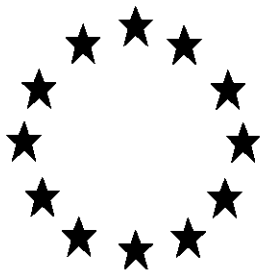
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report[i]



Dazomet

Product-type 8
(Wood preservatives)

11 March 2010

Annex I - Belgium

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of **Dazomet** as **product-type 8** (Wood Preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Dazomet (CAS no. **533-744-4**) was notified as an existing active substance, by **BASF SE**, hereafter referred to as the applicant, in **product-type 8**. At the time of this report, **Dazomet** is only known to be included in one product, Wolmanit Fume, marketed by Dr Wolman GmbH, part of BASF Group.

Commission Regulation (EC) No 1451/2007 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, **Belgium** was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for **Dazomet** as an active substance in **Product Type 8** was **24/03/2004**, in accordance with Annex V of Regulation (EC) No 1451/2007.

On **22/03/2004**, Belgian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on **18/10/2004**.

On **17/04/2007**, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on **17/04/2007**. The competent authority report included a recommendation for the inclusion of **Dazomet** in **Annex I** to the Directive for **product-type 8**.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on **09/10/2007**. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of Dazomet in **Annex I** to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 11 March 2010.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 11 March 2010.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Dazomet in **Annex I** to Directive 98/8/EC for **product-type 8**. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in **product-type 8** that contain Dazomet. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing Dazomet for the product-type 8, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

3 http://ec.europa.eu/comm/environment/biocides/index.htm

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity

Dazomet, CAS No. 533-74-4, is a fungicide produced by BASF SE Ludwigshafen (Germany). The manufacturing process of Dazomet is described in the confidential data and information appendix of document IIIA and in appendix 2 of doc IIC.

Analysis of five technical grade batches, using CIPAC 146 TC-1984, which are representative of the current manufacturing process, demonstrated a minimum purity of 96 % w/w in compliance with BASF SE specifications. All impurities above the level of 1 g/kg have been fully identified. The main identification characteristics are given in the "Confidential Annex" document. The active substance must be technically equivalent to the specifications given. The evaluation has established that for the active substance notified by BASF SE none of the manufacturing impurities are considered to be of potential concern.

2.1.2. Physico-Chemical Properties

Dazomet technical grade is a colourless crystalline solid (microgranules) with a weak characteristic odour.

The relative density of purified Dazomet is 1.33 g/cm³ at 20°C. The melting point of Dazomet is found 103.2 – 105.2 °C. The vapour pressure is found to be 5.8E-04 Pa at 20°C. Dazomet has a very low volatility.

The water solubility of Dazomet ranges between 3.5 – 3.9 g/l (pH=5-9, 20.2°C). For risk assessment, a water solubility of 3.7 g/l (pH 7, 20°.2C,) is used. Dazomet is soluble in acetone and other organic solvents. The n-octanol/water partition coefficient is 0.3 (pH=5-9) at 24°C. Dazomet hydrolyses within hours.

Dazomet does not dissociate.

The exothermal decomposition of the technical grade starts at >150°C. Dazomet is not explosive, not auto-flammable and not oxidative.

During normal handling and storage of Dazomet in polyethylene laminated paper bags for 24 months, no leakage or rupture of the original packaging was observed. No interaction between the product and its original packaging was observed.

2.1.3. Methods of Analysis

Analytical methods for the active substance:

For Dazomet, a CIPAC method 146 is available. The CIPAC method 146 is applicable to Dazomet technical (146/TC/M/-) and Dazomet granules (146/GR/M/-). Dazomet is dissolved in acetonitrile and determined by high performance liquid chromatography on a reversed phase column using acetonitrile – water – acetic acid as mobile phase, UV-detection at 284 nm and external standardization, Specificity: Retention time about 4 min. These methods are fully described in the document IIIA.

For the determination of Dazomet and its impurities in the technical active ingredient, the analytical method CP 123 is available. The impurities in technical Dazomet are separated by reverse phase HPLC (eg. Acetonitrile/water) and quantitatively determined by UV detection with external calibration using reference substances. It was reported that the content of Dazomet, its "dehydro-dimers" and water sum up quantitatively to an average of 100% by weight. No unknown organic impurities detectable by UV with contents higher than the level of 0.1% by weight could be determined.

Analytical methods for residues:

Analytical methods for the determination of residues of MITC are available for

Soil:	GS-MS	LOQ = 0.05 mg/kg MITC
Air:	GS-MS	LOQ = 0.0003 µg/l MITC
Water:	GC-MS (EI)	LOQ = 0.02 µg/l MITC
Body fluids:	HPLC-MSD	LOQ = 0.05 mg/l N-acetyl-S-[(methylamino)carbo thioyl] cysteine (blood plasma and urine)
Crops:	GC-MS	LOQ = 0.02 mg/kg MITC (tomatoes, strawberries).

2.2. Intended Uses and Efficacy

Dazomet has been evaluated for its use in wood preservation belonging to Product Type 8 according to Annex V of the Directive 98/8/EC.

The active substance Dazomet, and the biocidal product Wolmanit Fume (> 99.9% Dazomet technical) is intended for use as a wood preservative in form of granules for remedial treatment of wooden transmission poles against internal decay of the poles by Basidiomycetes. In the known application of Dazomet, the substance is never applied on untreated wood, but always used on already impregnated wood (e.g. wooden poles which have received an initial basic use class 4 treatment). The treatment will be performed by using a semi-automated calibrated applicator to poles. Boreholes are drilled into the poles, and filled with the product using a calibrated applicator. The application volume is filled by gravity into the boreholes via a purging valve. In addition to this, the holes are immediately plugged. Dazomet is applied outdoors, by professional operators only.

The volume of Dazomet applied will be dependent of the size of the poles. 50 grams of Dazomet per treatment hole (3 holes per pole) corresponding to a total amount of 150 grams of Dazomet per pole is sufficient for a 25 cm diameter standing utility pole.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

Mode of action:

In contact with moisture, Dazomet is transformed into methyl-isothiocyanate (MITC). The hydrolysis product MITC, which is the active form of Dazomet binds to amines and SH-groups. This relatively unspecific effect will inhibit the metabolism of the fungi.

Dazomet decomposes in the presence of wood humidity slowly to form MITC in quantities sufficient for 10-year treatment cycles.

2.3. Classification and Labelling

2.3.1. Proposed classification/labelling for the active substance, Dazomet, following evaluation:

On the basis of a review of the data submitted, the BE CA concludes that the current classification of Dazomet on Annex 1 to Directive 67/548/EEC cannot be maintained. The available published human data does give evidence that Dazomet should be classified as a skin, eye, and respiratory tract irritant and a skin sensitizer through MITC formation. With regard to reproductive toxicity, Dazomet showed some effects (variations and runts) but with the data available, it cannot be ruled out that classification is warranted. We want to inform that possible classification as toxic to reproduction Cat.3 is not excluded.

The classification should therefore be:

Classification/Labelling	as proposed by the BE CA	
Class of danger	Xn	Harmful
	N	Dangerous for the environment
R phrases	R 22:	Harmful if swallowed
	R 36/37/38:	Irritating to eyes, respiratory system, and skin
	R 43:	May cause sensitisation by skin contact
	R63*:	Possible risk of harm to the unborn child
	R 50/53:	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment
	* possible classification cannot be excluded with the data available	
S phrases	S 2:	Keep out of the reach of children
	S 22:	Do not breathe dust

	S 24/25:	Avoid contact with skin and eyes
	S 36/37/39:	Wear suitable protective clothing, gloves, and eye/face protection
	S 45:	In case of accident or if you feel unwell, seek medical advice immediately
	S 60:	This material and its container must be disposed of as hazardous waste
	S 61:	Avoid release to the environment

And according to CLP:

Acute Tox. 4 H302

Eye Irrit 2 H319

STOT SE 3 H335

Skin Irrit 2 H315

Skin Sens. 1 H317

Repr. 2 H361d

Aquatic Acute 1 H400

Aquatic Chronic 1 H 410

P261: avoid breathing dust

P262: Do not get in eye, on skin, or on clothing

P280 : Wear Protective gloves/ protective clothing /eye protection

P284 : Wear respiratory protection

P312: Call a POISON CENTER or doctor/physician if you fell unwell.

P501: dispose of content in accordance to local, regional or national regulation

P273: Avoid release to the environment

2.3.2. Proposed classification/labelling for the biocidal product Wolmanit Fume, following evaluation:

Classification on the basis of toxicological and environmental effects of the biocidal products shall, in the absence of experimental data, be deduced from the respective properties of the active substance(s) and the inactive ingredients on the basis of the conventional (calculation) method referred to in Article 6 and Annex II (tox.) and Article 7 and Annex III, Parts A and B (environment) of Directive 1999/45/EC.

Classification on the basis of toxicological properties from experimental data is only allowed if test results on animals already exist or it can be scientifically demonstrated that the toxicological properties of the preparation cannot correctly be determined by the conventional method. The proposed classification/labelling for the biocidal product Wolmanit Fume, containing >99.9% w/w Dazomet technical:

Classification/Labelling	as proposed by the BE CA	
Class of danger	Xn	Harmful
	N	Dangerous for the environment
R phrases	R 22:	Harmful if swallowed
	R 36/37/38:	Irritating to eyes, respiratory system, and skin
	R 43:	May cause sensitisation by skin contact
	R63*:	Possible risk of harm to the unborn child
	R 50/53:	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment
	* possible classification cannot be excluded with the data available	
S phrases	S 2:	Keep out of the reach of children
	S 22:	Do not breathe dust
	S 24/25:	Avoid contact with skin and eyes
	S 36/37/39:	Wear suitable protective clothing, gloves, and eye/face protection
	S 45:	In case of accident or if you feel unwell, seek medical advice immediately
	S 60:	This material and its container must be disposed of as hazardous waste
	S 61:	Avoid release to the environment

And according to CLP:

Acute Tox. 4 H302

Eye Irrit 2 H319

STOT SE 3 H335

Skin Irrit 2 H315

Skin Sens. 1 H317

Repr. 2 H361d

Aquatic Acute 1 H400

Aquatic Chronic 1 H 410

P102; Keep out of reach of children

P261: Avoid breathing dust

P262: Do not get in eye, on skin, or on clothing

P280 : Wear Protective gloves/ protective clothing /eye protection

P284 : Wear respiratory protection

P312: Call a POISON CENTER or doctor/physician if you fell unwell.

P501: Dispose of content in accordance to local, regional or national regulation

P273: Avoid release to the environment

2.3.3. Proposed classification/labelling for the degradation product/metabolite MITC, following evaluation:

Classification/Labelling	as proposed by the BE CA	
Class of danger	T	Toxic
	N	Dangerous for the environment
R phrases	R 23/25:	Toxic by inhalation and if swallowed
	R 21:	Harmful in contact with skin
	R 34:	Causes burns
	R 37:	Irritating to respiratory system
	R 41:	Risk of serious damage to eyes
	R 43:	May cause sensitisation by skin contact
	R 50/53:	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment
S phrases		

And according to CLP

Acute Tox 3 H331

Acute Tox 3 H330

Acute Tox 3 H 331

Acute tox 4 H 312

Skin Corr 1b H 314

STOT SE 3 H335

Eye Dam.1 H318

Skin sen 1 H317

Aquatic Acute 1 H400

Aquatic Chronic1 H410

2.4. Summary of the Risk Assessment

2.4.1. Human Health Risk Assessment

2.4.1.1. Hazard identification

Considering human health, particular consideration must be given to the decomposition of Dazomet in contact with water or humid air, generating gaseous MITC. Under practical working conditions there will be an unpredictable degree of Dazomet decomposition occurring. For the human health effects assessment, both the toxicity data from Dazomet and its daughter compound have been discussed, as the observed effects may have been caused by Dazomet, MITC, or both. The most relevant data for each endpoint is brought forward for the risk characterisation.

Active substance dazomet:

The **ADME**- studies show that oral administration of Dazomet is followed by a rapid and extensive absorption in the rat. Thus, no correction for incomplete oral absorption is necessary in the risk assessment. The substance is quickly distributed throughout the body tissues with the highest level found in the organs responsible for elimination and biotransformation (kidneys, urinary bladder, gastro-intestinal tract and liver) and the thyroids. The majority of the administered dose is excreted rapidly mostly via urines. There are no indications of accumulation in any tissue. Dazomet is efficiently metabolised. The major metabolic pathway of Dazomet is the breakdown to a main intermediary, MITC, and the subsequent conjugation of MITC with amino acids. There are no toxicokinetic studies available in other animal species, nor studies using the dermal route of exposure. An in vivo dermal absorption study of Dazomet, applied topically for 8 hours on the rat skin, revealed a dermal absorption of 3% for the concentrate and 9% for the 1/10 aqueous dilution (after 168 hours). As Dazomet will not be diluted for the intended use, an absorption rate of 3% is considered relevant for the risk assessment for the operator treating the transmission poles.

In **acute toxicity studies**, Dazomet was found to be harmful by the oral route and of low toxicity by inhalation and dermal application when the rat is used as the test species.

Dazomet has no potential for skin or eye **irritation** and is not **sensitising** to the skin in the regulatory animal tests performed. However, based on plenty of reliable human data, it can be concluded that as a result of MITC formation, Dazomet must be considered to be a skin, respiratory tract, and eye irritant, it is possibly a vesicant, it is sensitising to the skin, and may cause contact dermatitis under practical working conditions. The LOAEL = 5 mg/m³ for respiratory tract irritation through MITC formation was based on atrophy of the olfactory epithelium (4-week inhalation study, rat, MITC).

The **short-term dermal toxicity** of Dazomet was studied in a 21-day dermal toxicity study in rabbits. No local effects were observed at a dose level of 1,000 mg/kg bw/d. Apart from one mortality at the highest dose, no substantial systemic effects were observed. Therefore, the NOAEL for systemic effects was set at 100 mg/kg bw/d.

The **short-term oral toxicity** of Dazomet was studied in rats, mice and dogs. In the subchronic rodent studies, the blood and the liver were detected as the target tissue/organ. In the rat, fatty hepatocyte degeneration was observed. In the mouse, spleen haemosiderin deposits confirmed the haematological disorders. The dog showed the same toxicological profile, supplemented with methaemoglobinemia, increased alkaline phosphatase and alanine aminotransferase activities, and extramedullary haematopoiesis in the 90 days study. In the 1-year study, at the top dose some animals exhibited moderate to severe hepatitis or cirrhosis. The rat was found to be the most sensitive species. The lowest NOAEL was established in the 90 days rat study, i.e. 1.5 mg/kg bw/d, based upon the liver toxicity (increased liver weight, fatty liver degeneration) observed at 4.6 mg/kg bw/d.

NOAEL short-term = NOAEL (90-days, oral, rat) = 1.5 mg/kg bw/d.

The **long-term oral toxicity** of Dazomet was studied in rats. The effects were in line with those observed in the short-term studies. The liver was detected as the target organ.

Hepatotoxicity (increased weight, increased liver enzymes, decreased protein) was confirmed by centrilobular fatty degeneration. The long-term NOAEL was established at 0.9 mg/kg bw/d, based on the decrease in haematological and clinical-chemical parameters found at 5.3 mg/kg bw/d in females in the 2-year rat study. Chronic dermal and inhalation toxicity was not investigated.

NOAEL long-term = NOAEL (2-year, oral, rat) = 0.9 mg/kg bw/d.

No evidence was found that Dazomet is **genotoxic**. In vitro: In bacterial cells Dazomet was negative for the induction of mutagenic changes. In contrast, in eukaryotic cells, results of different tests revealed a mutagenic and clastogenic potential for Dazomet which was observed generally in absence of metabolic activation. Endoreduplication and/or polyploidisation occurred in 2 assays (mouse lymphoma, human lymphocytes) at doses where mitotic indices were not suppressed. In vivo: Micronuclei were weakly induced in mouse bone-marrow when Dazomet was administered intraperitoneally. However, the majority of the data (including a UDS study, a mouse micronucleus test with oral administration, and higher-tier germ cells assays: the spermatogonia chromosome aberration test and the SLRL Drosophila assay) indicate that Dazomet in not genotoxic. In conclusion, the global weight-of-evidence suggests that Dazomet should not be considered a genotoxicant.

Carcinogenicity studies were conducted in rats and mice. In female rats, at the highest dose, liver toxicity and an increased incidence of mixed cell and basophilic foci in the liver were seen in the carcinogenicity study. The high dose males showed an increased incidence and severity of diffuse hepatocellular fat deposition and hepatocellular vacuolisation in the liver. Confirming findings were seen in a chronic toxicity study. In mice, the target organ was also the liver, with increased liver weights and fat deposit as well as an increased incidence of basophilic foci being observed at the highest dose. In high dose females, there was a (non significant) increase in adenomas. This tumorigenic potential is not considered relevant to humans as it is only found in a sensitive mouse strain and at very high dose levels. In conclusion, Dazomet was considered not carcinogenic.

In a **two-generation study** in rats the only observations were the liver toxicity and some effects on body weight development in the parental generation. There was no effect seen on reproductive parameters or in the offspring. $NOAEL_{parental}$ = 0.5 mg/kg bw; $NOAEL_{offspring}$ = 18 mg/kg bw; $NOAEL_{reproduction\ parameters}$ = 18 mg/kg bw.

In the **developmental toxicity studies** in the rat foetotoxic effects (increased incidence of runts) were noted at a very slight maternal toxic dose level (characterised by a trend to decreased food consumption, a slight decrease in uterus weight, and corrected bw gain at 10 mg/kg bw/d). Additionally, a more than 10% increase in bilateral and total dilated renal pelvis (foetal- and litter-based) as well as in total hydroureters (litter-based) at all tested doses was observed, although without a dose-response relationship. In the rabbit, foetotoxic effects (decreased foetal weight, increased number of resorptions/post-implantation loss, increased rib/sternebrae variations) were only noted in the presence of marked maternal toxicity (1 fatality, clinical signs), thus indicating that these effects were secondary to maternal toxicity. With the available data it cannot be excluded that the embryo/foetotoxic effect seen in the rat study are the result of direct embryo/foetal exposure to Dazomet and not the result of maternal toxicity. Consequently, in the absence of further clarifying data it cannot be ruled out that classification is warranted. We want to inform that possible classification as toxic to reproduction Cat.3 is not excluded by the BE RMS. $NOAEL_{marternal}$ = 3 mg/kg bw;

$NOAEL_{developmental}$ < 3 mg/kg bw (↑ number of runts at 10 mg/kg bw/d, ↑ hydroureters and dilated renal pelvis at 3 mg/kg bw/d).

The potential **neurotoxicity** was investigated in an acute and sub-chronic neurotoxicity study in the rat. The findings in the acute study were only a reflection of an impairment of the general state of health. Neither were neurotoxic changes induced in the subchronic study. Dazomet does not have a specific neurotoxic potential in rats.

Degradation product/metabolite MITC:

The **ADME**- studies show that oral administration of MITC is also followed by a rapid and extensive absorption in the rat. No correction for incomplete oral absorption is necessary in risk assessment. The substance is quickly distributed throughout the body tissues with the highest level found in the thyroid gland and in the organs responsible for elimination and biotransformation (liver, kidney). The majority of the administered dose is excreted rapidly mostly via urine. There are no indications of accumulation in any tissue. MITC is efficiently metabolised. Similar to Dazomet, a total of five urinary metabolites were found, with 2 major metabolites being present. The principal component in the rat was the N-acetylcysteine conjugate of MITC. There are no toxicokinetic studies available in other animal species, nor studies using the dermal route of exposure. No dermal absorption studies have been submitted.

In **acute toxicity studies**, MITC was found to be toxic by the oral route and by inhalation and harmful by the dermal route when the rat is used as the test species.

MITC is considered **corrosive to the skin** and a **severe eye irritant.** MITC was found to be a **skin sensitiser** in the guinea pig maximisation assay. MITC was also found to be a **respiratory tract irritant**.

Short-term inhalation toxicity. The subacute 4-week inhalation study with MITC in rats was characterized by severe respiratory irritation and inflammation consisting of bronchopneumonia, epithelial proliferation, single cell necrosis and pathological changes in the nasal cavity. The $NOAEL_{systemic}$ = 5 mg/m³ (1.2 mg/kg bw/d) is based on decreased body weight (gain), clinical signs, increased non-focal atrophy of the olfactory epithelium, and increased neutrophils still observed at 20 mg/m³. The $LOAEL_{local}$ = 5 mg/m³ is based on focal atrophy of the olfactory epithelium observed at 5 mg/m³.

NOAEL short-term = NOAEL (4-week, inhalation, rat) = 1.2 mg/kg bw/d.

Considering the **short-term oral and long-term oral and dermal toxicity** of MITC, only summarized information is made available. Validation of these summarised studies is not possible.

No evidence was found that MITC is **genotoxic**. In vitro: MITC tested negative in bacteria and in the in vitro chromosome aberration test. In contrast, the open literature pointed to a possible positive outcome in a single cell gel assay in HepG2 cells, a weak positive result was obtained in an in vitro micronucleus assay, and DNA-comets were present in the Comet-assay. In vivo: MITC showed no evidence of mutagenic potential in mouse bone marrow when administered by gavage in an in vivo micronucleus test as discussed in the 91/414 DAR of Metam-Na and

Dazomet. In conclusion, the global weight-of-evidence suggests that MITC should not be considered a genotoxicant.

Considering **carcinogenicity,** only summarized information was made available. The studies were generally performed before the introduction of GLP or testing guidelines and are often limited in the scope of the investigations. Consequently, validation of these studies is not possible and this information should be regarded as supportive evidence only. According to these studies MITC was found not carcinogenic in rats and mice.

Considering fertility, only summarized information was made available. Consequently, validation of these studies is not possible and this information should be regarded as supportive evidence only. There was no effect on **reproductive** parameters or in the offspring according to the briefly reported two-generation study in rats.

The **developmental** studies led after oral administration of MITC to the rat to mild foetotoxic effects (increased incidence of runts) but at the next higher (maternal toxic) dose when compared with Dazomet, malformations, both visceral and skeletal, remained unaffected. In the rabbit, MITC showed the same toxicological profile as Dazomet, as the maternal toxicity LOAELs were comparable (10 -15 mg/kg bw/d). In the offspring, MITC did not alter the resorption rate or foetal viability up to and including the top-dose (10 mg/kg bw/d). The treatment with MITC was without effect on the number of malformations in the rabbit. $NOAEL_{maternal}$ = 3 mg/kg bw; $NOAEL_{developmental}$ = 10 mg/kg bw.

The **neurotoxicity** of MITC was not investigated.

2.4.1.2. Effects assessment, AEL setting

Dazomet

The critical endpoints of Dazomet in the toxicological studies are identified as the effect on the liver, characterised by increase in liver weight and fatty liver degeneration, decrease in haematological and clinical-chemical parameters. The NOAELs have been derived from the studies in the most sensitive species showing these effects. In addition, another relevant critical endpoint, the developmental toxicity of Dazomet, was identified and characterised by an increased incidence of runts and an increased incidence of bilateral and total dilated renal pelvis and total hydroureters. With the available data it cannot be excluded that the embryo/foetotoxic effects (variations/runts) seen are the result of direct embryo/foetal exposure to Dazomet (rather than the result of maternal toxicity). It was concluded to adopt a precautionary approach and to consider these effects in the risk assessment.

Acute $LOAEL_{developmental}$ = 3 mg/kg bw/d (rat, reproduction study)

(critical effects: increased incidence of runts and increased incidence of bilateral and total dilated renal pelvis and total hydroureters)

Medium-term $NOAEL_{subchronic}$ = 1.5 mg/kg bw/d (rat, oral, 90-days study)

(critical effects: increased absolute and relative liver weight, fatty liver degeneration)

Long-term $NOAEL_{chronic}$ = 0.9 mg/kg bw/d (rat, oral, 2-years study)

(critical effects: decrease in haematological and clinical-chemical parameters, indicative for liver toxicity)

As there is no indication for route-specific differences in toxicity which are not reflected by absorption data and as dazomet did not elicit any local effects in experimental animals, there is no hindrance for the use of an AEL derived from a NOAEL/LOAEL based on studies using the oral route of administration, i.e. setting the level of internal exposure that is toxicologically acceptable.

Assessment factors: default 100-fold (10 x 10). To convert the selected $LOAEL_{developmental}$ into an AEL, an additional 2-fold factor was considered because the derivation was based on a LOAEL adopting a precautionary approach.

Oral absorption: 100%

In conclusion: **Acute AEL = 0.015 mg/kg bw/d**

Medium-term AEL = 0.015 mg/kg bw/d

Long-term AEL = 0.009 mg/kg bw/d

MITC

The MITC 4-week inhalation study in rats was considered the most relevant study for the determination of the acute AEL for MITC. For the determination of the medium-term and long-term AELs for MITC, the most appropriate Dazomet NOAELs/LOAELs were used.

Acute $NOAEL_{inhalation}$ = 1.2 mg/kg bw/d (MITC, rat, 4-week inhalation, 6h/d)

(critical effects: decreased bw (gain), clinical signs, increased non-focal atrophy of the olfactory epithelium, increased neutrophils)

Short-term $LOAEL_{developmental}$ = 1.5 mg/kg bw/d (Dazomet, rat, oral, 90-days study)

(critical effects: increased absolute and relative liver weight, fatty liver degeneration)

Long-term $LOAEL_{developmental}$ = 0.9 mg/kg bw/d (Dazomet, rat, oral, 2-years study) (critical effects: decrease in haematological and clinical-chemical parameters, indicative for liver toxicity)

Assessment factors: default 100-fold (acute), 100-fold (short- and long-term). Oral absorption: 100%. Respiratory absorption: 100%. Conversion factor: 0.45

In conclusion: **Acute AEL = 0.012 mg/kg bw/d**

Medium-term AEL = 0.007 mg/kg bw/d

Long-term AEL = 0.004 mg/kg bw/d

For the local effect of respiratory tract irritation, an external reference value (AEC) has been derived:

AEC for route specific local effects: respiratory tract irritation

$LOAEL_{inhalation, local effects}$ = 5 mg/m³ (MITC, rat, 4-week inhalation, 6h/d) (critical effect: focal atrophy of the olfactory epithelium)

AF: 10 x 10 x 10 (default assessment factors 10 x 10, multiplied with an additional factor because starting from a LOAEL)

In conclusion: **$AEC_{respiratory\ tract\ irritation}$ = 0.005 mg/m³**

2.4.1.3. Exposure assessment

Primary exposure to humans is estimated for the intended use of Wolmanit Fume, containing >99.9% Dazomet technical, as wood preservative in form of granules for outdoor remedial treatment of wooden transmission poles. Wolmanit Fume is applied outdoors, by professional operators only. As such, the task (exposure scenario) foreseen in primary exposure is for professional operators: outdoor remedial treatment of transmission poles.

Typically, boreholes are drilled into the poles and filled with Wolmanit Fume using a ready-to-use semi-automated calibrated applicator. The application volume is filled by gravity into the boreholes via a purging valve. The boreholes are then plugged to minimise human and environmental exposure.

Potential risks to workers are associated with the dermal and inhalation routes of exposure. Workers are expected to wear chemical resistant gloves, goggles, footwear, and protective clothing so that a dermal contact with the biocidal product, Wolmanit Fume, is kept minimal.

The professional operator works typically for 8 hours a day. Typically 32 poles can be impregnated during the working day. The time needed for the treatment of one pole is assumed to amount approximately 15 minutes: 5 minutes for drilling the 3 holes, 5 minutes for filling the 3 holes, 5 minutes for walking around the pole during application and for walking from one pole to another. Therefore, a professional worker uses 4.8 kg Wolmanit Fume per day. The actual exposure time to the biocidal product is estimated to be 2 hours per day.

For exposure assessment purposes (Dazomet), an attempt was made to use the Technical Notes for Guidance (TNsG) - Human Exposure to Biocidal Products (2002) and perform some calculations according to the recommendations. However, when completing the User Guidance version 1, it became clear that for this very specific pattern of use no generic data, and hence no useable model, are available. Nevertheless, the inhalation exposure values were estimated with the Mixing and Loading model 5 (tier1). Further refinement of the dermal exposure assessment was undertaken by applying a reverse reference scenario (tier 2).

The only foreseen exposure route to MITC, is exposure by inhalation. The inhalational exposure to MITC may only occur during the short time the drilled treatment hole is filled with Dazomet (5 minutes/pole) which is minimized by the use of the semi-automated applicator. After the filling, the treatment hole will be capped with a tight fitting cap. From this point no further exposure to MITC is possible. The used model for MITC does not account explicitly for additional water in the drilled holes. As such, the application of Dazomet is not acceptable during rainy days or on wet wood.

Table 2.4.1.3.1: professional exposure to Dazomet and MITC, potential internal (and external) exposure

Exposure scenario: Professional outdoor remedial treatment of transmission poles				
DAZOMET				
Inhalation: M&Lmodel 5		**Estimated inhalation uptake (mg/kg bw/d)**		
	-RPE	0.00285		
	+RPE	0.00014		
Dermal: reverse reference scenario		**Estimated dermal uptake (mg/kg bw/d)**		
	+PPE, 3% dermal absorption, 100-fold AF	To exceed the AEL (0.009 mg/kg bw/d), the Dazomet contamination would need to exceed 180 mg/day (182 mg Wolmanit Fume) which is 38% of the product loss during application that would fall on the hands, remain on the hands, and would be available for dermal uptake[4]		
MITC				
calculated		**Estimated Internal Exposure**		
		Estimated inhalation uptake (mg/kg bw/d)	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
	-RPE	0.000045	-	0.000045
	+RPE	0.23×10^{-5}	-	0.23×10^{-5}
calculated		**Estimated External Exposure**		
		Estimated inhalation exposure (mg/m^3)	**Estimated dermal exposure (mg/cm^2)**	**Estimated total exposure (mg/m^3)**
	-RPE	0.0008	-	0.0008
	+RPE	0.00004	-	0.00004

Non-professional use is not intended, the use of the wood preservative is restricted to professional operators, outdoor use only.

[4] Further refinement for combined exposure (as requested by the FR C.A.):

Even with the knowledge that the inhalation exposure estimated with M&L model 5 is far too conservative, the reverse calculation for dermal exposure was redone, taking into account combined exposure (inhalation and dermal).
Considering inhalation exposure (0.00285 mg/kg bw/d) is 32% of the AEL, the dermal exposure must not exceed 68% of the AEL. This implies that the dermal dazomet contamination would need to exceed 123 mg dazomet/day (124 mg Wolmanit Fume) which is 26% of the product loss during application that would fall on the hands, remain on the hands, and would be available for dermal uptake. This situation can still be regarded as unrealistic

Secondary exposure. Secondary acute exposure for the bystander and general public are considered as not relevant because Wolmanit Fume is only used outdoors and the boreholes are immediately plugged. Additionally it can be concluded that also secondary chronic exposure is negligible.

2.4.1.4. Risk characterisation

The risk characterisation is in general based on the assumption that the products are used according to the conditions for normal use. It is furthermore assumed that the recommended personal protective equipment (PPE) will always be worn by professional users.

2.4.1.4.1. Human health risk for professional operators (Primary exposure)

Table 2.4.2.1.1. Professional operator: primary exposure to Dazomet – risk characterisation

Exposure Scenario (long-term)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 M&L model 5 (- PPE/-RPE)	Professional outdoor remedial treatment of transmission poles	-	0.00285	0.4063	0.4092	NOAEL: 0.9 mg/kg bw/d chronic AEL: 0.009 mg/kg bw/d	100	**2.2***	**45***
(+PPE/-RPE)		-	0.00285	0.0406	0.0435	NOAEL: 0.9 mg/kg bw/d chronic AEL: 0.009 mg/kg bw/d	100	**21***	**4.8***

Tier 2 inhalation exposure: M&L model 5 (-RPE)	**Professional outdoor remedial treatment of transmission poles**		0.00285			NOAEL: 0.9 mg/kg bw/d chronic AEL: 0.009 mg/kg bw/d	100	316	0.32
dermal exposure: reverse reveference scenario (+PPE)		To exceed the AEL (0.009 mg/kg bw/d), the Dazomet contamination would need to exceed 180 mg/day (182 mg Wolmanit Fume) which is 38% of the product loss during application that would fall on the hands, remain on the hands, and would be available for dermal uptake. This situation can be regarded as unrealistic.							

* refinement needed

Table 2.4.2.1.2. Professional operator: primary exposure to MITC – risk characterisation for systemic effects

Exposure Scenario **(long-term)**		**Estimated Internal Exposure**				**Relevant NOAEL/ LOAEL**	**AF**	**MOE**	**Exposure /AEL**
		estimated oral uptake [mg/kg b.w/day]	**estimated inhalation uptake [mg/kg b.w/day]**	**estimated dermal uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**	**[mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)**	**MOE_{ref}**		
Tier 1 (-RPE)	**Professional outdoor remedial treatment of transmission poles**	-	0.000045	-	0.000045	NOAEL: 0.9 mg/kg bw/d chronic AEL: 0.004 mg/kg bw/d	222	2×10^4	0.01
Tier 2[§] (+RPE)	Professional outdoor remedial treatment of transmission poles					NOAEL: 0.9 mg/kg bw/d chronic AEL: 0.004 mg/kg bw/d			

[§] for your information only

Table 2.4.2.1.3. Professional operator: primary exposure to MITC – risk characterisation for local effects

Exposure Scenario (long-term)		Estimated External Exposure / Estimated Inhalation Exposure [mg/m³]	Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
Tier 1 (-RPE)	**Professional outdoor remedial treatment of transmission poles**	0.0008	LOAEL: 5 mg/m³ Local AEC for respiratory tract irritation: 0.005 mg/m³	1000	6250	0.16
Tier 2[§] (+RPE)	Professional outdoor remedial treatment of transmission poles	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

[§] for your information only

Dazomet and its degradation product/metabolite, MITC, are both classified as irritants to the skin, eye, and respiratory tract and as a skin sensitiser. As such, risk managing tools were already taken into consideration. For the biocidal use, outdoor remedial treatment of transmission poles – to be used by professional operators only-, the biocidal product Wolmanit Fume will be made available as a ready-to-use semi-automated applicator to reduce exposure. Additionally, the professional operators are assumed to be trained and skilled in the main tasks of their occupation and, as such, are expected to wear chemical resistant gloves, goggles, footwear, and protective clothing so that a dermal contact with the biocidal product, Wolmanit Fume, is kept minimal.

In practice, primary dermal and inhalation exposure of the professional operator will be reduced by the effects of exposure reduction measures (ready-to-use semi-automated applicator) and the use of PPE (proper work clothing, chemical resistant footwear, goggles, gloves). Thus, with the assumption that the obligatory PPE is used, a sufficient margin of

exposure is maintained and the total internal dose is below the long-term AEL for both Dazomet and MITC. No additional RPE is required. Moreover, the external inhalation exposure to MITC is below the local $AEC_{respiratory\ tract\ irritation}$ for MITC, even without the protection of RPE.

Conclusion: There is no concern for the professional operator, using the biocidal product, Wolmanit Fume, in the granular form for the outdoor remedial treatment of transmission poles with the ready-to-use semi-automated calibrated applicator and the immediate sealing of the holes after application, provided appropriate PPE is worn and provided Wolmanit Fume is is neither used in rainy weather nor on wet wood.

2.4.1.4.2. Human health risk for non-professional users (Primary exposure)

The biocidal product is foreseen to be used by trained professionals only and outdoors. Thus, a risk characterisation for non-professional users (primary exposure) is not relevant.

2.4.1.4.3. Human health risk from indirect exposure as a result of use (Secondary exposure)

No secondary exposure of non-professionals is anticipated. Chronic possible exposure of the general public is considered negligible (only used outdoors for treatment of utility poles). As such, the general public will not be exposed to Dazomet in its regular use as an internal remedial wood preservative.

Extension of the use pattern beyond the one reviewed will require a re-evaluation of the Annex I entry of Dazomet in order to establish whether the proposed extensions of use satisfy the requirements of Article 10(1).

2.4.2. Environmental Risk Assessment

Regarding the emission of dazomet in the environment following the envisaged use, (wood preservative for transmission poles PT8) particular consideration must be given to the impossibility for the active as such to leach out of the wood in his solid sate. In contact of water or humidity, dazomet decomposes in gaseous MITC. Only MITC emission to the environment has to be expected under normal use conditions. For the effects assessment the most relevant endpoints for dazomet and MITC are presented

2.4.2.1. Fate and distribution in the environment

Dazomet hydrolyses rapidly in MITC (methyl-isothiocyanate) (DT_{50}= 0.59 d, 12°C, pH= 7). After two days the active substance is no longer detectable in water. It is not readily biodegradable but additional studies indicate that it is inherently biodegradable. In biologically active soils, is degraded to MITC with a half-life of few hours (DT_{50} > 0.5day).

Leaching studies in soil showed that dazomet adsorbs very little to soil particle and was rapidly degraded under the conditions of the available studies. MITC adsorbs very little to soil particle

and is degraded with a half-life of (32.7d at 10°C). A mobility study shows that MITC doesn't show tendency to move in the deeper soil layer and that there is no lateral displacement.

The very low vapour pressure (5.8 x 10^{-4} Pa at 20°C) of dazomet indicates that it has a low tendency to volatilise. However, MITC is subject to rapid evaporation due the high vapour pressure. (2500Pa). In the air, MITC has a half-life of 4.5 day.

Dazomet is characterized by a log P_{ow} value below 1 and a calculated BCF value of 2.39 indicating no significant risk of bioaccumulation of the substance in organisms. For the degradation product MITC, a log P_{ow} of 1.2 and a calculated BCF value of 3.16 were reported, indicating no significant risk of bioaccumulation of this substance in organisms.

2.4.2.2. Effects assessment

Dazomet show a high acute toxicity to aquatic organism particularly to fish. (LC_{50} 96h = 0.16mg/l) However, since dazomet rapidly degrade in MITC in water, this effect could not be clearly attributed to dazomet. MITC show a higher 96h toxicity to fish in comparison to dazomet (LC_{50} 96h = 0.053mg/l).

The $PNEC_{water}$ was derived based on the NOEC (28d)= 0.005mg/l for MITC on fish (Rainbow trout), with an AF of 50

PNEC water= 0.1µg/l

Dazomet and MITC also show acute toxicity to microbial organisms. Therefore, depending on conditions and existing concentrations, disturbances in the biodegradation process of activated sludge of wastewater treatment plants are possible. The $Pnec_{stp}$ was derived from the MITC EC50 of sewage sludge micro organisms from an activated sludge growth inhibition test, with an AF of 10.

$PNEC_{stp}$ =150µg/l

Toxicity studies on earthworms indicate that the toxicity level for dazomet and MITC are in the same range. Dazomet and MITC show moderate toxicity to earthworms. For the purpose of the risk assessment, only MITC is relevant. The $PNEC_{soil}$ was derived from the LD_{50} (14d) = 2.79 mg/kg soil $_{dry, weight}$ with an AF of 1000.

$PNEC_{soil}$ = 2.79 µg/$kgsoil_{d,w}$

Since the KOC value for both Dazomet and MITC are below 500, this exclude the need to derive any PNEC for the sediment compartment according to the Technical Guidance Document.

The main degradation product MITC has a very high vapour pressure (2500 Pa) therefore the air compartment could be of concern. In the air, the major pathway for MITC degradation is direct photolysis, which one is influenced by the O_2 content of the air. MITC is degraded in the troposphere with typical DT_{50} value comprised between 108 and 960 hours. Calculations with

AOPwin (v1.91) result in a half-life of 118 d (24 h day, 5 x 10^5 OH/cm³). Referring to Annex D of the Stockholm Convention on Persistent Organic Pollutants (POP convention, 2004) the active substance MITC has a potential for long-range environmental transport.

2.4.2.3. PBT assessment

Dazomet

Dazomet undergo rapid degradation in aquatic environment, freshwater and sediments, and should therefore not be considered as Persistent (P).

Dazomet is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt. Dazomet is not bioaccumulable (B)

There is no chronic NOEC of Dazomet for marine or freshwater organisms. Dazomet does not meet T criteria (T)

Therefore, dazomet should be considered as not fulfilling the criteria for Persistence Bioaccumulation and Toxicity.

MITC

MITC does not degrade in fresh water by hydrolysis. However other removal processes such as volatilization, photolysis or binding to particulate matter lower the concentration in water. In sediment MITC disappear rapidly. Less than 2% can be found in sediment after 14d. The majority of the MITC formed in water-sediment system is further detected in the volatile fraction. Most of the subtance and of the degradation products are further mineralised in CO_2. Based on these considerations, MITC cannot be regarded as persistent (P)

MITC is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt. MITC cannot be regarded as Bioaccumulable (B)

The chronic NOEC of MITC for freshwater organisms is > 0,01mg/l. MITC is toxic by inhalation and if swallowed. MITC has to be considered as Toxic. (T)

In Conclusion, MITC should be considered as not fulfilling the criteria for Persistence, Bioaccumulation and Toxicity.

2.4.2.4. Exposure assessment

The OECD ESD guidance available is limited to local exposure calculation. The relevant scenario for the application of the product based on the claim of the applicant is the transmission pole scenario. No emission of the active to the environment is foreseen during production phase or and no industrial use is claim. The emissions during life stage are limited to MITC emission to soil and air. Theses have been evaluated and the only relevant target compartment identified was the soil.

2.4.2.5. Risk characterisation

For the environment, the only relevant substance is the degradation product MITC. Therefore, risk characterisation for the environment has been discussed for MITC only.

2.4.2.4.1.1 Water/sediment compartment

The water compartment was not identified as a target compartment following application of dazomet. Moreover, no PNECsed needs to be derived as regard to the KOC values of dazomet and MITC. Therefore, no unacceptable risk to water compartment from in service leaching has been quantified. For the sediment in the absence of PNECsed, no risk has been quantified.

2.4.2.4.1.2 Soil compartment

The hazard profile for dazomet has shown that it rapidly degrades to MITC in all compartments. Data has been presented to shown that MITC in soil will be removed by volatilisation and also by biotic (under aerobic conditions) and abiotic degradation.

The short (30 days) and long term (10 years corresponding to the application rate) risk posed to the local soil compartment during life stages were acceptable for MITC. The RCR values were calculated to be 24.6 and 3.58 for 30d and 10 years respectively. Therefore, a risk for the soil compartment can not be excluded based on the actual results. Further monitoring of the MITC concentrations in soil around treated poles is needed to completely exclude a risk in real conditions. Please refer to doc II C of the CAR for extensive argumentation.

2.5. Listing of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. PROPOSAL FOR THE DECISION

3.1. Background to the Proposed Decision

The overall conclusion from the evaluation of Dazomet for use in Product Type 8 (Wood Preservatives), is that it may be possible for Member States to issue authorisations of products containing Dazomet in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

Article 10 of the Biocides Directive 98/8/EC addresses the inclusion of an active substance in the Annexes I, IA or IB. For the decision of non-inclusion, it has to be examined if the criteria of article 10 (1) are fulfilled.

The physico-chemical properties of the preservative product, Wolmanit Fume (99.9% w/w Dazomet technical) are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

Assessed from the documentation for the active substance Dazomet, and the biocidal product Wolmanit Fume, containing 99.9% w/w Dazomet technical, the proposed application manner and area of use of Wolmanit Fume intended to control Basidiomycetes may be sufficient effective for this specific use and without unacceptable risks neither to human health nor to the environment.

The estimation of hazards and the exposure assessment for human health for Wolmanit Fume and Dazomet showed the following results: the active substance Dazomet / the biocidal product Wolmanit Fume is harmful when swallowed and of low toxicity by inhalation or applied to the skin. With regard to reproductive toxicity, Dazomet showed some effects but with the data available, it cannot be ruled out that classification is not warranted. We want to inform that possible classification as toxic to reproduction Cat.3 is not excluded. Based on published human data, Dazomet / Wolmanit Fume may induce skin, eye, and respiratory tract irritation and skin sensitisation through MITC formation. Dazomet / Wolmanit Fume is unlikely to be genotoxic or to pose a carcinogenic risk to humans.

The risk assessment evaluation is focused on the specific use the applicant applied for: the use of Wolmanit Fume, containing 99.9% Dazomet technical, as a wood preservative in form of granules for remedial treatment of wooden transmission poles against fungal attack. The treatment will be performed outdoors by professional users only, by using a semi-automated calibrated applicator to poles.

This overall conclusion relies on the fact that users of the biocidal product will be applying the basic principles of good practice and respect the conditions for the normal use recommended on the label of the product.

Regarding to the environmental aspects, Dazomet/ Wolmanit Fume is toxic for water and soil organisms. The estimation of the emission into environment following application of Wolmanit Fume in wood utility poles associated to the fate and behaviour of the active substance and the main degradation product has shown that water compartment is not of concern. For soil compartment unacceptable risks have not been fully excluded.

3.2. Proposed Decision regarding Inclusion in Annex

BE CA recommends that Dazomet is included in Annex I of the Directive 98/8/EC as an active substance to be used in wood preservative products (Product Type 8), subject to the following specific provisions:

1. The technical active substance Dazomet, as manufactured, shall have a minimum purity of ≥ 96% w/w
2. The identity and maximum content of impurities (found in the "Confidential Annexes") must not differ in such a way as to invalidate the assessment for the inclusion of the active substance on to annex I.
3. The Annex I - entry should, however, only include the intended uses supported by data and the content of the inclusion directive shall reflect the conditions and restrictions for the use of Dazomet as a wood preservative proposed in the report. Dazomet has been assessed only for professional use outdoors for the remedial treatment of wooden poles, such as transmission poles, by insertion of granules.
4. Professional workers must use suitable PPE to prevent exposure under all conditions.

3.3. Factors to be taken into account by Member States when authorising products

- Wolmanit Fume is intended for use as a wood preservative in form of granules for the remedial treatment of wooden poles, such as transmission poles, against internal decay of the poles by Basidiomycetes.
- Wolmanit Fume should not be authorised for other purposes without performing a risk assessment for the new use.
- Womanit Fume should be applied in the form of granules, by using a semi-automated calibrated applicator to boreholes in the pole. Immediately after application the boreholes must be plugged.
- Wolmanit Fume is not accepted for use in rainy weather, and is not used to treat wet wood.
- Product must be labelled appropriately to ensure their safe storage, handling, use and disposal in accordance with national arrangements
- The need to address any specific national condition and/or undertake regional assessments should be considered, as only local environmental risk assessments have been carried out in this evaluation.
- At the stage of product authorisation, a monitoring study of MITC concentration in soil has to be provided in order to describe the fate and behaviour of the main degradation product MITC in soil. The study design should follow the monitoring

test protocol for measurement of MITC in soil around poles treated with dazomet provided in addendum.

- Direct release to sewage or to natural water should be avoided and the waste should be collected and eliminated in accordance with the regional regulations of the Member State authorising individual product.

3.4. Requirement for further information

The information and justifications supplied in accordance with Annex II and Annex III of Directive 98/8/EC has been accepted as sufficient to recommend an inclusion of Dazomet on Annex I.

3.5. Updating this Assessment Report

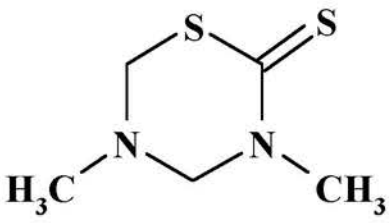
The technical information in this Assessment Report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of Dazomet in Annex I to the Directive.

Appendix I: Listing of end points

Chapter 1:Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Dazomet
Function (e.g. fungicide)	Fungicide
Rapporteur Member State	Belgium

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione
Chemical name (CA)	2H-1,3,5-thiadiazine-2-thione, tetrahydro-3,5-dimethyl-
CAS No	533-74-4
EC No	208-576-7
Other substance No.	146
Minimum purity of the active substance as manufactured (g/kg or g/l)	The commercial batches are analysed using CIPAC 146 TC – 1984. This method leads to a min. 99% purity as there is no distinction between Dazomet and its dimeric isomers. The correct content for Dazomet itself is minimum 960 g/kg. (96%)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	This information is presented in the 'Confidential Annex'
Molecular formula	C5H10N2S2
Molecular mass	162.3
Structural formula	C1SC(=S)N(C)CN1(C) (Smiles code) 

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	103.2 – 105.2 °C (99.8% purity) / MITC: 35.9 °C
Boiling point (state purity)	Decomposition before boiling/ (99.8% purity) (MITC: 119 °C)
Temperature of decomposition	> 150 °C, Maximum at 180 °C MITC > 160 °C
Appearance (state purity)	Solid, colourless, weak characteristic odour (99.8% purity)
Relative density (state purity)	$d_{20/4}$ = 1.330 MITC: density d = 1.069 g/cm^3 at 37 °C
Surface tension	69.4 mN/m at 20^{0}C for a 0.1% solution
Vapour pressure (in Pa, state temperature)	5.8 x 10^{-4} Pa at 20°C (MITC: 2500 Pa at 20 °C)
Henry's law constant (Pa m^3 mol $^{-1}$)	2.5 x 10^{-5}Pa m^3/mol (MITC: 22 Pa m^3/mol)
Solubility in water (g/l or mg/l, state temperature)	pH__5____: 3.5 g/l at 20.2 °C pH__9____: 3.9 g/l at 20.2 °C pH__7____: 3.7 g/l at 20.2 °C (used for risk assessment) MITC: 8.36 g/l at pH 6.6 – 7.0 and 20 °C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	<0.1 g/l n-heptane 8.6 g/l toluene 234 g/l dichlormethane 21.3 g/l methanol 89.7 g/l acetone 28.5 g/l ethylacetate 112 g/l acetonitrile 3.6 g/l iso-propanol 2.2 g/l octanol 1.7 g/l olive oil all at 20^{0}C
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Organic solvents not used in the biocidal products
Partition coefficient (log K_{OW}) (state temperature)	pH___5___: 0.3 at 24 °C pH___9___: 0.3 at 24 °C pH___7___: 0.3 at 24 °C

	MITC: 1.2 at pH 6.8 – 7.1 and 25 °C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH__5__: 6 hr at 25^0C (MITC: 49.2 d)
	pH__7__: 5 hr at 25^0C (MITC: 104.59 d)
	pH__9__: 2.9 hr at 25^0C (MITC: 11.14 d)
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	The substance does not dissociate
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	ε = 11378 mol^{-1} cm^{-1} at 283.0 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	pH__7__: 7.6 sunlight hours (latitude 35 °; river water) MITC: pH__7__: 885 sunlight hours (latitude 35 °; river water)
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	Not required
Flammability	Not highly flammable
Auto-flammability	Not auto-flammable
Explosive properties	Not explosive / MITC: not explosive

Summary of intended uses:

Field of use/ Product type	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
			Type	Conc. of as	method kind	number min max	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Fungicide/ PT8	**Wolmanit Fume**	**Wood destroying fungi (Basidiomycetes)**	**Ready to use granulate for remedial treatment of the inner part of wood-products**	**99.9% ***	**Borehole treatment:** Semi-automated process: Boreholes are drilled into the poles, and filled with the product, in form of granules, using a calibrated applicator. The application volume is filled by gravity into the boreholes via a purging valve. In addition to this, the holes are immediately plugged.	**1 time**	**8-10 years**	**150g per pole distributed in 3 boreholes**			**professional use outdoors for the remedial treatment fo wooden poles, such as transmission poles, by insertion of granules**

*Dazomet technical

Classification and proposed labelling - DAZOMET

with regard to physical/chemical data	no classification required
with regard to toxicological data	Xn; R22, R36/37/38, R43, R63* * possible classification cannot be excluded with the data available.
with regard to fate and behaviour data	
with regard to ecotoxicological data	N; R50/53

Classification and proposed labelling - MITC

with regard to physical/chemical data	no classification required
with regard to toxicological data	T; R23/25, R21, R34, R41, R37, R43
with regard to fate and behaviour data	
with regard to ecotoxicological data	N; R50/53

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC-UV Dazomet is dissolved in acetonitrile and determined by high performance liquid chromatography on a reversed phase column using acetonitrile – water – acetic acid as mobile phase, UV-detection at 284 nm and external standardisation.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC-UV The impurities in technical Dazomet are separated by reversed phase HPLC (C18, acetonitrile/water) and quantitatively determined by UV detection with external calibration using reference substances.

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	GC-MS determination of MITC LOQ = 0.05 mg/kg MITC
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GC-MS determination of MITC LOQ = 0.0003 µg/l MITC
Water (principle of method and LOQ) (Annex IIA, point 4.2)	GC- MS (EI) determination of MITC LOQ = 0.02 µg/l MITC
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	HPLC-MSD confirmed by HPLC-MS/MS LOQ = 0.05 mg/l N-acetyl-S-[(methylamino)carbothioyl]cysteine

	(blood plasma, urine)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Crop: tomato, strawberry GC-MS determination of MITC LOQ = 0.02 mg/kg MITC
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	no data, not required

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

DAZOMET

Rate and extent of oral absorption:	Rapid, extensive absorption; bioavailability approx. 100%
Rate and extent of dermal absorption:	In vivo dermal absorption in the rat (8 hours topical application), after 168 hours: 3% for concentrate (formulation, 97% pure a.s.) 9% for aqueous 1/10 dilution
Distribution:	Highest concentrations in kidney, urinary bladder, gastro-intestinal tract, liver, and thyroid
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Rapid, mostly via urine (64-70%) and expired air (18-33%), feces (2.5-3.6%), biliary (6.5-8.2%)
Toxicologically significant metabolite	Methylisothiocyanate MITC

MITC

Rate and extent of oral absorption:	Rapid, extensive absorption; bioavailability approx. 100%
Rate and extent of dermal absorption:	No data
Distribution:	Highest concentrations in kidney, liver, and thyroid
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	mostly via urine (approx. 85%) and expired air (10-16%), feces (2%)
Toxicologically significant metabolite	Principal component: N-acetylcysteine conjugate of MITC

Acute toxicity (Annex IIA, point 6.1)
DAZOMET

Rat LD_{50} oral	415 mg/kg bw	Xn, R22
Rat LD_{50} dermal	> 2000 mg/kg bw	-
Rat LC_{50} inhalation	8400 mg/m³	-
Skin irritation	Animal testing: not irritating Human findings: irritating through MITC formation	Xi, R38
Eye irritation	Animal testing: not irritating Human findings: irritating through MITC formation	Xi, R36
Respiratory tract irritation	Animal testing: not irritating Human findings: irritating through MITC formation	Xi, R37
Skin sensitization (test method used and result)	Animal testing: not sensitising (Maximization test) Human findings: sensitising through MITC formation	R43

MITC

Rat LD_{50} oral	147 mg/kg bw	T, R25
Rat LD_{50} dermal	1290 mg/kg bw	Xn, R21
Rat LC_{50} inhalation	540 mg/m³	T, R23
Skin irritation	Corrosive	C, R34
Eye irritation	Severely irritating	Xi, R41
Respiratory tract irritation	Irritating	Xi, R37
Skin sensitization (test method used and result)	Sensitizing (Maximization test)	R43

Short-term Repeated dose toxicity (Annex IIA, point 6.3)
DAZOMET

Species/ target / critical effect	Oral toxicity was studied in rats, mice and dogs. The liver and the blood were detected as the target organ/tissue. In rodents, hepatotoxicity (increased liver weight) was confirmed by hepatocyte fatty degeneration. Rat: most sensitive species. Study: rat, oral, 90-days
Lowest relevant oral NOAEL / LOAEL	NOAEL = 1.5 mg/kg bw/d (rat, 90-days) LOAEL = 4.6 mg/kg bw/d (rat, 90-days)
Lowest relevant dermal NOAEL / LOAEL	NOAEL = 100 mg/kg bw (rabbit, 3 weeks)
Lowest relevant inhalation NOAEL / LOAEL	Not required for dazomet.

MITC

Species/ target / critical effect	Severe respiratory irritation and inflammation consisting of bronchopneumonia, epithelial proliferation, single cell necrosis and pathological changes in the nasal cavity. Critical systemic effects: decreased body weight (gain), clinical signs, increased non-focal atrophy of the olfactory epithelium. Critical local effect: Focal atrophy of the olfactory epithelium. Study: rat, inhalation, 4-weeks
Lowest relevant oral NOAEL / LOAEL	-
Lowest relevant dermal NOAEL / LOAEL	-
Lowest relevant inhalation NOAEL / LOAEL	Systemic: NOAEL = 5 mg/m³ = 1.2 mg/kg bw LOAEL = 20 mg/m³ Local: LOAEL = 5 mg/m³

Long-term Repeated dose toxicity (Annex IIA, point 6.3)
DAZOMET

Species/ target / critical effect	Oral chronic toxicity was studied in rats. The liver and the blood were detected as the target organ/tissue. Hepatotoxicity (increased weight, increased liver enzymes, decreased protein) was confirmed by centrilobular fatty degeneration. Critical effect: decrease in haematological and clinical-chemical parameters Study: rat, oral, 2-year
Lowest relevant oral NOAEL / LOAEL	NOAEL = 0.9 mg/kg bw/d (rat, oral, 2 year) LOAEL = 5.3 mg/kg bw/d (rat, oral, 2-year)
Lowest relevant dermal NOAEL / LOAEL	-
Lowest relevant inhalation NOAEL / LOAEL	-

MITC

Species/ target / critical effect	Only summarised information available. Validation not possible.
Lowest relevant oral NOAEL / LOAEL	-
Lowest relevant dermal NOAEL / LOAEL	-
Lowest relevant inhalation NOAEL / LOAEL	-

Genotoxicity (Annex IIA, point 6.6) **DAZOMET and MITC**	Dazomet and MITC: not genotoxic. Dazomet: In vitro and in bacterial cells Dazomet was negative for the induction of mutagenic changes as well in the presence as in the absence of metabolic activation. In contrast, in eukaryotic cells, results of different tests revealed a mutagenic and clastogenic potential for Dazomet which only was observed in absence of metabolic activation. In vivo, the majority of the data (only one exception reported) indicate that Dazomet in not genotoxic. MITC: The major breakdown product of Dazomet is not genotoxic. Only one case of in vitro clastogenicity was reported for MITC, though at cytotoxic doses. In vivo, there was no evidence of mutagenic potential in mouse bone marrow when administered by gavage in a micronucleus test.

Carcinogenicity (Annex IIA, point 6.4)

DAZOMET

Species/type of tumour	Mouse: liver adenoma at 68 mg/kg bw/d, but no carcinoma; not carcinogenic
lowest dose with tumours	/

Reproductive toxicity (Annex IIA, point 6.8)

DAZOMET

Species/ Reproduction target / critical effect	A two-generation study in the rat: The only observations were the liver toxicity and some effects on body weight development in the parental generation. There was no effect seen on reproductive parameters or in the offspring.
Lowest relevant reproductive NOAEL / LOAEL	NOAEL(offspring) = 18 mg/kg bw/day NOAEL (fertility) = 18 mg/kg bw/day NOAEL (parent) = 0.5 mg/kg bw/d
Species/Developmental target / critical effect	Rat, Rabbit,Teratogenicity: Rat: foetotoxic effects (increased incidence of runts) were noted at a very slight maternal toxic dose level (characterised by a trend to decreased food consumption, a slight decrease in uterus weight, and corrected bw gain at 10 mg/kg bw/d). In addition, a more than 10% increase in bilateral and total dilated renal pelvis (fetal- and litter-based) as well as in total hydroureters (litter-based) at all tested doses was observed, although without a dose-response relationship. With the available data it cannot be excluded that the embryo/foetotoxic effects (variations, runts) seen in the rat study are the result of direct embryo/foetal exposure to Dazomet and not the result of maternal toxicity. Rabbit: foetotoxic effects (decreased foetal weight, increased number of resorptions/post-implantation loss, increased rib/sternebrae variations) only noted in the presence of marked maternal toxicity (1 fatality, clinical signs). These effects were considered secondary to maternal toxicity.
Lowest relevant developmental NOAEL / LOAEL	LOAEL(developmental) = 3 mg/kg bw/d (rat: ↑ number of runts at 10 mg/kg bw/d, ↑ hydroureters and dilated renal pelvis at 3 mg/kg bw/d), precautionary approach NOAEL(maternal) = 3 mg/kg bw/d (rat)

MITC

Species/ Reproduction target / critical effect	Only summarised information available. Validation not possible.
Lowest relevant reproductive NOAEL / LOAEL	-
Species/Developmental target / critical effect	Rat, Rabbit, Teratogenicity: In rats and in rabbits, no indication of malformations or any other embryo-/foetotoxic effect due to MITC. In rats, very mild foetotoxic effects (increased incidence of runts) were reported at maternal toxic dose levels (30 mg/kg bw).
Lowest relevant developmental NOAEL / LOAEL	NOAEL (developmental) = 10 mg/kg bw (rat) NOAEL (maternal) = 3 mg/kg bw (rat) NOAEL (developmental) = 10 mg/kg bw (rabbit) NOAEL (maternal) = 3 mg/kg bw (rabbit)

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

DAZOMET (no data available for MITC)

Species/ target/critical effect	Rat (acute and sub-chronic studies): FOB and MA measurements and neuropathological examinations were performed. Not neurotoxic
Lowest relevant developmental NOAEL / LOAEL.	/

Medical data (Annex IIA, point 6.9)

	Irritation of Dazomet under work place conditions in industry is low. **Over a period of at least 10 years only 17 cases of irritation to skin and eyes**

	have been reported in production personnel. Due to the low stability of Dazomet in aqueous systems especially under acidic conditions, **most human health effects seen with Dazomet might be due to** MITC formation, the main metabolite and degradation product of Dazomet. **MITC has a high acute toxicity as experienced from a case of fatal human intoxication** where ingestion of 50g was lethal and caused necrosis of exposed mucosa tissue. Even at low concentrations **MITC is strongly irritant to exposed human tissues** (skin, eye, respiratory and gastrointestinal tract) causing skin rash, itching and inflammation. **MITC is a very potent allergen in humans** (based on the limited exposure and high incidence of cases).

Summary (Annex IIA, point 6.10) **DAZOMET**	Value	Study	Safety factor
ADI (if residues in food or feed) → Not required	—		
Acute AEL	0.015 mg/kg bw/d	Dazomet, developmental study, oral, rat $LOAEL_{develop}$ = 3 mg/kg bw/d Precautionary approach!	200
Medium-term AEL	0.015 mg/kg bw/d	Dazomet, 90-days study, oral, rat $NOAEL_{subchronic}$ = 1.5 mg/kg bw/d	100
Long-term AEL	0.009 mg/kg bw/d	Dazomet, 2-years study, oral, rat $NOAEL_{chronic}$ = 0.9 mg/kg bw/d	100
Drinking water limit	—		
ARfD (acute reference dose)	—		
Summary (Annex IIA, point 6.10) **MITC**	Value	Study	Safety factor
ADI (if residues in food or feed) → Not required	—		

Acute AEL	0.012 mg/kg bw/d	MITC, 4 weeks, inhalation, rat, NOAEL = 1.2 mg/kg bw/d	100
Medium-term AEL	0.007 mg/kg bw/d	Dazomet, 90-days study, oral, rat $NOAEL_{subchronic}$ = 1.5 mg/kg bw/d conversion factor: 0.45	100
Long-term AEL	0.004 mg/kg bw/d	Dazomet, 2-years study, oral, rat $NOAEL_{chronic}$ = 0.9 mg/kg bw/d conversion factor: 0.45	100
AEC respiratory tract irritation	0.005 mg/m³	MITC, 4 weeks, inhalation, rat, LOAEL = 5 mg/m³	1000
Drinking water limit	—		
ARfD (acute reference dose)	—		

Acceptable exposure scenarios (including method of calculation)

Professional users: Outdoor remedial treatment of transmission poles with a semi-automated application system.	<u>+PPE/-RPE:</u> systemic effects Dazomet inhalation: MOE = 316, Exposure/AEL = 0.32 Dazomet dermal: To exceed the AEL (0.009 mg/kg bw/d), the Dazomet contamination would need to exceed 180 mg/day (182 mg Wolmanit Fume) which is 38% of the product loss during application that would fall on the hands, remain on the hands, and would be available for dermal uptake. This situation can be regarded as unrealistic.[5]

[5] Further refinement for combined exposure (as requested by the FR C.A.):

Even with the knowledge that the inhalation exposure estimated with M&L model 5 is far too conservative, the reverse calculation for dermal exposure was redone, taking into account combined exposure (inhalation and dermal).
Considering inhalation exposure (0.00285 mg/kg bw/d) is 32% of the AEL, the dermal exposure must not exceed 68% of the AEL. This implies that the dermal dazomet contamination would need to exceed 123 mg dazomet/day (124 mg Wolmanit Fume)

	MITC: MOE = 2 x 10^4, Exposure/AEL = 0.01 local effects – respiratory tract irritation MITC: MOE = 6250, Exposure/AEC = 0.16 **No concern, provided appropriate PPE is worn, and provided Wolmanit Fume is neither used in rainy weather nor on wet wood.**
Non-professional users	Not intended
Indirect exposure as a result of use	Not applicable

which is 26% of the product loss during application that would fall on the hands, remain on the hands, and would be available for dermal uptake. This situation can still be regarded as unrealistic

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of Dazomet (DT_{50})	pH__4____: 0.36 d at 25 °C; 0.12 at 35 °C
Hydrolysis of Dazomet (DT_{50})	pH__5____: 0.25 d at 25 °C; 0.11 at 35 °C
Hydrolysis of Dazomet (DT_{50})	pH___7___: 0.21 d at 25 °C; 0.007 at 35 °C
Hydrolysis of Dazomet (DT_{50})	pH___9___: 0.12 d at 25 °C; 0.05 at 35 °C
Hydrolysis of MITC (DT_{50})	pH__4____: 107.25 d at 25 °C; **
Hydrolysis of MITC (DT_{50})	pH__5____: 49.2 d at 25 °C; **
Hydrolysis of MITC (DT_{50})	pH___7___: 104.59 d at 25 °C; **
Hydrolysis of MITC (DT_{50})	pH___9___: 11.14 d at 25 °C; **
**: degree of freedom too small, no reliable estimation of half-life possible	
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Dazomet DT50 value: between 3.6 and 4.7 hours under experimental conditions corresponding to 7.6 to 9.9 spring sunlight hours. (highest values used for the risk assessment) MITC DT50 value: between 417 and 461 hours under experimental conditions corresponding to 885 to 980 spring sunlight hours. (highest values used for the risk assessment)
Readily biodegradable (yes/no)	Dazomet and MITC cannot be considered readily biodegradable according to OECD 301 D
Biodegradation in seawater	No data are available
Non-extractable residues	Not determined
Distribution in water / sediment systems (active substance = Dazomet; metabolite = MITC)	Dazomet and MITC were found to adsorb very little to any soil type. For dazomet, Koc values of 129-394 have been determined for adsorption. Desorption showed values between 1034 and > 5011. This difference is based on rapid degradation of dazomet to MITC by hydrolysis.

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic) values for Dazomet were 0.28 (Li 35b: r^2 = 0.97), 0.54 (Lufa 2.2) and 0.3 days (Lufa 3A), respectively.
	The DT_{50lab} values for MITC were in the range of

	5.0 – 13.6 days at 20°C (r^2 = 0.80 – 0.97).
	DT_{50lab} (10°C, aerobic): At 10 °C, the DT50 of Dazomet was 1.3 day (r^2 = 0.89). The degradation of Dazomet resulted in the formation of MITC, which was quickly further degraded to CO_2 and non-extractable residues. The DT50 of MITC was 32.7 days at 10°C (r^2 = 0.89).
	DT_{50lab} (20°C, anaerobic): Estimated half-lives were 0.01 days for Dazomet and 120.9 days for MITC.
	Degradation in the saturated zone: no data available, not relevant
Field studies: The soil types according to the German classification were loamy silt (trial 1, Germany) or loamy sand (trials 2 and 3, Spain). 5 soil samples were taken at 10 sampling times up to 30 days (trial 1) and 20 days (trial 2 and 3), respectively.	DT_{50f}: Dazomet was rapidly degraded in all 3 field trials with DT50 values ranging from 0.9 to 1.6 days. MITC DT50 values of 1.3 (trial 3, with plastic cover) and 2.1 days (trial 2, without plastic cover) were determined. In trial 1, the dissipation was slightly retarded during coverage of the soil (12 days) yielding a DT50 value of 20.3 days. After removal of the plastic sheet and aeration of the soil, the dissipation of MITC was significantly enhanced resulting in a DT50 value of 6.1 days from day 12 onward.
	DT_{90f}: Dazomet DT90 values were between 2.9 and 5.2 days. MITC DT90 values of 4.5 and 7.1 days were determined. In trial 1, the dissipation was slightly retarded during coverage of the soil (12 days). After removal of the plastic sheet and aeration of the soil, the dissipation of MITC was significantly enhanced resulting in a DT90 value of 20.2 days from day 12 onward.
Anaerobic degradation	Dazomet was immediately degraded under anaerobic soil conditions. The major degradation pathway was the formation of MITC, which reached a maximum of 72 % of the total applied radioactivity (TAR) after 2 days. Dazomet and MITC were further degraded to minor amounts of other compounds and finally to CO_2 and non-extractable residues. The overall amount of CO_2 was formed up to 38.6 % of TAR after 120 days incubation. A number of further degradation products could be detected, however, these peaks appeared only in minor amounts. Soil bound residues were formed in moderate amounts of up to 30.3 % TAR after 120 days. It was

	shown that the radioactivity from the non-extractable residues was tightly bound to the soil matrix, which could not be released even with harsh extraction methods. Estimated half-lives were 0.01 days for Dazomet and 120.9 days for MITC.
Soil photolysis	Degradation of ^{14}C-Dazomet on moist, microbially active soil surfaces was investigated: Under irradiated and non-irradiated conditions, the parent concentration decline was independent of light exposure. From an initial value of 102.6 - 104.9% of dose Dazomet, the concentration rapidly decreased with a concurrent rapid generation of Methylisothiocyanate (MITC} within 24 hours (maximum 74.1% of dose from irradiated, 80.0% of dose from dark). Non-extractable residues were a maximum of 4.5% of dose for irradiated soils and 3.6% of dose for dark soils. No distinction could be made for irradiated vs. non-irradiated soils. A further study revealed the degradation of ^{14}C-dazomet, when exposed on plates to the light source, (apparent half-life of 5.4 hours between 2 and 24 hours). On dark control plates the half-life was 62.6 hours for the period 4-48 hours. The major degradation product was MITC (identified by GC-MS), which was found on the soil and in the ethyl acetate solvent traps. No more than 1.3% of the radioactivity was detected in the traps of ethoxyethanol : ethanolamine indicating only a small proportion of the 14C-dazomet was degraded to $^{14}CO_2$. In the 24- and 48-hour exposed soils, only approximately 45% of the radioactivity was recovered indicating the loss of volatile radioactivity not trapped by the solvent used. It is likely that this volatile material was CS2 or COS. In the corresponding control samples more than 88% of the radioactivity was recovered.
Non-extractable residues	See above
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	See above
Soil accumulation and plateau concentration	The adsorption/desorption were investigated for dazomet in Spare (1992) and for MITC in Komatsu (1990). HPLC analysis demonstrated conversion of dazomet to MITC within 4 hours adsorption phase. Dazomet and MITC were found to adsorb very little to any soil type. For dazomet, Koc values of 129-394 have been determined for adsorption.

	Desorption showed values between 1034 and > 5011. This difference is based on rapid degradation of dazomet to MITC by hydrolysis.

Adsorption/desorption of Dazomet (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd	0.808-1.834; in the range of 3.91 to >23*
Ka_{oc} , Kd_{oc}	values ranged from 1034 to >5011*,
pH dependence (yes / no) (if yes type of dependence)	No (highest values used for the risk assessment)

* based on estimate

Adsorption/desorption of MITC (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd	0.32-0.68; Kd: n.d.
Ka_{oc} , Kd_{oc}	27-46 (mean 36),Kd: n.d.
pH dependence (yes / no) (if yes type of dependence)	No (highest values used for the risk assessment)

n.d. not determined

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis of MITC in air	The tropospheric degradation of MITC was investigated in a smog chamber experiment at room temperature (399 K). In this study, direct photolysis was observed to dominate in the observed decay, OH contributed less than 15% to the degradation.
Quantum yield of direct photolysis	No data available
Photo-oxidative degradation in air	Latitude: sea level in middle Europe Season: summer DT_{50} = 4.5 days
Volatilization	Dazomet is not volatile, MITC is volatile

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	No monitoring conducted for wood treatment. A monitoring study of MITC concentration in soil has to be provided by the applicant at product authorisation level
Surface water (indicate location and type of study)	No monitoring conducted for wood treatment

Ground water (indicate location and type of study)	No monitoring conducted for wood treatment
Air (indicate location and type of study)	No monitoring conducted for wood treatment

Chapter 5: Effects on Non-target Species

Dazomet

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Lepomis macrochirus	96 h	LC50	>0.464-<1.000 mg/l
Salmo gairdneri	96 h	LC50	0.16 mg/l
Invertebrates			
Daphnia magna	48 h	50% immobilisation	0.30 mg/l
Algae			
Scenedesmus subspicatus	72 h	50% reduction of growth rate	1.015 mg/l
Microorganisms			
Activated sludge	0.5 h	20% inhibition of oxygen consumption	Ca. 17 mg/l
Pseudomonas putida	17 hours	10% inhibition of growth	1.8 mg/l

MITC

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Salmo gairdneri	96 h	LC50	0.0531 mg/l
Salmo gairdneri	28d	NOEC	0.005 mg/l
Invertebrates			
Daphnia magna	48 h	50% immobilisation	0.076 mg/l
Daphnia magna	21d	Reproduction and mobility	0.0125mg/l

Algae			
Selenastrum capricornutum	72 h	50% reduction of growth rate	0.58 mg/l
Microorganisms			
Activated sludge	0.5 h	10% inhibition of oxygen consumption	Ca. 1.5 mg/l

Effects on earthworms or other soil non-target organisms

Acute toxicity of Dazomet to Eisenia fetida (Annex IIIA, point XIII.3.2)	Artificial soil, 14 d LC50 (mg/kg soil): 6.7
Acute toxicity of MITC to Eisenia fetida (Annex IIIA, point XIII.3.2)	Artificial soil, 14 d LC50 (mg/kg soil): 2.79
Reproductive toxicity (Annex IIIA, point XIII.3.2)	No data

Effects on soil microorganisms (Annex IIA, point 7.4)

Nitrogen mineralization Carbon mineralization	BAS 002 01 N applied once a year (500mkg/ha) resulted in short-term and mid-term effects on the functions of soil microorganisms. This was particularly true for the nitrate production (stimulation). One year after application, both, the carbon and the nitrogen transformation processes turned back to normal levels indicating recovery of the microbial functions.

Effects of Dazomet on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	Dazomet: LD50 rats, oral: ca. 500 mg/kg bw LD50 rats, dermal: > 2000 mg/kg bw LC50 rats, inhalation: ca. 8.4 mg/l Not irritating to skin and eye Not sensitizing MITC: LD50 rats, oral: 100 – 150 mg/kg bw LD50 rats, dermal: = 1290 mg/kg bw

	LC50 rats, inhalation: 0.54 mg/l Severely irritating to skin and eye Sensitizing
Acute toxicity to birds (not mentioned in Annex IIIA, point XIII.1.1, no key study)	Colinnus virginianus, LD50 = 415 mg/kg bw
Dietary toxicity to birds (not mentioned in Annex IIIA, point XIII.1.2, no key study)	Colinnus virginianus, LC50 = 1850 ppm
Reproductive toxicity to birds (not mentioned in Annex IIIA, point XIII.1.3, no key study)	Anas platyrhynchas, Colinnus virginianus: NOEC = 100 mg/kg diet

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Study not performed
Acute contact toxicity	Study not performed

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	No data
Acute contact toxicity	No data
Acute toxicity to other arthropods	Poecilus cupreus: No effects on Poecilus cupreus exposed to aged soil after application of 500 kg/ka BAS 002 001 N were observed (the reference item Perfekthion EC resulted in a mortality of 96.7% (corrected value: 96.6%). Folsomia candida: Treated soil was covered and left under outdoor conditions for 7 days. Thereafter, the uncovered soil was left to age (DA 0; DA 7 and DA 14; DA = days of aging) Collembola were exposed under laboratory conditions for 28 days. DA 0: mortality was 100%; reproduction was reduced by 100%. DA 7: mean mortality (22% +/- 16%) and mean reproduction (673 +/-116 juveniles, equivalent to 109% of control) were not significantly different from control. DA 14: mean mortality (10% +/-10%) and mean

	reproduction (657 +/-67 juveniles, equivalent to 95% compared to control) were not significantly different from the control. No abnormal behaviour or conditions were observed with the surviving Collembola in either bioassay.

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Dazomet: calculation, (SRC - BCFWIN v2.14): BCF = 2.39 MITC: calculation, (SRC - BCFWIN v2.14): BCF = 3.16
Depuration time(DT_{50}) (DT_{90})	Not applicable
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not applicable

Appendix II: List of Intended Uses

Dazomet is used in the wood preservation area as a fungicide.

Wolmanit Fume (> 99.9% Dazomet technical) is intended for professional use outdoors for the remedial treatment of wooden poles, such as transmission poles, by insertion of granules, against internal decay of the poles by Basidiomycetes (Hazard class 4).

Appendix III: List of Studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii).

These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.12.2 (06)	Alexeeff G. V. et al.	1994	Dose-assessment of airborne methyl isothiocyanate (MITC) following a Metam Sodium spill, Risk Analysis, 14 (2), p 191- 198, BASF DocID 1994/1000292, 1994 Published	N	_
A6.3.2 (02) A6.4.1 (05) A6.4.1 (06) A6.4.1 (07) A6.4.3 (01) A6.5 (04) A6.5 (05) A6.6.2 (05) A6.6.2 (06) A6.6.3 (03) A6.6.4 (02) A6.7 (03) A6.7 (04) A6.8.2 (02)	Anonymous	1990	Summary of toxicity data on Methyl Isothiocyanate (MITC), Agrochemical Division, Nihon Schering K.K. and Agrochemical & Animal Health Products Development, Shionogi & Co., Ltd., published data, J. Pesticide Sci. 15, 297-304, BASF DocID 1990/0571, 1990 Not GLP, published	N	_

6 Should refer to the section number in Doc III-A or III-B. If the study is non-key, and hence not summarised in Doc III but mentioned in Doc II, it should be included in the reference list alongside related references and its location in Doc II indicated in brackets. (If there is a need to include a cross-reference to PPP references then an additional column can be inserted).

7 Should include the author's surname before initial (s) to enable the column to be sorted alphabetically. If the Human Rights Charter prevents author's surnames on unpublished references being included in non-confidential documents, then it will be necessary to consider including 'Unpublished [number/year & letter] ' in Doc II, and both ' Unpublished [number/year & letter]' and the 'Authors Name' in the reference list'. This may necessitate the need for an additional column to state whether a reference is unpublished which can then be sorted.

8 Blackened authors names are considered confidential. The full version of the reference list is accessible to MS via The confidential part of the Circa

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.7 (02)	Anonymous	1989	Amended Pathology report, study of the oncogenic potential of Dazomet in mice dietary administration for 78 weeks (BASF AG project 65C00318/8585), EPL Scientific Limited, Cambridge, U.K., unpublished report 102-00 dated 13 Mar 1989, BASF DocID 1989/5210, 18 Sep 1989 GLP, unpublished	N	_
A6.12.1 (01)	Anonymous	2000	BASF, Medical department (2000) personal communication, Unpublished	Y	KST
A6.12.3 (01)	Anonymous	1998	Test report: field operator exposure test with Basamid granular, Jai Research Foundation, JRF test number: 571, BASF DocID 1998/1003934, 1998 Unpublished	N	_
A4.1/01	Anonymous	2000	Dazomet, HPLC method for technical and GR formulations, CIPAC No. 146, CIPAC/4109. CIPAC, Harpenden AL5 2 HG, UK BASF DocID 2000/1021646 No GLP / Published	N	-
A7.4.1.4 (01)	[redacted]	2001	Determination of the inhibition of the oxygen consumption by activated sludge in the activated sludge respiration inhibition test, BASF AG, Department of Product Safety, Ludwigshafen/Rhein, Germany, BASF Doc ID 2001/1014685, 02 Oct 2001 GLP, Unpublished	Y	KST
	Baillie T.A.et al. :	1991	Glutathione: a vehicle for het transport of chemically reactive metabolites in vivo. Acc Chem Res, 24, 9: 264-270	N	-
	BASF AG	1961	Ergebnis der Gewerbetoxikologischen Vorprüfung, Departement of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report XI/99, BASF DocID 1961/0003	Y	KST
B 7.4.1.4/01	[redacted]	1980	Department of Ecology, unpublished results, 18.11.1980	Y	KST
Doc II B	BASF	2000	Medical department (2000) personal communication.	Y	BASF
	BASF AG	2004	Document III-B summaries on the biocidal product Wolmanit Fume Section B8 Measures necessary to protect man	Y	BASF

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
Doc II A 4.1.1.4	[redacted]	2003	Field soil dissupation of BAS 002N(Dazomet) in the formulation BAS 002 01N on bare soil in Germany and Spain 2002.(BASF doc ID 2003/1005449)	Y	BASF
A6.12.2 (07)	Bearer C. F. et al.	1993	Pediatric consequences of methyl isothiocyanate exposure, Pulmonology, Abstract No. 2245, p 378A, BASF DocID 1993/1000270, 1993 Published	N	_
A6.8.1 (04)	[redacted]	1986b	Embryotoxicity (including teratogenicity) study with MITC, ZNT-No. 85/231-2 in the rabbit, Research & Consulting Company AG (RCC), Itingen, Switzerland, unpublished report 056687, BASF DocID 1986/395, 05 Sep 1986 GLP, unpublished	Y	KST
A6.8.1 (04)	[redacted]	1986a	Dose-finding embryotoxicity (including teratogenicity) study with MITC, ZNT-No. 85/231-2 in the rabbit, Research & Consulting Company AG (RCC), Itingen, Switzerland, unpublished report056676, BASF DocID 1986/085, 17 Jan 1986 GLP, unpublished	Y	KST
Doc IIA, 3.4.1	Bello D. et al.	2007	Skin exposure to isocyanates : Reasons for concern, Environmental Health Perspectives, 115 (3), 328-335	N	_
A6.6.7 (01)	[redacted]	1979	Mutagenicity evaluation of N-521 technical, batch #149, in the sex-linked recessive lethal test in Drosophila melanogaster, Litton Bionetics, Inc., Kensington, USA, unpublished report LBI 21093, BASF DocID 1979/0166, Jul 1979 GLP, unpublished	Y	KST
A6.12.6 (08)	Black H.	1973	Subject: dazomet and chloropicon, Contact Dermatitis, 7, p 410 - 411, BASF DocID 1973/1000101, 1973 Published	N	_
A6.12.2 (04)	Bolognesi C. et al.	1993	Frequency of mircronuclei in lymphocytes from a group of floriculturists exposed to pesticides, Toxicol. Environ. Health, 40, 405-411, BASF DocID 1993/1000207, 1993 Published	N	_

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.12.2 (04)	Bolognesi C. et al.	1995	Genotoxic risk from occupational exposure to pesticides in floriculture, Clinical Chemistry, 41, 1919-1922, BASF DocID 1995/1002991, 1995 Published	N	–
A6.6.2 (04)	[redacted]	1979	Mutagenicity evaluation of N-521 in an in vitro cytogenetic assay measuring sister chromatid exchange and chromosome aberrations, Litton Bionetics, Inc., Kensington, USA, unpublished report LBI 20990, BASF DocID 1979/0167, Mar 1979 Not GLP, unpublished	Y	KST
A6.5 (01)	[redacted]	1989	24 months chronic toxicity (feeding) study with Dazomet in the rat (BASF report 70C0318/8583), Pathology report, RCC, Itingen, Switzerland, unpublished report 200384, BASF DocID 1989/0276, 19 Jun 1989 GLP, unpublished	Y	KST
A6.7 (01)	[redacted]	1989	24 months oncogenicity (feedind) study with Dazomet in the rat, Pathology report part 1, RCC, Ittingen, Schwitzerland, unpublished report RCC project 200395 (BASF project 70C0318/8584), BASF DocID 1989/0277, 07 Jul 1989 GLP, unpublished	Y	KST
A6.6.3 (02)	[redacted]	1985	Evaluation of Dazomet in the rat primary hepatocyte unscheduled DNA synthesis assay, Litton Bionetics, Inc., Kensington, USA, unpublished report LBI20991, BASF DocID 1985/217, Jun 1985 GLP, unpublished	Y	KST
A6.6.5 (01)	[redacted]	1986	Evaluation of Dazomet techn. (99.3 %) CH.03584, 84/198 in the in vivo/in vitro rat hepatocyte unscheduled DNA synthesis assay, Hazleton Biotechnologies Company (alt), Kensington, USA, unpublished report HBC20991, BASF DocID 1986/249, Sep 1986 GLP, unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.1.3 (03)	[redacted]	1981	Methyl Isothiocyanate - Acute inhalation toxicity in rats - 4 hour exposure, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report BSF 378/801109, BASF DocID 1981/082, 09 Apr 1981 GLP, unpublished	Y	KST
	Cone J.E. et al.	1994	Persistent respiratory health effects after a metam sodium pesticide spill, Chest, 106 (2): 500-508.	N	-
A3.1.1/01 A3.1.2/01 A3.3/01 A3.10/01	[redacted]	2000a	Determination of the melting point, the appearance, the thermal stability and the stability in air of Dazomet PAI, Study Code PCP05774, Oct 19, 2000 BASF AG, Agricultural Center Limburgerhof, Germany BASF DocID 2000/1017122, GLP / Unpublished	Y	KST
A3.4/01	[redacted]	2000b	UV-, NMR-, IR-, MS-Spectra of Dazomet, Study Code PCP05773, Sep 26, 2000 BASF AG, Agricultural Center Limburgerhof, Germany BASF DocID 2000/1016963, GLP / Unpublished	Y	KST
A3.5/03	[redacted]	2000c	Determination of the Solubility in Water of Dazomet, Study Code PCP05716, Apr 06, 2000 BASF AG, Agricultural Center Limburgerhof, Germany, BASF DocID 2000/1004142, GLP / Unpublished	Y	KST
A3.6/01	[redacted]	2000d	Determination of the Dissociation Constant of Dazomet, Study Code PCP05589, Jan 10, 2000 BASF AG, Agricultural Center Limburgerhof, Germany, BASF DocID 2000/1000073 GLP / Unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A3.9/03	[redacted]	2000e	Determination of the Octanol/Water-partition Coefficient of Dazomet, Study Code PCP05588, Jan 10, 2000 BASF AG, Agricultural Center Limburgerhof, Germany, BASF DocID 2000/1000072, GLP / Unpublished	Y	KST
A6.12.2 (03)	De Ferrari M. et al.	1991	Cytogenetic biomonitoring of an Italian population exposed to pesticides: chromosome aberration and sister-chromatid exchange analysis in peripheral blood lymphocytes. Mutation Research, 260, p 105 -113, BASF DocID 1991/1000317, 1991 Published	N	_
A7.4.1.2 (02)	[redacted]	2002	Effect of Methyl-isothiocyanate (MITC) on the immobility of Daphnia magna Straus in a 48 hour semi-static, acute toxicity test, BASF AG, Agricultural Center Limburgerhof, Germany, unpublished report No. 58330, BASF Doc ID 2002/1006188, 22 Jul 2002 GLP, Unpublished	Y	KST
B 7.5.1.2/02 See A7.5.1.2/06	[redacted]	1991	BASF Doc. ID 1991/10280 Freilandversuch Regenwurmer	Y	KST
Doc IIC	[redacted]	1991	Field Trial on the effect of BAZAMID Granular (BAS002 01 N) treatment on soil arthropods	Y	BASF
A3.5/01	[redacted]	2002a	Water Solubility of Dazomet, Study No. 01L00627, 19. Feb. 2002 BASF AG, Ludwigshafen/Rhein, Germany, BASF DocID 2002/1017608 GLP / Unpublished	Y	KST
A3.9/01	[redacted]	2002b	Partition Coefficient n-Octanol/Water (log Pow) of Dazomet, Study No. 01L00628, 18. Feb. 2002 BASF AG, Ludwigshafen/Rhein, Germany, BASF DocID 2002/1017609 GLP / Unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.12.2 (02)	Dulout F. et al.	1985	Sister-chromatid exchanges and chromosomal aberrations in a population exposed to pesticides. Mutation Research, 143 (4), p 237 -244, BASF DocID 1985/1000081, 1985 Published	N	_
	ECB	2002	Technical Notes of Guidance in support of Directive 98/8/EC of the European parliament and the council concerning the placing of biocidal products on the market, Guidance on exposure estimation, part 3. Final draft	N	-
	ECB	2002a	Technical Notes for Guidance: Human exposure to biocidal products – guidance on exposure estimation. Report 2002. http://ecb.jrc.it/biocides	N	-
	ECB	2002b	Technical Notes of Guidance in support of Directive 98/8/EC of the European parliament and the council concerning the placing of biocidal products on the market, Guidance on exposure estimation. Final draft.	N	-
	ECB	2005	Technical Guidance Documents in support of Directive 93/87/EEC on risk assessment for new notified substances and the commission regulation (EC) 1488/94 on risk assessment for existing substances, part 1, chapter 4, human risk characterization, revision document TGD_H_RC_dr_ECB_01.doc	N	-
A6.2 (01)	[redacted]	1993	Amendment No. 1 to "Distribution and metabolism of 14C-Dazomet in rats", Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 487/921420 dated 01 Dec 1992, BASF Doc ID1993/10354, 25 Mar 1993 GLP, unpublished	Y	KST
A6.2 (01)	[redacted]	1992	Distribution and metabolism of 14C-Dazomet in rats, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 487/921420, BASF DocID 1992/11478, 01 Dec 1992 (sponsored by BASF AG, Limburgerhof, Germany) GLP, unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.2 (02)	[redacted]	1987b	The biokinetics and metabolism of ^{14}C-Dazomet in the rat, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 455/87954, BASF DocID 1987/0469, 12 Nov 1987 (sponsored by BASF AG, Limburgerhof, Germany) GLP, unpublished	Y	KST
A6.2 (04)	[redacted]	1987a	The biokinetics and metabolism of methyl isothiocyanate-^{14}C in the rat, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 456/87983, BASF DocID 1987/0463, 19 Sep 1987 (sponsored by BASF AG, Limburgerhof, Germany), GLP, unpublished	Y	KST
A6.6.2 (01)	[redacted]	1989	Amendment to the report of April 4, 1989 on the in vitro cytogenetic investigations of Dazomet (ZST test substance No.: 85/318) in human lymphocytes, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 30M0318/854174 dated 04 Apr 1989, BASF DocID 1989/0247, 03 Jul 1989 GLP, unpublished	Y	KST
A6.6.4 (01)	[redacted]	1985	Cytogenetic investigations in NMRI mice after a single oral administration of Dazomet - Micronucleus test, BASF AG, Ludwigshafen/Rhein, Germany, unpublished report 26M0198/8421, BASF Doc ID 1985/154, 24 May 1985 GLP, unpublished	Y	KST
A6.6.2 (01)	[redacted]	1989	In vitro cytogenetic investigations of Dazomet in human lymphocytes, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 30M0318/854174, BASF DocID 1989/0094, 04 Apr 1989 GLP, unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.6.1 (02)	[redacted]	1986	Report on the study of Methylisothiocyanate (ZNT test substance No.: 85/231) in the AMES test (standard plate test with Salmonella typhimurium), BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 40/1M0231/85, BASF DocID 1986/010, 28 Jan 1986 GLP, unpublished	Y	KST
A6.6.2 (02)	[redacted]	1987	In vitro cytogenetic investigations in human lymphocytes with Methylisothiocyanate, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 30M0231/8575, BASF DocID 1987/0184, 26 May 1987 GLP, unpublished	Y	KST
A 3/02	[redacted]	2001	Physicochemical properties of Methylisothiocyanate, BASF AG, Report No 2001/1020522, GLP, unpublished	Y	KST
A6.12.6 (04)	Garnier R. et al.	1993	Dermite de contact au dazomet: 7 cas, Arch. mal prof., 54 (8), p 649 – 651, BASF DocID 1993/1000208, 1993 Published	N	–
A 7.4.1.1/01	[redacted]	1981	Prüfung der akuten Toxizität am Karpfen, BASF AG, report No: 80/46 (2521), no GLP, unpublished	Y	KST
A 6.1.3/01	[redacted]	1986	Study of the acute inhalation toxicity LC50 4 hours (rat); dust study of Dazomet BASF AG, Report No. 86/289 (85/318) GLP, Unpublished	Y	KST
B 7.4.1.1/03 See A7.4.1.1/02	[redacted]	1980	Report on testing for acute toxicity, Rainbow Trout BASF.Dept Toxicology, unpublished, Report No. 81/10083 21.08.1981, no GLP	Y	KST
B 7.4.1.1/01 See A7.4.1.1/03	[redacted]	1986	Bericht über die Prüfung der akuten Toxizität von Basamid-Granulat am Sonnenbarsch (Bluegill), BASF AG, Department of Toxicology, no GLP, unpublished, Report No. 84/198, 04 Apr. 1986	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A7.4.1.4 (02)	[redacted]	1988	Influence of Dazomet on the growth of, BASF AG, Agricultural Research and Development Environmental Research, Ludwigshafen/Rhein, Germany, unpublished report No. 2560, BASF DocID 88/10116, 13 Jul 1988 GLP, Unpublished	Y	KST
A3.11/01 A3.12/01 A3.15/01 A3.16/01	[redacted]	2000	Evaluation of Safety Characteristics (A9 - A17), SIK-No. 00/0778, Apr. 13, 2000, BASF AG, Safety Engineering, Ludwigshafen, Germany, BASF DocID 2000/1013166, GLP / Unpublished	Y	KST
A3.1.1/03 A3.1.3/05	[redacted]	1990	Physical Properties Report, Laboratory Study Code PCF 00310, August, 1990 BASF AG, Agricultural Center Limburgerhof, Germany, BASF DocID 91/10049, GLP / Unpublished	Y	KST
A3.2/01	[redacted]	1988	Determination of the Vapour Pressure of Dazomet, Dec. 13, 1988 BASF AG, Agricultural Center Limburgerhof, Germany BASF DocID 88/11670, No GLP / Unpublished	Y	KST
A6.6.3/01	[redacted]	1986	Point mutation test carried out on CHO cells (HGPRT locus) with the test substance DazometBASF AG, Report No. 84/198 (1986/215) Not GLP, unpublished	Y	KST
A7.1.1.1.1 (01)	[redacted]	2003	Hydrolysis of BAS 002 N (Dazomet), BASF AG, Agricultural Center Limburgerhof, Germany, unpublished report No. 58299, BASF Doc ID 2003/1000964, 24 Feb 2003 GLP, Unpublished	Y	KST
A7.2.2.4 (02)	[redacted]	1986b	The metabolism of 14C Dazomet in soil under anaerobic condition, Huntingdon Research Centre, Huntington, UK, BASF DocID 1986/0449, 1986 GLP, unpublished	Y	KST
	[redacted]	1987	The photolysis of 14C-Dazomet in water, HRC, Report No. 1987/0396, Unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.2 (04)	[redacted]	1988a	1st Amendment to HRC/BSF 456/87983 - The biokinetics and metabolism of methyl isothiocyanate-14C in the rat, Huntingdon Research Centre, Huntingdon, UK, unpublished report HRC/BSF 456/87983 dated 19 Sep 1987, BASF DocID 1988/0095, 1988 GLP, Unpublished	Y	KST
A6.2 (02)	[redacted]	1988b	1st Amendment to HRC/BSF 455/87954 - The biokinetics and metabolism of ^{14}C-Dazomet in the rat, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 455/87954 dated 12 Nov 1987, BASF DocID 1988/0096, 02 Feb 1988 GLP, unpublished	Y	KST
A6.2 (03)	[redacted]	1985	The absorption and disposition of ^{14}C-Dazomet in rats, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 423/85945, BASF DocID 1985/0455 GLP, unpublished	Y	KST
A7.2.2.1 (03)	[redacted]	1986a	The metabolism of 14C Dazomet in soil under aerobic condition, Huntingdon Research Centre, Hundington, UK, BASF DocID 86/0429, 1986 GLP, unpublished	Y	KST
A6.2 (04)	[redacted]	1988a	1st Amendment to HRC/BSF 456/87983 - The biokinetics and metabolism of methyl isothiocyanate-^{14}C in the rat, Huntingdon Research Centre, Huntingdon, United Kingdom, unpublished report HRC/BSF 456/87983 dated 19 Sep 1987, BASF DocID 1988/0095, 1988 GLP, unpublished	Y	KST
A 3.2.1/02	[redacted]	2002	Methylisothiocyanate (MITC) - Estimation of Henry's law constant, DHD Consulting, Report No BAS-2002-03, no GLP, unpublished	Y	KST
B 5.10.2/02	Helsing G.G., Morrell J., Graham D.	1984	Evaluations of fumigants for control of internal decay in pressure-treated Douglas-fir poles and piles, published	N	-

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.3.1 (01)	[redacted]	1989d	Study on the oral toxicity of Dazomet in rats - Dietary administration for 4 weeks (range-finding study), BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 20C0318/8527, BASF DocID 1989/0089, 21 Mar 1989 (translation, original report in German dated 28 Dec 1988) GLP, unpublished	Y	KST
A6.4.1 (01)	[redacted]	1987a	Report on the study of the oral toxicity of Dazomet in rats after 3-month administration in the diet, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 30C0318/8544, BASF DocID 1987/0448, 17 Dec 1987 (translation, original report in German dated 11 Dec 1987) GLP, unpublished	Y	KST
A6.4.1 (03)	[redacted]	1989a	Report on the study of the oral toxicity of Dazomet in mice, dietary administration for 4 weeks (prolonged to 91 days), (range-finding study), BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 25C0318/8530, BASF DocID1989/0053, 07 Feb 1989 (translation, original report in German dated 03 Feb 1988) GLP, unpublished	Y	KST
A6.4.1 (04)	[redacted]	1987b	Report on the study of the toxicity of Dazomet in Beagle dogs after 3-month administration via the diet, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 31D0318/8533, BASF DocID1987/ 0456, 21 Dec 1987 (translation, original report in German dated 09 Sep 1987) GLP, unpublished	Y	KST
A6.5 (03)	[redacted]	1989c	Report on the study of the toxicity of Dazomet in Beagle dogs, administration via the diet over 12 months, BASF AG, Department of Toxicology, Ludwigshafen/Rhein, Germany, unpublished report 33D0318/85118, BASF DocID1989/0050, 24 Feb 1989 GLP, unpublished	Y	KST

CA report Section No / Reference No[6]	Author(s)[7,8]	Year	Title	Data Protection Claimed (Yes(i)/Yes(ii)/ No)	Owner
A6.8.2 (01)	[redacted]	1989b	Reproduction study with Dazomet in rats - Continuous dietary administration over 2 generations (2 litters in the first and 1 litter in the second generation), BASF AG, Ludwigshafen/Rhein, Germany, unpublished report 71R0318/8597, BASF DocID 1989/0051, 22 Feb 1989 GLP, unpublished	Y	KST
A6.8.1 (01)	[redacted]	1987b	Report on the study of the prenatal toxicity of Dazomet in rats after oral administration (gavage), BASF AG, Ludwigshafen/Rhein, Germany, unpublished report 34R0318/8564, BASF DocID 1987/0457, 29 Dec 1987 GLP, unpublished	Y	KST
A6.8.1 (02)	[redacted]	1987a	Report on the study of the prenatal toxicity of MITC in rats after oral administration (gavage), Department of Toxicology, BASF AG, Ludwigshafen/Rhein, Germany, unpublished report 34R0231/8537, BASF DocID 1987/0326, 2 Sep 1987 GLP, unpublished	Y	KST
A6.8.1 (03)	[redacted]	1993	Study of the prenatal toxicity of Dazomet in rabbits after oral administration (gavage), BASF AG, Ludwigshafen/Rhein, Germany, unpublished report 40R0062/92058, BASF DocID 1993/10969, 17 Sep 1993 GLP, unpublished	Y	KST
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A3.9/02 (MITC)	[redacted]	2001b	Determination of Partition Coefficient (n-octanol/water) of Methyl isothiocyanate, Laboratory Project ID IET 00-6015-4, Institute of Environmental Toxicology, Japan, BASF DocID 2001/1010589 GLP / Unpublished	Y	KST
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