CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Dazomet is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Belgium, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of dazomet in Annex I to Council Directive 91/414/EEC.

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

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Belgium, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 10 December 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 11 December 2009. The EFSA collated and forwarded all comments received to the Commission on 25 January 2010.

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

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1 On request from the European Commission, Question No EFSA-Q-2010-00133, issued on 30 September 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L224, 21.08.2002, p.25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 333, 11.12.2008, p.11
6 OJ L 15, 18.01.2008, p.5
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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of dazomet as a soil fumigant (nematicide, fungicide, herbicide, insecticide) on lettuce, strawberries and soil-grown tomatoes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No data gaps or critical areas of concern are identified in the section identity, physical and chemical properties and analytical methods.

A critical area of concern (and a related data gap) is identified with regard to the compliance of the batches tested in mammalian toxicology with the proposed specification. In addition, the operator and worker exposure assessment in greenhouses could not be finalised.

Based on the metabolism studies performed in fruit crops (tomato, strawberry), root crops (radish), and leafy crops (cabbage), the residue for monitoring and risk assessment was defined by default as methyl isothiocyanate (MITC) alone. No residues were detected in the supervised residue trials and MRLs were proposed at the LOQ (0.01 mg/kg) for all representative uses. The Theoretical Maximum Daily Intake (TMDI) is less than 1% of the Acceptable Daily Intake (ADI) for all diets included in the EFSA PRIMo model, and the maximum acute intake is less than 2 % of the Acute Reference Dose (ARfD).

Reliable soil degradation half-lives and kinetic formation fractions for the relevant metabolite MITC are not available. This missing information combined with uncertainty in the available groundwater modelling due to the volatile nature of MITC results in a critical area of concern, as the available assessments provide less robust reassurance that groundwater contamination can be avoided from the representative uses assessed, than is the normal case for regulatory leaching assessments. A critical area of concern is also identified over the potential for long-range atmospheric transport of MITC.

Two data gaps are identified in the ecotoxicology section. The acute risk assessment to insectivorous birds for the representative field uses could not be finalised with the available data. Risk mitigation measures are required to address the risk from MITC to aquatic organisms (exposure via deposition).

KEY WORDS

Dazomet, methyl isothiocyanate, peer review, risk assessment, pesticide, soil fumigant, nematicide, fungicide, herbicide, insecticide

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BACKGROUND

Legislative framework

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

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

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

Dazomet is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR (Belgium, 2007) provided by the designated rapporteur Member State, Belgium, which was received by the EFSA on 5 June 2007.

The peer review was initiated on 8 October 2007 by dispatching the DAR to the applicant Kanesho Soil Treatment SPRL/BVBA and on 22 October 2007 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of dazomet in Annex I to Council Directive 91/414/EEC.

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

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of dazomet in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Kanesho Soil Treatment SPRL/BVBA made a resubmission application for the inclusion of dazomet in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR, and the issues and comments raised by Member States on the DAR.

In accordance with Article 18, Belgium, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Belgium, 2009). The Additional Report was received by the EFSA on 10 December 2009.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 11 December 2009. In addition, the EFSA conducted a public consultation

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

on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 25 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 22 February 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on dazomet within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 24 February 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of environmental fate and behaviour and ecotoxicology, and that further information should be requested from the applicant in the areas of identity, physical and chemical properties, mammalian toxicology, and environmental fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a soil fumigant (nematicide, fungicide, herbicide, insecticide) on lettuce, strawberries and soil-grown tomatoes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2010) comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 26 February 2010),
- the Evaluation Table (15 September 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of July 2010 containing all individually submitted addenda) (Belgium, 2010) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Dazomet is the ISO common name for 3,5-dimethyl-1,3,5-thiadiazinane-2-thione or tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (IUPAC).

The representative formulated product for the evaluation was 'Basamid Granular', a microgranule (MG) containing 965 g/kg dazomet, registered under different trade names in Europe.

The representative uses evaluated comprise indoor and outdoor applications by incorporation in moist soil at depths of 10 to 20 cm to control nematodes, soil fungi, soil insects and seed weeds in lettuce, strawberries and soil-grown tomatoes. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of dazomet technical material is 950 g/kg, which meets the requirements of the FAO specification 146/TC(2001) of minimum 940 g/kg.

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 dazomet or the respective formulation. The main data regarding the identity of dazomet and its physical and chemical properties are given in Appendix A.

Analytical methods are available for the determination of dazomet and the impurities in the technical material and for the determination of the active substance in the representative formulation. Adequate analytical methods are available for the determination of the compound methyl isothiocyanate (MITC) in the residue definition for monitoring in food of plant origin and in the environmental matrices. Methods for food of animal origin are not required as no MRL is proposed. An adequate analytical method is available for the determination of the acetyl cysteine conjugate of MITC in body fluids.

2. Mammalian toxicity

The applicant was asked to demonstrate that the batches tested in the mammalian toxicology section are in compliance with the proposed specification. No sufficient information was provided, therefore a data gap was identified, leading also to a critical area of concern.

Dazomet is harmful if swallowed (Xn; R22 "**Harmful if swallowed**"); in humans cases of skin, eye and upper airways irritation, and skin sensitisation are reported (classified as Xi; R36/R37/R38 "**Irritating to eyes, respiratory system, skin**" and R43 "**May cause sensitisation by skin contact**"). After repeated exposure in subacute and subchronic studies, the liver was affected with increased liver weight and hepatocyte fatty degeneration (the relevant No Observed Adverse Effect Level (NOAEL) is 1.5 mg/kg bw/day in rats and 1 mg/kg bw/day in dogs). In long-term toxicity studies the relevant NOAEL in rodents is 0.9 mg/kg bw/day, based on decreased red blood cells, haematocrit and proteins, and increased polychromasia/anisocytosis. The overall weight of evidence indicates that dazomet is not a genotoxic compound. Dazomet is neither a reproductive, nor a teratogenic toxicant. The parental NOAEL is 0.5 mg/kg bw/day, while the offspring and reproductive NOAELs are established at 18 mg/kg bw/day; the maternal and developmental toxicity NOAELs are set at 3 mg/kg bw/day.

The Acceptable Daily Intake (ADI) of dazomet is 0.01 mg/kg bw/day (based on the NOAEL of the 2-year study in rats, supported by the NOAEL of the 1-year study in dogs; with a safety factor of 100); the Acceptable Operator Exposure Level (AOEL) is 0.015 mg/kg bw/day, based on the NOAEL of the 90-day oral study in rats, with a safety factor of 100. The Acute Reference Dose (ARfD) is 0.03 mg/kg bw, based on the developmental toxicity study NOAELs with a safety factor of 100. The ADI and AOEL of the dazomet metabolite MITC are 0.004 mg/kg bw/day, based on the 90-day oral study in dogs, with a safety factor of 100; the ARfD is 0.03 mg/kg bw, based on the rat developmental toxicity study with a safety factor of 100.

For the greenhouse exposure, the submitted exposure values were considered to be indicative only given the small scale of the greenhouse trial presented, therefore it was not possible to conclude and a data gap has been identified. The exposure to dazomet of the operator loading the product in the hopper and driving the tractor during application was measured in a field study: exposure measurements were performed with operators using PPE (coverall, nitrile gloves and boots) and RPE (A1P2, combi-filter protecting for both particle and organic vapour, with a protection of at least 98 %); tractors were equipped with air-conditioned cabins with carbon filters. The exposure level during loading + application was 62 % of the AOEL (and 10 % of the AOEL for MITC); the worker exposure for film application, day 1, is 3 % (driver) and about 7 % (worker) of the AOEL for dazomet even without RPE (for MITC 6 % and 8 % of the AOEL for the driver and worker, respectively); on week 3 and 4 after application, the exposure to MITC was below the AOEL for both the worker and the driver, even in the absence of RPE (but with the same PPE as for operators). Calculated exposure for an unprotected bystander, staying 1h in the neighbourhood of a field during granule incorporation was estimated to be 36 % of the AOEL (dazomet). MITC was monitored during a period of 1 – 4 days, via continuous monitoring, and considering 1h presence in the middle of the field; the exposure levels were 60 % of the AOEL. It is noted that the exposure measurements below the AOEL were obtained considering a work rate of 1.5 ha/day using Surefill containers and a work rate of 1 ha/day using form-fill-seal (FFS) bags.

3. Residues

Metabolism in plants was investigated in three groups of crops; on root/tuber, fruit and leafy crops, using ^{14}C-labelling on the thio-carbon, as this position was assumed to be the most appropriate to detect the MITC generated by the degradation of dazomet in soil. Studies on radish, tomatoes, strawberries and cabbage were performed using a reduced dose rate of 4 g a.s./m², but the crops were planted/sowed 13 to 15 days only after treatment when the concentrations of dazomet in soil were assumed to be similar to those observed after a treatment at the critical dose rate. The study on strawberries was conducted according to the representative GAP, with a dose rate of 56 g a.s./m² and planting 7 weeks after the soil application, following a positive cress test result.

At harvest, on mature crops and in the edible parts, total radioactive residues (TRRs) were in the range of 0.12 to 0.61 mg/kg. Most of the radioactivity was released by solvent extraction (58 % to 82 % TRR), and was mainly composed of polar compounds that remained in the aqueous phases after partition (*ca.* 50 % TRR). The characterisation of the radioactivity in the different extracts shows the residues to be composed of numerous compounds, all present in low proportions and at low levels (< 10 % TRR, < 0.01 mg/kg). Dazomet, MITC, MMTU, DMTU and TMTU were tentatively identified at trace levels in some fractions (0.2 – 6 % TRR). However, in most of the cases this identification was not fully conclusive, and the presence of a metabolite detected in one chromatographic system was often not confirmed by using an alternative system. Therefore, none of the identified compounds were considered as an appropriate marker for the residues and it was finally decided to define by default the residue for monitoring and risk assessment as MITC alone, since dazomet is almost completely degraded to MITC in soil. Moreover, this definition is supported by toxicological considerations, as the biological activity in soil is due to MITC, and this compound has a lower ADI than dazomet (see sections 2 and 4).

No residues of MITC above the limit of quantification (LOQ) (0.01 mg/kg) were detected in the samples collected in the supervised residue trials conducted in the EU on strawberries and lettuce (outdoor), and on tomatoes (indoor). For strawberry, residue data from southern EU were not submitted, however numerous trials carried out in the USA were provided to confirm that MITC is not expected to be present above the LOQ (0.02 mg/kg) in strawberries at harvest. Therefore no additional trials were requested and the residue database was considered sufficient to derive MRLs. The storage stability data indicated that MITC residues can be considered stable up to 2 months in tomatoes, and 3 months in pepper and strawberries. Nevertheless, this limited stability covers the EU residue trials, as the samples were analysed within a maximum of 62 days after harvest. Animal metabolism study, livestock feeding study, and processing studies were not provided and not requested, as no residues above the LOQ were detected in the crop commodities.

No chronic or acute risk was identified for the consumers, the TMDI being less than 1% of the ADI for all diets included in the EFSA PRIMo model, and the IESTI less than 2 % of the ARfD (tomato).

4. Environmental fate and behaviour

Dazomet is a precursor of the soil fumigant MITC. In laboratory soil incubations under aerobic conditions in the dark, dazomet exhibits very low to low persistence being transformed to MITC partly through the intermediate TDL-S (very low to moderate persistent in soil). For MITC low to moderate persistence in soil would be anticipated from the analysis of the data (that included MITC collected in the organic volatiles traps). However, the quantification of volatilised MITC is highly uncertain due to the fact that a sodium hydroxide trap preceded the organic one in most of the experiments. In this way, a significant fraction of the radioactivity quantified as CO_2 may be expected to correspond to MITC hydrolysed in the alkaline trap. This was confirmed by experiments (Belgium, 2009; B.8.1.1.1, (Herrchen M. 2009a)), in which organic traps were placed before the alkaline traps. In these experiments, the amount of volatilised MITC exceeded by 2 to 10 times the amount of CO_2 collected. However, these experiments were too short to derive conclusive kinetic end points. Therefore, the degradation half-lives determined on the basis of the available data indicate faster degradation than is the real situation. Consequently, a data gap has been identified for better aerobic soil degradation half-lives for MITC. MITC breaks down in soil producing the major degradation products formaldehyde and methylamine. Methylamine was considered by the meeting of experts PRAPeR 78 as a substance of no concern with respect to soil organisms and potential groundwater contamination. Radioactivity collected in the NaOH volatiles trap ranged from 37.8 % AR to 75.8 % AR at study termination (34 d - 64 d). As indicated above, a significant amount of this radioactivity would correspond to hydrolysed MITC and the actual levels of mineralisation may not be derived from these experiments. Non-extractable residues reach a maximum of 28.6 % AR after 14 d (study termination). Soil dissipation of formaldehyde was investigated (aerobic laboratory incubations), it exhibited very low to low persistence in soil. The behaviour of dazomet was also investigated under anaerobic conditions in one experiment with flooded soil. In this experiment MITC exhibited high persistence. Photolysis does not seem to contribute significantly to the degradation of dazomet and MITC in soil.

The dissipation of dazomet was investigated under field conditions in three trials (1 trial in Germany; 2 trials in Spain). The trials tried to reproduce realistic patterns of use with incorporation of granules to soil and sealing of soils either with plastic cover (Germany and Spain) or with surplus irrigation (Spain). However, sealing was shorter than proposed in the representative GAP (only 8-12 d sealing versus 7 weeks proposed). Dissipation of dazomet occurs at rates comparable to those observed in the laboratory studies. Quantification of MITC is not fully reliable as indicated by the results of the residues stability test of the trial performed in Germany. The data were corrected by the applicant to account for the losses during the storage of samples; however some uncertainties still remain on how this correction has been performed (see Evaluation Table open point 4.5; EFSA, 2010). The most reliable kinetic analysis (Belgium, 2009; B.8.1.1.1, (Klein 2009a)) did not identify significant differences in the degradation rate before and after plastic coverage. In all three trials quantifiable residues of MITC were found at levels up to 0.27 mg MITC/kg (equivalent to 405 g/ha) in the horizon of 40-50 cm (lowest deep sampled), indicating at least some potential movement to deeper soil layers. Volatilisation of MITC is expected to be the primary dissipation route under field conditions, followed by degradation and leaching. PEC soil were calculated for dazomet, MITC, TDL-S, formaldehyde and methylamine, using worst-case field trial half-lives where applicable (see Appendix A).

Adsorption of dazomet in soil was investigated in four different soils (3 with unrepresentatively low organic carbon contents compared to European soils typically used for agriculture/horticulture). The measured values resulting from these experiments are uncertain due to the fast conversion of dazomet to MITC in soil, but indicate high to medium mobility. Due to the short half-life of dazomet in soil, it is not expected that the exposure assessment of this compound will be significantly affected by the uncertainty of this parameter. The directly measured values presented in the DAR are retained in

Appendix A and were used for modelling. Batch adsorption / desorption studies indicated that MITC may be expected to exhibit very high mobility in soil.

A study with three lysimeters in Germany is available. In this study the agricultural practices proposed (incorporation 0-20 cm and sealing with plastic cover for some days before aeration) are simulated, however, soil was sealed only for one week instead of the 7 weeks in the GAP. MITC levels in the leachate were < 0.1 µg/L (not all samples were analysed). High amounts of non-identified radioactivity were found in the leachate (up to 126.9 µg/L). Since the leachate has been analysed for MITC and other potential metabolites (methylurea, N,N'-dimethylurea, 1,3,5-trimethyl-hexahydro-triazinethione), the presence of discrete metabolites was excluded by the applicant in a reasoned statement. The explanation provided was considered reasonable and no further information was necessary in relation to this non-identified fraction.

In water, at environmentally relevant temperatures and pH, dazomet is rapidly hydrolysed to MITC. MITC is essentially stable under acidic and neutral conditions, but hydrolyses under alkaline conditions. Other major hydrolysis products are carbon disulfide, DMTU, M123, M137 + M139, methylamine and formaldehyde. In the dossier of dazomet the formation of metam by hydrolysis of MITC was not reported. However, this is known to occur (EFSA, 2008 reports that some kind of equilibrium existed between MITC and metam in water). Aqueous photolytic reactions enhanced the formation of MITC. A major aqueous photolytic metabolite (M91) was ascribed tentative structures (see Appendix B). Dissipation of dazomet was investigated in two aerobic water/sediment systems under dark conditions. Very fast transformation of dazomet yielded MITC as the major metabolite in the system. The main dissipation route for MITC from the experimental system was volatilisation. In addition, MATM, formaldehyde/formic acid and methylamine were observed as major metabolites in water. PEC_{SW} were calculated considering run-off and drainage of the residues of MITC remaining after seven weeks of plastic coverage, following FOCUS SW (FOCUS, 2001) recommendations[11]. Band application to only 2/3 of surface is proposed by the applicant as a mitigation measure to reduce surface water exposure by drainage and run-off. Additionally, PEC_{SW} of MITC at the time of application of dazomet considering volatilisation and deposition were calculated following FOCUS AIR guidance (FOCUS, 2008) (see Addendum May 2010; Belgium, 2010).

The potential groundwater contamination by dazomet and metabolites MITC, TDL-S and formaldehyde was assessed by calculation of the 80th percentile annual average leachate concentrations leaving the top 1m of soil over a 20 years period according to FOCUS GW guidance (FOCUS 2000)[12] and the models PELMO 3.3.2 and PEARL 3.3.3 (following EFSA 2004; see Addendum May 2010; Belgium, 2010). Application was limited to once every third year, following the representative GAP. Climate data input parameters were modified in the scenarios to account for the period of time under plastic cover (lettuce, strawberries; minimum of 7 weeks), and the greenhouse conditions (tomatoes; soil-grown). The calculations for lettuce were considered to represent a worst case with respect to strawberries for the southern EU scenarios Thiva and Porto, and Châteaudun. The other scenarios for strawberries were separately simulated to account for the different irrigation pattern. For the uses on tomatoes, modelling of potential groundwater contamination according to the representative GAP (with modified scenarios simulating plastic film soil coverage for only three weeks instead of seven weeks) was not available. In the calculations, TDL-S did not exceed the limit of 0.1 µg/L for any of the situations and scenarios simulated. However, the concentration of the soil fumigant MITC exceeded the trigger of 0.1 µg/L in some of the scenarios. The number of scenarios increased with the application rate considered (up to 3 out of 7 scenarios for the application rate of 500 kg/ha). For the application rates above 192 kg/ha at least one scenario exceeded 0.75 µg/L. Additionally, the applicant has proposed band application (2 m untreated zone between treated strips of max. 4 m) as a mitigation measure against potential groundwater contamination. However, when this mitigation is assumed, some scenarios still exceed the limits of 0.1 µg/L and 0.75 µg/L. Finally, it

[11] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[12] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

must be taken into account that a high uncertainty is associated with these modelling calculations, since the input parameters used for MITC represent best-case degradation and the FOCUS GW models are recognised not to be fully appropriate to describe the fate of volatile substances. In addition, the scenarios needed to be modified to account for the special application with plastic covers. Because of this high uncertainty, a data gap has been identified to better address the groundwater contamination potential of MITC. Also, due to this uncertainty this has been identified as a critical area of concern.

The groundwater concentrations calculated for formaldehyde are uncertain since the implementation of the formation fraction of 2 has not been confirmed by the RMS' assessment. However, taking into account the short half-life of this metabolite, and that the values obtained in the current calculations are well below 0.1 µg/L, the potential for contamination of groundwater by formaldehyde above regulatory levels was concluded to be low.

The main route of dissipation of MITC from soil and surface water is volatilisation. MITC is expected to have a half-life of 78.7 days in the atmosphere by photochemical oxidative degradation according to the standard Atkinson calculation. This exceeds the standard trigger of 2 days, taken to alert for potential risk of contamination in remote areas through long-range atmospheric transport. Experimental values have been provided by the applicant showing half-lives due to photochemical oxidative degradation of 40 days and by direct photolysis of 4.5 days (assuming optimum process with quantum yield of 1). Quantum yields higher than 1 are only possible on photochemical induced chain reactions. This kind of reaction is not expected to occur for MITC diluted in the atmosphere and therefore the quantum yield of 3 necessary to reach atmospheric half-lives shorter than the trigger of 2 days is not justified. The experts at PRAPeR 78 agreed that the long-range transport of MITC cannot be excluded. This is therefore indicated as a critical area of concern. In the interest of consistency of assessments, EFSA refers to the conclusion on metam (EFSA, 2008). In that document the need to address the potential for MITC to contribute to global warming and ozone depletion was identified. In this context, however, the low rate of photochemical degradation discussed above would seem to suggest that MITC might have a low potential for ozone depletion. The potential for contribution to global warming of MITC generated from dazomet has not been addressed within the information provided in the dazomet dossier. In practice, any meaningful global warming assessment would need to consider the overall amount of MITC released to the atmosphere (including sources other than dazomet) and an assessment restricted to the European geographical region might have limited relevance in this context.

The applicant addressed the atmospheric fate of formaldehyde formed in soil after application of dazomet in a position paper (evaluated in Addendum May 2010; Belgium, 2010). Photochemical degradation in the atmosphere is expected to occur with a half-life of 1.3 days (AOPWIN, EPA), below the trigger of 2 days. Formaldehyde produced would therefore not be expected to be subject to long-range atmospheric transport.

5. Ecotoxicology

Dazomet acts as a fumigant through rapid degradation to MITC, therefore the environmental risk assessment was performed for MITC.

The risk assessment for birds and mammals was carried out according to the revised guidance document (EFSA, 2009). Birds and mammals were not expected to be exposed from the glasshouse uses of dazomet. For the field uses, a short-term risk assessment for birds was not considered necessary, as the exposure to MITC via food items remaining at the soil surface was not expected. Consequently, only the acute and long-term risk was assessed for birds. The acute risk to the relevant focal species was assessed as low, except for insectivorous birds. A refinement was proposed based on the results of a field study, which showed that no soil arthropods/insects (dead or alive) were in the soil and its surface after treatment with 'Basamid Granular'. However, as it was a non-GLP study and no negative control was available, it was considered that this study could not be used in the risk assessment. Therefore, a data gap has been identified for further information to address the acute risk to insectivorous birds. The acute risk to mammals via dietary exposure was assessed as low at tier 1.

The experts at the PRAPeR 77 meeting agreed to use the lowest reproductive end point from *Colinus virginianus* (NOEL of 10.6 mg a.s./kg bw/day) in the long-term risk assessment. Based on the available information a long-term risk to birds and mammals could not be excluded for the representative field uses. It was agreed by Member State experts that further information was required to address the long-term risk to birds and mammals from exposure to arthropods that may remain or recover in soil after the removal of the film. It was agreed that a field study is preferred, conducted according to the representative GAP, taking into account the presence of arthropods and measured residues in order to conduct a realistic risk assessment. A risk assessment to earthworm-eating and fish-eating birds and mammals was not required ($\log P_{ow} < 3$).

Dazomet and MITC were very toxic to aquatic organisms. The formulation did not have any significant impact on the toxicity of the active substance. Due to the rapid degradation of dazomet in soil, it was not justified to perform a specific aquatic risk assessment with the active substance and its formulation. The risk to aquatic organisms was assessed as low for the glasshouse uses. For the field uses, the risk assessment for MITC was based on two scenarios: firstly, entering surface water by drainage and run-off, and secondly, entering surface water via deposition.

For exposure via drainage and run-off: A low risk was identified for algae and aquatic plants for all representative field uses, based on FOCUSsw step 3 PEC values. For the high application rate of 500 kg a.s./ha in lettuce and strawberries, PECsw refinements based on band application were applied, in order to identify a low risk to fish and aquatic invertebrates in 4 out of 7 full FOCUS scenarios (acute) and 3 out of the 7 full FOCUS scenarios (chronic risk). For the lower application rate of 300 kg a.s./ha in lettuce and strawberries, PECsw were additionally refined based on band application in order to identify a low risk to fish and aquatic invertebrates in 5 out of 7 full FOCUS scenarios (acute) and 4 out of the 7 full FOCUS scenarios (chronic risk). Member States having geoclimatic conditions comparable to the FOCUS scenarios, which do not comply with Annex VI triggers, may need to address the risk to aquatic organisms (fish and aquatic invertebrates) further.

For exposure via deposition: The risk for aquatic invertebrates, algae, and aquatic plants was assessed as low, based on risk mitigation measures comparable to 30 m and 20 m no-spray buffer zones for the representative uses on lettuce and strawberries for the high (500 kg a.s./ha) and lower (300 kg a.s./ha) application rates, respectively. The acute and chronic risk to fish was assessed as low, based on risk mitigation measures comparable to 40 m and 30 m no-spray buffer zones for all relevant scenarios, for the field uses on lettuce and strawberries at 500 kg a.s./ha and 300 kg a.s./ha, respectively.

The risk from further metabolites (MATM and formaldehyde) was assessed as low for aquatic organisms for all representative uses, as their toxicity was considered to be expressed in the toxicity testing of the parent substance. Moreover, the aquatic exposure to MATM and formaldehyde was considered to be negligible for the representative uses (see Appendix A, section Environmental fate and behaviour).

A potential high risk was assumed from the results of the extended laboratory tests with two soil-dwelling species (*A. bilineata* and *F. candida)*. Therefore, the potential for recolonisation was investigated in field studies, which showed that recolonisation of the field with non-target arthropods took place within one year after treatment. Therefore the risk to non-target arthropods was assessed as low for the representative field uses of dazomet. A low risk was assumed for non-target arthropods following glasshouse uses.

The risk of dazomet and its metabolites (MITC, formaldehyde, TDL-S) to earthworms was assessed as low based on field studies, demonstrating that recovery of the earthworms population was possible within one year after the exposure to dazomet. The risk assessment for soil non-target macro-organisms was based on a litter bag study and field studies. The results of the tests showed that all the taxonomic groups recolonised the treated field. Therefore, the risk from dazomet and its metabolites (MITC, formaldehyde, TDL-S) to soil non-target macro-organisms was assessed as low for the representative field uses on lettuce and strawberries. A risk assessment for non-target soil macro-organisms in glasshouses was not considered relevant.

The risk to bees, non-target soil micro-organisms, non-target plants, and the function of waste water treatment plants was assessed as low for the representative uses.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Dazomet	Very low to low ($DT_{50\ 20\ C}$ = 0.07d – 5.4 d)	The risk to earthworms was assessed as low, based on results from field tests. A low risk was identified for non-target soil macro- and micro-organisms.
MITC	Uncertain due to poor determination of volatiles in most of the experiments ($DT_{50\ 20\ C} \geq$ 4.67 d– 10.7 d)	The risk to earthworms was assessed as low, based on results from field tests. A low risk was identified for non-target soil macro- and micro-organisms.
TDL-S	Very low to moderate ($DT_{50\ 20\ C}$ = 0.13d – 43.7 d)	The risk to earthworms was assessed as low, based on results from field tests. A low risk was identified for non-target soil macro- and micro-organisms.
Formaldehyde	Very low to low ($DT_{50\ 20\ -22\ C}$ = 0.97d – 2.32 d)	The risk to earthworms was assessed as low, based on results from field tests. A low risk was identified for non-target soil macro- and micro-organisms.

6.2. Ground water

Compound (name and/or code)	**Mobility in soil**	**>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
Dazomet	Estimated to be high to medium (uncertain due to fast degradation during batch adsorption / desorption experiments). (K_{Foc} ≈ 129 – 394 mL / g)	FOCUS GW: No	Yes	Yes	Yes
MITC	Very high mobility (K_{Foc} = 9.0 – 20.2 mL / g)	FOCUS GW: Yes. 0.1 and 0.75 µg/L limits exceeded for some of the uses and scenarios simulated. Lysimeter: No	Yes	Yes	Yes
TDL-S	Estimated by QSAR (EPI-WIN) to be highly mobile. (K_{Foc} ≈ 104 mL / g)	FOCUS GW: No	No	No data	No
Formaldehyde	Estimated to be very high mobile (HSDB). (K_{Foc} ≈ 37 mL / g)	FOCUS GW: No	No	No data	No

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Dazomet	Very toxic to aquatic organisms. Risk assessment carried out with MITC due to the rapid degradation of dazomet.
MITC	Very toxic to aquatic organisms. Risk mitigation measures up to 40 m non-spray buffer zones are necessary to protect the aquatic organisms for the field uses (exposure via deposition). The risk to aquatic organisms was considered low for the glasshouse uses.
MATM	The risk of MATM was assessed as low for aquatic organisms.
Formic acid (including formaldehyde)	The risk of formaldehyde was assessed as low for aquatic organisms.

6.4. Air

Compound (name and/or code)	Toxicology
MITC	Very toxic via inhalation; irritant to respiratory upperways.
Formaldehyde	Classified as Toxic by inhalation (Directive 67/548/EEC - 22th ATP)

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

- Compliance of batches tested in the mammalian toxicology section with the proposed specification should be demonstrated (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).

- Operator and worker exposure assessment in greenhouses (relevant for the glasshouse uses; submission date proposed by the applicant: unknown; see section 2).

- Laboratory soil degradation studies of MITC formed from dazomet with quantification of organic volatiles trapped before any alkaline trap would be needed to derive reliable MITC kinetic parameters and correct quantification of mineralization (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Potential for groundwater contamination by MITC need to be reassessed when more reliable kinetic parameters and/or more suitable models to estimate the fate of volatile substances become available. In addition, soil coverage by plastic film of three weeks in tomatoes will need to be assessed (currently it seems that only coverage for seven weeks has been simulated) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Further information to address the acute risk to insectivorous birds (relevant for the representative use on lettuce and strawberries; submission date proposed by the applicant: unknown; see section 5).

- Further information to address the long-term risk to birds and mammals arising from exposure to arthropods that may remain or recover in soil after the removal of the film (relevant for the representative use on lettuce and strawberries; submission date proposed by the applicant: unknown; see section 5).

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

- Exposure measurements considered a work rate of 1.5 ha/day using Surefill containers and for a work rate of 1 ha/day using form-fill-seal (FFS) bags. Exposure assessments were performed with operators using PPE (coverall, nitrile gloves and boots) and RPE (A1P2, combi-filter protecting for both particle and organic vapour, with a protection of at least 98%); tractors were equipped with air-conditioned cabins with carbon filters. For the worker exposure assessment RPE was not considered (the same PPE was considered as for operators).

- Only application limited to once every third year has been assessed for potential groundwater contamination.

- Coverage of soils by plastic for at least 7 weeks after the treatment has been assumed in the assessment of field uses. The exposure assessment for groundwater and surface water risk assessment presented here are only representative of situations where this practice is strictly observed (with the limitations already indicated in the conclusion). Sealing of soils with water with surplus irrigation is not addressed by the current assessment and is suspected to potentially enhance concerns identified with respect to groundwater contamination by MITC.

- Due to the uncertainties associated with the estimation of groundwater concentrations for MITC, EFSA proposes that focused monitoring programs on this fumigant should be considered as a tool to clarify the risks of groundwater contamination associated with this compound and to design appropriate management strategies.

- Risk mitigation measures comparable to a 40 m no-spray buffer zone are necessary to protect aquatic organisms from exposure via deposition for the representative field uses on lettuce and strawberries for the high application rate (500 kg a.s./ha).

- Risk mitigation measures comparable to a 30 m no-spray buffer zone are necessary to protect aquatic organisms from exposure via deposition for the representative field uses on lettuce and strawberries for the lower application rate (300 kg a.s./ha).

ISSUES THAT COULD NOT BE FINALISED

- Operator and worker exposure assessment in greenhouses could not be finalised.

- Modelling of potential groundwater contamination for uses on tomatoes according to the representative GAP (with modified scenarios simulating plastic film soil coverage for only three weeks instead of seven weeks) is not available.

- The acute risk to insectivorous birds could not be finalised with the available data for the representative field uses on lettuce and strawberries.

- The long-term risk to birds and mammals could not be finalised with the available data for the representative field uses on lettuce and strawberries.

CRITICAL AREAS OF CONCERN

- Compliance of the batches tested in the mammalian toxicology section with the proposed specification could not be demonstrated.

- The current assessment of potential groundwater contamination by MITC is associated with a high degree of uncertainty and possibly underestimates the groundwater contamination potential, as too favourable soil degradation rates and uncertain kinetic formation fractions have been used in the simulations. The available assessments provide less robust reassurance that groundwater contamination can be avoided from the representative uses assessed, than is the normal case for regulatory leaching assessments.

- Potential long-range transport of MITC through the atmosphere cannot be excluded with the available data.

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APPENDICES

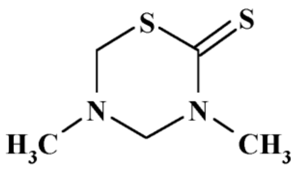
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Dazomet
Function (*e.g.* fungicide)	nematicide, fungicide, herbicide, insecticide

Rapporteur Member State	Belgium
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3,5-dimethyl-1,3,5-thiadiazinane-2-thione or tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione
Chemical name (CA) ‡	tetrahydro-3,5-dimethyl-2H-1,3,5-thiadiazine-2-thione
CIPAC No ‡	146
CAS No ‡	533-74-4
EC No (EINECS or ELINCS) ‡	208-576-7 (EINECS)
FAO Specification (including year of publication) ‡	146/TC (2001): Dazomet content not less than 940 g/kg
Minimum purity of the active substance as manufactured ‡	950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula ‡	$C_5H_{10}N_2S_2$
Molecular mass ‡	162.3 u
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	105 °C (99.8%)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	150 °C (99.8%)
Appearance (state purity) ‡	Colourless, crystalline solid (99.8%)
	White, fine granular solid (Basamid, 97% pure)
Vapour pressure (state temperature, state purity) ‡	1.1×10^{-3} Pa at 20°C; 2.1×10^{-3} Pa at 25°C (99%)
Henry's law constant ‡	5.10×10^{-5} Pa m³/mol at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	3.5 g/L at 20 °C (pH 6-7) (99.8%)
	No effect of pH
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (99.9%):

	Solubility at 20°C (g/L)
dichloromethane	234
acetonitrile	112
acetone	89.7
ethyl acetate	28.5
methanol	21.3
toluene	8.6
iso-propanol	3.6
octanol	2.2
n-heptane	< 0.1

Surface tension ‡ (state concentration and temperature, state purity)	Basamid, 97% pure: 69.4 mN/m at 0.1% w/v (20°C) 69.9 mN/m at 1.0% w/v (20°C)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 0.63 at 20°C (pH 5.8) (99.9%)
	Effect of pH was not investigated, since there is no dissociation in water in the environmentally relevant pH range.
Dissociation constant (state purity) ‡	No dissociation (99.9%) (OECD 112)

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Purity 99.8 %, methanol solution, pH 6.2: <table><tr><td></td><td>λ_{max} (nm)</td><td>ε ($L.mol^{-1}.cm^{-1}$)</td></tr><tr><td rowspan="6">7. pH 6.2 (methanol)</td><td>208.0</td><td>7308</td></tr><tr><td>at λ 228.5</td><td>4209</td></tr><tr><td>246.0</td><td>6209</td></tr><tr><td>at λ 260.0</td><td>4631</td></tr><tr><td>283.0</td><td>11378</td></tr><tr><td>at λ 300 nm</td><td>3682</td></tr></table> Absorbance maximum wavelengths and the corresponding molar absorption coefficients are not significantly affected by pH changes.
Flammability ‡ (state purity)	Basamid, 97% pure: not highly flammable, not auto-flammable
Explosive properties ‡ (state purity)	Not explosive (theoretical consideration)
Oxidising properties ‡ (state purity)	Not oxidising (theoretical consideration)

In the resubmission dossier, the applicant proposed the following GAP (see table below). Compared to the previous GAP, considered in the original DAR (*vide supra*), the following changes were noted:

(i) *Concentration of a.s. in the formulation:* originally '960 g/kg'; now '965 ± 15 g/kg'.

The MG formulation Basamid® consists for 99.9% (w/w) of dazomet technical grade active ingredient (TGAI), hence the content of pure a.s. (dazomet) in the formulation is merely dependent on the purity of the dazomet technical. In the original GAP table, 960 g/kg was stated, as this was the proposed minimum purity of dazomet technical. However, following the evaluation of the new 5-batch analysis study (see Vol.4, C.1.2.3), the minimum purity of dazomet technical has been established at 950 g/kg. The content of dazomet in the formulation is stated in the GAP table as a nominal content with a tolerance range (965 ± 15 g/kg), as proposed by the applicant under IIA 1.9 (see B.1.1.9), enabling calculation of a minimum and maximum application rate (of the a.s.) per treatment.

(ii) *Number of applications:*

The use is now limited to one application in three years for <u>all</u> crops, i.e. also for lettuce and tomatoes (cf. in original GAP only for strawberries).

(iii) *Application rate per treatment:*

In the previous GAP table, the application rate was stated to be 500 kg <u>a.s.</u>/ha. However, for practical use, application of 500 kg of the <u>formulation</u> (Basamid) for treatment of 1 ha is more appropriate. The GAP table was amended to reflect this more realistic, intended use under field conditions and thus, the application rate of 500 kg Basamid/ha corresponds to maximum 490 kg a.s./ha (in case of control of seed weeds: 300 kg Basamid/ha corresponding to 294 kg a.s./ha). The RMS notes that this slightly lower application rate is fully covered by the risk assessment, which may have been performed in some sections on the basis of a maximum application rate of 500 kg a.s./ha. Moreover, the slightly lower application rate is not expected to have a significant impact on the efficacy.

(iv) *Pests controlled:*

The use against seed weeds has been added. However, a lower application rate per treatment is implicated with this use, i.e. 300 kg formulation/ha, corresponding to 285 – 294 kg a.s./ha. Therefore, this addition is considered to have no impact on the risk assessment, which was performed on the basis of the highest application rate.

(v) ***'Band application':***

In the resubmission dossier, the applicant additionally proposed a possible alternative way of treatment, so-called 'band application', by which a 2-meter untreated zone is left in between treated strips with a maximum width of 4 meters. Although in this case, the applied rates of Basamid per treated area (50 or 30 g/m^2) remain the same, the total field area effectively treated is reduced (i.e. maximally 2/3 of the area will be treated).

The RMS considers this 'band application' to be an additional measure that <u>may</u> be effective to mitigate some risks (e.g. improve the recolonisation of treated areas with soil non-target organisms), but has not further considered it and has based its risk assessment on the maximum application rate of 500 kg Basamid / ha (i.e. 475 – 490 kg dazomet/ha), with the exception of groundwater and surface water exposure assessments and consequent risk assessments, where the band application was considered in the assessment.

Summary of representative uses evaluated (Dazomet)* in the framework of the resubmission (December 2009)

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or group of pests controlled (c)	Formulation: Type (d-f)	Formulation: Conc. of as (i)	Application: Method kind (f-h)	Application: Growth stage & season (j)	Application: Number min max (k)	Application: Interval between applications (min)	Application rate per treatment: kg as/hl min max	Application rate per treatment: water L/ha min max	Application rate per treatment: kg as/ha min max	PHI (days) (l)	Remarks: (m)
Lettuce	Northern Europe	Basamid Granular	F	nematodes soil fungi soil insects	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 20 cm	2 months before planting May-June	1	every 3rd year	n.a.	n.a.	475 – 490	n.r.	Coverage of soil with plastic sheets for 7 weeks after treatment. Soil tillage and planting 1 week after removal of plastic sheet. [1] [2] [3]
Lettuce	Northern Europe	Basamid Granular	F	seed weeds	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 10 cm	2 months before planting May-June	1	every 3rd year	n.a.	n.a.	285 – 294	n.r.	
Lettuce	Southern Europe	Basamid Granular	F	nematodes soil fungi soil insects	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 20 cm	2 months before planting April-June	1	every 3rd year	n.a.	n.a.	475 – 490	n.r.	
Lettuce	Southern Europe	Basamid Granular	F	seed weeds	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 10 cm	2 months before planting April-June	1	every 3rd year	n.a.	n.a.	285 – 294	n.r.	
Strawberries	Northern Europe	Basamid Granular	F	nematodes soil fungi soil insects	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 20 cm	2 months before planting May-June	1	every 3rd year	n.a.	n.a.	475 – 490	n.r.	Constant coverage of soil with plastic mulch. Planting occurs directly into plastic film (planting-through technique). Drip irrigation is applied during growing season (spring/ summer). [1][2] [3]
Strawberries	Northern Europe	Basamid Granular	F	seed weeds	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 10 cm	2 months before planting May-June	1	every 3rd year	n.a.	n.a.	285 – 294	n.r.	

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or group of pests controlled (c)	Formulation Type (d-f)	Formulation Conc. of as (i)	Application Method kind (f-h)	Application Growth stage & season (j)	Application Number min max (k)	Application Interval between applications (min)	kg as/hl min max	water L/ha min max	kg as/ha min max	PHI (days) (l)	Remarks: (m)
Strawberries	Southern Europe	Basamid Granular	F	nematodes soil fungi soil insects	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 20 cm	2 months before planting Apr-Sep	1	every 3rd year	n.a.	n.a.	475 – 490	n.r.	Constant coverage of soil with plastic mulch. Planting occurs directly into plastic film (planting-through technique). Drip irrigation is applied during growing season (spring/ summer). [1][2] [3]
Strawberries	Southern Europe	Basamid Granular	F	seed weeds	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 10 cm	2 months before planting Apr-Sep	1	every 3rd year	n.a.	n.a.	285 – 294	n.r.	
Tomato (soil-grown)	Northern and Southern Europe	Basamid Granular	G	nematodes soil fungi soil insects	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 20 cm	1 month before planting	1	every 3rd year	n.a.	n.a.	475 – 490	n.r.	Coverage of the soil for 3 weeks. Soil tillage and planting of the crop 1 week after removal of the plastic sheet. [1] [2][4]
Tomato (soil-grown)	Northern and Southern Europe	Basamid Granular	G	seed weeds	MG	965 ± 15 g/kg	incorporation in moist soil at depth of 10 cm	1 month before planting	1	every 3rd year	n.a.	n.a.	285 – 294	n.r.	

[1] Compliance of the batches tested in the mammalian toxicology section with the proposed specification could not be demonstrated.
[2] The available uncertain groundwater exposure assessment indicates there is a potential for groundwater contamination by MITC, and MITC has the potential for long-range atmospheric transport. The GAP proposed for tomatoes is not covered by the current groundwater simulations since plastic coverage has been assumed to last a minimum of 7 weeks (instead of 3 weeks only).
[3] The acute risk to insectivorous birds, and the long-term risk to birds and mammals could not be finalised with the available data.
[4] Operator and worker exposure assessment in greenhouses could not be finalised.

Remarks:
(a) For crops, Codex (or other, *e.g*. EU) classification should be used; where relevant, the use situation should be described (*e.g*. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g*. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(h) Kind, *e.g*. overall, broadcast, aerial spraying, row, individual plant, between the plants – type of equipment used must be indicated
(i) g/kg or g/l
(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

(e) GCPF codes – GIFAP Technical Monograph No. 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

n.a.: not applicable; n.r.: not relevant;

* Uses for which the risk assessment cannot be concluded are marked grey.

(k) The minimum and maximum number of applications possible under practical conditions of use must be provided.
(l) PHI – minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV; Azeotropic distillation
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		MITC
Food of animal origin		none
Soil		MITC
Water	surface	MITC
	drinking/ground	MITC
Air		MITC
Body fluids and tissues		N-acetyl-S-(methylcarbamothioyl)cysteine (i.e. acetyl cysteine conjugate of MITC)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Single method: GC-MS (conf. by comparison of ion ratios; ILV) → LOQ = 0.01 mg/kg MITC *(strawberry, tomato, lettuce, lemon).*
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required, as no MRL's are proposed.
Soil (analytical technique and LOQ)	Headspace-GC-MSD (conf. by column different polarity) → LOQ = 0.01 mg/kg MITC
Water (analytical technique and LOQ)	Headspace SPME – GC-MSD (conf. by column different polarity) → LOQ = 0.05 µg/L MITC *(surface water, drinking water, ground water)*
Air (analytical technique and LOQ)	GC-MSD (conf. by column different polarity) → LOQ = 0.3 µg/m³ MITC
Body fluids and tissues (analytical technique and LOQ)	HPLC-MS (conf. by HPLC-MS-MS) → LOQ = 0.05 mg/L N-acetyl-S-(methylcarbamothioyl)cysteine *(blood plasma, urine)*

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid (within 24 h) and complete
Distribution ‡	Wide distribution, affinity to the thyroid
Potential for accumulation ‡	none
Rate and extent of excretion ‡	Rapid (within 24 h), limited (6-8%) enterohepatic circulation; elimination via urine (64-70%) and via exhaled air (18-33 %).
Metabolism in animals ‡	Extensively metabolised (no dazomet remaining): hydrolytic ring opening and formation of MITC (0.5-2 %), further phase II deactivation through reaction with GSH, leading to M2 (cystein conjugate, 4-6.5 %) and its oxidation product M4 (pyruvic derivative, 4-6 %) and otherwise the N-acetylcysteine conjugate (16-30 %); formation of 4-10 % highly polar metabolites. Exhaled metabolites including CS_2 and COS (both 3-6 % at low dose, 5-19 % at high dose) and CO_2 (11-18 %).
Toxicologically relevant compounds ‡ (animals and plants)	MITC
Toxicologically relevant compounds ‡ (environment)	MITC, MIC, formaldehyde

Acute toxicity (Annex IIA, point 5.2)	**DAZOMET**	
Rat LD_{50} oral ‡	596 mg/kg bw (males) – 415 mg/kg bw (females)	Xn; R22
Rat LD_{50} dermal ‡	>2000 mg/kg bw	-
Rat LC_{50} inhalation ‡	Dazomet : >8.4 mg/L (males) - 7.3 mg/L (females) Upper airway irritant in humans (case studies)	- Xi; R37
Skin irritation ‡	skin irritant in humans (case studies)	Xi; R38
Eye irritation ‡	eye irritant in humans (case studies)	Xi; R36
Skin sensitisation ‡	sensitiser in humans (case studies)	R43
	MITC	
Rat LD_{50} oral ‡	163 mg/kg bw (males) – 147 mg/kg bw (females)	T; R25
Rat LD_{50} dermal ‡	1000 mg/kg bw (males) -1930 mg/kg bw (females)	Xn; R21
Rat LC_{50} inhalation ‡	8.4 mg/L (males) -7.3 mg/L (females) Irritant for the upper airways	T; R23 Xi; R37
Skin irritation ‡	corrosive	C; R34
Eye irritation ‡	severe eye irritant	Xi; R41
Skin sensitisation ‡	sensitiser (M&K)	R43

Short term toxicity (Annex IIA, point 5.3)	**DAZOMET**	
Target / critical effect ‡	Increased liver weight, hepatocyte fatty degeneration	
Relevant oral NOAEL ‡	1.5 mg/kg bw/day (rat, 90-day) 1 mg/kg bw/day (dog, 1-year)	
Relevant dermal NOAEL ‡	100 mg/kg bw/day (rat, 28-day)	
Relevant inhalation NOAEL ‡	-	

Short term toxicity (Annex IIA, point 5.3)	**MITC**	
Target / critical effect ‡	Body weight decrease, haematological and clinical chemistry findings	
Relevant oral NOAEL ‡	0.4 mg/kg bw/day (dog, 90-day)	
Relevant dermal NOAEL ‡	-	
Relevant inhalation NOAEL ‡	-	

Genotoxicity ‡ (Annex IIA, point 5.4)	**DAZOMET and MITC**	
	Not genotoxic	

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

Target/critical effect ‡	Decreased red blood cells, decreased haematocrit, decreased proteins, increase polychromasia/ anisocytosis	
Relevant NOAEL ‡	0.9 mg/kg bw/day (rat, 2-year) 4 mg/kg bw/day (mouse, 78-week)	
Carcinogenicity ‡	Mouse: liver adenoma at 68 mg/kg bw/day, but no carcinoma; not carcinogenic	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Decreased body weight, hepatocellular fatty change (rat)	
Relevant parental NOAEL ‡	0.5 mg/kg bw/day	
Relevant reproductive NOAEL ‡	18 mg/kg bw/day	
Relevant offspring NOAEL ‡	18 mg/kg bw/day	

Developmental toxicity	**DAZOMET**	
Developmental target / critical effect ‡	Decreased uterus weight (maternal), runts (embryo-	

	foetal toxicity) (rat)	
Relevant maternal NOAEL ‡	3 mg/kg bw/day	
Relevant developmental NOAEL ‡	3 mg/kg bw/day	
Developmental toxicity	**MITC**	
Developmental target / critical effect ‡	Decreased body weight gain (rat)	
Relevant maternal NOAEL ‡	3 mg/kg bw/day	
Relevant developmental NOAEL ‡	3 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Not neurotoxic	
Repeated neurotoxicity ‡	Not neurotoxic	
Delayed neurotoxicity ‡	Not applicable	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Dazomet: cell transformation assay (negative)
Studies performed on metabolites or impurities ‡	Extensive literature concerning the volatile degradates formaldehyde and MIC, with sufficient information to support the existing occupational exposure limits. Lowest values: German-MAK of 0.3 ppm = 0.086 mg/kg bw/d for formaldehyde, and of 0.01 ppm (0.006 ppm from reviewed studies) = 0.005 mg/kg bw/d for MIC.

Medical data ‡ (Annex IIA, point 5.9)

Epidemiological evidence after accidents: rapid (< 24h) onset of chiefly upper- but also lower airway irritation consistent with RADS (Reactive Airway Dysfunction Syndrome), and potential to aggravate pre-existing asthma. Symptoms include nose and throat irritation, shortness of breath, chest tightness, cough, wheezing. Early symptoms also include eye irritation, or skin rash and itching. Clinical data indicate skin sensitizing potential (human patch test). Dazomet may cause bullous eruption, sore itching, erythema, oedema and scaling after skin contact, most probably caused by MITC. Systemic effects like hepatotoxicity (increase of transaminases) are possible, as well as gastro-intestinal dysfunction (nausea, irritation, vomiting), and more general symptoms (headache, dizziness).

Summary (Annex IIA, point 5.10) **DAZOMET**

	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw/day	2-year rat, diet	100
AOEL ‡	0.015 mg/kg bw/day	90-day rat, diet	100
ARfD ‡	0.03 mg/kg bw	rat developmental	100

Summary (Annex IIA, point 5.10) **MITC**

	Value	Study	Safety factor
ADI ‡	0.004 mg/kg bw/day	90-day dog, oral, gavage	100
AOEL ‡	0.004 mg/kg bw/day	90-day dog, oral, gavage	100
ARfD ‡	0.03 mg/kg bw	rat developmental	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Basamid, GR)	3% on active substance (the formulation is 97% pure active substance)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Loading + application: 62 % of AOEL (**Dazomet**)[A, C] Loading + application: 10 % of AOEL (**MITC**)[A, C]
Workers	Film application, day 1: 3 % (driver) - 7 % (worker) of AOEL (**Dazomet**)[B,C] Film application, day 1: 6 % (driver) - 8 % (worker) of AOEL (**MITC**)[B,C] Film removal, day 21: 0.4 % (worker) of AOEL (**MITC**)[B,C] Soil rotovation, day 28: 0.2 % (driver) of AOEL (**MITC**)[B,C]
Bystanders	Dazomet: calculated estimate for an unprotected bystander, staying 1h in the neighbourhood of a field during granule incorporation 36 % of the AOEL (**Dazomet**)[C] MITC: based upon ambient peak concentration during the period d1-d4, continuous monitoring, and 1h presence in the middle of the field. 60% of the AOEL (**MITC**)[C]

A: PPE (coverall, nitrile gloves and boots) and RPE (A1P2, combi-filter protecting for both particle and organic vapour, with a protection of at least 98%) were used; tractors were equipped with air-conditioned cabins with carbon filters.
B: RPE not needed, but the same PPE was worn as for operators.
C: A work rate of 1.5 ha/day using Surefill containers and a work rate of 1 ha/day using form-fill-seal (FFS) bags were assumed.

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

	RMS/peer review proposal
Substance classified (name)	**DAZOMET** Xn; R22 Harmful if swallowed Xi; R36/R37/38 Irritating to eyes, respiratory system, skin R43 May cause sensitisation by skin contact
	MITC Xn; R21Harmful in contact with skin T; R23/25 Toxic by inhalation and if swallowed Xi; R37 Irritating to respiratory system C; R34 Causes burns R43 May cause sensitisation by skin contact

Residues

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

Plant groups covered	-Root/tuber vegetables (radishes) -Fruit (tomatoes, strawberries) -Leafy vegetables (Chinese cabbage)
Rotational crops	Studies not required.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. The primary crops can be regarded as rotational crops according to the GAP.
Processed commodities	Processing studies not required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-
Plant residue definition for monitoring	MITC
Plant residue definition for risk assessment	MITC
Conversion factor (monitoring to risk assessment)	None.

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

Animals covered	Metabolism studies not required.
Time needed to reach a plateau concentration in milk and eggs	-
Animal residue definition for monitoring	Not required.
Animal residue definition for risk assessment	Not required.
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	No. Log $P_{o/w}$ for Dazomet: 0.63

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

	Not required when considering the DT_{50}. -*Northern and Central Europe:* DT_{50} Dazomet: 1.1 d DT_{50} MITC: 7.4 d -*Southern Europe:* DT_{50} Dazomet: 1.16-1.49 d DT_{50} MITC: 2.1-2.77 d

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

	When stored at -20°C, MITC residues stable up to: - 2 months in tomato (extrapolated from recoveries after 1 month (85 %) and 3 months (55 %)). - 3 months in pepper and strawberry (borderline since recoveries 67 – 68 % only).

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):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not required	Not required	Not required
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Livestock metabolism studies are not required since significant residues (> 0.1 mg/kg DM) were not recovered in potential livestock feed. Moreover, the representative uses (strawberry, lettuce, tomato) are not considered as potential feeding stuffs for livestock and no dietary burden calculation must be achieved.

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

Crop	Northern Southern Region field or glasshouse	Trials results relevant to representative uses (a)	**Recommendation/comments**	**MRL** estimated from trials according to representative use	**HR** (c)	**STMR** (b)
Strawberry	NE (Outdoor)	Whole fruit: 4x <0.01 Soil: 0.238, 0.165, 0.130, 0.070	485 kg a.s./ha, 1 application, PHI: 258 to 281 days (BBCH 85).	0.01*	0.01*	0.01*
	USA (considered representa-tive of southern EU)	Whole fruit: 22x <0.02 The samples were analysed for the determination of MITC according to the Mc Kenzie Laboratories method N0. PRM-044, validated with a LOQ of 0.02 mg/kg. However, this method does not meet the requirement for MRLs enforcement purposes (see Vol 3, point B.5.2.1.1).	514 to 599 kg a.s./ha, 1 application, PHI: 59 to 198 days. These residue trials were carried out in California (Mediterranean climate), in Florida, and North Carolina (humid subtropical climate). These States can be considered as representative for Southern Europe. Three other trials conducted in Oregon, Indiana and Pennsylvania, which do not have a similar climate, were provided in order to confirm the "no-residue" situation. In all trials, residues were below the LOQ in the whole fruit (0.02 mg/kg for MITC and 0.01 mg/kg for both DMTU and MMTU).			
Lettuce	NE	Lettuce head: 4x <0.01 Soil: 0.104, 0.259, 0.320, 0.337	485 kg a.s./ha, 1 application onto the soil, PHI : 56 to 62 days (BBCH 49).	0.01*	0.01*	0.01*
	SE	No data provided.	No further trial on lettuce for Southern Europe is required.			
Tomato	NE	No data provided.	485 kg a.s./ha, 1 application onto the soil, PHI: 86 to 110 days (BBCH growth stage 81)-Indoor conditions. The database provided under greenhouse conditions can be considered as complete, covering Northern and Southern EU due to the situation of no residue.	0.01*	0.01*	0.01*
	SE (Indoor)	Tomato fruit: 4x <0.01 Soil : 0.029, 0.044, 0.521, 0.694				

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

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

ADI	**MITC**: 0.004 mg/kg bw/day	
TMDI (% ADI) according to WHO European diet	-	
TMDI (% ADI) according to national (to be specified) diets	-	
TMDI (% ADI) according to EFSA PRIMo rev.2a	Highest TMDI: 0.9 % ADI (WHO Cluster diet B)	
IEDI (WHO European Diet) (% ADI)	-	
NEDI (specify diet) (% ADI)	-	
Factors included in IEDI and NEDI	-	
ARfD	**MITC**: 0.03 mg/kg bw	
IESTI (% ARfD) according to EFSA PRIMo rev.2a	Children: 1.9 % tomatoes 0.9 % lettuce 0.5 % strawberries	Adults: 0.5 % tomatoes 0.4 % lettuce 0.2 % strawberries
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-	
Factors included in IESTI and NESTI	None.	

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

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

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

Strawberries (field)	0.01*
Lettuce (field)	0.01*
Tomato (indoor conditions)	0.01*

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Environmental fate and behaviour

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

Mineralization after 100 days ‡	Values up to 75.8 % AR are reported. However, these measurements are highly uncertain. The order of the traps for volatiles in most of the available experiments does not guarantee correct quantification of CO_2 and volatilised MITC. In most experiments the NaOH trap preceded the organic trap. In the NaOH trap a non-negligible portion of volatilized MITC could have been hydrolysed. In the only study where organic trap preceded the NaOH trap most of the volatiles (up to 14.1 % AR) corresponded to MITC. Mineralisation was practically negligible (0.74 – 3.6 % AR). However, this study was too short (48 h) to derive conclusive end points.
Non-extractable residues after 100 days ‡	13.2-28.0 % after 34-64d (study termination), [2-^{14}C]-label (n= 4) 28.6 % after 14 d (study termination), [4,6-C14, 5-N-methyl-^{14}C]-label (n= 1) 4-9% after 48 hours (study termination), [2-^{14}C]-label (n= 3)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	MITC: max level of 49-74% (including amounts in traps for volatiles) at 1-2 d [2-^{14}C]-label (n= 7). At least partly underestimated due to the order of the volatile traps. TDL-S: max level of 16.0-45 % at 0 d both labels (n= 8) Methylamine: max level of 9.2% at 4 d [4,6-C14, 5-N-methyl-^{14}C]-label (n= 1) Formaldehyde: max level of 20.5% at 0 d [4,6-C14, 5-N-methyl-^{14}C]-label (n= 1) Formic acid, max. 8.1% after 1 day [4,6-C14, 5-N-methyl-^{14}C]-label (n= 1)

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

Anaerobic degradation ‡

Mineralization after 100 days	7.8 % after 120 d, [2-^{14}C]-label (n= 1)
Non-extractable residues after 100 days	30.3 % after 120 d, [2-^{14}C]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	MITC: max level of 72.0 % at 2 d [2-^{14}C]-label (n= 1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	MITC: max level of 72.9 % and 75.5 % respectively for irradiated and dark samples, after 24 h [2-^{14}C]-label (n= 1)

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

Laboratory studies ‡

Parent	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (chi²)	Method of calculation
Bruch West silty sand (Reinhard – 2003)	7.8 (H2O)	20°C/40% MWHC	3.19/10.6 (DT_{50} by Pseudo-SFO)	-	13.9	FOMC α : 0.19 β : 0.001
Bruch West silty sand (Herrchen – 2009a)	7.1 (CaCl2)	20°C/40% MWHC	0.07/0.23 (DT_{50} by Pseudo-SFO)	-	9.1	DFOP
Li35b silty sand (Ebert 2003)	7.4 (H2O)	20°C/40% MWHC	0.34 / 1.13 (DT_{50} by Pseudo-SFO)	-	7.4	DFOP
Lufa 2.2 silty sand (Ebert - 2003)	6.6 (H2O)	20°C/40% MWHC	0.6 / 2 (DT_{50} by Pseudo-SFO)	-	11.2	DFOP
Lufa 2.2 silty sand (Herrchen – 2009a)	5.4 (CaCl2)	20°C/40% MWHC	0.17 / 0.57 (DT_{50} by Pseudo-SFO)	-	7.6	DFOP
Lufa 3A silty sand (Ebert - 2003)	7.8 (H2O)	20°C/40% MWHC	5.4 / 18 (DT_{50} by Pseudo-SFO)	-	9.1	DFOP
Refesol 01-A loamy sand (Herrchen – 2009a)	5.6 (CaCl2)	20°C/50% MWHC	0.24 / 0.8 (DT_{50} by Pseudo-SFO)	-	6.6	DFOP
Li35b silty sand	7.4	10°C/40% MWHC	1.3/4.4	-	0.89	SFO non linear
Geomean DT_{50} at 20°C			0.52			

MITC	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (chi²)	Method of calculation
Bruch West silty sand (Reinhard – 2003)	7.8 (H2O)	20°C/40% MWHC	9.96 / 33.6	0.48	-	12.9	SFO
Li35b silty sand (Ebert 2003)	7.4 (H2O)	20°C/40% MWHC	10.3 / 34.3	0.42	-	3.8	SFO
Lufa 2.2 silty sand (Ebert - 2003)	6.6 (H2O)	20°C/40% MWHC	4.67 / 15.5	0.39	-	9.8	SFO
Lufa 3A silty sand (Ebert - 2003)	7.8 (H2O)	20°C/40% MWHC	10.7 / 35.5	0.46	-	20.1	SFO
Li35b silty sand	7.4	10°C/40% MWHC	32.7/108.8	-	-	0.89	SFO non-linear
Geomean DT_{50} at 20°C / geometric mean for f.f.			≥ 8.5	0.44			

TDL-S	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (chi²)	Method of calculation
Bruch West silty sand (Reinhard – 2003)	7.8 (H2O)	20°C/40% MWHC	43.7 / 89.9 (DT_{50} based on k2)	0.28	-	14	DFOP
Bruch West silty sand (Herrchen – 2009a)	7.1 ($CaCl_2$)	20°C/40% MWHC	0.13 / 0.39	0.35	-	13	SFO
Li35b silty sand (Ebert 2003)	7.4 (H2O)	20°C/40% MWHC	0.18 / 0.59	0.39	-	26.7	SFO
Lufa 2.2 silty sand (Ebert - 2003)	6.6 (H2O)	20°C/40% MWHC	2.95 / 1.93 (DT_{50} based on k2)	0.42	-	15.2	DFOP
Lufa 2.2 silty sand (Herrchen – 2009a)	5.4 ($CaCl_2$)	20°C/40% MWHC	0.29 / 1	0.61		16.4	SFO
Lufa 3A silty sand (Ebert - 2003)	7.8 (H2O)	20°C/40% MWHC	15.2 / 50.5	0.20	-	37.5	SFO
Refesol 01-A loamy sand (Herrchen – 2009a)	5.6 ($CaCl_2$)	20°C/50% MWHC	0.28 / 0.94	0.47	-	12.4	SFO
Li35b silty sand	7.4	10°C/40% MWHC	3.6/11.9	-	-	0.99	SFO non-linear
Geomean DT_{50} at 20°C / geometric mean for f.f.			1.21	0.367			

All TDL-S was expected to be fully transformed into MITC (formation fraction of 1 for MITC from TDL-S)

Methylamine	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2) / (chi²)	Method of calculation
Bruch West loamy sand (Janz & Bayer – 2004)	8.04	20°C/40% MWHC	2.04/6.8	-*	-	10.57	SFO non linear
median			2.04				

* obtained from the maximum amount applying a SFO kinetic

Formaldehyde	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2) / (chi²)	Method of calculation
Bruch West loamy sand (Janz & Bayer – 2004)	8.04	20°C/40% MWHC	0.97 / 3.24	*	0.97	14.75	SFO
Ippa (Japan) (Keller – 1980)		22°C/40% MWHC	2.14 / 7.10	-	2.56	6.7	SFO
Lufa 2.3 (Germany) (Keller – 1980)		22°C/40% MWHC	2.32 / 7.70	-	2.78	8.8	SFO
Geomean DT_{50} at 20°C					1.90		

* obtained from the maximum amount applying a SFO kinetic

Formic acid	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Bruch West loamy sand	8.04	20°C/40% MWHC	1.4/4.5	-	-	0.96	SFO non linear
median			1.4				

Field studies ‡

Dazomet	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (chi²)	DT_{50} (d) Norm.	Method of calculation
Loamy silt (plastic cover)	Germany	6.0	0-20	0.78	2.6	0.3	-	DFOP (DT_{50} by Pseudo-SFO)
Loamy sand (no plastic cover)	Spain	6.8	0-20	1.2	3.8	12.3	-	SFO

Field studies ‡

Dazomet	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (chi²)	DT_{50} (d) Norm.	Method of calculation
Loamy sand (plastic cover)	Spain	6.8	0-20	1.4	4.6	9.7	-	DFOP (DT_{50} by Pseudo-SFO)
median				1.2	3.8			

Field studies ‡

MITC	Aerobic conditions (values are uncertain due to the instability of residues in samples during the storage time before its analysis, data have been corrected on basis of storage stability study)							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT_{50} (d)$^{+}$ actual	DT_{90}(d) actual	St. (chi²)	DT_{50} (d) Norm.	Method of calculation
Loamy silt (plastic cover)	Germany	6.0	0-20	7.4	24.5	33.9	-	SFO
Loamy sand (no plastic cover)	Spain	6.8	0-20	2.1	7.1	12.8	-	SFO
Loamy sand (plastic cover)	Spain	6.8	0-20	2.8	9.2	15.5	-	SFO
median				2.8	9.2			

+Corresponds to the half-life of MITC calculated on basis of the whole experiment duration (no significant differences on the dissipation before and after cover plastic coverage were indentified by the kinetic analysis).

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not relevant

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (chi²)	Method of calculation
Bruch West silty sand	7.8	20°C/ flooded	0.0065	-	5.01	DFOP

MITC	Anaerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Bruch West silty sand	7.8	20°C/ flooded	115.3	0.70	-	11.92	SFO
median			115.3				

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Dazomet ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Mississippi - clay	1.418	5.7	-	-	1.834	129	0.833
Maryland - sand	0.229	5.9	-	-	0.904	394	0.825
Maryland - sandy clay loam	0.459	7.1	-	-	0.975	212	0.805
California - sandy loam	0.265	6.1	-	-	0.808	305	0.889
Arithmetic mean						260	0.838
pH dependence, Yes or No			No				

MITC ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Hokkaido Tokachi*	2.56	5.8 (KCl)			0.68	27	1.12
Refesol 01-A - loamy sand	1.02	5.55	-	-	0.21	20.2	0.845
Refesol 03- G - clay loam	4.03	7.25	-	-	0.42	10.5	0.819
Refesol 04-A – loamy sand	2.84	5.41	-	-	0.43	15.3	0.825
Refesol 05-G – loam	3.29	4.78	-	-	0.42	12.7	0.905
Refesol 06-A – loam	2.74	6.86	-	-	0.25	9.0	0.755
Arithmetic mean						15.8	0.88
pH dependence (yes or no)			no				

*From the only experiment considered valid in Komattsu K, 1990 study (Belgium, 2009)

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

Column leaching ‡	Not required
Aged residues leaching ‡	Not required
Lysimeter/ field leaching studies ‡	Location: Schmallenberg (Germany) Study type: lysimeter Soil properties: sand (Borstel, Germany), pH = 6.2-5.5 ,

	OC= 1.5% in the 0-30 cm upper layer, MWHC = 20-34% in vol in the 0-30 cm upper layer Crop: lettuce, cabbage and spring barley during first year, winter cereals and potatoes during 2^{nd} and 3^{rd} year Interception estimated: 0%, lysimeters covered with a polyethylene foil after incorporation. The foil has been removed after one week Number of applications, application rate, date of application, duration: 1 application of 598 kg a.s./ha on 09/05/90 (spring appl.), every 3 years 1 application of 400 kg a.s./ha on 30/05/90 (spring appl.), every 3 years 1 application of 210 kg a.s./ha on 04/09/90 (autumn appl.), every 3 years Average annual rainfall (mm): 900 mm Average annual leachate volume (mm): 773-941 mm % radioactivity in leachate (maximum/year): x % AR Individual annual maximum concentrations: Due to very short DT_{50} of dazomet, no effort was made to determine the a.s. < 0.1 µg MITC/L in the 3 lysimeters on 1^{st} and 2^{nd} years 14.63 to 180.02 µg CO_2/L in the 3 lysimeters on 1^{st} year 85.6-372.4 µg a.s. equivalent / L as NIR in the 3 lysimeters on 1^{st} year (Not Identified Radioactivity is constituted of polar substances) Individual annual average concentrations: Due to very short DT_{50} of dazomet, no effort was made to determine the a.s. < 0.1 µg MITC/L in the 3 lysimeters on 1^{st} and 2^{nd} years 0.4-62.3 µg CO_2/L in the 3 lysimeters on 1^{st} and 2^{nd} years 4.6-126.9 µg a.s. equivalent / L as NIR in the 3 lysimeters on 1^{st} and 2^{nd} years (Not Identified Radioactivity is constituted of polar substances) Amount of radioactivity in the soils at the end of the study: 4-6% AR; not further characterised

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	Models : ESCAPE 2.0 for dazomet and MITC ESCAPE 2.0 (without normalization activation) for dazomet and TDL-S Excel sheets for formaldehyde and methylamine

Dazomet

Method of calculation **Dazomet and MITC**	**Dazomet Field DT_{50}:** Double first-order in parallel DT_{50} 1 = 0.062 days DT_{50} 2 = 1.11 days FF Dazomet_MITC (%): 100 **MITC Field DT_{50}:** Single first-order kinetic DT_{50} = 7.4 days The degradation of the precursor dazomet and the formation are taken into account
Method of calculation **Dazomet and TDL-S**	**Dazomet lab DT_{50}:** Single first-order kinetic DT_{50} = 0.2 day FF Dazomet_TDL-S (%): 58.7 **TDL-S lab DT_{50}:** Single first-order kinetic DT_{50} = 0.29 day The degradation of the precursor dazomet and the formation are taken into account
Method of calculation **Dazomet – formaldehyde**	PECs formaldehyde based on the initial PECs value of the precursor dazomet, assuming the theoretically maximum formation rate of 200%. **formaldehyde lab DT_{50}:** Single first-order kinetic DT_{50} = 2.78 days
Method of calculation **Dazomet – methylamine**	PECs methylamine based on the initial PECs value of the precursor dazomet, assuming the theoretically maximum formation rate of 100%. **methylamine lab DT_{50}:** Single first-order kinetic DT_{50} = 2.04 days
Application rate	1 x 500 kg dazomet/ha (20 cm soil depth) 1 x 300 kg dazomet/ha (10 cm soil depth) No crop interception - soil incorporation

<u>**Application rate of 500 kg/ha in treated area – incorporation over 20 cm**</u>

PECs of dazomet with the applicant rate of 500 kg a.s./ha (incorporation over 20 cm)

Dazomet	Time [d]	$PEC_{s,act}$ [mg kg^{-1}]	$PEC_{s,twa}$ [mg kg^{-1}]
Initial	0	166.6667	---
Short-term	1	44.8983	105.7825
	2	24.0448	70.1270
	4	6.8964	42.1505
Long-term	7	1.0593	25.4644
	14	0.0134	12.8557
	21	0.0002	8.5715
	28	<0.0001	6.4287
	42	<0.0001	4.2858
	50	<0.0001	3.6000
	100	<0.0001	1.8000

PECs of MITC with the applicant rate of 500 kg a.s./ha (incorporation over 20 cm)

MITC	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	59.3330	---
Short-term	1	59.0576	59.1953
	2	56.4707	58.4797
	4	48.9097	57.1789
Long-term	7	37.5916	52.7977
	14	19.5992	41.9269
	21	10.1748	33.7345
	28	5.2817	27.5526
	42	1.4232	19.5522
	50	0.6727	16.6172
	100	0.0062	8.3945

($PEC_{s,act}$ at 49 DAT amounts to 0.739 mg/kg)

PECs of TDL-S with the applicant rate of 500 kg a.s./ha (incorporation over 20 cm)

TDL-S	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	86.5423	---
Short-term	1	10.633	48.5876
	2	1.0587	45.9294
	4	0.0092	24.5709
Long-term	7	<0.0001	14.0491
	14	<0.0001	7.0245
	21	<0.0001	4.683
	28	<0.0001	3.5123
	42	<0.0001	2.3415
	50	<0.0001	1.9669
	100	<0.0001	0.9834

PECs of formaldehyde with the applicant rate of 500 kg a.s./ha (incorporation over 20 cm)

Formaldehyde	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	61.790	-
Short-term	1	48.283	54.759
	2	37.728	48.774
	4	23.036	39.277
Long-term	7	10.991	29.420
	14	1.955	17.326
	21	0.348	11.861
	28	0.062	8.937
	42	0.002	5.964
	49	< 0.001	5.112
	50	< 0.001	5.010
	100	< 0.001	2.505

($PEC_{s,act}$ at 49 DAT amounts to < 0.001 mg/kg)

PECs of methylamine with the applicant rate of 500 kg a.s./ha (incorporation over 20 cm)

Methylamine	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	31.897	-
Short-term	1	22.708	27.043
	2	16.167	23.148
	4	8.194	17.440
Long-term	7	2.957	12.168
	14	0.274	6.648
	21	0.025	4.467
	28	0.002	3.352

Methylamine	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
	42	< 0.001	2.235
	50	< 0.001	1.878
	100	< 0.001	0.939

($PEC_{s,act}$ at 49 DAT amounts to < 0.001 mg/kg)

Application rate of 300 kg/ha in treated area – incorporation over 10 cm

PECs of dazomet with the applicant rate of 300 kg a.s./ha (incorporation over 10 cm)

Dazomet	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	200.0000	-
Short-term	1	53.8779	126.9390
	2	28.8537	84.1524
	4	8.2757	50.5805
Long-term	7	1.2712	30.5573
	14	0.0161	15.4269
	21	0.0002	10.2858
	28	< 0.0001	7.7144
	42	< 0.0001	5.1429
	50	< 0.0001	4.3201
	100	< 0.0001	2.1600

PECs of MITC with the applicant rate of 300 kg a.s./ha (incorporation over 10 cm)

MITC	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	71.1996	-
Short-term	1	70.8691	71.0344
	2	67.7648	70.1757
	4	58.6917	68.6147
Long-term	7	45.1099	63.3572
	14	23.5191	50.3123
	21	12.2098	40.4814
	28	6.3380	33.0632
	42	1.7078	23.4626
	50	0.8072	19.9406
	100	0.0075	10.0734

($PEC_{s,act}$ at 49 DAT amounts to 0.886 mg/kg)

PECs of TDL-S with the applicant rate of 300 kg a.s./ha (incorporation over 10 cm)

TDL-S	**Time [d]**	**$PEC_{s,act}$ [mg kg^{-1}]**	**$PEC_{s,twa}$ [mg kg^{-1}]**
Initial	0	103.8507	--
Short-term	1	12.7596	58.3052
	2	1.2704	55.1153
	4	0.0111	29.4851
Long-term	7	<0.0001	16.8589
	14	<0.0001	8.4295
	21	<0.0001	5.6196
	28	<0.0001	4.2147
	42	<0.0001	2.8098
	50	<0.0001	2.3602
	100	<0.0001	1.1801

PECs of formaldehyde with the applicant rate of 300 kg a.s./ha (incorporation over 10 cm)

Formaldehyde	**Time**	**$PEC_{s,act}$**	**$PEC_{s,twa}$**
	[d]	**[mg kg^{-1}]**	**[mg kg^{-1}]**
Initial	0	74.000	-
Short-term	1	57.823	65.580
	2	45.183	58.412
	4	27.588	47.038
Long-term	7	13.162	35.233
	14	2.341	20.750
	21	0.416	14.205
	28	0.074	10.703
	42	0.002	7.142
	49	< 0.001	6.122
	50	< 0.001	6.000
	100	< 0.001	3.000

($PEC_{s,act}$ at 49 DAT amounts to < 0.001 mg/kg)

PECs of methylamine with the applicant rate of 300 kg a.s./ha (incorporation over 10 cm)

Methylamine	**Time**	**$PEC_{s,act}$**	**$PEC_{s,twa}$**
	[d]	**[mg kg^{-1}]**	**[mg kg^{-1}]**
Initial	0	38.200	-
Short-term	1	27.196	32.387
	2	19.361	27.722
	4	9.813	20.886
Long-term	7	3.541	14.572
	14	0.328	7.961
	21	0.030	5.349
	28	0.003	4.015
	42	< 0.001	2.677
	50	< 0.001	2.249
	100	< 0.001	1.124

($PEC_{s,act}$ at 49 DAT amounts to < 0.001 mg/kg)

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	[2-^{14}C]-dazomet at 25°C Dazomet pH 4: 0.4 d at 25 °C (SFO, non-linear) pH 7: 0.2 d at 25 °C (SFO, non-linear) pH 9: 0.1 d at 25 °C (SFO, non-linear) MITC max. 81.7% of AR at day 2 (pH 4) max. 83.4% of AR at day 7 (pH 7) max. 62.6% of AR at day 2 (pH 9) pH 4: 107.3 d at 25 °C (SFO, non-linear, calculated from maximum observed) pH 7: 104.6 d at 25 °C (SFO, non-linear, calculated from maximum observed) pH 9: 11.1 d at 25 °C (SFO, non-linear, calculated from maximum observed)) Carbon disulfide (CS_2) max. 11.5% of AR at day 1 (pH 4) max. 25.7% of AR after 12 hrs (pH 7) max. 8.8% of AR after 6 hrs (pH 9) DMTU max. 10.1% of AR at day 30 (pH 7) max. 6.3% of AR at day 30 (pH 9) (methylamino)(thioxo)methanesulfenic acid or isomer hydroxymethyldithiocarbamic acid (=M123) max. 24.1% of AR at day 1 (pH 7) max. 34.0% of AR after 12 hrs (pH 9) (methylamino)thioxo)methanethiosulfenic acid and [1,2,4]dithiazolidine-3-thione (= M137 + M139) *(could not be separated)* max. 25.1% of AR after 9 hrs (pH 7) max. 25.4% of AR after 6 hrs (pH 9) dissolved CO_2 max. 50.4% of AR at day 21 (pH 9)

	[4,5,6-N-methyl-[14]C]-dazomet, at 25°C in pH 4, 7 and 9 buffer solutions: <u>methylamine (CH_3NH_2):</u> max. conc. in range of 26% to 30% of AR, reached their maximum after 1 or 2 days and remained almost constant during the rest of the test period <u>formaldehyde (CH_2O):</u> max. conc. in range of 66% to 73% of AR , reached their maximum after 1 or 2 days and remained almost constant during the rest of the test period
Photolytic degradation of active substance and metabolites above 10 % ‡	<u>Dazomet</u> DT_{50} : 3.6-4.7 h under light conditions, 8.2-6.4 hours under dark conditions Estimated DT_{50} at 35°N 7.6-9.9 hours <u>MITC</u> Estimated DT_{50} at 35°N 885-980 hours <u>M91</u> Estimated DT_{50} at 35°N 92.8-680 hours <u>N-methylformamide</u> 30-36% AR at day 30
Quantum yield of direct phototransformation in water at Σ > 290 nm	Φ= 1.04 x 10^{-2} mol/Einstein
Readily biodegradable ‡ (yes/no)	a.s. not ready biodegradable MITC not ready biodegradable

Degradation in water / sediment

Parent	Distribution (max in water 94.4-105.9% at 0 d. Max. sed 0.2-1.3 % after 0.25-2 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} Sed	St. (r^2)	Method of calculation
Kellmetschweiher	8.25	6.8	20	0.63 – 2.08	9.6				-	SFO
Berghäuser Altrhein	7.6	7.4	20	0.40 – 1.32	18.2				-	SFO
median				0.52 – 1.7						

MITC	Distribution Max. in water 59.9-64.3 %AR after 2-4 d. Max. in sediment 5.1-10.4 % after 4-8 d. Max. in volatile traps 49.5-56.6% after 59-100 d. Updated kinetic analysis for MITC in whole system (amount in water plus sediment, plus volatilised, plus CO_2)								
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} Sed	St. (r^2)	Method of calculation
Kellmetschweiher	8.25	6.8	20	> 1000 - >1000	7.1					SFO
Berghäuser Altrhein	7.6	7.4	20	> 1000 - >1000	9.9					SFO
median				>1000 - >1000						

Methylamine	Distribution (max. in water 20.5-18.2 %AR after 2 d. Max. sed 1.5-2.5 % after 14-30 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} Sed	St. (r^2)	Method of calculation
Kellmetschweiher	8.25	6.8	20	16.1-53.6	0.98	12.8-42.4	0.98	Not calculated	-	SFO, non linear
Berghäuser Altrhein	7.6	7.4	20	9.2-30.7	0.98	6.6-21.8	0.98	Not calculated	-	SFO, non linear
median				12.7-42.1		9.7-32.1				

Formic acid	Distribution (max. in water 57.7-43.8 %AR after 2-4 d. Max. sed 6.7-4.2 % after 4-59 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} Sed	St. (r^2)	Method of calculation
Kellmetschweiher	8.25	6.8	20	34.7-115.1	0.98	29.0-96.3	0.98	5.2-17.3	0.98	SFO, non linear
Berghäuser Altrhein	7.6	7.4	20	6.1-20.3	0.98	5.7-18.8	0.98	0.6-3.8	0.98	SFO, non linear
median				20.4-67.7		17.3-57.6		2.9-10.6		

MATM	Distribution (max. in water 11.0-14.8 %AR after 2-1 d. <0.1% AR in sediment)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} Sed	St. (r^2)	Method of calculation
Kellmetschweiher	8.25	6.8	20	0.5-1.5	0.98	0.5-1.5	0.98	Not calculated	-	SFO, non linear
Berghäuser Altrhein	7.6	7.4	20	0.7-2.4	0.98	0.7-2.4	0.98	Not calculated	-	SFO, non linear

median		0.6-19.5		0.6-19.5				

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization (end of the study)	Non-extractable residues in sed. max	Non-extractable residues in sed. (end of the study)
Kellmetschweiher	8.25	6.8	17.6-36.7 %AR after 100 d.	7.1-31.6 %AR after 59 d.	6.7-26.0 %AR after 100 d.
Berghäuser Altrhein	7.6	7.4	66.6-80.6%AR after 100 d.	12.2-28.5 %AR after 59-14 d.	7.9-17.7 %AR after 100 d.

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

Dazomet, MATM, TDL-S and formaldehyde

Method of calculation	Dazomet is rapidly degraded in moist soil within a few days (DTf_50 < 2 day). After removal of the VIFilm no residual parent substance will be present to be potentially subjected to run-off or drainage fluxes. Consequently, an estimation of PEC values for the parent substance dazomet was not conducted. Since MATM is a water metabolite of dazomet, intermediate in the formation of MITC, and exposure to dazomet is precluded for the representative uses evaluated, no estimation of PEC values for MATM was conducted. Similarly, the degradation products TDL-S and formaldehyde were not considered further, as concentrations in soil rapidly decline, reaching values below 0.01 mg/kg within a maximum of six weeks after application of dazomet.

MITC

Method of calculation	Model FOCUS Steps 1-2 tool: Models FOCUS Step 3: SWASH version 2.1, PRZM, version 2.6, FOCUS-MACRO, version 4.3b, TOXSWA, version 2.5, SWAN, version 1.1.4

Input parameters of MITC for FOCUSsw Step 2

Parameters	Unit	MITC	Reference/ Remark
Substance specific data			
Solubility in water at 25°C	[mg/L]	8940	EFSA conclusion report on Metam-Na
K_{OC}-value	[mL/g]	13.5	Herrchen (2009c)
DT_{50} in soil	[d]	7.65	Klein (2010a), modified during the evaluation period
DT_{50} in sediment/water system	[d]	1000	FOCUS default
DT_{50} in water	[d]	1000	Peter & Klein (2010b)
DT_{50} in sediment	[d]	1000	FOCUS default
Application pattern			
Application rate: nematodes etc., full appl. weeds, full appl.	[g/ha]	2250 Corresponding to the initial application rate of 500 kg a.s./ha	calculated from PECsoil at time of removal of VIFilm after 7 weeks (Klein, 2009c)
Number of applications per season	[-]	1	GAP
Crop interception	[-]	no interception	-
Crop type	[-]	No drift (incorp or seed trtmt)	GAP
Region and season of application	[-]	Northern & Southern Europe ; June - September	-

Input parameters of MITC for FOCUSsw Step 3

Parameters	Unit	MITC	Reference/ Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	73.1	-
Vapour pressure [20°C]	[Pa]	1739	EFSA conclusion report on Metam-Na
Molar enthalpy of vaporisation	[J/mol]	95000	default
Solubility in water [20°C]	[mg/L]	8940	EFSA conclusion report on Metam-Na
Molar enthalpy of dissolution	[J/mol]	27000	FOCUS default
Diffusion coefficient in water	[m²/d]	4.3×10^{-5}	FOCUS default
Diffusion coefficient in air	[m²/d]	0.43	FOCUS default
Sorption parameter			
K_{OC}-value	[mL/g]	13.5	Herrchen (2009c)
Exponent of the Freundlich isotherm	[-]	0.83	Herrchen (2009c)
Ref concentration in liquid phase	[g/m3]	1	FOCUS default
Uptake and Wash-Off			
Factor for the uptake by plant roots in soil:	[-]	0	not applied to crop
Wash-Off factor from crop	[1/mm] [1/cm]	0 [MACRO] 0 [PRZM]	not applied to crop
Transformation parameters			
Water half-life time at 20°C	[d]	1000	Peter & Klein (2010b)
Soil half-life time at 20°C	[d]	7.65	Klein (2010a), modified during the evaluation period
Sediment half-life time at 20°C	[d]	1000	Peter & Klein (2010b)
Crop half-life time at 20°C	[d]	10.00	default

Activation energy (TOXSWA)	[J/mol]	65400	PPR Panel (2007)
Exponent (MACRO)	[1/K]	0.0948	PPR Panel (2007)
Q10fac (PRZM)	[-]	2.58	PPR Panel (2007)
Metabolism scheme			
Metabolism	[-]	MITC as "parent only"	Klein (2009b)
Management related substance parameters			
Crops	[-]	Vegetables, leafy	GAP
Application rate: nematodes etc., full application nematodes etc., bandw. appl. weeds, full application weeds, bandw application Bandwise appl. are applications where a 2-meter untreated zone is left between treated strips of 4 meters. PECsw/sed with this kind of application are obtained by multiplying with a factor of 2/3 the PECsw/sed of the corresponding full application rate.	[kg/ha]	 2.25 1.50 1.35 0.864	calculated from PECsoil at time of removal of VIFilm after 7 weeks (Klein, 2009c)
Number of applications		1	GAP
Dates of application	[-]	According to PAT	Jul-Aug
Application method nematodes etc., full application nematodes etc., bandw. appl. weeds, full application weeds, bandw application	[-]	soil incorporation at 0.2 m 0.2 m 0.1 m 0.1 m	GAP

STEP 2 results

Step 2 PECsw and PECsed of MITC ("application rate": 2.25 kg/ha) prior to planting of lettuce (vegetables, leafy) corresponding to an application of dazomet at 500 kg/ha – Northern Europe

Time after maximum peak [d]	PECsw [µg/L]		PECsed [µg/kg]	
	Actual	TWA	Actual	TWA
0	102.5515	---	13.8445	---
1	102.4805	102.516	13.8349	13.8397
2	102.4095	102.4805	13.8253	13.8349
4	102.2676	102.4095	13.8061	13.8253
7	102.0552	102.3032	13.7774	13.8109
14	101.5612	102.0556	13.7108	13.7775
21	101.0696	101.8088	13.6444	13.7442
28	100.5804	101.5628	13.5784	13.711
42	99.6091	101.0732	13.4472	13.6449
50	99.0583	100.7948	13.3729	13.6073
100	95.684	99.0781	12.9173	13.3755

Step 2 PECsw and PECsed of MITC ("application rate": 2.25 kg/ha) prior to planting of lettuce (vegetables, leafy) corresponding to an application of dazomet at 500 kg/ha – Southern Europe

Time after maximum peak [d]	PECsw [µg/L]		PECsed [µg/kg]	
	Actual	TWA	Actual	TWA
0	153.8273	---	20.7667	---
1	153.7207	153.774	20.7523	20.7595
2	153.6142	153.7207	20.7379	20.7523
4	153.4014	153.6143	20.7092	20.7379
7	153.0827	153.4547	20.6662	20.7164
14	152.3418	153.0833	20.5661	20.6663
21	151.6044	152.7132	20.4666	20.6163
28	150.8706	152.3442	20.3675	20.5665
42	149.4136	151.6098	20.1708	20.4673
50	148.5874	151.1922	20.0593	20.4109
100	143.526	148.6171	19.376	20.0633

STEP 3 results

Step 3 PECsw and PECsed of MITC ("application rate": 2.25 kg/ha) after application of dazomet (500 kg a.s./ha) prior to planting of lettuce – exposition by drainage/run-off

Scenario	Global max. concentration in surface water [µg/L]	Global max. concentration in sediment [µg/kg]
D3 Vredepeel; ditch	0.050	0.099
D4 Skousbo; pond	0.071	0.062
D4 Skousbo; stream	1.051	0.659
R1 Weiherbach; pond	0.040	0.006
R1 Weiherbach; stream	0.646	0.076
D6 Thiva; ditch	< 0.001	< 0.001
R2 Porto; stream	0.034	0.004
R3 Bologna; stream	1.126	0.155
R4 Roujan; stream	2.256	0.302

Step 3 PECsw and PECsed of MITC ("application rate": 1.35 kg/ha) after application of dazomet (300 kg a.s./ha) prior to planting of lettuce – exposition by drainage/run-off

Scenario	Global max. concentration in surface water [µg/L]	Global max. concentration in sediment [µg/kg]
D3 Vredepeel; ditch	0.023	0.049
D4 Skousbo; pond	0.039	0.035
D4 Skousbo; stream	0.520	0.354
R1 Weiherbach; pond	0.048	0.007
R1 Weiherbach; stream	0.761	0.088
D6 Thiva; ditch	< 0.001	< 0.001
R2 Porto; stream	0.017	0.002
R3 Bologna; stream	1.343	0.183
R4 Roujan; stream	2.683	0.355

STEP 4 results

Predicted Environmental Concentrations of MITC in surface water using band application (2-meter untreated zone is left between treated strips of 4 meters) as mitigation measure

Step 4 PECsw and PECsed of MITC after band application of dazomet at an apparent dose rate of 2/3 × 500 kg a.s./ha = 333 kg a.s./ha prior to planting of lettuce - exposition by drainage/run-off

Scenario		Global max. concentration in surface water [µg/L]	Global max. concentration in sediment [µg/kg]
D3	Vredepeel; ditch	0.033	0.066
D4	Skousbo; pond	0.047	0.041
D4	Skousbo; stream	0.701	0.439
R1	Weiherbach; pond	0.027	0.004
R1	Weiherbach; stream	0.431	0.051
D6	Thiva; ditch	< 0.001	< 0.001
R2	Porto; stream	0.023	0.003
R3	Bologna; stream	0.751	0.103
R4	Roujan; stream	1.504	0.201

Note: PECsw and PECsed calculated with an application rate of 500 kg a.s./ha were multiplied by a factor of 2/3.

Step 4 PECsw and PECsed of MITC after band application of dazomet at an apparent dose rate of 2/3 × 300 kg a.s./ha = 192 kg a.s./ha prior to planting of lettuce - exposition by drainage/run-off

Scenario		Global max. concentration in surface water [µg/L]	Global max. concentration in sediment [µg/kg]
D3	Vredepeel; ditch	0.015	0.033
D4	Skousbo; pond	0.026	0.023
D4	Skousbo; stream	0.347	0.236
R1	Weiherbach; pond	0.032	0.005
R1	Weiherbach; stream	0.507	0.059
D6	Thiva; ditch	< 0.001	< 0.001
R2	Porto; stream	0.011	0.001
R3	Bologna; stream	0.895	0.122
R4	Roujan; stream	1.789	0.237

Note: PECsw and PECsed calculated with an application rate of 300 kg a.s./ha were multiplied by a factor of 2/3.

Predicted Environmental Concentrations of MITC in surface water due to deposition after volatilisation

Step 4 PECsw after deposition of volatilised MITC in different distances from the edge of field for all relevant FOCUS scenarios and each of the initial dazomet application rates

Application amount of Dazomet [kg/ha]			500 kg/ha		333 kg/ha		300 kg/ha		192 kg/ha	
FOCUS Scenario			Global max. conc. [µg/L] of MITC after deposition at a distance of							
Scenario	Meteo Station	Water body	30 m	40 m	20 m	30 m	20 m	30 m	10 m	20 m
Northern Europe										
D3	Vredep	ditch	0.64	0.12	0.72	0.21	0.60	0.14	0.71	0.20
D4	Skousb	pond	0.33	0.16	0.37	0.19	0.33	0.17	0.37	0.19
D4	Skousb	stream	0.55	0.30	0.58	0.34	0.53	0.30	0.58	0.34
R1	Weiher	pond	0.28	0.14	0.32	0.16	0.28	0.14	0.32	0.16
R1	Weiher	stream	0.61	0.26	0.66	0.32	0.58	0.27	0.66	0.31
Southern Europe										
D6	Thiva	ditch	0.55	0.05	0.62	0.13	0.51	0.07	0.61	0.13
R2	Porto	stream	0.75	0.40	0.80	0.46	0.72	0.42	0.80	0.46
R3	Bologna	stream	0.09	0.05	0.09	0.05	0.09	0.05	0.09	0.05
R4	Roujan	stream	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	**Modelling** according to FOCUS (2000) FOCUS groundwater scenarios for dazomet, metabolite MITC, metabolite TDL-S, and metabolite formaldehyde using FOCUS **PELMO 3.3.2** and modified climate files in order to reproduce the conditions generated by the coverage of the soil (coverage by VI film for 7 weeks in outdoor for lettuce and strawberries) and in order to reproduce the conditions in glasshouse (tomatoes).
Application rate	nematodes etc., full appl.: 1 x 500 kg a.s./ha nematodes etc., bandwise appl.: 1 x 333 kg a.s./ha weeds, full appl.: 1 x 300 kg a.s./ha weeds, bandwise appl: 1 x 192 kg a.s./ha Bandwise appl. are applications where a 2-meter untreated zone is left between treated strips of 4 meters. PECgw with this kind of application are obtained by multiplying with a factor of 2/3 the PECgw of the corresponding full application rate (e.g. PECgw at 333 kg a.s./ha = 2/3 * PECgw at 500 kg a.s./ha).
Crop	lettuce (cabbage), strawberries, tomato (glasshouse, soil-grown) plant uptake factor used in FOCUS PELMO 3.3.2: 0
Application date and period	Every third year Lettuce, strawberries: April – July Tomatos (glasshouse, soil grown): March
Incorporation depth	nematodes etc., full appl.: 0.2 m nematodes etc., bandw. appl.: 0.2 m weeds, full appl.: 0.1 m weeds, bandw appl.: 0.1 m

Calculation of the proportional transformation rates for [4,6-14C-5-N-methyl-14C]-labelled dazomet (in days^{-1})

Parameters	**Dazomet to Formaldehyde**
Original transformation rate (parent)	1.333 (geomean DT_{50} = 0.52)
Maximum formation rates [%]	200
Proportional transformation rates	2.666
Transformation rate (metabolite to CO_2/Bound residues)	0.3648 (geomean DT_{50} = 1.9)

Calculation of the proportional transformation rates for 2-C14-labelled dazomet (in days^{-1})

Parameters	**Dazomet to TDL-S**	**Dazomet to MITC**	**Dazomet to CO_2/Bound Residues**
Original transformation rate (parent)	1.333 (geomean DT_{50} = 0.52)		
Maximum formation rates [%]	36.7	38.8*	21.0*
Proportional transformation rates	0.4892	0.5172*	0.2799*

*Uncertain due to the uncertainty in the quantifications performed in the laboratory studies.

Calculation of the proportional transformation/volatilisation rates for 2-C14-labelled metabolites of parent dazomet (in days^{-1})

Parameters	**TDL-S to MITC**	**MITC to CO_2/Bound Residues**	**Volatilisation loss MITC**
Transformation rate (metabolite)	0.5729	0.0906	0.0082

Substance-specific input parameters of [4,6-14C-5-N-methyl-14C]-labelled dazomet for the model PELMO 3.3.2

Parameters	**Unit**	**Dazomet**	**Reference/ Remark**
Physico-chemical parameters			
Molecular weight	[g/mol]	162.3	-
pKa-value	[-]	20	Default FOCUS 2000
Saturated vapour pressure [20° C]	[Pa]	0	see modification of climate parameters
Reference pH value at which K_{oc} value was determined	[-]	7	Default FOCUS 2000
Solubility in water [20° C]	[mg/L]	3500	Daum (2000)
Diffusion coefficient air	[cm^2/s]	0.0498	Default FOCUS 2000
Volatilisation depth	[cm]	0.1	Default FOCUS 2000
Degradation parameters			
DT_{50} value	[d]	0.52	Klein (2010a), modified during the evaluation period
Reference temperature	[° C]	20	Default FOCUS 2000
Reference soil moisture	[kPa]	10	Default FOCUS 2000
Parameter, relating degradation rate to soil temperature			
Q10-factor	[-]	2.58	PPR-Panel (2007)
Sorption parameters			
K_{oc}-value	[L/kg]	260	Spare (1992)
Exponent of the Freundlich isotherm	[-]	0.84	Spare (1992)

Substance specific input parameters of formaldehyde ([4,6-14C-5-N-methyl-14C]-labelled dazomet) for the model PELMO 3.3.2

Parameters	Unit	Formaldehyde	Reference/ Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	30.03	
pKa-value	[-]	20	Default FOCUS 2000
Reference pH value at which Koc value was determined	[-]	7	Default FOCUS 2000
Limit for Freundlich	[µg/L]	0.01	Default FOCUS 2000
Annual increase	[%]	0	Default FOCUS 2000
Volatilization depth	[cm]	nr	
Degradation parameters			
DT_{50}	[d]	1.9	Peter & Klein (2010a)
Reference temperature	[°C]	20	Default FOCUS 2000
Reference soil moisture	[kPa]	10	Default FOCUS 2000
Parameter, relating degradation rate to soil temperature			
Q10-factor	[-]	2.58	PPR-Panel (2007)
Sorption parameter			
KOC-value	[mL/g]	37	estimated (HSDB)
Exponent of the Freundlich isotherm	[-]	1	request by EFSA

Substance specific input parameters of 2-C14-labelled dazomet for the model PELMO 3.3.2

Parameters	Unit	Dazomet	Reference/ Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	162.3	-
pKa-value	[-]	20	Default FOCUS 2000
Saturated vapour pressure [20° C]	[Pa]	0	see modification of climate parameters
Reference pH value at which K_{oc} value was determined	[-]	7	Default FOCUS 2000
Solubility in water [20° C]	[mg/L]	3500	Daum, A., 2000 Doc. No. 114-002
Diffusion coefficient air	[cm^2/s]	0.0498	Default FOCUS 2000
Volatilisation depth	[cm]	0.1	Default FOCUS 2000
Degradation parameters			
DT_{50} value	[d]	0.52	Klein (2010a), modified during the evaluation period
Reference temperature	[° C]	20	Default FOCUS 2000
Reference soil moisture	[kPa]	10	Default FOCUS 2000
Parameter, relating degradation rate to soil temperature			
Q10-factor	[-]	2.58	PPR-Panel (2007)
Sorption parameters			
K_{oc}-value	[L/kg]	260	Spare (1992)
Exponent of the Freundlich isotherm	[-]	0.84	Spare (1992)

Substance specific input parameters of TDL-S (2-C14-labelled dazomet) for the model PELMO 3.3.2

Parameters	Unit	TDL-S	Reference/ Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	148.2	
pKa-value	[-]	20	Default FOCUS 2000
Reference pH value at which Koc value was determined	[-]	7	Default FOCUS 2000
Limit for Freundlich	[µg/L]	0.01	Default FOCUS 2000
Annual increase	[%]	0	Default FOCUS 2000
Volatilization depth	[cm]	nr	
Degradation parameters			
DT_{50}	[d]	1.21	Klein (2010a), modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Reference soil moisture	[kPa]	10	Default FOCUS 2000
Parameter, relating degradation rate to soil temperature			
Q10-factor	[-]	2.58	PPR-Panel (2007)
Sorption parameter			
KOC-value	[mL/g]	104.5	estimated (Epi-Win)
Exponent of the Freundlich isotherm	[-]	1	request by EFSA

Substance specific input parameters of MITC (2-C14-labelled dazomet) for the model PELMO 3.3.2

Parameters	Unit	MITC	Reference/ Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	73.12	
pKa-value	[-]	20	Default FOCUS 2000
Reference pH value at which Koc value was determined	[-]	7	Default FOCUS 2000
Limit for Freundlich	[µg/L]	0.01	Default FOCUS 2000
Annual increase	[%]	0	Default FOCUS 2000
Volatilisation depth	[cm]	nr	
Degradation parameters			
DT_{50}	[d]	7.65*	Klein (2010a), modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Reference soil moisture	[kPa]	10	Default FOCUS 2000
Parameter, relating degradation rate to soil temperature			
Q10-factor	[-]	2.58	PPR-Panel (2007)
Sorption parameter			
K_{oc}-value	[mL/g]	13.5	Herrchen (2009c)
Exponent of the Freundlich isotherm	[-]	0.83	Herrchen (2009c)

*Uncertain due to the uncertainty in the quantifications performed in the laboratory studies. The value used should be considered a best-case estimation.

Estimated concentration of [4,6-14C-5-N-methyl-14C]-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for lettuce (cabbage)

Scenario	**500°kg/ha incorporated to 20cm**
Châteaudun	< 0.001
Hamburg	< 0.001
Jokioinen	< 0.001
Kremsmünster	< 0.001
Porto	< 0.001
Sevilla	< 0.001
Thiva	< 0.001

Estimated concentration of [4,6-14C-5-N-methyl-14C]-labelled formaldehyde in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for lettuce (cabbage)

Scenario	**500°kg/ha incorporated to 20cm**
Châteaudun	< 0.001
Hamburg	< 0.001
Jokioinen	< 0.001
Kremsmünster	< 0.001
Porto	< 0.001
Sevilla	< 0.001
Thiva	< 0.001

Estimated concentration of [4,6-14C-5-N-methyl-14C]-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for strawberries

Scenario	**500°kg/ha incorporated to 20cm**
Hamburg	< 0.001
Jokioinen	< 0.001
Kremsmünster	< 0.001
Sevilla	< 0.001

Estimated concentration of [4,6-14C-5-N-methyl-14C]-labelled formaldehyde in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for strawberries

Scenario	**500°kg/ha incorporated to 20cm**
Hamburg	< 0.001
Jokioinen	< 0.001
Kremsmünster	< 0.001
Sevilla	< 0.001

Estimated concentration of 2-C14-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for lettuce (cabbage)

Scenario	**500°kg/ha incorp. to 20cm**	**333°kg/ha incorp. to 20cm**	**300°kg/ha incorp. to 10cm**	**192°kg/ha incorp. to 10cm**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001

Estimated concentration of 2-C14-labelled TDL-S in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for lettuce (cabbage)

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001

Estimated concentration of 2-C14-labelled MITC in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for lettuce (cabbage). This calculation cannot be considered fully reliable due to the limitation of FOCUS models to deal with volatile substances and the uncertainty associated with the formation fraction and degradation rates of MITC.

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	0.137	0.091	0.001	< 0.001
Jokioinen	6.409	4.273	0.002	0.001
Kremsmünster	0.005	0.003	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001

Estimated concentration of 2-C14-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for strawberries

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001

Estimated concentration of 2-C14-labelled TDL-S in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for strawberries

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	<0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001

Estimated concentration of 2-C14-labelled MITC in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PELMO 3.3.2 for strawberries. This calculation cannot be considered fully reliable due to the limitation of FOCUS models to deal with volatile substances and the uncertainty associated with the formation fraction and degradation rates of MITC.

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	0.001	< 0.001	< 0.001	< 0.001
Jokioinen	0.772	0.515	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	**Modelling** according to FOCUS (2000) FOCUS groundwater scenarios for dazomet, metabolite MITC, metabolite TDL-S, and metabolite formaldehyde using **FOCUS PEARL 3.3.3** and modified climate files in order to reproduce the conditions generated by the coverage of the soil (coverage by VI film in outdoor for lettuce and strawberries for a at least 7 weeks) and in order to reproduce the conditions in glasshouse (tomatoes).
Application rate	nematodes etc., full appl.: 1 x 500 kg a.s./ha nematodes etc., bandwise appl.: 1 x 333 kg a.s./ha weeds, full appl.: 1 x 300 kg a.s./ha weeds, bandwise appl: 1 x 192 kg a.s./ha Bandwise appl. are applications where a 2-meter untreated zone is left between treated strips of 4 meters. PECgw with this kind of application are obtained by multiplying with a factor of 2/3 the PECgw of the corresponding full application rate (e.g. PECgw at 333 kg a.s./ha = 2/3 * PECgw at 500 kg a.s./ha).
Crop	lettuce (cabbage), strawberries, tomato (glasshouse, soil-grown) plant uptake factor used in FOCUS PEARL 3.3.3: 0
Application date and period	Every third year Lettuce, strawberries: April – July Tomatoes (glasshouse, soil grown): March
Incorporation depth	nematodes etc., full appl.: 0.2 m nematodes etc., bandw. appl.: 0.2 m weeds, full appl.: 0.1 m weeds, bandw. appl.: 0.1 m

Substance specific input parameters of [4,5,6-N-methyl-14C]-dazomet for the model FOCUS PEARL 3.3.3

Parameters	Unit	Dazomet	Reference/Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	162.3	
Solubility in water (20°C)	[mg/L]	3500	Daum (2000)
Molar enthalpy of dissolution	[kJ/mol]	27	Default FOCUS 2000
Vapour pressure	[Pa]	0	see modification of climate parameters
Molar enthalpy of vaporisation	[kJ/mol]	95	Default FOCUS 2000
Degradation parameters			
DT_{50} soil value (lab / field)	[d]	0.52	Klein (2010a) modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Exponent for the effect of liquid	[-]	0.7	Default FOCUS 2000
Optimum moisture conditions (pF 2 or wetter)	[-]	Yes	Default FOCUS 2000
Molar activation energy	[kJ/mol]	65.4	PPR-Panel (2007)
Diffusion parameters			
Reference temperature for diffusion	[° C]	20	Default FOCUS 2000
Reference diffusion coefficient in water	[m^2/d]	4.3×10^{-5}	Default FOCUS 2000
Reference diffusion coefficient in air	[m^2/d]	0.43	Default FOCUS 2000
Sorption parameter			
K_{OC} value	[mL/g]	260	Spare (1992)
K_{OM} value, pH independent	[mL/g]	150.8	Calculated from K_{OC}
Freundlich sorption exponent	[-]	0.84	Spare (1992)
Molar enthalpy of sorption	[kJ/mol]	0	Default FOCUS 2000
Reference concentration in liquid phase	[mg/L]	1	Default FOCUS 2000
Metabolism scheme			
Metabolism	[-]	degradation to formaldehyde (ff 2)	Janz and Bayer (2004)

Parameters	Unit	Dazomet	Reference/Remark
Crop related Parameters			
Wash-off factor	$[m^{-1}]$	0.0001	Default FOCUS 2000
Canopy process option	[-]	Lumped	Default FOCUS 2000
Half-life at crop surface	[d]	1000000	Default FOCUS 2000

Substance specific input parameters of metabolite formaldehyde ([4,5,6-N-methyl-14C]-labelled dazomet) for the model FOCUS PEARL 3.3.3

Parameters	Unit	formaldehyde	Reference/Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	30.03	
Solubility in water (25°C)	[mg/L]	40000	estimated (Epi-Win)
Molar enthalpy of dissolution	[kJ/mol]	27	Default FOCUS 2000
Vapour pressure	[Pa]	0	see modification of climate parameters
Molar enthalpy of vaporisation	[kJ/mol]	95	Default FOCUS 2000
Degradation parameters			
$DT_{50\ soil}$ value (lab / field)	[d]	1.9	Peter & Klein (2010a)
Reference temperature	[°C]	20	Default FOCUS 2000
Exponent for the effect of liquid	[-]	0.7	Default FOCUS 2000
Optimum moisture conditions (pF 2 or wetter)	[-]	Yes	Default FOCUS 2000
Molar activation energy	[kJ/mol]	65.4	PPR-Panel (2007)
Diffusion parameters			
Reference temperature for diffusion	[° C]	20	Default FOCUS 2000
Reference diffusion coefficient in water	$[m^2/d]$	4.3×10^{-5}	Default FOCUS 2000
Reference diffusion coefficient in air	$[m^2/d]$	0.43	Default FOCUS 2000
Sorption parameter			
K_{OC} value	[mL/g]	37	estimated (Epi-Win)
K_{OM} value, pH independent	[mL/g]	21.5	Calculated from K_{OC}
Freundlich sorption exponent	[-]	1	request by EFSA
Molar enthalpy of sorption	[kJ/mol]	0	Default FOCUS 2000
Reference concentration in liquid phase	[mg/L]	1	Default FOCUS 2000
Metabolism scheme			
Metabolism	[-]	Mineralisation and bound residues	
Crop related Parameters			
Wash-off factor	$[m^{-1}]$	0.0001	Default FOCUS 2000
Canopy process option	[-]	Lumped	Default FOCUS 2000
Half-life at crop surface	[d]	1000000	Default FOCUS 2000

Substance specific input parameters of 2-C14-labelled dazomet for the model FOCUS PEARL 3.3.3

Parameters	Unit	Dazomet	Reference/Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	162.3	
Solubility in water (25°C)	[mg/L]	3500	Daum (2000)
Molar enthalpy of dissolution	[kJ/mol]	27	Default FOCUS 2000
Vapour pressure (25°C)	[Pa]	0	see modification of climate parameters
Molar enthalpy of vaporisation	[kJ/mol]	95	Default FOCUS 2000
Degradation parameters			
$DT_{50\ soil}$ value (lab / field)	[d]	0.52	Klein (2010a), modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Exponent for the effect of liquid	[-]	0.7	Default FOCUS 2000
Optimum moisture conditions (pF 2 or wetter)	[-]	Yes	Default FOCUS 2000
Molar activation energy	[kJ/mol]	65.4	PPR-Panel (2007)
Diffusion parameters			
Reference temperature for diffusion	[° C]	20	Default FOCUS 2000
Reference diffusion coefficient in water	[m^2/d]	4.3×10^{-5}	Default FOCUS 2000
Reference diffusion coefficient in air	[m^2/d]	0.43	Default FOCUS 2000
Sorption parameter			
K_{OC} value	[mL/g]	260	Spare (1992)
K_{OM} value, pH independent	[mL/g]	150.8	Calculated from K_{OC}
Freundlich sorption exponent	[-]	0.84	Spare (1992)
Molar enthalpy of sorption	[kJ/mol]	0	Default FOCUS 2000
Reference concentration in liquid phase	[mg/L]	1	Default FOCUS 2000
Metabolism scheme			
Metabolism	[-]	degradation to TDL-S (ff 0.367), MITC (ff 0.388)	Klein (2010a), modified during the evaluation period

Parameters	Unit	Dazomet	Reference/Remark
Crop related Parameters			
Wash-off factor	[m^{-1}]	0.0001	Default FOCUS 2000
Canopy process option	[-]	Lumped	Default FOCUS 2000
Half-life at crop surface	[d]	1000000	Default FOCUS 2000

Substance specific input parameters of TDL-S (2-C14-labelled dazomet) for the model FOCUS PEARL 3.3.3

Parameters	Unit	TDL-S	Reference/Remark
Physico-chemical parameters			
Molecular weight	[g/mol]	148.2	
Solubility in water (25°C)	[mg/L]	10000	estimated (Epi-Win)
Molar enthalpy of dissolution	[kJ/mol]	27	Default FOCUS 2000
Vapour pressure	[Pa]	0	see modification of climate parameters
Molar enthalpy of vaporisation	[kJ/mol]	95	Default FOCUS 2000
Degradation parameters			
$DT_{50\ soil}$ value (lab / field)	[d]	1.21	Klein (2010a), modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Exponent for the effect of liquid	[-]	0.7	Default FOCUS 2000
Optimum moisture conditions (pF 2 or wetter)	[-]	Yes	Default FOCUS 2000
Molar activation energy	[kJ/mol]	65.4	PPR-Panel (2007)
Diffusion parameters			
Reference temperature for diffusion	[° C]	20	Default FOCUS 2000
Reference diffusion coefficient in water	[m^2/d]	4.3×10^{-5}	Default FOCUS 2000
Reference diffusion coefficient in air	[m^2/d]	0.43	Default FOCUS 2000
Sorption parameter			
K_{OC} value	[mL/g]	104.5	estimated (Epi-Win)
K_{OM} value, pH independent	[mL/g]	60.6	Calculated from K_{OC}
Freundlich sorption exponent	[-]	1	request by EFSA
Molar enthalpy of sorption	[kJ/mol]	0	Default FOCUS 2000
Reference concentration in liquid phase	[mg/L]	1	Default FOCUS 2000
Metabolism scheme			
Metabolism	[-]	mineralisation, degradation to MITC (ff 1)	Klein (2010a)
Crop related Parameters			
Wash-off factor	[m^{-1}]	0.0001	Default FOCUS 2000
Canopy process option	[-]	Lumped	Default FOCUS 2000
Half-life at crop surface	[d]	1000000	Default FOCUS 2000

Substance specific input parameters of MITC (2-C14-labelled dazomet) for the model FOCUS PEARL 3.3.3

Parameters	**Unit**	**MITC**	**Reference/Remark**
Physico-chemical parameters			
Molecular weight	[g/mol]	73.12	
Solubility in water (25°C)	[mg/L]	7600	estimated (Epi-Win)
Molar enthalpy of dissolution	[kJ/mol]	27	Default FOCUS 2000
Vapour pressure	[Pa]	0	see modification of climate parameters
Molar enthalpy of vaporisation	[kJ/mol]	95	Default FOCUS 2000
Degradation parameters			
$DT_{50\ soil}$ value (lab / field)	[d]	7.65	Klein (2010a), modified during the evaluation period
Reference temperature	[°C]	20	Default FOCUS 2000
Exponent for the effect of liquid	[-]	0.7	Default FOCUS 2000
Optimum moisture conditions (pF 2 or wetter)	[-]	Yes	Default FOCUS 2000
Molar activation energy	[kJ/mol]	65.4	PPR-Panel (2007)
Diffusion parameters			
Reference temperature for diffusion	[° C]	20	Default FOCUS 2000
Reference diffusion coefficient in water	[m^2/d]	4.3×10^{-5}	Default FOCUS 2000
Reference diffusion coefficient in air	[m^2/d]	0.43	Default FOCUS 2000
Sorption parameter			
K_{OC} value	[mL/g]	13.5	Herrchen (2009c)
K_{OM} value, pH independent	[mL/g]	7.83	Herrchen (2009c)
Freundlich sorption exponent	[-]	0.83	Herrchen (2009c)
Molar enthalpy of sorption	[kJ/mol]	0	Default FOCUS 2000
Reference concentration in liquid phase	[mg/L]	1	Default FOCUS 2000
Metabolism scheme			
Metabolism	[-]	Mineralisation and Bound Residues	
Crop related Parameters			
Wash-off factor	[m^{-1}]	0.0001	Default FOCUS 2000
Canopy process option	[-]	Lumped	Default FOCUS 2000
Half-life at crop surface	[d]	1000000	Default FOCUS 2000

Estimated concentration of [4,5,6-N-methyl-14C]-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for lettuce (cabbage)

Scenario	500°kg/ha incorporated to 20cm
Châteaudun	< 0.0001
Hamburg	< 0.0001
Jokioinen	< 0.0001
Kremsmünster	< 0.0001
Porto	< 0.0001
Sevilla	< 0.0001
Thiva	< 0.0001

Estimated concentration of [4,5,6-N-methyl-14C]-labelled formaldehyde in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for lettuce (cabbage)

Scenario	500°kg/ha incorporated to 20cm
Châteaudun	< 0.0001
Hamburg	< 0.0001
Jokioinen	< 0.0001
Kremsmünster	< 0.0001
Porto	< 0.0001
Sevilla	< 0.0001
Thiva	< 0.0001

Estimated concentration of [4,5,6-N-methyl-14C]-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for strawberries

Scenario	500°kg/ha incorporated to 20cm
Hamburg	< 0.0001
Jokioinen	< 0.0001
Kremsmünster	< 0.0001
Sevilla	< 0.0001

Estimated concentration of [4,5,6-N-methyl-14C]-labelled formaldehyde in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for strawberries

Scenario	500°kg/ha incorporated to 20cm
Hamburg	< 0.0001
Jokioinen	< 0.0001
Kremsmünster	< 0.0001
Sevilla	< 0.0001

Estimated concentration of 2-C14-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for lettuce (cabbage)

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Châteaudun	< 0.0001	< 0.001	< 0.0001	< 0.001
Hamburg	< 0.0001	< 0.001	< 0.0001	< 0.001
Jokioinen	< 0.0001	< 0.001	< 0.0001	< 0.001
Kremsmünster	< 0.0001	< 0.001	< 0.0001	< 0.001
Porto	< 0.0001	< 0.001	< 0.0001	< 0.001
Sevilla	< 0.0001	< 0.001	< 0.0001	< 0.001
Thiva	< 0.0001	< 0.001	< 0.0001	< 0.001

Estimated concentration of 2-C14-labelled TDL-S in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for lettuce (cabbage)

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Châteaudun	< 0.0001	< 0.001	< 0.0001	< 0.001
Hamburg	< 0.0001	< 0.001	< 0.0001	< 0.001
Jokioinen	< 0.0001	< 0.001	< 0.0001	< 0.001
Kremsmünster	< 0.0001	< 0.001	< 0.0001	< 0.001
Porto	< 0.0001	< 0.001	< 0.0001	< 0.001
Sevilla	< 0.0001	< 0.001	< 0.0001	< 0.001
Thiva	< 0.0001	< 0.001	< 0.0001	< 0.001

Estimated concentration of 2-C14-labelled MITC in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for lettuce (cabbage). This calculation cannot be considered fully reliable due to the limitation of FOCUS models to deal with volatile substances and the uncertainty associated with the formation fraction and degradation rates of MITC.

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Châteaudun	0.0917	0.0611	0.0001	0.0001
Hamburg	0.2076	0.1384	0.0236	0.0157
Jokioinen	8.9567	5.9711	1.1204	0.7469
Kremsmünster	0.1785	0.1190	0.0170	0.0113
Porto	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Sevilla	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Thiva	< 0.0001	< 0.0001	< 0.0001	< 0.0001

Estimated concentration of 2-C14-labelled dazomet in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for strawberries

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	< 0.0001	< 0.001	< 0.0001	< 0.001
Jokioinen	< 0.0001	< 0.001	< 0.0001	< 0.001
Kremsmünster	< 0.0001	< 0.001	< 0.0001	< 0.001
Sevilla	< 0.0001	< 0.001	< 0.0001	< 0.001

Estimated concentration of 2-C14-labelled TDL-S in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for strawberries

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	< 0.0001	< 0.001	< 0.0001	< 0.001
Jokioinen	< 0.0001	< 0.001	< 0.0001	< 0.001
Kremsmünster	< 0.0001	< 0.001	< 0.0001	< 0.001
Sevilla	< 0.0001	< 0.001	< 0.0001	< 0.001

Estimated concentration of 2-C14-labelled MITC in the percolate at 1 m soil depth in µg/L (80th percentile) calculated with PEARL 3.3.3 for strawberries. This calculation cannot be considered fully reliable due to the limitation of FOCUS models to deal with volatile substances and the uncertainty associated with the formation fraction and degradation rates of MITC.

Scenario	500°kg/ha incorp. to 20cm	333°kg/ha incorp. to 20cm	300°kg/ha incorp. to 10cm	192°kg/ha incorp. to 10cm
Hamburg	0.0067	0.0045	0.0002	0.0001
Jokioinen	1.4958	0.9972	0.1609	0.1073
Kremsmünster	0.0100	0.0067	0.0001	0.0001
Sevilla	< 0.0001	< 0.0001	< 0.0001	< 0.0001

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

Direct photolysis in air ‡	MITC: experimentally measured of 4.5 d
Quantum yield of direct phototransformation	Φ (dazomet) = 1.04×10^{-2} mol/Einstein
Photochemical oxidative degradation in air ‡	DT_{50} dazomet of 0.85 hours derived by the Atkinson model (version AOPWIN v1.88) using a 24 hr day with global OH-concentration of 0.8×10^{6} OH radicals/cm^3 DT_{50} MITC of 78.7 days derived by the Atkinson model (version AOPWIN v1.88) using a 24 hr day with global OH-concentration of 1.5×10^{6} OH radicals/cm^3 DT_{50} MITC: Experimental measured value available of 40 d
Volatilisation ‡	From plant surfaces: Not relevant
	From soil surfaces: maximum volatility rates of 50.4-83.2 µg MITC /cm^2/hour
Metabolites	DT_{50} formaldehyde of 1.3 days derived by the Atkinson model (version AOPWIN) using a 24 hr day with global OH-concentration of 1.5×10^{6} OH radicals/cm^3 .

PEC (air)

Method of calculation	Not available

$PEC_{(a)}$

Maximum concentration	Not calculated

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	**Soil:** dazomet, MITC, TDL-S, formaldehyde. **Groundwater:** dazomet, MITC, TDL-S, formaldehyde. **Surface water:** dazomet, MITC, MATM, formic acid. **Sediment:** dazomet, MITC. **Air:** MITC, formaldehyde

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available

Air (indicate location and type of study)	Not available

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

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Ecotoxicology

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

Species	Test substance	Time scale	End point (mg a.s./kg bw/day)	End point (mg a.s./kg feed)
Birds ‡				
Colinus virginianus.	dazomet	Acute	LD_{50} > 415	-
Colinus virginianus	Basamid Granular	Acute	LD_{50} = 498	-
Colinus virginianus	dazomet	Short-term	LC_{50} = 197	1850
Anas platyrhynchos	dazomet	Short-term	LC_{50} > 341	> 5000
Colinus virginianus	Basamid Granular	Short-term	LC_{50} > 545	> 4965
Anas platyrhynchos	Basamid Granular	Short-term	LC_{50} > 388	> 4965
Coturnix japonica	dazomet	Short-term	LC_{50} >1222 mg a.s./kg bw/day	> 5000
Colinus virginianus	dazomet	Long-term	NOEL = 10.6	100
Anas platyrhynchos	dazomet	Long-term	NOEL = 16.7	100
Mammals ‡				
Rat	dazomet	Acute	LD_{50} = 595 (male) LD_{50} = 415 (female)	- -
Mouse	MITC	Acute	LD_{50} = 120 (male) LD_{50} = 100 (female)	- -
Rat	dazomet	Long-term	NOAEL = 18	-
Additional higher tier studies ‡				
Not required.				

The LD_{50} of MITC derived from dazomet and metam are respectively 224 mg/kg bw (498/2.22) and 119 mg/kg bw (211/ 1.77) (the latter was accepted as a more critical endpoint).

During PRAPeR 77 it was decided that the long-term risk assessment should be based on the lowest reproductive end point and not the geometric mean value. NOEL (*Colinus virginianus*, 25 weeks) = 10.6 mg a.s./kg bw/day = 4.77 mg MITC/kg bw/day based on a 1 / 1 molar transformation from dazomet to MITC.

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

Acute TERs for the indicator species and for the focal species

Bird type	Time scale	Food type	Residue concentration	FIR/g bw	ETE [mg/kg bw]	Toxicity value	TER	Trigger value
Small granivorous bird "finch"	Acute	100% seeds	0.65 (90th)	0.3	0.195	119	610	10
Small insectivorous bird "woodlark"	Acute	100% soil invertebrates	32.14 (90th)	0.7	22.5	119	**5.29**	10
Small granivorous bird "woodlark"	Acute	100% seeds	0.65 (90th)	0.2	0.13	119	915	10
Small omnivorous bird "woodlark"	Acute	50% seeds 50% soil invertebrates	0.65 (90th) 32.14 (90th)	0.3	4.92	119	24.2	10
Small insectivorous bird "yellow wagtail"	Acute	100% soil invertebrates	32.14 (90th)	0.8	25.7	119	**4.63**	10

Short-term TERs for the indicator species and for the focal species. The RMS did not accept the short-term risk assessment provided by the applicant, as exposure to MITC via food items remaining at the soil surface was not expected. Consequently, only the acute and long-term risk was assessed for birds.

Long-term TERs for the indicator species and for the focal species

Bird type	Time scale	Food type	Residue concentration	FIR/g bw	ETE [mg/kg bw]	Toxicity value	TER	Trigger value
Small granivorous bird "finch"	*Long term*	*100% seeds*	*0.362 (mean)*	*0.3*	*0.1086*	*4.77*	*44*	*5*
Small insectivorous bird "woodlark"	*Long term*	*100% soil invertebrates*	*13.16 (mean)*	*0.7*	*9.212*	*4.77*	***0.52***	*5*
Small granivorous bird "woodlark"	*Long term*	*100% seeds*	*0.362 (mean)*	*0.2*	*0.0724*	*4.77*	*66*	*5*
Small omnivorous bird "woodlark"	*Long term*	*50% seeds 50% soil invertebrates*	*0.362 (mean) 13.16 (mean)*	*0.3*	*2.0283*	*4.77*	***2.35***	*5*
Small insectivorous bird "yellow wagtail"	*Long term*	*100% soil invertebrates*	*13.16 (mean)*	*0.8*	*10.528*	*4.77*	***0.45***	*5*

Acute TERs for the indicator species and for the focal species

Mammal type	Time scale	Food type	Residue concentration	FIR/g bw	ETE [mg/kg bw]	Toxicity value	TER	Trigger value
Small insectivorous mammal "wood mouse"	Acute	100% soil invertebrates	13.16 (mean)	0.44	5.8	100.0	17.3	10
Small granivorous	Acute	100% seeds	0.362 (mean)	0.16	0.1	100.0	1726.5	10

mammal "wood mouse"								
Small omnivorous mammal "wood mouse"	Acute	50% seeds 50% soil invertebrates	0.362 (mean) 13.16 (mean)	0.24	1.6	100.0	61.6	10

Long-term TERs for the indicator species and for the focal species

Mammal type	**Time scale**	**Food type**	**Residue concentration**	**FIR/g bw**	**ETE [mg/kg bw]**	**Toxicity value**	**TER**	**Trigger value**
Small insectivorous mammal "wood mouse"	*Long term*	*100% soil invertebrates*	*13.16 (mean)*	*0.44*	*5.8*	*0.44*	***0.076***	*5*
Small granivorous mammal "wood mouse"	*Long term*	*100% seeds*	*0.362 (mean)*	*0.16*	*0.058*	*0.44*	*7.60*	*5*
Small omnivorous mammal "wood mouse"	*Long term*	*50% seeds 50% soil invertebrates*	*0.362 (mean) 13.16 (mean)*	*0.24*	*1.6*	*0.44*	***0.27***	*5*

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Lepomis macrochirus	dazomet	96 h (static)	Mortality, LC_{50}	0.3 mg a.s./L (nom)
Oncorhynchus mykiss	dazomet	96 h semi-static	Mortality, LC_{50}	> 3 mg a.s./L (nominal)
Cyprinus carpio	dazomet	96 h semi-static	Mortality, LC_{50}	37 mg a.s./L (mean measured)
Oncorhynchus mykiss	Basamid Granular	96 h (static)	Mortality, LC_{50}	> 4.64 mg form/L (nom)
Lepomis macrochirus	Basamid Granular	96 h (static)	Mortality, LC_{50}	> 1.00 mg form/L (0.993 mg a.s./L) (nom)
Oncorhynchus mykiss	MITC	96 h (semi-static)	Mortality, LC_{50}	**0.0531 mg/L** (mm)
Brachidanio rerio	leachate from lysimeter study	96 h (static)	Mortality, LC_{50}	> 0.12 mg a.s. equivalents/L (mm)
Oncorhynchus mykiss	MITC	28 d (flow-through)	Growth, NOEC	**0.004 mg MITC/L** (mean measured)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Aquatic invertebrate				
7	dazomet	48 h flow-through	Mortality, EC_{50}	19 mg a.s./L (mean measured)
Daphnia magna	Basamid Granular	48 h (static)	Mortality, EC_{50}	0.427 mg form/L (0.418 mg a.s./L) (nom)
Daphnia magna	MITC	48 h (semi-static)	Mortality, EC_{50}	**0.076 mg/L** (mm)
Daphnia magna	leachate from lysimeter study	48 h (static)	Mortality, EC_{50}	> 0.12 mg a.s. equivalents/L (mm)
Daphnia magna	MITC	21 d (semi-static)	Reproduction, NOEC	0.01275 mg /L (mean measured)
Daphnia magna	MITC	21 d (semi-static)	Reproduction, NOEC	**0.00625 mg/L** (nom)
Sediment-dwelling organisms				
Not required. Considering the low Koc, the high solubility of the metabolites in water, the low level of the active substance and metabolites observed transiently in the sediment phase of the w/s study in the section on “fate and behaviour”, it can be expected that the PEC sediment values are an overestimation of the reality, based on unrealistic assumptions. Exposure to sediment-dwelling organisms is not expected and testing on sediment-dwelling organisms is not required.				
Algae				
Pseudokirchneriella subcapitata	dazomet	72 h static	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOEC	0.16 mg a.s./L (measured concentrations) 0.59 mg a.s./L (measured concentrations) 0.056 mg a.s./L (measured concentrations)
Desmodesmus subspicatus	Basamid Granular	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.015 mg form/L (nom) -

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Pseudokirchneriella subcapitata	MITC	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} EC_{50} (yield) EC_{50} (growth rate) EC_{50} (biomass)	0.28 mg/L (initial meas.) 0.58 mg/L (initial meas.) 0.077 mg/L (mean measured) **0.275 mg/L** (mean measured) 0.075 mg/L (mean measured)
Anabaena flos-aquae	MITC	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} EC_{50} (yield) EC_{50} (growth rate) EC_{50} (biomass) NOEC (yield, growth rate, biomass)	2.12 mg/L (initial meas.) 3.72 mg/L (initial meas.) 0.416 mg/L (mean measured) 0.910 mg/L (mean measured) 0.497 mg/L (mean measured) 0.218 mg/L (mean measured)
Pseudokirchneriella subcapitata	leachate from lysimeter study	72 h (static)	Biomass: E_bC_{50}	> 0.12 mg a.s. equivalents/L (mm)
Higher plant				
Lemna gibba	dazomet	14 d (static)	Fronds, EC_{50} EC_{50} (yield) NOEC (yield) EC_{50} (growth rate) NOEC (growth rate)	3.5 mg a.s./L (initial measured) 0.970 mg a.s./L (mean measured) 0.306 mg a.s./L (mean measured) 4.43 mg a.s./L (mean measured) 0.592 mg a.s./L (mean measured)
Lemna gibba	MITC	7 d (semi-static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} NOEC	**0.59 mg/L** (mm initial) 1.18 mg/L (mm initial) 0.09 mg/L (mm initial)
Microcosm or mesocosm tests				
Not required since the laboratory data available are sufficient for the aquatic risk assessment.				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Basamid Granular: formulation containing 95 % dazomet

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

PEC_{SW} and acute and chronic TER values for aquatic species exposed to MITC after application of 500 kg a.s./ha (drainage and run-off)

FOCUS-Scenario	PEC_{SW} (Step 3) [µg/L]	Acute TER	Chronic TER	PEC_{SW} (considering band application) [µg/L]	Acute TER	Chronic TER
Rainbow trout (*Oncorhynchus mykiss*)						
D3 Vredepeel, ditch	0.050	1062	80.0		-	-
D4 Skousbo, pond	0.071	748	56.3		-	-
D4 Skousbo, stream	1.051	**50.5**	**3.81**	0.7	**75**	**5.7**
R1 Weiherbach, pond	0.040	1328	100			
R1 Weiherbach, stream	0.646	**82.2**	**6.19**	0.431	123	**9.3**
D6 Thiva; ditch	0.001	53100	16000			
R2 Porto; stream	0.034	1561	117			
R3 Bologna; stream	1.126	**47.1**	**3.55**	0.751	**13.3**	**5.3**
R4 Roujan; stream	2.256	**23.5**	**1.7**	1.504	**35.3**	**2.7**
Daphnia magna						
D3 Vredepeel, ditch	0.050	1520	125	-	-	-
D4 Skousbo, pond	0.071	1070	88	-	-	-
D4 Skousbo, stream	1.051	**72**	**6**	-	-	-
R1 Weiherbach, pond	0.040	1900	156			
R1 Weiherbach, stream	0.646	118	10			
D6 Thiva; ditch	0.001	76000	6250			
R2 Porto; stream	0.034	2235	183			
R3 Bologna; stream	1.126	**67**	**5.5**	0.751	**101**	**8.3**
R4 Roujan; stream	2.256	**33.7**	**2.7**	1.504	**50**	**4.1**
Pseudokirchneriella subspicata						
D3 Vredepeel, ditch	0.050	-	1500	-	-	-
D4 Skousbo, pond	0.071	-	1056	-	-	-
D4 Skousbo, stream	1.051	-	71	-	-	-
R1 Weiherbach, pond	0.040	-	1875			
R1 Weiherbach, stream	0.646	-	116			
D6 Thiva; ditch	0.001		75000			
R2 Porto; stream	0.034		2205			
R3 Bologna; stream	1.126		66.6			
R4 Roujan; stream	2.256		33.2			
Duckweed (*Lemna gibba*)						
D3 Vredepeel, ditch	0.050	-	11800	-	-	-
D4 Skousbo, pond	0.071	-	8310	-	-	-
D4 Skousbo, stream	1.051	-	561	-	-	-
R1 Weiherbach, pond	0.040	-	14750	0.016	-	36875
R1 Weiherbach, stream	0.646	-	913	0.293	-	2014
D6 Thiva; ditch	0.001		590000			
R2 Porto; stream	0.034		17352			
R3 Bologna; stream	1.126		523.9			
R4 Roujan; stream	2.256		261			

D3 and D4: Northern European drainage scenarios
R1: Northern European run-off scenarios

PEC_{SW} and acute and chronic TER values for aquatic species exposed to MITC after application of 500 kg a.s./ha (deposition)

FOCUS-Scenario	PEC_{SW} (buffer zone 30 m) [µg/L]	TER		PEC_{SW} (buffer zone 40 m) [µg/L]	TER	
		Acute	Chronic		Acute	Chronic
Rainbow trout (*Oncorhynchus mykiss*)						
D3 Vredepeel, ditch (N)	0.633	**83.9**	**6.32**	0.109	487	39.7
D4 Skousbo, pond (N)	0.319	166	12.5	0.158	336	25.3
D4 Skousbo, stream (N)	0.547	**97.1**	**7.31**	0.293	181	13.7
R1 Weiherbach, pond (N)	0.276	192	14.5	0.130	408	30.8
R1 Weiherbach, stream (N)	0.602	**88.2**	**6.65**	0.249	213	16.1
D6 Thiva, ditch (S)	0.533	**99.7**	**7.51**	0.044	1207	90.9
R2 Porto, stream (S)	0.750	**70.8**	**5.33**	0.402	132	10.0
R3 Bologna, stream (S)	0.088	603	45.5	0.047	1130	85.1
Daphnia magna						
D3 Vredepeel, ditch (N)	0.633	120	10	0.109	697	57
D4 Skousbo, pond (N)	0.319	238	20	0.158	481	40
D4 Skousbo, stream (N)	0.547	139	11	0.293	259	21
R1 Weiherbach, pond (N)	0.276	275	23	0.130	585	48
R1 Weiherbach, stream (N)	0.602	126	10	0.249	305	25
D6 Thiva, ditch (S)	0.533	143	12	0.044	1728	142
R2 Porto, stream (S)	0.750	101	8	0.402	189	16
R3 Bologna, stream (S)	0.088	864	71	0.047	1617	133
Pseudokirchneriella subspicata						
D3 Vredepeel, ditch (N)	0.633	-	118	0.109	-	688
D4 Skousbo, pond (N)	0.319	-	235	0.158	-	475
D4 Skousbo, stream (N)	0.547	-	137	0.293	-	256
R1 Weiherbach, pond (N)	0.276	-	272	0.130	-	577
R1 Weiherbach, stream (N)	0.602	-	125	0.249	-	301
D6 Thiva, ditch (S)	0.533	-	141	0.044	-	1705
R2 Porto, stream (S)	0.750	-	100	0.402	-	187
R3 Bologna, stream (S)	0.088	-	852	0.047	-	1596
Duckweed (*Lemna gibba*)						
D3 Vredepeel, ditch (N)	0.633	-	932	0.109	-	5413
D4 Skousbo, pond (N)	0.319	-	1850	0.158	-	3734
D4 Skousbo, stream (N)	0.547	-	1079	0.293	-	2014
R1 Weiherbach, pond (N)	0.276	-	2138	0.130	-	4538
R1 Weiherbach, stream (N)	0.602	-	980	0.249	-	2369
D6 Thiva, ditch (S)	0.533	-	1107	0.044	-	13409
R2 Porto, stream (S)	0.750	-	787	0.402	-	1468
R3 Bologna, stream (S)	0.088	-	6705	0.047	-	12553

D3, D4, R1: Northern European drainage (D) and run-off (R) scenarios
D6, R2, R3: Southern European drainage (D) and run-off (R) scenarios

PEC_{SW} and acute and chronic TER values for aquatic species exposed to MITC after application of 300 kg a.s./ha (drainage and run-off)

FOCUS-Scenario	PEC_{SW} (Step 3) [µg/L]	Acute TER	Chronic TER	PEC_{SW} (considering band application) [µg/L]	Acute TER	Chronic TER
Rainbow trout (*Oncorhynchus mykiss*)						
D3 Vredepeel, ditch	0.023	2309	174	-	-	-
D4 Skousbo, pond	0.039	1362	103	-	-	-
D4 Skousbo, stream	0.520	102	**7.69**	0.347	153	11.5
R1 Weiherbach, pond	0.048	1106	83.3			
R1 Weiherbach, stream	0.761	**69.8**	**5.26**	0.507	104	**7.9**
D6 Thiva; ditch	0.001	53100	16000			
R2 Porto; stream	0.017	3122	235			
R3 Bologna; stream	1.343	**39.5**	**2.9**	0.895	**59.3**	**4.5**
R4 Roujan; stream	2.683	**19.3**	**1.5**	1.789	**29.7**	**2.2**
Daphnia magna						
D3 Vredepeel, ditch	0.023	3304	272	-	-	-
D4 Skousbo, pond	0.039	1949	160	-	-	-
D4 Skousbo, stream	0.520	146	12	-	-	-
R1 Weiherbach, pond	0.048	1583	130			
R1 Weiherbach, stream	0.761	**99.9**	**8**	0.507	150	12
D6 Thiva; ditch	0.001	76000	6250			
R2 Porto; stream	0.017	4470.6	367.6			
R3 Bologna; stream	1.343	**56.5**	**4.6**	0.895	**85**	**7**
R4 Roujan; stream	2.683	**27.2**	**2.3**	1.789	**42.3**	**3.5**
Pseudokirchneriella subspicata						
D3 Vredepeel, ditch	0.023	-	3261	-	-	-
D4 Skousbo, pond	0.039	-	1923	-	-	-
D4 Skousbo, stream	0.520	-	144	-	-	-
R1 Weiherbach, pond	0.048	-	1563			
R1 Weiherbach, stream	0.761	-	99			
D6 Thiva; ditch	0.001		75000			
R2 Porto; stream	0.017		4411			
R3 Bologna; stream	1.343		55.8			
R4 Roujan; stream	2.683		28			
Duckweed (*Lemna gibba*)						
D3 Vredepeel, ditch	0.023	-	25652	-	-	-
D4 Skousbo, pond	0.039	-	15128	-	-	-
D4 Skousbo, stream	0.520	-	1135	-	-	-
R1 Weiherbach, pond	0.048	-	12292			
R1 Weiherbach, stream	0.761	-	775			
D6 Thiva; ditch	0.001		590000			
R2 Porto; stream	0.017		34705			
R3 Bologna; stream	1.343		439			
R4 Roujan; stream	2.683		220			

D3 and D4: Northern European drainage scenarios
R1: Northern European run-off scenarios

PEC_{SW} and acute and chronic TER values for aquatic species exposed to MITC after application of 300 kg a.s./ha (deposition)

FOCUS-Scenario	PEC_{SW} (buffer zone 20 m) [µg/L]	TER		PEC_{SW} (buffer zone 30 m) [µg/L]	TER	
		Acute	Chronic		Acute	Chronic
Rainbow trout (*Oncorhynchus mykiss*)						
D3 Vredepeel, ditch (N)	0.589	**90.2**	**6.79**	0.127	418	13.5
D4 Skousbo, pond (N)	0.318	167	12.6	0.165	322	24.2
D4 Skousbo, stream (N)	0.523	102	**7.65**	0.303	175	13.2
R1 Weiherbach, pond (N)	0.276	192	14.5	0.136	390	29.4
R1 Weiherbach, stream (N)	0.570	**93.2**	**7.02**	0.262	203	15.3
D6 Thiva, ditch (S)	0.491	108	8.15	0.061	980	65.6
R2 Porto, stream (S)	0.717	**74.1**	**5.58**	0.415	128	10.0
R3 Bologna, stream (S)	0.084	632	47.6	0.049	1084	81.6
Daphnia magna						
D3 Vredepeel, ditch (N)	0.589	129	11	0.127	598	49
D4 Skousbo, pond (N)	0.318	239	20	0.165	461	38
D4 Skousbo, stream (N)	0.523	145	12	0.303	251	21
R1 Weiherbach, pond (N)	0.276	275	23	0.136	559	46
R1 Weiherbach, stream (N)	0.570	133	11	0.262	290	24
D6 Thiva, ditch (S)	0.491	155	13	0.061	1246	102
R2 Porto, stream (S)	0.717	106	9	0.415	1831	15
R3 Bologna, stream (S)	0.084	905	74	0.049	1551	128
Pseudokirchneriella subspicata						
D3 Vredepeel, ditch (N)	0.589	-	127	0.127	-	591
D4 Skousbo, pond (N)	0.318	-	236	0.165	-	455
D4 Skousbo, stream (N)	0.523	-	143	0.303	-	248
R1 Weiherbach, pond (N)	0.276	-	272	0.136	-	551
R1 Weiherbach, stream (N)	0.570	-	132	0.262	-	286
D6 Thiva, ditch (S)	0.491	-	153	0.061	-	1230
R2 Porto, stream (S)	0.717	-	105	0.415	-	181
R3 Bologna, stream (S)	0.084	-	893	0.049	-	1531
Duckweed (*Lemna gibba*)						
D3 Vredepeel, ditch (N)	0.589	-	1001	0.127	-	4546
D4 Skousbo, pond (N)	0.318	-	1855	0.165	-	3576
D4 Skousbo, stream (N)	0.523	-	1128	0.303	-	1947
R1 Weiherbach, pond (N)	0.276	-	2138	0.136	-	4338
R1 Weiherbach, stream (N)	0.570	-	1035	0.262	-	2252
D6 Thiva, ditch (S)	0.491	-	1202	0.061	-	9672
R2 Porto, stream (S)	0.717	-	823	0.415	-	1422
R3 Bologna, stream (S)	0.084	-	7024	0.049	-	12041

D3, D4, R1: Northern European drainage (D) and run-off (R) scenarios
D6, R2, R3: Southern European drainage (D) and run-off (R) scenarios

Bioconcentration				
	dazomet	MITC	Metabolite2	Metabolite3
$logP_{O/W}$	0.63	< 3	-	-
Bioconcentration factor (BCF)[1] ‡	Not required.			

Bioconcentration				
Annex VI Trigger for the bioconcentration factor	-	-	-	-
Clearance time (days) (CT_{50})	-	-	-	-
(CT_{90})	-	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-	-	-	-

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

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

The specific application system of ‘Basamid Granular’ guarantees that the product is incorporated into the soil (20 cm depth), covered by a plastic sheeting and that the fumigation takes place within the treated and sealed soil layer (“closed system”). The product is applied specifically without any drift to off-field areas. Therefore, bees are not at risk in-field or off-field following the application of ‘Basamid Granular’.

The fumigating activity of dazomet is based on the rapid hydrolytic release of fumigant gases of which MITC is the most relevant. After removal of the plastic sheeting, the soil is loosened and aerated by means of a thorough cultivation to allow the non-mineralised gases to disperse. The check upon completion of the fumigation process is performed by the cress germination test. Cress is very sensitive to MITC, and a successful cress germination test indicates that the remaining MITC residues in soil cannot induce any damage to the following crop. As a result, no contaminated crops or weeds are available for bees in the field. Therefore, the risk is considered low for the representative uses in the field.

Bees are not exposed to the use in greenhouse, therefore the risk is considered low for the representative use in greenhouses.

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

Laboratory tests with standard sensitive species

-

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
Poecilus cupreus	adults	Basamid Granular, LUFA 2.1 soil, 14 d	485 kg a.s./ha, DAR 0	Corrected mortality Effect on food consumption	- 3.4 % + 5.8 %	50 % 50 %
Aleochara bilineata	adults	Basamid Granular, LUFA 2.1 soil, 77 d	485 kg a.s./ha, DAR 0	Effect on reproduction	- 99.6 %	50 %
		Basamid Granular, LUFA 2.1 soil, 75 d	485 kg a.s./ha, DAR 7	Effect on reproduction	+ 18.2 %	50 %
Folsomia candida	adults	Basamid Granular, LUFA 2.1 soil, 28 d	485 kg a.s./ha, DAR 0	Corrected mortality Effect on reproduction	+ 100 % -	50 % 50 %

Species	**Life stage**	**Test substance, substrate and duration**	**Dose (g/ha)[1,2]**	**End point**	**% effect[3]**	**Trigger value**
			485 kg a.s./ha, DAR 7	Corrected mortality Effect on reproduction	+ 9.3 % + 9.0 %	50 % 50 %
			485 kg a.s./ha, DAR 14	Corrected mortality Effect on reproduction	- 7.1 % - 4.8 %	50 % 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 if positive percentages relate to adverse effects or not

Basamid Granular: formulation containing 95 % dazomet
DAR: days after plastic sheet removal
Corrected Mortality: positive result: adverse effects
negative result: no adverse effects
Effect on food consumption and effect on reproduction: negative result: adverse effects,
positive result: no adverse effects

Field or semi-field tests
Field studies evaluated under B.9.7 are available where following taxa are investigated (*Collembola*, *Acari*, *Coleoptera*, *Isopoda*, *Diplopoda* and *Araneae*).

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	Basamid Granular	Acute 14 days	LC_{50} = 6.7 mg form/kg soil d.w. (6.5 mg a.s/kg soil d.w.)
Eisenia fetida	MITC	Acute 14 days	LC_{50} = 4.0 mg/kg soil d.w.
Other soil macro-organisms			
Field studies were submitted with Collembola populations and fauna of small-scale agricultural biotopes. Also, a litterbag study was submitted.			
Collembola			
Results of the extended laboratory study with *Folsomia candida* are presented under the section on effects on other arthropod species.			
Soil micro-organisms			
Field study was submitted.			
Field studies[2]			
Summary of field studies here below.			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Basamid Granular: formulation containing 95 % dazomet

The first field study with earthworms (Krieg W., 2003a) was conducted at the application rate of 500 kg Basamid Granular/ha, with incorporation into the soil and covered for 8 days by a plastic sheeting. At the end of the fumigation period, the plastic sheeting was removed. Basamid Granular, applied once a year at 500 kg/ha did not indicate any sustained adverse influences on earthworm populations.

The second field study with Collembola populations (Krieg W., Schick H., 2004) was conducted at the application rate of 500 kg Basamid Granular/ha on 26th of June 2001, with incorporation into the soil and covered for 8 days by a plastic sheeting. Following the soil fumigation (field-management plus chemical treatment) in June 2001, mesofauna population was recolonising the plots until May 2002 and was evenly distributed in September 2002.

The third field study with fauna of small-scale agricultural biotopes (Ufer A., Schmider F., Alberti G., 1994) was conducted at the application rate of 400 kg Basamid Granular/ha in autumn 1990, with incorporation into the soil and covered for 4 weeks by a plastic sheeting. The recolonisation of the treated field was mainly determined by the high rate of reproduction of the surviving animals and not by a high degree of mobility. Changes in dominance and a reduced diversity were visible for more than one year.

The fourth field study (litterbag, Krieg W., Wolf A., 2003a) was conducted at the application rate of 500 kg Basamid Granular/ha on 26th of June 2001, with incorporation into the soil and covered for 8 days by a plastic sheeting. At the end of the fumigation period, the plastic sheeting was removed. One year after application, the process tested reached similar levels in the treated plots compared to those in the untreated plots.

The fifth field study (Dohmen, G.P. 1991) was conducted at the application rate of 600 kg Basamid Granular/ha in August 1989, with incorporation into the soil and covered for 1 week by a plastic sheeting. At the end of the fumigation period, the plastic sheeting was removed. The number of adult *Coleoptera*, beetle larvae and *Diptera* was similar to the control on the Basamid treated areas. The number of spiders did not differ significantly from the untreated control. The number of *Diplopoda* was still lower on the field-managed and Basamid treated plots than on the control plots.

The sixth field study with soil non-target micro-organisms (Krieg W., 2003b) was conducted at the application rate of 500 kg Basamid Granular/ha on 26th of June 2001, with incorporation into the soil and covered for 8 days by a plastic sheeting. The formulation Basamid Granular, applied once per year at maximum 500 kg/ha did cause short-term and mid-term effects on functions of soil micro-organisms. Particularly, nitrate production in the field soil was clearly stimulated. One year after application, the processes tested, i.e. transformation of both carbon and nitrogen, reached similar levels in the treated plots compared to the untreated plots.

Toxicity/exposure ratios for soil organisms

The field studies were conducted according to the representative GAP for Basamid Granular, 1 application at 500 kg/ha, covering with a plastic sheet for 1 week and thorough cultivation to allow the non-mineralised gases to disperse. Monitoring of the effects on soil organisms was done for more than 1 year. Therefore, the field studies cover the risk of the parent dazomet and its subsequent metabolites (MITC, formaldehyde, TDL-S).

The risk of dazomet and its subsequent metabolites (MITC, formaldehyde, TDL-S) to earthworms, other soil non-target macro-organisms, and soil micro-organisms is low for the representative uses.

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

'Basamid Granular' is incorporated into the soil (20 cm depth) and covered by a plastic sheeting, the fumigation takes place within the treated and sealed soil layer ("closed system"). The product is applied specifically without any drift to off-field areas. Therefore, non-target plants are not at risk off-field following the application of 'Basamid Granular'.

The fumigating activity of dazomet is based on the rapid hydrolytic release of fumigant gases of which MITC is the most relevant one. After removal of the plastic sheeting, the soil is loosened and aerated by means of a thorough cultivation to allow the non-mineralised gases to disperse. The check upon completion of the fumigation process is performed by the cress germination test. Cress is very sensitive to MITC, and a successful cress germination test indicates that the remaining MITC residues in soil cannot induce any damage to the following crop. Therefore, the risk of dazomet and MITC to non-target plants is considered low for the representative uses in the field.

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

Test type/organism	Endpoint
Activated sludge	EC_{50} (30 min) = *ca*. 160 mg Basamid Granular/L (155 mg a.s./L)
	EC_{50} (30 min) = *ca*. 25 mg MITC/L

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

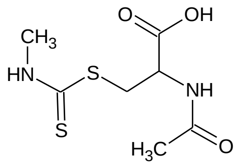
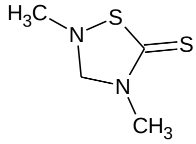
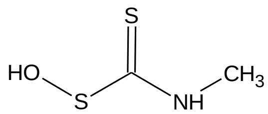
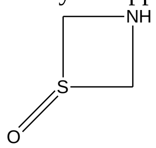
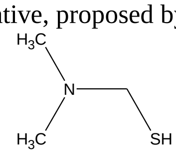
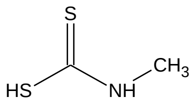
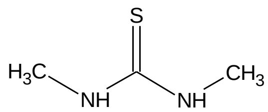
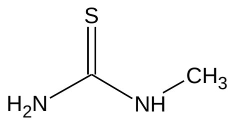
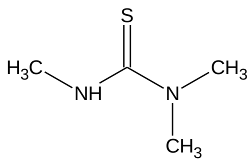
Compartment	
soil	Dazomet, MITC
water	Dazomet, MITC
sediment	Dazomet, MITC
groundwater	MITC

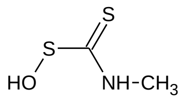
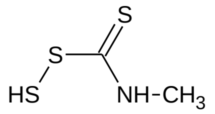
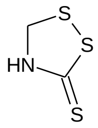
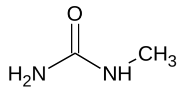
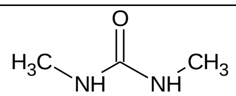
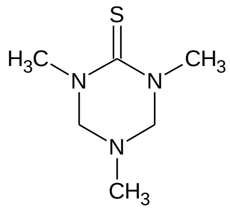
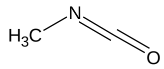
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N; R50

	RMS/peer review proposal
Preparation	N; R50 for Basamid Granular

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
MITC	methyl isothiocyanate	CH_3-N=C=S
acetyl cysteine conjugate of MITC	*N*-acetyl-*S*-(methylcarbamothioyl)cysteine	
TDL-S	2,4-dimethyl-1,2,4-thiadiazolidine-5-thione	
MATM	1-(hydroxysulfanyl)-*N*-methyl-1-thioxomethanamine	
M91 (aqueous photolysis metabolite)	Tentative structure 1: 1,3-thiazetidine 1-oxide Tentative structure 2: (dimethylamino)methanethiol	Tentative structure 1 (proposed by the applicant)  Tentative structure 2 (alternative, proposed by EFSA) 
metam	methyldithiocarbamic acid	
DMTU	1,3-dimethylthiourea	
MMTU	1-methylthiourea	
TMTU	1,1,3-trimethylthiourea	

Code/Trivial name	Chemical name*	Structural formula*
M123 (hydrolysis metabolite)	1-(hydroxysulfanyl)-*N*-methyl-1-thioxomethanamine	
M137 + M139 (hydrolysis metabolites)	[(disulfanylcarbonothioyl)amino]methane 1,2,4-dithiazolidine-3-thione	 
methylurea	methylurea	
N,N'-dimethylurea	1,3-dimethylurea	
1,3,5-trimethyl-hexahydro-triazinethione	1,3,5-trimethyl-1,3,5-triazinane-2-thione	
MIC	methyl isocyanate	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FFS	form-fill-seal
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography

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

NIR	non-identified radioactivity
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SE	southern Europe
SFO	single first-order
SPME-GC-MSD	solid phase microextraction gas chromatography with mass spectrometric detection
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule

WHO	World Health Organisation
wk	week
yr	year