can be considered as low.

Also no studies addressing the long term/reproductive risk were submitted. The representative use is an application of 1-MCP after harvesting of the apples (late August – late October) which is outside the bird breeding season. Based on the application timing and very low levels of 1-MCP in soil, water and air following release from a CAF, the long term/ reproductive risk to birds is considered to be low.

The risk to mammals was calculated according to the EPPO decision scheme for an herbivorous mammal in grass and an insectivorous mammal. It was noted by EFSA that the acute ETE is expressed in mg/kg diet. Furthermore, it was noted by EFSA that the most appropriate available long term endpoint would be 543 mg a.s./kg bw (developmental toxicity study) and the long term ETE should not have been recalculated for food uptake. Nevertheless, the acute and long term TER values would still be above the respective trigger values if these assumptions were corrected, indicating a low risk to mammals from the representative use of 1-MCP in a CAF.

As this risk was calculated according to EPPO, a similar risk assessment was made available by EFSA based on the "Guidance Document on Risk Assessment for Birds and Mammals under Council

Directive 91/414/EEC" (Sanco/4145/2000 of 25. September 2002). According to this assessment (see addendum by EFSA) the risk to mammals can be regarded as low as the calculated acute and long term TER values are above the respective Annex VI trigger values for the representative use of 1-MCP in a CAF.

Secondary poisoning of birds and mammals is not considered relevant for this compound, since the potential for bioaccumulation is expected to be low (log Pow < 3).

5.2. RISK TO AQUATIC ORGANISMS

Studies addressing the acute toxicity of 1-MCP to aquatic organisms were conducted using the formulated product. The resulting LC/EC_{50}-values for fish, *Daphnia magna* and the algae *Selenastrum capricornutum* were all above the highest concentration tested. The resulting TER-values are all several orders of magnitude above the Annex VI trigger value indicating a low acute risk to aquatic organisms.

No studies on the chronic risk to aquatic organisms are considered necessary as repeated exposure of aquatic organisms is considered unlikely given the low release of 1-MCP into the atmosphere following venting of the CAF (see section 4.2.1).

Water-sediment studies are not required by the section on Fate and behaviour as contamination of natural surface waters due to the representative use of 1-MCP may be precluded. Hence also the risk to sediment dwelling organisms from the representative use of 1-MCP may be regarded as low.

No studies with the metabolites are required as contamination of natural surface waters due to the proposed use of 1-MCP may be precluded. Therefore no water-sediment studies were triggered to identify metabolites in surface water and sediment.

As the logPow is below 3, no study on bioconcentration in fish is considered necessary.

5.3. RISK TO BEES

No studies were provided to address the risk from 1-MCP to bees. An acute toxicity study with the formulation to bees is available which resulted in an LD_{50} above 10 ppm (v/v). Given the volatile nature of the product it is not possible to express the result of this acute toxicity study in µg a.s./bee and hence it is not possible to calculate a HQ value. If compared to the maximum representative use rate of 1 ppm (v/v), the risk to bees can be considered as low.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was low in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* as effects were below 30% at 10 ppm (v/v). If compared to the

maximum representative use rate of 1 ppm (v/v), the risk to non-target arthropods can be considered as low. No studies on other species are considered necessary.

5.5. RISK TO EARTHWORMS

No studies were provided to address the risk from 1-MCP to earthworms. An acute toxicity study with the formulation to earthworms is available which resulted in an LD_{50} above 10 ppm (v/v). The resulting TER-value (taking into account a correction factor of 2 for the LogPow) is above the Annex VI trigger value of 10 indicating a low acute toxicity to earthworms.

The representative use of 1-MCP will be indoor use in a CAF. Therefore, contamination of natural soils due to the proposed use of 1-MCP may be precluded (see section 4.1.2). Hence, no long term toxicity studies with earthworms are considered necessary.

No studies with the metabolites are required as contamination of natural soils due to the proposed use of 1-MCP may be precluded. Therefore no soil degradation studies were triggered to identify soil metabolites.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

1-MCP is not expected to be persistent in soil, additionally no adverse effects were observed on earthworms and non target arthropods. Therefore, no further testing on other soil non-target macro-organisms is considered necessary for the compound.

No studies with the metabolites are required as contamination of natural soils due to the proposed use of 1-MCP may be precluded. Therefore no soil degradation studies were triggered to identify soil metabolites.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The RMS stated in the DAR that no studies are considered necessary as the DT_{90f} is expected to be below 100 d. EFSA does not agree that this is a valid reason for not requesting a study but agrees that no studies are necessary in this case as contamination of natural soils may be precluded due to the use in CAF and hence exposure of soil micro-organisms can be regarded as negligible.

No studies with the metabolites are required as contamination of natural soils due to the proposed use of 1-MCP may be precluded. Therefore no soil degradation studies were triggered to identify soil metabolites.

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

The risk to non-target flora is expected to be low based on the low expected exposure following venting of a CAF after application of the representative use of 1-MCP.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The risk for biological methods of sewage treatment is considered to be low as exposure from the parent compound to surface water is considered to be negligible (see section 4.1.2).

6. Residue definitions

Soil

Definitions for risk assessment: Not applicable

Definitions for monitoring: Not applicable

Water

Ground water

Definitions for risk assessment: Not applicable

Definitions for monitoring: Not applicable

Surface water

Definitions for risk assessment: Not applicable

Definitions for monitoring: Not applicable

Air

Definitions for risk assessment: 1-MCP

Definitions for monitoring: 1-MCP

Food of plant origin

Definitions for risk assessment: 1-MCP

Definitions for monitoring: 1-MCP

Food of animal origin

Definitions for risk assessment: not necessary/not proposed

Definitions for monitoring: not necessary/not proposed

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
1-MCP	No data, no contamination of soil expected from the proposed representative use.	See sections 5.5, 5.6 and 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 activity**	**Ecotoxicological activity**
1-MCP	No data, no contamination of soil expected.	No data, no contamination of soil expected from the proposed representative use.	-	-	-

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
1-MCP. No data, no contamination of surface water expected.	See section 5.2.

Air

Compound (name and/or code)	Toxicology
1-MCP	Concentrations of 1-methylcylopropene in air resulting form the proposed use will be low and unlikely to persist

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

- None

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as plant growth regulator as proposed by the notifier which comprises room treatment via a gas supply generator used for the storage of apples at application rate up to 2.24 mg 1-MCP per cubic meter or 0.009 mg per kg apple. The representative formulated product for the evaluation was "smart fresh", a water soluble powder, which release 1-MCP when dissolved in water (vapour releasing product, VP).

Adequate methods are available to monitor all compounds given in the respective residue definition. No analytical methods for the determination of residues in soil and water have been required, since 1-MCP is a gas and it is unlikely to reach these compartments.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

A limited toxicology data set was submitted since 1-MCP is a gas at room temperature and it was only tested in inhalation studies. Ten percent of 1-MCP inhaled into the lungs on each breath was absorbed. 1-MCP is not acutely toxic (LC50 > 2.5 mg/L). Based on available data 1-MCP gave negative results in *in vitro* and *in vivo* genotoxicity assays. However, the two impurities, 1-chloro-2-methylpropene (1-CMP) and 3-chloro-2-methylpropene (3-CMP), evident at a low concentration, are reported in the published literature to give positive results in genotoxicity studies. Thus, a classification of 1-MCP of T; R46 is proposed.
In the short-term toxicity studies, repeated inhalation of 1-MCP resulted in destruction of red blood cells. Other target organs of 1-MCP toxicity were the liver and kidneys. The NOAELs were based on the kidney and RBC effects in all short-term studies. The NOAEC in the 3 week study was 107 ppm corresponding to a NOAEL of 68 mg/kg bw/day. In the 90-day study the NOAEC was 23.5 ppm corresponding to a NOAEL of 9 mg/kg bw/day.
1-MCP was not tested for neurotoxicity. No studies on long term toxicity or reproductive toxicity were submitted. A developmental study was submitted and no effects were observed, the NOAEC was 1029 ppm corresponding to a NOAEL of 543 mg/kg bw/day (i.e. highest dose tested).
The Acceptable Daily Intake (ADI), the inhalation AOEL as well as the systemic AOEL was derived from the 90 day inhalation study in rats (NOAEL of 9.0 mg/kg bw/day). For the ADI, an additional safety factor of 10 were added for extrapolating a short term study to a life time exposure as well as correcting for the10 % inhalatory absorption. Thus, the uncertainty factor is 10 000 resulting in an **ADI of 0.0009 mg/kg bw/day**.
The inhalation AOEL is 0.09 mg/kg bw/day applying the assessment factor of 100.

The systemic AOEL is 0.009 mg/kg bw/day applying the assessment factor of 100 and adjusting for 10 % inhalatory absorption.
An acute reference dose (ARfD) is needed since effects on the red blood cell may occur after a single dose. It was set on the NOAEL of 68 mg/kg bw/day in the 3 week inhalation study in male rats. Applying a standard assessment factor of 100 and adjusting for inhalation absorption which was 10% gives an **ARfD of 0.07 mg/kg bw/day**.
On the basis of field measurements, a treated store contains a maximum possible air concentration of 1-MCP (1.0 ppm). The maximum concentration of 1-MCP in air would contain a maximum combined concentration of <0.05 ppm of toxicologically significant impurities. The estimated operator exposure is approximately < 1% of the systemic AOEL. Worker exposure is estimated to be < 2% of the inhalatory AOEL and bystander exposure is negligible.

The metabolism of 1-MCP following application on plant commodities was not investigated, as based on the representative GAP on apples a theoretical maximum residue level was calculated as 0.009 mg/kg from the amount of active ingredient applied to a given weight of apples at the maximum proposed concentration. From a residue study with radiolabelled 1-MCP it became evident that total residues on apples will in fact hardly ever exceed 50 % of the theoretical calculated level. Thus, the level of potential metabolites present is deemed insignificant. Moreover their nature would be not identifiable at these low levels. The dietary risk assessment for consumers demonstrated that intakes are less than 1% of the ADI and the ARfD, respectively, for all considered population subgroups except for children of 1-4 years of age. For the latter group, the national estimate of daily intake calculated using the UK model was 14% of the ADI.
Use of 1-MCP will be restricted to indoor use in post-harvest storage. Therefore, contamination of natural soils, surface and ground waters may be precluded. Studies to investigate the fate of 1-MCP in these compartments are not required.
The active ingredient 1-MCP is a gas under environmental relevant conditions. Emission from a CAF through ventilation after the treatment processes may not be precluded. However, concentrations expected in open air as a consequence venting storage facilities will be low and unlikely to persist.

The risk to birds, mammals, aquatic organisms, bees, non-target arthropods, soil micro- and macro-organisms, including earthworms, non-target plants and biological methods for sewage treatment is low with respect to 1-MCP as far as investigated.

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

- Risk assessment is based on the assumption that under the proposed conditions of use in post harvest storage no exposure to soil and surface water occurs. Therefore, uses that may result on a potential contamination of soil and or surface water will be not covered by this risk assessment and should be prevented.

- The maximum limit for each of the impurities 1-chloro-2-methylpropene (1-CMP) and 3-chloro-2-methylpropene (3-CMP) in the technical material should be equal or less than 0.8 g/kg (0.08%).

Critical areas of concern

- Since 1-MCP is a gas at room temperature a limited data package has been submitted containing only inhalation studies and no long term studies or multigeneration studies.
- The impurities 1-chloro-2-methylpropene (1-CMP) and 3-chloro-2-methylpropene (3-CMP), evident at a low concentration, are reported in the published literature to give positive results in genotoxicity studies and are carcinogenic.

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) ‡	1-methylcyclopropene (an ISO Common Name will not be considered for this active substance)
Function (e.g. fungicide)	Plant growth regulator for food storage practice

Rapporteur Member State	UK
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	1-methylcyclopropene
Chemical name (CA) ‡	1-methylcyclopropene
CIPAC No ‡	Not allocated
CAS No ‡	3100-04-7
EEC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification ‡ (including year of publication)	Not allocated
Minimum purity of the active substance as manufactured ‡ (g/kg)	960
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	3-CMP: ≤ 0.8 g/kg 1-CMP: ≤ 0.8 g/kg
Molecular formula ‡	C_4H_6
Molecular mass ‡	54
Structural formula ‡	

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

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	< -100 °C (from literature)
Boiling point (state purity) ‡	4.7 °C (calculation)
Temperature of decomposition	240 °C (this is for the technical material which is also the formulated product.)
Appearance (state purity) ‡	Colourless gas
Relative density (state purity) ‡	Not required for a gas
Surface tension	Not required for a gas
Vapour pressure (in Pa, state temperature) ‡	$2x10^5$ Pa (calculation) (25 °C)
Henry's law constant (Pa m^3 mol^{-1}) ‡	Not required for a gas at room temperature
Solubility in water ‡ (g/l or mg/l, state temperature)	pH 7: 137 mg/l at 20°C
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	*n*-heptane 2450 mg/l xylene 2250 mg/l ethyl acetate 12500 mg/l methanol 11000 mg/l acetone 2400 mg/l dichloromethane 2000 mg/l (at 20 °C)
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH ≈7: 2.4 at 26 °C
Hydrolytic stability (DT50) ‡ (state pH and temperature)	At 50 °C at pH 4-9, 1-MCP is unstable in water (>70% degradation in 2.4 hours). In a ready biodegradability study (20-22 °C), the compound was stable for up to 28 days (in both sterile control samples and in the presence of viable sewage sludge inoculum). Stable to hydrolysis:
Dissociation constant ‡	Not applicable
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	205 nm
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	Not required
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Not required

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

Flammability ‡	The active is a hydrocarbon gas and it would be classified as flammable. **Note**: The manufacturing process for 1-MCP produces the gas in an encapsulated form. The free form is not isolated or transported.
Explosive properties ‡	Not applicable this classification does not apply to gases

‡ Endpoint identified by the 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 as/hl min max	water l/ha min max	kg as/ha min max		
Apples	Belgium France Germany Italy Spain The Netherlands United Kingdom *Austria* *Ireland* *Greece* *Portugal*	Smart-Fresh	I	N/A (Plant growth regulator)	Vapour releasing product (VP)	3.3%	Propri-etary generator	After harvest (not later than 7 days after harvest)	One per stored batch of apples	N/A	N/A (see Remarks)	N/A (see Remarks)	518-1000	0	(See Nota Bene below) **Critical GAP** considered for risk assessment = 1000 ppb as in the air = 2.24 mg as / m3 = 0.009 mg as./ kg apples **Minimum use rate** = 545 ppb as in the air = 1.22 mg as / m3 = 0.0049 mg as./ kg apples

NB: -The relationship between 1-MCP in ppb vs. mg is expressed by the law of gases, thus following the formula:
milligrams 1-MCP/cubic meter = selected concentration of 1-MCP in the air in ppm x molecular weight 1-MCP (=54 g/mol)/volume occupied by 1 mole of gas at 20°c (24.06 liters).
Minimum use rate is 545 ppb 1-MCP, equivalent to 0.545*54/24.06 = 1.22 mg/m3
Critical use rate is 1000 ppb 1-MCP, equivalent to 1*54/24.06 = 2.24 mg/m3
-Storage room filling density considered is 250 kg of fruit/m3

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

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

	(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

‡ Endpoint identified by the 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)	GC-FID with isobutylene as the standard.
Impurities in technical as (principle of method)	GC-FID with isobutylene as the standard.
Plant protection product (principle of method)	GC-FID with isobutylene as the standard.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	GC-FID with isobutylene as the standard. LOQ 0.01 mg/kg (apples)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required since no residue definition is proposed.
Soil (principle of method and LOQ)	Not required the active substance is a gas and is unlikely to reach soil (produces as gas in an encapsulated form).
Water (principle of method and LOQ)	Not required the active substance is a gas and is unlikely to reach water (produces as gas in an encapsulated form).
Air (principle of method and LOQ)	GC-FID with isobutylene as the standard. LOQ 0.031 mg/m^3
Body fluids and tissues (principle of method and LOQ)	Not required the active substance is neither toxic nor very toxic.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	To be considered by ISPRA (in particular with respect to flammability)

‡ Endpoint identified by the 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 ‡	Estimated to be 10% across the lungs
Distribution ‡	Distributed throughout the body
Potential for accumulation ‡	Low potential for accumulation
Rate and extent of excretion ‡	Moderate rate of excretion
Metabolism in animals ‡	Metabolism evident, but metabolites not elucidated
Toxicologically significant compounds ‡ (animals, plants and environment)	1-MCP

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	No data submitted
Rat LD_{50} dermal ‡	No data submitted
Rat LC_{50} inhalation ‡	LC_{50} >2.5 mg/L
Skin irritation ‡	No data submitted
Eye irritation ‡	No data submitted
Skin sensitization ‡ (test method used and result)	No data submitted

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Proteinuria as indicated by the increased incidence of hyaline droplets in the renal cortical tubular epithelium in males, and splenic haemosiderosis, also in males.
Lowest relevant oral NOAEL / NOEL ‡	No data submitted
Lowest relevant dermal NOAEL / NOEL ‡	No data submitted
Lowest relevant inhalation NOAEL / NOEL ‡	68 mg/kg bw (i.e; 107 ppm), 3 week study in rat 9 mg/kg bw (i.e; 23.5 ppm), 90-day study in rat

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

Genotoxicity ‡ (Annex IIA, point 5.4)

.....	I-MCPA not genotoxic. However, impurities (1-CMP and 3-CMP) are demonstrated to be genotoxic *in vivo* as well as carcinogenic in the mouse **R 46**

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

Target/critical effect ‡	No data submitted
Lowest relevant NOAEL / NOEL ‡	No data submitted
Carcinogenicity ‡	No data submitted

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No data submitted
Lowest relevant reproductive NOAEL / NOEL ‡	No data submitted
Developmental target / critical effect ‡	Test material not teratogenic
Lowest relevant developmental NOAEL / NOEL ‡	56 mg/kg bw/day (107 ppm), maternal effects 543 mg/kg bw/day (i.e. 1029 ppm), developmental effects (highest dose)

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

.....	No data submitted

Other toxicological studies ‡ (Annex IIA, point 5.8)

Published data on the impurities 1-CMP and 3-CMP	1-chloro-2-methylpropene (1-CMP) Negative results in 9/10 Ames tests. Positive results in a heritable translocation assay in *Drosophila melanogaster*, a sex-linked recessive lethal mutation assay, in an *in vitro* mammalian cell mutation assay in *D. melanogaste*r, at the tk locus in L5178Y cells, and in an *in vitro* sister chromatid exchange assay in CHO cells. It was carcinogenic in mice. 3-chloro-2-methylpropene (3-CMP) Positive results in 5/7 Ames assays, a 'genetic

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

	crossing over' or recombination assay in *D. melanogaste*r, a sister chromatid exchange in CHO cells, and chromosomal aberration assay also in CHO cell. Positive result in an *in vivo* assay in mammals (mouse micro nucleus test). It was carcinogenic in mice.

Medical data ‡ (Annex IIA, point 5.9)

.....	Likely to be an anaesthetic gas. No adverse effects from normal use reported.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.0009 mg/kg bw/d	90 day inhalation, rat	10 000*[#]
Short term inhalation AOEL ‡	0.09 mg/kg bw/d	90 day inhalation, rat	100
Short term systemic AOEL ‡	0.009 mg/kg bw/d	90 day inhalation, rat	1000*
ARfD ‡	0.07 mg/kg	3 week inhalation, rat	1000*

* including adjustment for inhalatory absorption (10%).
[#] Additional safety factor of 10 for extrapolating to long term exposure from a short term study

Dermal absorption (Annex IIIA, point 7.3)

.....	No data submitted. Inhalation the most significant route of exposure.

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

Acceptable exposure scenarios (including method of calculation)

Operator	On the basis of the results from an extensive range of laboratory and field studies and exposure estimates based on worst case assumptions, the level of exposure to 1-mMCP for an unprotected operator handling and activating a generator, venting a store and retrieving and emptying the water from a spent generator is likely to be negligible. The level of exposure to the impurities of toxicological significance is estimated to be considerable lower than the predicted negligible level of exposure to 1-MCP. On basis of field measurements, the estimated exposure to 1-MCP (and the toxicologically significant impurities) is approximately < 1% of the systemic AOEL.
Worker	On the basis of field study measurements, residues data and worst case calculations, the level of exposure to 1-MCP (and the toxicologically significant impurities) for a worker entering treated areas after venting and handling treated apples is likely to be negligible or approximately < 2% of the inhalatory AOEL.
Bystander	On the basis of field study measurements and worst case exposure estimates, the level of exposure to 1-methylcyclopropene (and the toxicological significant impurities) for a bystander at the time of treatment and during venting is likely to be negligible.

Classification and proposed labelling (Annex IIA, point 10)

With regard to toxicological data	T; R 46 May cause heritable genetic damage

‡ Endpoint identified by the 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 crop
Rotational crops	Not applicable the product is only applied to stored apples.
Plant residue definition for monitoring	1-methylcyclopropene
Plant residue definition for risk assessment	1-methylcyclopropene
Conversion factor (monitoring to risk assessment)	Not applicable.

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

Animals covered	Not applicable.
Animal residue definition for monitoring	Not applicable.
Animal residue definition for risk assessment	Not applicable.
Conversion factor (monitoring to risk assessment)	Not applicable.
Metabolism in rat and ruminant similar (yes/no)	Not applicable.
Fat soluble residue: (yes/no)	Not applicable.

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

.....	Not applicable.

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

.....	Not applicable.

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

.....	Not applicable.

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

.....	Not applicable.

‡ Endpoint identified by the 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	0.0009 mg/kg bw/day
TMDI (% ADI) (European Diet)	≤ 1%
NEDI (% ADI)	≤ 14% (Children, 1-4 years of age) < 1% all other population groups.
Factors included in NEDI	None
ARfD	0.07 mg/kg bw/day
Acute exposure (% ARfD)	< 1%

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

None

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

Apples 0.01 mg/kg (Maximum theoretical residue is 0.009 mg/kg)

*) LOQ

‡ Endpoint identified by the 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 ‡	No data submitted, not required.
Non-extractable residues after 100 days ‡	No data submitted, not required.
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	No data submitted, not required.

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

Anaerobic degradation ‡	No data submitted, not required.
Soil photolysis ‡	No data submitted, not required.

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

Method of calculation	No data submitted, not required.
Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): no measured data available. Soil contamination precluded for the uses proposed. QSAR estimate of 15 days (first order). Only illustrative since a 10 fold uncertainty is estimated. DT_{90lab} (20°C, aerobic): no measured data available. QSAR estimate of 50 days. Only illustrative since a 10 fold uncertainty is estimated. Soil contamination precluded for the uses proposed. DT_{50lab} (10°C, aerobic): 33 days, calculated using a Q10 of 2.2 from a QSAR estimate. Only illustrative since a 10 fold uncertainty is estimated. DT_{50lab} (20°C, anaerobic): No data submitted, not required.
	degradation in the saturated zone: ‡ No data submitted, not required.
Field studies ‡ (state location, range or median with n value)	DT_{50f}: No data submitted, not required.
	DT_{90f}: No data submitted, not required.
Soil accumulation and plateau concentration ‡	No data submitted, not required.

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡ pH dependence ‡ (yes / no) (if yes type of dependence)	No measured data available. Soil contamination precluded for the uses proposed. QSAR estimated koc of 42.7 ml/g. Only illustrative since a 10 fold uncertainty is estimated.

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

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

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Soil contamination precluded for the uses proposed. Illustrative modelling of vented concentration from a store followed by wet and dry deposition and even incorporation into the top 5 cm of soil.
Application rate	1 ppm in a fruit store atmosphere

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial (Tier 1)	0.00533 mg/kg			
Initial (Tier 2)	0.000127 mg/kg			

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)	pH_4: expected stable to hydrolysis at 20°C 70% degradation after 2.4 hours at 50°C, proposed as a result of self reaction at the elevated temperature pH_7: expected stable to hydrolysis at 20°C 70% degradation after 2.4 hours at 50°C, proposed as a result of self reaction at the elevated temperature

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

	pH_9: expected stable to hydrolysis at 20°C 70% degradation after 2.4 hours at 50°C, proposed as a result of self reaction at the elevated temperature
Photolytic degradation of active substance and relevant metabolites ‡	No data submitted, not required, no UV adsorption maximum in aqueous solution >240nm
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡	No data submitted, not required. Surface water contamination precluded for the uses proposed.
Mineralization	No data submitted, not required. Surface water contamination precluded for the uses proposed.
Non-extractable residues	No data submitted, not required. Surface water contamination precluded for the uses proposed.
Distribution in water / sediment systems (active substance) ‡	No data submitted, not required. Surface water contamination precluded for the uses proposed.
Distribution in water / sediment systems (metabolites) ‡	No data submitted, not required. Surface water contamination precluded for the uses proposed.

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

Parent

Method of calculation	Illustrative modelling of vented concentration from a store followed by dry deposition and mixing into a static 30cm deep water body.
Application rate	1ppm in a fruit store atmosphere
Main routes of entry	Dry deposition from the atmosphere

$PEC_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial (Tier 1)	1.35 µg/l			
Initial (Tier 2)	0.000622 µg/l			

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

PEC (sediment)

Parent

Method of calculation	Surface water contamination precluded for the uses proposed. Expert judgement considering minimal predicted surface water concentration, volatility and QSAR estimate of Koc.
Application rate	1ppm in a fruit store atmosphere

PEC$_{(sed)}$ (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	negligible			

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Soil contamination precluded for the uses proposed. Illustrative modelling PELMO 3.0 German National Hamburg scenario.
Application rate	1ppm in a fruit store atmosphere

PEC$_{(gw)}$

Maximum concentration	<0.001µg/l
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	<0.001µg/l

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

Direct photolysis in air ‡	No data submitted, not required
Quantum yield of direct phototransformation	No data submitted, not required
Photochemical oxidative degradation in air ‡	Average rate of the reaction of 1-methylcyclopropene with OH· was measured to be = 2.7 ± 1.3 x 10^{-11} cm^3 s^{-1}. Assuming a typical 12-hour average concentration of OH· of 1.5 x 10^6 molecules/cm^3, an atmospheric half life of 4.4 hours is calculated.
Volatilization ‡	from plant surfaces: it is a gas from soil: not applicable

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

PEC (air)

Method of calculation	US-EPA's Industrial Source Complex, short term (ISCST3) model (US-EPA, 1995)[4] With an application rate of 1ppm

$PEC_{(a)}$

Maximum concentration	1.1 ppb v/v at approximately 50 to 75 meters downwind from the first 80 min of venting of a fruit store.

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: not applicable for the uses proposed Surface water: not applicable for the uses proposed Sediment: not applicable for the uses proposed Ground water: not applicable for the uses proposed Air: 1-methylcyclopropene

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

Soil (indicate location and type of study)	New active substance, not available, will not be feasible to monitor approved use.
Surface water (indicate location and type of study)	New active substance, not available, will not be feasible to monitor approved use.
Ground water (indicate location and type of study)	New active substance, not available, will not be feasible to monitor approved use.
Air (indicate location and type of study)	New active substance, not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R53 as is not readily biodegradable.

[4]Users Guide for the Industrial Source Complex (ISC3) dispersion models, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards Emissions, Monitoring and Analysis Division, Research Triangle Park, NC. Internet WRL: http://www.epa.gov/ttn/scram/

‡ Endpoint identified by the 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 ‡	LC50: >2.5 mg a.s./L or > 500 mg a.s./kg bw (rat)
Reproductive toxicity to mammals	NOAEL = 543 mg a.s./kg bw (rat)
Acute toxicity to birds ‡	No data available[1]
Dietary toxicity to birds ‡	No data available[1]
Reproductive toxicity to birds ‡	No data available[1]

[1] Exposure expected to be negligible

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

Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.0022	Apples in store	Large grazing mammal	Acute	>1000	10
0.0022	Apples in store	Large grazing mammal	Long-term	>190000[1]	5
0.0022	Apples in store	Small insectivorous mammal	Acute	>52000	10
0.0022	Apples in store	Small insectivorous mammal	long-term	>1000000[2]	5

[1] This value was calculated by the RMS with a NOEC value > 20833 mg as/kg diet. EFSA recalculated this value with the NOAEL of 543 mg/kg bw which gives a TER value of 2424 (see addendum).
[2] This value was calculated by the RMS with a NOEC value > 6944 mg as/kg diet. EFSA recalculated this value with the NOAEL of 543 mg/kg bw which gives a TER value of 42093 (see addendum).

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	BAS 5-80 (formulation)	96 h	LC50	>0.966
Daphnia magna	BAS 5-80 (formulation)	48 h	EC50	>0.776
Selenastrum capricornutum	BAS 5-80 (formulation)	96 h	EbC50	>0.838

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

Microcosm or mesocosm tests
No data available

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

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.0022	Apples in store	*Oncorhyncus mykiss*	Acute	-	>1500000	100
0.0022	Apples in store	*Daphnia magna*	Acute	-	>1200000	100
0.0022	Apples in store	*Selenastrum capricornutum*	Acute	-	>1300000	10

Bioconcentration

Bioconcentration factor (BCF) ‡	Low potential for bioconcentration (Log P_{ow} 2.4 at 20 °C). Therefore as the Log P_{ow} is ≤ 3 a study is not required
Annex VI Trigger:for the bioconcentration factor	Not required
Clearance time (CT_{50}) (CT_{90})	Not required
Level of residues (%) in organisms after the 14 day depuration phase	Not required

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

Acute oral toxicity ‡	Active substance: 10 ppm (v/v)
Acute contact toxicity ‡	No data available

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
10 ppm (v/v)	Apple	Oral	<50	50

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

Field or semi-field tests
No data available

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests ‡						
Aphidius rhopalosiphi	Adult	Formulation	10 ppm (v/v)	Mortality	<30%	>30%
Typhlodromus pyri	Protonymph	Formulation	10 ppm (v/v)	Mortality	<30%	>30%

Field or semi-field tests
No data available

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

Acute toxicity ‡	LC_{50} (14 day): 5* ppm (v/v)
Reproductive toxicity ‡	No data available

* Corrected by a factor of 0.5 due to the high organic carbon content of OECD soil and the Log Pow > 2

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
1ppm in a fruit store atmosphere	Apple	Acute	>57	10

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

Nitrogen mineralization ‡	No data available
Carbon mineralization ‡	No data available

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

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	Active substance R50 Very toxic to aquatic organisms* R53 May cause long-term adverse effects in the aquatic environment*

(*) R50 and R53 classifications were proposed on the basis of studies where the concentrations of the test substance were limited by the low solubility of the active substance and were below the cut-off point for the R50 classification. In addition, the formulation rapidly releases 1-MCP as a gas when exposed to water.

‡ Endpoint identified by the 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 Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent degradation / dissipation
DT_{90}	period required for 90 percent degradation / dissipation
ε	decadic molar extinction coefficient
EC_{50}	effective concentration, median
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography or high pressure 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
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
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
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