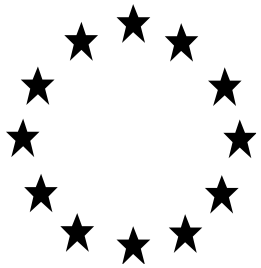
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Carbendazim

Product-type 7
(Film Preservative) and 10 (Construction Material Preservative)

November 2019

eCA: DE

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance carbendazim for product-type 7 (film preservative) and 10 (construction material preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Carbendazim (CAS no. 10605-21-7) was notified as an existing active substance, by Troy Chemical Company BV, hereafter referred to as the applicant, in product-type 7 and 10.

Commission Regulation (EC) No 1062/2014 of 04.08.2014[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

On 31.10.2008, DE competent authorities received a dossier from Troy Chemical Company BV. The evaluating Competent Authority (eCA) accepted the dossier as complete for the purpose of the evaluation on 28.04.2009.

On 02.08.2013, the eCA submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

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 "Agency" (ECHA). Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of carbendazim for product-type 7 and 10, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, 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 from the Agency web-site shall be taken into account.

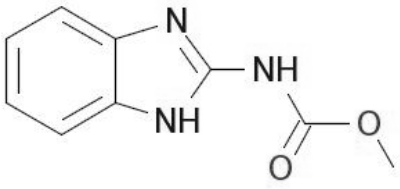
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

[1] COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014, p. 1

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Common name	Carbendazim
Chemical name (IUPAC)	Methyl -benzimidazol-2-ylcarbamate
CAS no.	10605-21-7
EINECS no.	234-234-0
Molecular formula	$C_9H_9N_3O_2$
Molecular mass	191.21 g/mol
Structural formula	

Carbendazim (Methyl-benzimidazol-2-ylcarbamate) is a sand-coloured, odourless crystalline powder. It is moderate soluble in water, slightly soluble in acetone, chloroform and some other organic solvents. The vapour pressure of carbendazim is very low (9 x 10-5 Pa at 20 °C) and it has a Henrys law constant of 3.17 x 10-3 Pa m3/mol (24°C). Furthermore, carbendazim has a log P_{OW} of 1.38 – 1.51 depending on the pH and no surface tension properties (72.5 mN/m; c = 7 mg/L, 20 °C).

Carbendazim is thermally stable, non-flammable, non-explosive and non-oxidising in the sense of test methods according to Directive 92/69/EEC, and therefore users are not at risk due to its physico-chemical properties.

Analytical methods are available for determination of carbendazim (determined as carbendazim) in soil, drinking water, surface water, body fluids and tissues. Relevant exposure of plants and plant products, and animal products is unlikely by the intended uses. Therefore, analytical methods are not needed for these matrices.

Soil: Residues of carbendazim in soil are expected, if a treated paint is used outdoor. From that reason, analytical methods are required for soil. Validated primary and confirmatory methods are provided. The limit of quantification is 0.02 mg/kg.

Air: The applicant assured that the treated paints are brushed and not sprayed. Therefore, an exposure via air (aerosols) is not assumed and an analytical method for carbendazim in air is not required. As soon as other intended uses of the paint containing biocide include spraying, analytical methods for air have to be provided on member state level before authorization of products.

Water: The active substance carbendazim is also used as a pesticide. Based on TNsG on Data Requirements, Chapter 2, Part A, Point 4.2.c, analytical methods for water are needed in that case. Primary as well as a confirmatory methods are available for drinking water and surface

water. The limit of quantification is 0.1 µg/L for drinking water and for surface water.

Animal and human body fluids and tissues: The active substance carbendazim is classified as toxic (T). Therefore analytical methods for these matrices are needed. A primary method based on LC-MS/MS is available. The limit of quantification is 1 µg/L. For tissues, an analytical methods based on LC-MS/MS is validated for meat, egg, milk and fat. The limit of quantification is 0.05 mg/kg. A confirmatory method based on ratio of two MS/MS transitions of carbendazim in plasma is available and is also applicable for the confirmation of carbendazim in tissues.

Identity, Physico-chemical Properties and Method of Analysis of biocidal model formulation

The applicant submitted only information on a dummy product. The dummy product is a model formulation and consists of the active substance and water. No further information about the physico-chemical properties and method of analysis are submitted; the applicant refers to the active substance, which is acceptable in the frame of active substance approval but not for product authorisation.

2.1.2. Intended Uses and Efficacy

Carbendazim is a systemic fungicide with protective action which is used for film and masonry preservation.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The active substance acts by inhibiting development of the germ tubes, the formation of appressoria, and the growth of mycelia.

PT 7

Carbendazim based film preservation products (PT 7) are used in products such as paints. The active substance is either mixed as biocidal product or incorporated directly into the respective end-product. The biocidal product is only used by industrial users and the end-products can be used by either professionals or by non-professionals.

Fungicidal efficacy of carbendazim as a film preservative has been demonstrated in a laboratory test according to EN 15457. It showed fungicidal efficacy at a concentration of 250 mg/kg (ppm; lowest concentration tested). The efficacy of carbendazim as a film preservative in paints is sufficiently proven for inclusion in the Union list of approved active substances. The study performed with the active substance provided is sufficient to show a basic efficacy as required for inclusion. In the frame of product authorisation essentially more information concerning efficacy under realistic use conditions, e.g. field tests, has to be provided.

PT 10

Carbendazim based masonry preservation products are used in products such as plaster. The active substance is either mixed as biocidal product or incorporated directly into the respective end-product. The biocidal product is only used by industrial users and the end-products can be used by either professionals or by non-professionals.

Carbendazim showed fungicidal efficacy at a concentration of 200 mg/kg (ppm) on plaster and 400 ppm on grout. The efficacy of carbendazim as a masonry preservative is sufficiently proven for inclusion in the Union list of approved active substances. The study performed with the active substance provided is sufficient to show a basic efficacy as required for inclusion. In the frame of product authorisation essentially more information concerning efficacy under realistic use conditions, e.g. field tests, has to be provided.

World-wide resistance and cross-resistances to benzimidazole fungicides have been found in many fungal species. Resistance to benzimidazole fungicides is related primarily to specific alterations in the binding sites on the ß-tubulin protein. Based on the available information it cannot be excluded that resistance may occur. Therefore the occurrence of resistance of microorganisms against carbendazim should be monitored. Periodic monitoring should be carried out in order to ensure that the target organisms remain susceptible to in-use concentrations of carbendazim. A resistance management strategy could be to alternate carbendazim containing products with products with a different active substance to prevent development of resistance due to prolonged use. In addition subinhibitory carbendazim concentrations – which may originate through dilution effects, should be avoided. At the renewal of the approval in addition to an updated systematic literature review concerning carbendazim resistance, available monitoring data should be submitted by the applicant.

2.1.3. Classification and Labelling

A harmonised classification is available for carbendazim. The current environmental classification (Aquatic Acute 1 and Aquatic Chronic 1) has already been scientifically agreed and legally harmonised under the 'Dangerous Substance Directive' (67/548/EWG). With entry into force of the CLP Regulation (EC) No 1272/2008 this classification has been translated and transferred into Annex VI:

Table 2-1 Current classification of carbendazim based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H340 H360FD H400 H410	May cause genetic defects May damage fertility. May damage the unborn child Very toxic to aquatic life Very toxic to aquatic life with long lasting effects

Table 2-2 Current labelling of carbendazim based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS08 GHS09	

Signal Word	Danger	
Hazard statements	H340 H360FD H410	May cause genetic defects May damage fertility. May damage the unborn child Very toxic to aquatic life with long lasting effects
Precautionary statements	See Remarks	

In accordance with the corresponding entry in Annex VI of Regulation (EC) No 1272/2008 Precautionary statements are not listed here either.

Currently there are no harmonised multiplying factors (M-factors) available for the harmonised classification as Aquatic Acute 1 and Aquatic Chronic 1. Hence, a CLH dossier has been submitted to ECHA to supplement the harmonised classification. The classification proposal is based on data evaluated within the framework of substance authorisation for the use in biocidal products and should enable the appropriate classification of mixtures (products) during product authorisation.

Acute aquatic hazard

Adequate acute toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants). Data for acute aquatic toxicity for fish, daphnia and algae were considered for classification of carbendazim. The fish species *Ictalurus punctatus* was the most sensitive species tested in the aquatic compartment. Based on the results of this study, LC_{50} = 0.019 mg/L (nominal concentration) was considered for the comparison with CLP criteria for acute aquatic toxicity classification.

The criterion for classification as H400 "Very toxic to aquatic life" is a $LC_{50} \leq 1$ mg/l. Hence, carbendazim fulfils this criterion and has to be classified as **Aquatic Acute 1, H400** with an acute multiplying factor of **M_{acute} = 10** (considering 0.01 mg/L < $LC_{50} \leq$ 0.1 mg/L).

Long-term aquatic hazard (including bioaccumulation potential and degradation)

In all simulation studies (water-sediment and soil), DegT50 values were higher than 16 days (at 12 °C) and mineralization did not reach 70 % within 28 days. Based on this information, carbendazim has to be considered as '**not rapidly degradable**'.

A measured **log K_{ow} = 1.5** does not exceed the trigger value of 4 and the measured **BCF_{fish} value of 27 L/kg** does not exceed the trigger value of 500 L/kg. Therefore a low potential for bioaccumulation was indicated for classification purposes.

Adequate chronic toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants). Hence, according to the classification criteria the classification of the longterm aquatic hazards has to be based on the available chronic data. However, there is no chronic data available for *I. punctatus*, which is by far the most sensitive fish species within the acute tests. Invertebrates represent the most sensitive trophic level for chronic toxicity in the aquatic compartment and a **NOEC of 0.0015 mg/L** for *Daphnia magna* was considered for classification.

For substances not fulfilling criteria for rapid degradation, the criterion for classification as H410 "Very toxic to aquatic life with long lasting effects" is EC_{10}/NOEC ≤ 0.1 mg/L. carbendazim fulfils this criterion and should be classified as **Aquatic Chronic 1, H410**, with a chronic multiplication factor **$M_{chronic}$ = 10** (considering 0.001 mg/L < NOEC < 0.01 mg/L for non-rapidly degradable substances).

Table 2-3 Proposed classification of carbendazim based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1, M (acute) = 10 Aquatic Chronic 1, M (chronic) = 10	
Hazard statements	H340 H360FD H317 H400 H410	May cause genetic defects May damage fertility. May damage the unborn child May cause an allergic skin reaction Very toxic to aquatic life Very toxic to aquatic life with long lasting effects

Remark:

The classification and labelling regarding genotoxicity and reproduction/developmental toxicity is in accordance with Regulation (EC) No. 1272/2008. Based on positive findings in a Guinea Pig Maximisation Test, additional classification with “Skin Sens. 1; H317 (May cause an allergic skin reaction)” is proposed. Sub-classification into category 1A or 1B could not be performed based on the information available.

Table 2-4 Proposed labelling of carbendazim based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS07 GHS08 GHS09	
Signal Word	Danger	
Hazard statements	H340 H360FD H317 H410	May cause genetic defects May damage fertility. May damage the unborn child May cause an allergic skin reaction Very toxic to aquatic life with long lasting effects

	Labelling	Wording
Precautionary statements	P201	Obtain special instructions before use
	P202	Do not handle until all safety precautions have been read and understood
	P272	Contaminated work clothing should not be allowed out of the workplace
	P273	Avoid release to the environment
	P280	Wear protective gloves, protective clothing and eye/face protection
	P308 + P313	IF exposed or concerned: Get medical advice/ attention
	P391	Collect spillage
	P405	Store locked up.
	P501	Dispose of contents/container to in accordance with local/regional/ national/international regulation (to be specified)

Conclusion on classification and labelling for environmental hazards

Considering the availability of adequate acute and chronic toxicity data for all three trophic levels and that carbendazim does represent a non-rapidly degradable substance, the following classification for the environment can be concluded:

Category Acute 1 with multiplying factor M_{acute} = 10

Category Chronic 1 with multiplying factor $M_{chronic}$ = 10

With regard to the environment and in accordance to Regulation of European Parliament (EC) No 1272/2008, the substance carbendazim has therefore to be classified with H400 and H410, Category Acute 1, M_{acute} = 10, and Chronic 1, $M_{chronic}$ = 10. For the labelling the GHS pictogram GHS09 and the hazard statement “Very toxic to aquatic life with long lasting effects” has to be applied with signal word ‘Warning’ and precautionary statements P273, P391 and P501 shall be recommended.

Classification and Labelling of the biocidal model formulation

Classification and labelling of the biocidal model formulation is based on data for the active substance. Other components do not contribute. There is a large number of the Precautionary statements; they were all recommended in Annex I of Regulation (EC) No 1272/2008 based on the given Hazard statements. To reduce their number only the most strictly was taken when there were several Precautionary statements with almost the same wording.

Table 2-5 Proposed classification of the biocidal model formulation based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H340 H360FD H317 H400 H410	May cause genetic defects May damage fertility. May damage the unborn child May cause an allergic skin reaction Very toxic to aquatic life Very toxic to aquatic life with long lasting effects

Remark:

Classification as proposed by the applicant is adopted concerning the human health part. The classification is based on the classification of the active substance. Other components do not contribute. In accordance with Regulation (EC) No. 1272/2008 and Commission Regulation (EU) 286/2011 (2nd ATP), environmental classification was performed on basis of the summation method and the acute and chronic M-factor.

Contrary to the applicant's proposed classification of the biocidal product, the hazard statements H400 and H410 have to be applied to the product. The active substance carbendazim is already classified as H400 and H410 and furthermore M_{acute} = 10 and $M_{chronic}$ = 10 are proposed. The product contains > 2.5 % carbendazim and the relevant LC_{50}-value from *Ictalurus punctatus* is 0.019 mg/L, therefore 0.01 mg/L < LC_{50} ≤ 0.1 mg/L. In accordance with Regulation 1272/2008 also the product has to be classified as H400 and H410.

Table 2-6 Proposed labelling of the biocidal model formulation based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS07 GHS08 GHS09	
Signal Word	Danger	
Hazard statements	H340 H360FD H317 H410	May cause genetic defects May damage fertility. May damage the unborn child May cause an allergic skin reaction Very toxic to aquatic life with long lasting effects

	Labelling	Wording
Precautionary statements	P201	Obtain special instructions before use
	P202	Do not handle until all safety precautions have been read and understood
	P261*	Avoid breathing dust/fume/mist/vapours/ spray
	P272	Contaminated work clothing should not be allowed out of the workplace
	P273	Avoid release to the environment
	P280	Wear protective gloves, protective clothing and eye/face protection
	P308 + P313	IF exposed or concerned: Get medical advice/ attention
	P391	Collect spillage
	P405	Store locked up
	P501	Dispose of contents/container to in accordance with local/regional/ national/international regulation (to be specified)

* Obsolete if exposure via inhalation is not anticipated (e.g. no spray application).

Remark:

The labelling of the biocidal product is transformed based on the rules of the Regulation (EC) No 1272/2008 (cf. table 2-8) and the recommendations given in the Guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (IHCP, DG Joint Research Centre, European Commission, 2009).

For sensitising products P362 + P364 are generally recommended. These precautionary statements are obsolete if disposable protection clothing is mandatory.

Summary & Conclusion:

According to GHS (Regulation (EC) No 1272/2008) the biocidal model formulation has to be classified and labelled as Skin Sens. 1 (May cause an allergic skin reaction), Muta. 1B; H340 (May cause genetic defects) and Repr 1B; H360FD (May damage fertility. May damage the unborn child), H400 (Very toxic to aquatic life) and H410 (Very toxic to aquatic life with long lasting effects).

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effects assessment

Absorption, Distribution, Excretion, and Metabolism

Oral Absorption, Distribution, Metabolism and Excretion

In rats, carbendazim was rapidly absorbed from the gastrointestinal tract (~80 %) and

extensively metabolised by oxidation (main metabolite methyl 5-hydroxy-2-benzimidazole-carbamate (5-HBC) and conjugation with GSH, sulfate and glucuronic acid.

More than 98 % of the recovered radioactivity was excreted within 72 h. Highest tissue levels were found in liver (~0.5 % after 72 h).

Excretion half-lives were approximately 12 h for both sexes. Urinary excretion reached up to 66 % of the dose during a 72-hour period.

Dermal Absorption

Several dermal absorption studies with carbendazim *in vitro* and *in vivo* in human and rat are available.

Overall, only two studies with human skin *in vitro* from 2009 on a solvent-free emulsion paint-containing 0.1 % (w/w) (1.34 g/L) carbendazim and a NF dispersion containing 10.6 % (w/w) a.s. are considered to be suitable for risk assessment. Both studies were discussed at the BPC-WG meeting II-2015. It was concluded that the presented data suggest dermal absorption values of 0.6 % for the [redacted] based solvent-free paint formulation containing 0.1 % a.s. and 1 % for the formulation [redacted] containing 10.6 % (w/w) a.s., respectively. For paint formulations of sufficiently similar composition but lower carbendazim concentrations, the “pro rata” extrapolation approach as recommended in the EFSA Guidance on Dermal Absorption (EFSA, 2012) can be used. Accordingly, a dermal absorption value of 2.4 % would be used for assessment of a paint of identical formulation containing 0.025 % (w/w) carbendazim, Further information showed that changes in formulation may significantly impact dermal absorption of carbendazim.

Respiratory Absorption

In the absence of data on absorption of carbendazim after inhalation 100 % default are used for risk assessment purposes.

Acute Toxicity

Carbendazim displayed low acute oral, dermal, inhalation and intraperitoneal toxicity. No mortalities were observed in the inhalation and dermal studies while in one of the oral studies a female animal died 14 days after administration of 6400 mg/kg bw carbendazim. In a second oral study no mortalities were observed after administration of 10,000 mg/kg bw. In an intraperitoneal study, no mortalities were observed in female rats and male and female mice up to and including a dose of 15000 mg/kg bw while in male rats the LD_{50} was 7230 mg/kg bw. Clinical symptoms reported in the acute studies were weight loss in the oral and dermal studies, lacrimation, apathetic behaviour, and shaky walk in the inhalation study as well as ascites in the intraperitoneal study.

Skin irritation

Slight dermal effects were observed after intracutaneous injection but not reported after dermal application. Dermal application of up to 10 % carbendazim dilution in sesame oil caused no symptoms of irritation on intact rabbit skin. Intracutaneous application of 10 % and 5 % dilutions of carbendazim in sesame oil caused slight to generalised reddening of the injection site.

Eye irritation

Carbendazim produced very slight eye irritation below classification threshold: one rabbit exhibited a score of 1 for conjunctival redness 1, 2 and 3 days after treatment. No other signs of ocular irritation were observed.

Skin sensitisation

Carbendazim was positive in a GLP- and guideline –conform Magnusson & Kligman test which revealed a skin sensitisation reaction in 4 out of 10 test animals. In a non-GLP Buehler test and a second not further specified test method no skin sensitising potential was detected. Based on the positive GPMT classification of carbendazim regarding skin sensitisation is proposed.

Short-term Toxicity

In 4-week dietary exposure studies in rats and dogs mainly liver effects (siderosis in rats, focal lesions, inflammation and hyperplastic bile ducts in dogs) were observed at doses ≥ 1000 mg/kg bw/d in rats and ≥ 100 mg/kg bw/d in dogs. Interference with testes morphology as expressed by desquamation of epithelial cells at doses ≥ 200 mg/kg bw/d and a treatment-dependent azoospermia were reported at high doses of 1000 and 5000 mg/kg bw/d in rats. From this study, a NOAEL of approx. 40 mg/kg bw/d was established based on testes effects. In the 90-d rat studies, reported effects were limited to reduced body weights in males at 780 mg/kg bw/d, resulting in a subchronic NOAEL of 163 mg/ kg bw/d for the key study, which is higher than the subacute NOAEL. .

The lowest NOAEL of 2.7 mg/kg bw/d based on testes and liver effects was observed in a 90-d dog study carried out with a formulation. As resorption of carbendazim is already high (80-85 %) and due to the low amounts of surfactants in the test material, resorption is not expected to be significantly increased by the formulants.

In the other dog studies the active substance was applied.

According to the definition of an overall NOAEL (JMPR, 2004), the margin between the LOAEL of this study (11.3 mg/kg bw/d) and the NOAEL of the other 90-d dog studies (~10-16 mg/kg bw/d) is too small (i.e., < 2) to set an overall NOAEL of about 10 mg/kg bw/d.

Hence, the NOAEL of 2.7 mg/kg bw/d from the study conducted by Sherman et al. (1970) is regarded as the relevant NOAEL for oral medium-term toxicity.

In a dermal study (exposure time: 10 days) carbendazim induced no signs of systemic toxicity up to the highest dose tested (2000 mg/kg bw/d). Treated skin areas revealed a local mild irritation reaction.

Genotoxicity

A number of assays with *Salmonella typhimurium* and *E. coli* strains were performed to investigate the potential of carbendazim to induce gene mutations in bacterial cells. The use of highly purified carbendazim samples gave consistently negative results using the standard plate incorporation procedure with and without metabolic activation.

In a number of studies, however, positive findings were obtained with some carbendazim batches at concentrations of 1 - 50 mg/plate, mainly in *Salmonella typhimurium* tester strains which are capable of indicating frame-shift mutations, e.g. TA98 and TA1537.

Several investigations comparing different carbendazim batches and preparations with variable amounts of impurities indicated that the positive mutagenic effects could be traced to two mutagenic impurities, namely 2,3-diamino-phenazine (DAP) and 2-amino-3-hydroxyphenazine (AHP). Carbendazim technical containing ≥1.8 ppm DAP was found to be mutagenic whereas a batch containing 0.6 ppm DAP and less than 4 ppm AHP was negative.

FAO set in 1992 a specification for carbendazim. For AHP, a maximum content of 0.0005 g/kg (0.5 ppm) carbendazim was proposed. This maximum content is lower than the content that induced no revertants (≤ 4 ppm / ≤ 0.004 g/kg). For DAP, a maximum content of 0.003 g/kg (3 ppm) carbendazim was set by FAO.

A new Ames test with a batch containing 2.3 ppm DAP and 0.3 ppm AHP was performed in the context of this evaluation. No increased numbers of revertants were observed in TA 1535, TA 1537, TA 98 and TA 100 and E. coli strain WP2 uvrA. Hence, concentrations of DAP and AHP must not exceed 0.3 mg/kg (AHP), and 2.3 mg/kg (DAP).

In a mouse lymphoma tests with L5178Y TK+/- cells carbendazim did not induce gene mutations.

Carbendazim was tested with several studies in somatic cells of rodents on structural chromosome aberrations and/or numerical aberrations (micronucleus test). Also, the covalent binding to rat liver DNA and protein was investigated.

Carbendazim proved to induce micronuclei in several micronucleus tests *in vivo*. The positive effect was obtained when doses higher than 50 mg/kg bw were administered orally. There is evidence that the induction of micronuclei resulted rather from a spindle inhibitory effect than from clastogenic mechanisms as the micronuclei observed are remarkable large. A DNA-binding assay proved that carbendazim did not bind to rat liver DNA but showed chemical affinity for proteins.

Additionally, evidence that carbendazim has no clastogenic but aneugenic properties was obtained from studies investigating the effects of carbendazim on the spindle apparatus. It was shown that carbendazim binds to tubulin and inhibits the assembly of microtubules and their polymerisation inducing micronuclei, aneuploidy and polyploidy. By using an immunofluorescent antikinetochore antibody technique, it was confirmed that carbendazim-induced micronuclei in bone marrow polychromatic erythrocytes (PECs) of BDF1 mice are due to aneuploidy rather than structural chromosome damage.

Carbendazim did not induce structural chromosome aberrations and/or lethal gene mutations but induced numerical chromosome aberrations in mouse and rat germ cells.

Thus, carbendazim is considered to have aneugenic properties not damaging the DNA directly but interacting with a non-DNA target (tubulin). It is scientifically accepted that for aneugenic agents of this kind, a threshold for mutagenic activity does exist (Parry et al., 1993, Aardema et al., 1998, Kirsch-Volders et al., 2000, Parry et al., 2000). Under *in vitro* conditions, dose-response curves and threshold concentrations for the induction of aneuploidy could be established. Based on the available data and taking into consideration non-disjunction as the most sensitive effect, the threshold for aneugenic activity of carbendazim in human lymphocytes *in vitro* was in the range of 0.2 to 0.6 µg/mL.

The experimental data show that for the induction of aneuploidy *in vivo* actually much higher oral doses are required to obtain effective blood or tissue concentrations than one would expect on the basis of a direct extrapolation from the *in vitro* effective concentrations. A single oral dose of 50 mg/kg bw did not increase the frequency of micronucleated erythrocytes in mouse bone marrow, while the lowest oral dose causing an increase in micronucleus incidence was 100 mg/kg bw, corresponding to a peak blood concentration of 12 µg carbendazim/mL. In contrast, a continuous blood concentration of 8 µg carbendazim/ml after i. p. administration was not sufficient to increase the micronucleus frequency. The lowest single oral NOAEL in rat germ cells was also 50 mg/kg bw regarding the occurrence of aneuploid and polyploid sperm. This NOAEL was confirmed by investigating the micronucleus frequency in immature rat spermatids.

Many of the toxicological effects of carbendazim are consistent with inhibition of microtubule function. This intrinsic activity is responsible for positive effects in some mutagenicity tests, for teratogenic action and decreased spermatogenesis.

The wealth of available data indicate that carbendazim is not a primary genotoxin (reacting with DNA and inducing mutations) but acts as spindle poison (inhibiting cytokinesis by tubulin binding). As reviewed by Oesch (1982) this mode of action indicates the existence of a threshold dose below which no effects are expected to occur.

Based on the pharmacological theory of receptor interaction, the magnitude of a response is directly proportional to the amount of occupancy of available cell receptors up to saturation. A drug with high receptor affinity such as colchicine will be more effective in eliciting a response than a substance with low affinity, such as exemplified by carbendazim.

In conclusion it can be stated that carbendazim is devoid of gene mutagenic or clastogenic activities, despite of occasional positive findings in *in vitro* tests. Positive findings have been traced to aminophenazine by-product impurities which are reduced in present manufacturing processes to amounts $\leq$ 3.5 ppm, not inducing gene mutations in *Salmonella typhimurium* strains.

For risk assessment purposes, it appears reasonably to rely on the *in vivo* NOAEL of 50 mg/kg bw for the induction of aneuploidy. Unlike primary mutagens, carbendazim does not interact with DNA and does not cause gene mutations or structural chromosome aberrations.

With regard to the positive results in the above-mentioned assays and the threshold which could be estimated for aneuploidy, classification of carbendazim in accordance with the Regulation (EC) 1272/2008 as Muta. Cat. 1B, H340 is proposed.

Chronic Toxicity / Carcinogenicity

In the long-term rat studies, administration of carbendazim did not increase the mortality rate and had no impact on general condition up to a dose of 10000 ppm although body weight development was altered at this highest dietary dose level. Adverse effects were confined to the upper dose range (2500/10000 ppm). The liver was identified as the target organ. Hepatotoxicity was evident not only by a slight increase in absolute and relative liver weight but also by changes in liver enzyme activities and histopathology. The NOAEL of 500 ppm (approximately 22 mg/kg bw/d) is based on liver toxicity and haematological changes as well as decreased bw gain at 5000 ppm (250 mg/kg bw/d). There was no test substance-related increase in the tumour rate in rats.

A total of three carcinogenicity studies in different strains of mice were submitted.

Liver toxicity was the most prominent effect caused by carbendazim in all three studies. In addition, an increase in mortality and body weight effects were noted in CD-1 mice but not in Swiss and NMRKf mice. There was some evidence that male mice were more affected than females.

General hepatotoxicity was characterised by an elevated organ weight and macroscopically or at least microscopically visible changes. A dose-dependent increase in liver tumour rate was observed in two sensitive mouse strains (CD-1 and Swiss mice).

In CD-1 mice, a NO(A)EL for carcinogenicity could not be established since the incidence of liver cell adenoma and the combined incidence of hepatocellular adenoma and carcinoma was still increased in both sexes at the low dose level of 500 ppm reaching statistical significance in the females.

In Swiss mice, an increased incidence of benign liver tumours in both sexes and in malign neoplasia in male animals was seen at the top dose level of 5000 ppm (approximately 750 mg/kg

bw/d). There is some evidence of a carcinogenic effect in males at the intermediate 300 ppm level (about 45 mg/kg bw/d), in particular when neoplastic nodules or nodular hyperplasia were regarded as precursors of tumours. The NO(A)EL for carcinogenicity was 150 ppm (equivalent to approximately 22.5 mg/kg bw/d) in this study.

In contrast, no oncogenic potential became apparent in the third study conducted with NMRKf mice with a known low spontaneous incidence of hepatocellular tumours suggesting that this is a non-sensitive mouse strain regarding liver tumours. There was no increase in the incidence of hepatocellular tumours up to a dietary level of 5000 ppm (corresponding to 550 and 680 mg/kg bw/d in males and females, respectively) although marked hepatotoxicity was apparent in both sexes at this highest dose.

Taking the outcome of all these studies into consideration, it can be assumed that the spontaneous hepatic tumour rate in susceptible mouse strains is enhanced by hepatotoxic action of the test compound. Generally, the mouse is well known to be particularly sensitive to liver tumour formation caused by the exposure to chemicals. The high potential of the mouse for developing liver tumours is known to be a particular problem in risk assessment of a chemical with respect to human beings. The relevance of such findings for man is considered rather low. In general, liver tumours occurring only in mice, esp. in strains known to have a high spontaneous incidence of liver tumours are not considered to indicate a specific carcinogenic hazard for humans when there was no increase in tumour incidence in any other organ system examined or in another species or mice strain tested. This was the case with carbendazim.

In Beagle dogs, two 2-yr studies are available. One study revealed an NOAEL of 8.9 mg/kg bw/d based on reduced bw and bw gain and changes in haematology and clinical chemistry pointing to hepatotoxicity (without histopathological findings).

In the second two-year dog study, the NOAEL was 2.6 mg/kg bw/d based on hepatotoxicity.

This study was carried out with a formulation. The results of both studies did not show that the formulation ingredients had an influence on the toxicological effects.

one of the formulation ingredients is considered to be biologically inert, passing through the gastrointestinal tract unchanged and without significant absorption. The other formulation ingredients are anionic surfactants. It is known, that surfactants might increase absorption. However, absorption of carbendazim is already high (80-85 %). Due to the low amounts of surfactants in the test material, no impact on the study result is expected.

According to the definition of an overall NOAEL (JMPR, 2004), the margin between the LOAEL of study (12.4 mg/kg bw/d) and the NOAEL of other study (8.9 mg/kg bw/d) is too small, i.e. < 2, to set an overall NOAEL of about 9 mg/kg bw/d. Hence, the long-term dog NOAEL was 2.6 mg/kg bw/d.

The long-term NOAEL in mice was 22.5 mg/kg bw/d.

The long-term NOAEL in rats was 22 mg/kg bw/d.

Developmental Toxicity

In rats, the dose level of 20 mg/kg bw/d given by gavage represents the maternal NOAEL based on impaired body weight gain during the treatment period. The NOAEL for embryo-/foetotoxic effects was 10 mg/kg bw/d based on an increased resorption rate, on a reduction in foetal weight and an increased frequency of skeletal variations. This effect was apparent in the absence of overt maternal toxicity.

A marked increase in the occurrence of malformations (e.g. hydrocephalus, anophthalmia) was confined to the highest dose level.

In a feeding study, the maternal and foetal NOAEL was 10000 ppm (the highest dose tested) as no adverse effects were observed.

The different NOAELs from the gavage and the feeding study are likely to be the result of differences in the pharmacokinetics of carbendazim. It has been shown in a great number of experiments that by a well-defined mechanism of action on the spindle apparatus during tubulin polymerisation in the course of mitosis, carbendazim may temporarily affect proliferative tissues, i.e., rapidly duplicating cells including target cells during development, when a specific threshold level is exceeded in the target organ. Due to the very rapid turnover, the very high plasma levels needed to induce effects can only be reached after gavage and will likely not be reached by dietary administration.

In rabbits, administration by gavage resulted in marked maternal toxicity at the high dose of 125 mg/kg bw/d, while no maternal toxicity was obvious at the medium dose level of 20 mg/kg bw/d. This dose was the LOAEL for embryo-/foetotoxic effects (decreased implantation, increased number of resorptions, decreased live litter size). Evidence of teratogenicity was confined to the highest dose level of 125 mg/kg bw/d.

Reproduction Toxicity

Administration of carbendazim to rats at dietary dose levels up to 318 mg/kg bw/d (10000 ppm) throughout two or three consecutive generations resulted in a reduction of the body weight of 21-day old weanlings at 220 mg/kg bw/d in the one study, with a NOAEL for offspring in a second study at 100 mg/kg bw/d, the highest dose tested. The ability to produce, deliver or rear offspring was not affected at any dose level. The combined analysis of results of the multigeneration studies demonstrates that the lowest parental NOAEL from these studies was identified at 100 mg/kg bw/d (Til, Koeter, van der Heijden, 1976).

Additional studies showed that exposure to carbendazim produced an early, reversible infertility in some males and irreversible infertility in others.

Acute oral dose levels at or above 1000 mg/kg bw caused microscopic and macroscopic findings showing tubules of the testes affected with a reduction of sperm. Additionally, atrophy (marked degeneration) and absence of spermatogenesis was observed. The LOAEL for effects on spermatogenesis after administration of repeated doses of carbendazim was found to be 40 mg/kg bw/d, the lowest dose tested.

Regarding the excretion in milk, no information was submitted.

Neurotoxicity

Carbendazim does not belong to a chemical class which is suspected to cause delayed neurotoxic effects, such as organophosphates or carbamates. Nevertheless, a study on delayed neurotoxicity was submitted.

The neurotoxic potential of carbendazim was tested in a study similar to OECD 418 (Delayed Neurotoxicity of Organophosphorus Substances following Acute Exposure). Clinical signs were observed at 500 (slight salivation, one hen) 2500 (very slight salivation, one hen). At 5000 mg/kg bw carbendazim, systemic toxicity was observed as well as transient neurotoxic signs (ataxia, leg weakness, mortalities). No evidence of neuropathy was obtained upon histological examination.

Further Studies

Activities of several phase I and phase II enzymes in livers of rats and mice were examined to clarify species-dependent differences in the toxicological response and to elicit the mechanism of a possible hepatotoxicity. Effects on induction of enzyme activity were compared with those induced after phenobarbital-Na treatment in drinking water. The enzyme induction by

carbendazim differs from that induced by phenobarbital-Na (moderate to marked increases in activity of all phase I and II enzymes except of the gamma-glutamyl transpeptidase).

In the carbendazim treatment groups, increases in phase I enzyme activities were less pronounced (for rats and mice) or even absent for some enzymes (rats). However, in contrast there were distinct differences between rats and mice in the stimulation of the respective enzymes pertaining to the phase II and in the glutathion content of the livers after carbendazim treatment. The induction of phase I enzyme activities is somewhat more pronounced in mice whereas the induction of phase II enzyme activities is significantly more pronounced in rats.

Medical Data

Medical surveillance data do not reveal adverse effects in workers from production plants up to 2008. However, the number of examined workers is limited.

One poisoning incident involving carbendazim is reported in open literature. Four confirmed cases of skin and eye irritation with products containing carbendazim and further active ingredients are reported by PSD. In most cases products with more than one active substance were used. Thus, carbendazim cannot be identified unequivocally as cause of the toxic effects reported. However, all adverse effects were of minor nature (slight skin and eye irritation, nervousness) or transient (neurological effects reversible within 19 d).

Summary & Conclusion

Carbendazim is rapidly absorbed up to 80 % from the gastrointestinal tract, extensively metabolised and rapidly excreted. For dermal absorption, values of 0.6 % and 1 % were derived for the paint formulation and the concentrated dispersion, respectively. Carbendazim proved to be neither acutely toxic after oral, dermal, inhalation, or intraperitoneal administration, nor irritating to skin or eyes. Carbendazim needs classification and labelling for sensitisation based on results of a Magnusson & Kligman test albeit it showed no skin sensitising potential under the conditions of the submitted Buehler test.

Target organs after repeated dose and chronic exposure are liver and testes. The most sensitive species was the dog. A 90-d study in dogs with a formulation revealed the lowest NOAEL of 2.7 mg/kg bw/d after medium-term exposure based on testes effects (moderate focal degeneration) and liver effects (increases in the cholesterol level at 500 ppm (14.4/11.3 mg/kg bw/d in males and females, respectively)). In a 2-yr study in dogs the NOAEL was 2.6 mg/kg bw/d based on hepatotoxicity at higher doses.

Testis toxicity was also observed in reproduction toxicity studies which revealed seminiferous tubular atrophy and depression of spermatogenesis in rats below 40 mg/kg bw (lowest dose tested). Based on these findings, carbendazim is classified and labelled for reproduction toxicity.

Developmental toxicity (increased resorptions, decreased litter size, decreased birth weight) was observed in rats and rabbits with a NOAEL of 10 mg/kg bw/d at doses that were not maternally toxic while teratogenicity (malformations) was confined to the highest dose level (90 mg/kg bw/d in rats, 125 mg/kg bw/d in rabbits). Thus, carbendazim requires classification and labelling for developmental toxicity.

Liver tumours were observed after chronic exposure to carbendazim in two related mouse strains (CD-1 and Swiss, strains known to have a high spontaneous incidence of liver tumours) but not in rats or NMRKf mice. Since there was no increase in tumour incidence in any other organ system examined or in rats or in NMRKf mice these findings are not considered to indicate a specific carcinogenic hazard for humans.

Carbendazim is considered to have aneugenic properties not damaging the DNA directly but interacting with a non-DNA target (tubulin) and thus affecting the spindle apparatus during mitosis. A threshold of NOAEL: 50 mg/kg bw for aneuploidy induction was observed after gavage administration in sperm and bone marrow of rats. Thus, carbendazim requires classification and labelling for genotoxicity. This effect is likely to be responsible also for the embryo-/foetotoxicity in rabbits and rats observed after gavage administration of 20 mg/kg bw/d but not in a rat feeding study at 474 mg/kg bw.

The testes effects observed at lower doses in feeding studies (LOAEL: 14 mg/kg bw/d in the dog) are consistent with desquamation and atrophy of the seminiferous tubule epithelium and are most likely due to cytoskeleton disturbance in Sertoli cells by disruption of the microtubules.

Summarising the study results and all considerations above carbendazim requires classification/labelling according to Regulation (EC) No 1272/2008 as follows:

Danger, Muta. 1B; H340, Repr. 1B; H360-FD, Skin Sens. 1; H317

The lowest relevant acute NOAELs of 10 mg/kg bw were found in developmental gavage studies in rats and rabbits. By using an increased assessment factor of 300 and assuming complete oral absorption (100 %), an

acute Acceptable Exposure Level (AEL_{acute}) of 0.03 mg/kg bw

is proposed for short-term exposure towards carbendazim.

The NOAEL of 10 mg/kg bw/d in the developmental studies in rats and rabbits is also regarded as the relevant starting point for setting a systemic reference dose for medium-term exposure. By using an increased assessment factor of 300 and assuming complete oral absorption (100 %), a

medium-term Acceptable Exposure Level ($AEL_{medium-term}$) of 0.03 mg/kg bw/d

is proposed for medium-term exposure towards carbendazim. This value is supported by a NOAEL of 2.7 mg/kg bw/d in the 90-d study in dogs, from which an identical AEL would be derived using the default assessment factor of 100.

Finally, the NOAEL of 10 mg/kg bw/d in the developmental studies in rats and rabbits is also regarded as the relevant starting point for setting a systemic reference dose for long-term exposure. By using an increased assessment factor of 300 and assuming complete oral absorption (100 %), a

long-term Acceptable Exposure Level ($AEL_{long-term}$) of 0.03 mg/kg bw/d

is proposed for long-term exposure towards carbendazim. This value is supported by a NOAEL of 2.6 mg/kg bw/d from the 2-yr study in dogs, from which an identical AEL would be derived using the default assessment factor of 100.

2.2.1.2. Exposure assessment and risk characterisation

Exposure of Professionals

PT 7

The active substance carbendazim is produced outside the EU and the biocidal products are produced within the EU. The biocidal product (model formulation) is a water based concentrate (≤ 10% carbendazim) and the end-products are ready-to-use paints containing 0.025 to 0.1 % carbendazim.

The following scenarios are covered by the exposure assessment in this report:

- Production of end-products (paints) (scenario 1)
- Professional application of paints by manual brushing (scenario 2)
- Secondary exposure to carbendazim (scenario 3)

The mixing of the biocidal product, i.e. of the film preservative into the end-use products is done in industrial scale under closed conditions and only professionals are employed (scenario 1).

The biocidal product (≤ 10 % carbendazim) is delivered to the production plant only in large containers (e.g. 1 m3 IBC), which – when full – cannot be handled manually but only by fork-lift. Only incidental exposure (hand contamination and exposure by inhalation) can occur during connecting/disconnecting the containers to/from the system and when handling empty drums. The connecting/disconnecting containers/handling of empty containers is assumed to be limited to 10 min/day. During the incorporation process, exposure to workers is not possible because a closed automated system is employed.

The inhalation exposure to carbendazim (10 % carbendazim) vapour during connecting/disconnecting and handling of containers is assessed as negligible due to the low vapour pressure of carbendazim. However as worst case the saturated vapour concentration (SVC) is considered as the maximum attainable concentration by vapour. Formation of aerosols during connecting/disconnecting and handling of containers is not expected.

For the dermal exposure to 10 % carbendazim during connecting/disconnecting and handling of containers a HEEG recommendation for the scenario connecting transfer lines is followed and the Model “RISKOFDERM Toolkit Connecting lines” is used. The ready-to-use paints containing 0.025 to 0.1% carbendazim are packed into small containers.

The paints are applied by brush to surfaces of walls and other objects such as sheds or fences (scenario 2). Dermal exposure of the applying person is possible by direct spills and by contact with the paint on the brush or on already painted surface. As the paints used for brushing are ready-to-use products, no mixing and loading needs to be considered.

The assessment of inhalation and dermal exposure to 0.1 % carbendazim during the brushing (application phase) is based on the worked example for product-type 7 in BEAT which is the scenario “Indoor decorative painting”. In addition an exposure estimate based on data from a study (Lingk et al. 2006) performed by the BfR (Germany) and the BMLFUW (Austria) is calculated since member states requested that the assessment of professional and non-professional brushing should be based on the same model (in this case Lingk et al. 2006). Both approaches assessed dermal and inhalation exposures and the result of the risk assessment leads to the same conclusion. Aerosol formation in the post-application phase is not expected. The inhalation exposure to vapour during application and post-application phase is assessed as negligible due to the low vapour pressure of carbendazim. However as worst case the saturated vapour concentration (SVC) is considered as the maximum attainable concentration by vapour.

The estimation of the potential dermal exposure during the cleaning of the brush is based on HEEG opinion No.11 “Exposure model primary exposure scenario – washing out of a brush which has been used to apply a paint” (TM III/2010).

A secondary exposure to carbendazim using ready-to-use paints containing 0.025 to 0.1 % carbendazim cannot be excluded (scenario 3).

Due to the very low vapour pressure of carbendazim for inhalation exposure as worst case the saturated vapour concentration (SVC) is taken into account. A potential dermal exposure to carbendazim is reasonable for dermal contact to treated surfaces and is based on a transfer factor from the treated surface to the hand.

The estimated inhalation uptake for each scenario is calculated with a body weight of 60 kg, a breathing volume of 10 m^3 per shift, and the default assumption of 100 % absorption by inhalation. For calculating estimated dermal uptake the same body weight and either dermal absorption of 0.6 % for in use concentrations of 0.1 % carbendazim or dermal absorption of 1 % for in use concentrations of 10 % carbendazim are used. To get total internal body burden (estimated uptake) estimated inhalation uptake and estimated dermal uptake are added.

It is noted that for clarity reasons systemic exposure values are rounded to two decimal places. However, the underlying calculations are based on unrounded exposure values.

Table 2-7 Overview of systemic exposure values (PT7)

Scenario	Estimated uptake mg/kg bw/d
1 - production of end-products	
Tier 1	$1.78x10^{-4}$
Tier 2	$3.96x10^{-5}$
2 - professional application of paints	
a) application - brushing ready to use product (BEAT)	
Tier 1	$5.99x10^{-3}$
Tier 2	$1.55x10^{-3}$
b) application - brushing ready to use product (Lingk)	
Tier 1	$2.14x10^{-3}$
Tier 2	$1.81x10^{-3}$
post application - cleaning brush	
Tier 1	$3.06x10^{-5}$
Tier 2	$1.40x10^{-5}$
a) total	
Tier 1	$6.02x10^{-3}$
Tier 2	$1.56x10^{-3}$
b) total	
Tier 1	$2.17x10^{-3}$
Tier 2	$1.82x10^{-3}$

3 - secondary exposure	
Tier 1	$1{,}26 \times 10^{-3}$

PT 10

The active substance carbendazim is produced outside the EU and the biocidal products are produced within the EU. The biocidal product is a water-based concentrate (≤10 % carbendazim) and the end-product (a dilution of the concentrate, ready for use) containing 0.02 to 0.1 % carbendazim.

The following scenarios are covered by the exposure assessment in this report:

- Production of end-products (plaster) (scenario 1)
- Professional application of plaster containing masonry preservatives (scenario 2)
- Secondary exposure to carbendazim (scenario 3)

The mixing of the biocidal product, i.e. of the masonry preservative into the end-use products is done in industrial scale under closed conditions and only professionals are employed (scenario 1).

The biocidal product (≤ 10 % carbendazim) is delivered to the production plant only in large containers (e.g. 1 m^3 IBC), which – when full – cannot be handled manually but only by fork-lift. Only incidental exposure (hand contamination and exposure by inhalation) can occur during connecting/disconnecting the containers to/from the system and when handling empty drums. These tasks are assumed to be limited to 10 min/day. During the incorporation process, exposure to workers is not possible because a closed automated system is employed.

The inhalation exposure to carbendazim (10 % carbendazim) vapour during connecting/disconnecting and handling of containers is assessed as **negligible** due to the low vapour pressure of carbendazim. However as worst case the saturated vapour concentration (SVC) is considered as the maximum attainable concentration by vapour. Formation of aerosols during connecting/disconnecting and handling of containers is not expected.

For the dermal exposure to 10 % carbenadzim during connecting/disconnecting and handling of containers a HEEG recommendation for the scenario *connecting transfer lines* is followed and the Model “RISKOFDERM Toolkit Connecting lines” is used.

The ready-to-use products (plasters) containing 0.02 to 0.1 % carbendazim are packed into small containers. They are applied by brush or a similar hand-held tool such as a trowel to surfaces of walls and only need to be stirred prior to use (scenario 2). For the stirring phase, hand contamination by incidental exposure is considered. Plasters are applied by brush to surfaces of walls. Inhalation exposure in this scenario derives from aerosol formation during brushing and exposure from vapour. Exposure by direct spills or by contact to contaminated tools is possible.

The assessment of dermal exposure during the mixing and loading phase is based on a BEAT model. The assessment of inhalation and dermal exposure to 0.1 % carbendazim during the application phase is based on the worked example for product-type 7 in BEAT which is the scenario "Indoor decorative painting". In addition an exposure estimate based on data from a study (Lingk et al. 2006) performed by the BfR (Germany) and the BMLFUW (Austria) is calculated since member states requested that the assessment of professional and non-professional brushing should be based on the same model (in this case Lingk et al. 2006). Both approaches assessed dermal and inhalation exposures and the result of the risk assessment leads to the same conclusion. Aerosol formation in the post-application phase is not expected. The estimation of the potential dermal exposure during the cleaning of the brush is based on HEEG opinion No.11 "Exposure model primary exposure scenario – washing out of a brush which has been used to apply a paint" (TM III/2010). The inhalation vapour exposure during mixing&loading, application and post-application phase is assessed as negligible due to the low vapour pressure of carbendazim. However as worst case the saturated vapour concentration (SVC) is considered as the maximum attainable concentration by vapour.

A secondary exposure to carbendazim using readymade plaster containing 0.02 to 0.1 % carbendazim cannot be excluded (scenario 3).

Due to the very low vapour pressure of carbendazim for inhalation exposure as worst case the saturated vapour concentration (SVC) is taken into account. A potential dermal exposure to carbendazim is reasonable for dermal contact to treated surfaces and is based on a transfer factor from the treated surface to the hand.

The estimated inhalation uptake for each scenario is calculated with a body weight of 60 kg a breathing volume of 10 m^3 per shift, and the default assumption of 100 % absorption by inhalation. For calculating estimated dermal uptake the same body weight and either dermal absorption of 0.6 % for in use concentrations of 0.1 % carbendazim or dermal absorption of 1 % for in use concentrations of 10 % carbendazim are used. To get total internal body burden (estimated uptake) estimated inhalation uptake and estimated dermal uptake are added.

It is noted that for clarity reasons systemic exposure values are rounded to two decimal places. However, the underlying calculations are based on unrounded exposure values.

Table 2-8 Overview of systemic exposure values (PT 10)

Scenario	Estimated uptake mg/kg bw/d
1 - production of end-products	
Tier 1	$1.78x10^{-4}$
Tier 2	$3.96x10^{-5}$
2 - professional application of plaster	
mixing & loading	
Tier 1	$1.09x10^{-3}$
Tier 2	$1.31x10^{-4}$
a) application - plaster (BEAT)	
Tier 1	0.01
Tier 2	$1.84x10^{-3}$

b) application - plaster (Lingk et al. 2006)	
Tier 1	2.14×10^{-3}
Tier 2	1.81×10^{-3}
post application - cleaning brush	
Tier 1	3.85×10^{-5}
Tier 2	1.48×10^{-5}
a) total	
Tier 1	9.31×10^{-3}
Tier 2	1.98×10^{-3}
b) total	
Tier 1	3.27×10^{-3}
Tier 2	1.95×10^{-3}
3 - secondary exposure	
Tier 1	2.23×10^{-3}

Exposure of Non-Professionals and the General Public

PT 7

Primary exposure

Application of paints containing the active substance as film preservative - acute exposure - Scenario according to TNsG on Human Exposure 2007 (p. 62)

$Exposure_{dermal}$: 3.54×10^{-4} mg/kg bw

$Exposure_{inhalation}$: 4.64×10^{-4} mg/kg bw

$Exposure_{total}$: 8.18×10^{-4} mg/kg bw

Application of paints containing the active substance as film preservative - acute exposure - Scenario according to Lingk et al. (2006)

$Exposure_{dermal}$: 1.63×10^{-4} mg/kg bw

$Exposure_{inhalation}$: 4.28×10^{-4} mg/kg bw

$Exposure_{total}$: 5.91×10^{-3} mg/kg bw

Secondary exposure

Exposure assessment is based on default values given for toddlers in the Recommendation no.

5 of the BPC Ad hoc Working Group on Human Exposure 'Non-professional use of antifouling paints: exposure assessment for a toddler' (2015).

Contact to wet freshly painted surfaces, inhalation of vapours - acute exposure –

$Exposure_{dermal}$: 4.84×10^{-4} mg/kg bw

$Exposure_{oral}$: 0.81×10^{-2} mg/kg bw

$Exposure_{inhalation}$: 2.36×10^{-3} mg/kg bw

$Exposure_{total}$: **1.09×10^{-2} mg/kg bw**

Contact to dried surfaces after painting, inhalation of vapours – medium- and long-term exposure

$Exposure_{dermal}$: 2.90×10^{-5} mg/kg bw/d

$Exposure_{oral}$: 2.42×10^{-3} mg/kg bw/d

$Exposure_{inhalation}$: 2.36×10^{-3} mg/kg bw/d

$Exposure_{total}$: **4.81×10^{-3} mg/kg bw/d**

PT 10

Primary exposure

Application of plaster containing the active substance as masonry preservative - acute exposure –

Scenario according to "Model 2 Diluting concentrate for non-professionals" (TNsG on Human Exposure 2007, p. 66) and "Model Non-professional painting, 2. Brushing sheds and fences, outdoor (direct from can)" (TNsG on Human Exposure 2007, p. 62)

$Exposure_{dermal}$: 3.54×10^{-4} mg/kg bw

$Exposure_{inhalation}$: 9.32×10^{-5} mg/kg bw

$Exposure_{total}$: **4.47×10^{-4} mg/kg bw**

Secondary exposure

Exposure assessment is based on default values given for toddlers in the Recommendation no. 5 of the BPC Ad hoc Working Group on Human Exposure 'Non-professional use of antifouling paints: exposure assessment for a toddler' (2015).

Contact to wet freshly painted surfaces, inhalation of vapours - acute exposure -

$Exposure_{dermal}$: 0.69×10^{-3} mg/kg bw

$Exposure_{oral}$:	1.15×10^{-2} mg/kg bw
$Exposure_{inhalation}$:	2.36×10^{-3} mg/kg bw
$Exposure_{total}$:	**1.46×10^{-2} mg/kg bw**

Contact to dried surfaces after painting, inhalation of vapours – medium- and long-term exposure -

$Exposure_{dermal}$:	2.90×10^{-5} mg/kg bw/d
$Exposure_{oral}$:	2.42×10^{-3} mg/kg bw/d
$Exposure_{inhalation}$:	2.36×10^{-3} mg/kg bw/d
$Exposure_{total}$:	**4.81×10^{-3} mg/kg bw/d**

2.2.1.3. Risk Characterisation

Risk Assessment for Professionals

PT 7 & 10

The risk characterisation is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 0.03 mg/kg/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of carbendazim.

The AEL (an internal reference value) is based upon the oral NOAEL of 10 mg/kg/d from developmental rat and rabbit studies and the assumption of a 100 % oral absorption rate. By using an assessment factor of 300, an $AEL_{long\text{-}term}$ of 0.03 mg/kg/d is derived for long term exposure towards carbendazim.

If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.

Regarding the dermal local effects of carbendazim no quantitative risk assessment is carried out as the NOAEL for local effects is greater than the NOAEL for systemic effects.

The ratio of estimated uptake and reference value is below 100 % for all professional exposure scenarios, resulting in no concern. Based on this analysis, there is no need for further refinement of this risk assessment. It is essential to recognize that this conclusion only applies to the active substance (carbendazim) in the biocidal product. Carbendazim obviously fulfils the exclusion criteria laid down in Article 5 of the Biocides regulation (EU) No 528/2012. However, these criteria do not apply for the approval of the a.s. as the CAR has been submitted before 1st September 2013.

Safety Measures for Professionals

PT 7 & 10

According to the systemic risk assessment, PPE (protective gloves, protective coverall or RPE) is not necessary. For the production of end-products (scenario 1) a dermal contact with the 10 %

carbendazim biocidal product is possible. As the biocidal product is classified with H 317 (May cause an allergic skin reaction), protective gloves are recommended for the opening of the closed system (e.g. during connection/disconnection of containers and handling of empty drums).

In general, for mutagenic substances - such as carbendazim - Dir. 2004/37/EC states that "*the employer shall ensure that the ... mutagen is, in so far as is technically possible, manufactured and used in a closed system*" (article 5 paragraph 2 of dir. 2004/37/EC). "*Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible ... (by) the following measures: ... (e.g.) design of work processes and engineering control measures" (article 5, paragraph 5 of dir. 2004/37/EC). Only as last resort (e.g. accidents), wearing of a respiratory equipment, protective coverall and protective gloves has to be prescribed and specified*."

Risk Assessment for Non-Professionals and the General Public

PT 7

Table 2-9 Summary risk assessment for primary non-professional exposure to carbendazim from PT 7

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose - Application of paints containing film preservatives (TNsG on Human Exposure)			
Inhalation	4.64×10^{-4}	0.03	1.5
Dermal	3.54×10^{-4}	0.03	1.2
Total	**8.18×10^{-4}**	**0.03**	**2.7**
Acute exposure - internal dose - Application of paints containing film preservatives (Lingk et al. 2006)			
Inhalation	4.28×10^{-4}	0.03	1.4
Dermal	1.63×10^{-4}	0.03	0.5
Total	**5.91×10^{-4}**	**0.03**	**2.0**

Table 2-10 Summary risk assessment for secondary exposure of the general public to carbendazim from PT 7

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose - Toddlers, stay in freshly painted rooms, contact to wet surfaces			
Dermal	4.84×10^{-4}	0.03	1.6
Oral	0.81×10^{-2}	0.03	27
Inhalation	2.36×10^{-3}	0.03	7.9
Total	**1.09×10^{-2}**	**0.03**	**36**
Long- / medium-term exposure - internal dose -Toddlers, stay in rooms that have been treated with biocidal product containing carbendazim, contact to dried			

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
surfaces			
Dermal	2.90×10^{-5}	0.03	0.1
Oral	2.42×10^{-3}	0.03	8.1
Inhalation	2.36×10^{-3}	0.03	7.9
Total	**4.81×10^{-3}**	**0.03**	**16**

PT 10

Table 2-11 Summary risk assessment for primary non-professional exposure to carbendazim from PT 10

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - application of plaster containing carbendazim for masonry preservation (TNsG on Human Exposure)			
Inhalation	9.32×10^{-5}	0.03	0.3
Dermal	3.54×10^{-4}	0.03	1.2
Total	**4.47×10^{-4}**	**0.03**	**1.5**

Table 2-12 Summary risk assessment for secondary exposure of the general public to carbendazim from PT 10

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose - Toddlers, stay indoors directly after application, contact to wet surfaces			
Dermal	0.69×10^{-3}	0.03	2.3
Oral	1.15×10^{-2}	0.03	38
Inhalation	2.36×10^{-3}	0.03	7.9
Total	**1.46×10^{-2}**	**0.03**	**49**
Long- term exposure - internal dose - Toddlers, stay in rooms that have been treated with biocidal product containing carbendazim, contact to dried surfaces			

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Dermal	2.90×10^{-5}	0.03	0.1
Oral	2.42×10^{-3}	0.03	8.1
Inhalation	2.36×10^{-3}	0.03	7.9
Total	**4.81×10^{-3}**	**0.03**	**16**

Exposure of the non-professional user and the general public is considered acceptable.

Safety Measures for Non-Professionals and the General Public

PT 7 & 10

Specific measures for non-professionals and the General Public are not required.

2.2.2. Environmental Risk Assessment

The estimation of predicted environmental concentrations (PECs) as well as the derivation of predicted no effect concentrations (PNECs) were performed for all relevant environmental compartments according to the Guidance on the Biocidal Product Regulation Vol. IV Environment – Assessment and Evaluation (Part B + C) (October 2017, Version 2.0), the EUBEES 2 Emission Scenario Document (ESD) for biocides used as film preservatives (product type 7) by EC DG ENV and RIVM (2004), the Emission Scenario Document for PT10, described in the EUBEES 2 document by Migné (2002) "Emission scenario document for biocides used as masonry preservatives (product type 10)", the Revised Emission Scenario Document for wood preservatives (PT 8, OECD, 2013) and the documents "Leaching from paints, plasters and fillers applied in urban areas" (final Version 6, November 2015) and "The assessment of direct emission to surface water in urban areas (PT 6.2/6.3 and 7-10)" which was endorsed at BPC-WG ENV III-2014. For the assessment of the indoor use (PT 7), the Emission Scenario Document on coating industry (Paints, Laquers and Varnishes) (OECD ESD Number. 22; ENV/JM/MONO, 2009) is used.

At BPC-WG ENV I-2017, the document "Refinement of $f_{house}/f_{marketshare}$ (scaling approach) for PT 6.2, 7, 9, 10 (city scenario, roof membranes)" was endorsed which is taken into account as well.

2.2.2.1. Fate and distribution in the environment

Biodegradation

The active substance carbendazim is classified as "not readily biodegradable". In a study according to OECD guideline 301 B, the amount of CO_2 produced in 28 days was less than 20 % of the theoretical CO_2 content. A screening test for inherent biodegradability of carbendazim according to OECD test guideline 302 B was considered not acceptable for the endpoint. A further study on inherent biodegradability as well as a study on aerobic elimination/biodegradation of carbendazim in sewage treatment plants (STP) was not required as higher tier studies are available investigating route and rate of biodegradation in freshwater systems and soils.

The dissipation of ^{14}C-carbendazim was studied in two water/sediment systems ("Bickenbach", "Unter Widdersheim"). They were incubated under aerobic conditions in the dark at 20 ± 2°C over a period of 149 days. The study results demonstrate that dissipation and degradation of carbendazim vary depending on the water-sediment system. In both test systems, radioactivity was translocated rapidly from the aqueous phase into the sediment. But the extent of metabolisation/transformation, sorption, extractability, formation of non-extractable radioactivity (NER) and mineralisation was different between the "Bickenbach" and "Unter Widdersheim" test system. For the aqueous phase, dissipation DT_{50} values of 10.8 days ("Bickenbach") and 3.9 days ("Unter Widdersheim"), respectively, were observed ($DissT_{50}$ 20.5 and 7.4 days converted to an average EU outdoor temperature of 12°C). Dissipation DT_{50} values of 34.5 days ("Bickenbach") and 99.8 days ("Unter Widdersheim") were derived for the sediment compartment ($DissT_{50}$ 65.4 and 189.3 days converted to an average EU outdoor temperature of 12°C). For the total system, degradation DT_{50} values of 15.1 days ("Bickenbach") and 76.8 days ("Unter Widdersheim") were calculated (DT_{50} 28.6 and 145.6 days converted to an average EU outdoor temperature of 12°C). No metabolite was detected above 10 % of applied radioactivity. Only the metabolite 2-AB (2-Aminobenzimidazole, CAS-Nr. 934-32-7) was identified in the sediment extracts with an amount of up to 6.3 % of applied radioactivity. The NER amount increased with time to maximum levels of 63.4 % and 59.4 % of applied radioactivity in the "Bickenbach" and "Unter Widdersheim" sediments, respectively. In the "Bickenbach" test system, 23 % of applied radioactivity was mineralised at the end of the study, in the "Unter Widdersheim" test system ≤ 6 % of applied radioactivity. The study results indicate that carbendazim can be considered as persistent in several water/sediment systems under aerobic conditions in the dark.

To investigate the degradation rate of ^{14}C-carbendazim in soil, five soils were incubated in flow-through soil metabolism systems under aerobic conditions at 20.2 ± 0.2°C over a period of 120 days. DT_{50} values of 12.0 – 137.5 days were derived for the soils investigated (DT_{50} 22.8 – 260.8 days converted to an average EU outdoor temperature of 12°C). The NER amount steadily increased with time to maximum levels of 40–81 %. The study results reflect a clear link between the amount of NER and the DT_{50} value. However, the NER content seems not to be correlated to a specific soil parameter like organic carbon content, pH or clay content. Mineralisation amount (CO_2 formation) increased with time but was generally low (<14 %). In the soil extracts the metabolite 2-AB was identified reaching maxima of 3.0-10.0 % of the applied radioactivity, single replicates up to 11.3 %. Therefore, 2-AB has to be considered as a relevant metabolite because its amount reached ≥ 10.0 % of applied radioactivity. The label position (phenyl ring or benzimidazole ring) of carbendazim did not influence the degradation results significantly. A geomean DT_{50} value of 95.2 days (at 12°C) was calculated for carbendazim and was used in the environmental exposure assessment.

In addition, the applicant provided a QSAR value of 30 days (presumably at 20°C) for the DT_{50} value of 2-AB in soil, which was initially accepted by the eCA for P- and risk assessment. The eCA considers a DT_{50} of 30 days (20°C) still valid after a recent re-evaluation of the soil degradation study using a new software (CAKE 3.2). Thus, acceptable half-lives could be calculated for 2-AB from at least four soils and both label-positions by simultaneous analysis of carbendazim and 2-AB (SFO-SFO), resulting in a geometric mean of 29.2 days (20°C, n=4).

For the endpoint extent and nature of bound residues two further studies were submitted. For a Marl soil samples it was observed that after an extended extraction procedure the amount of extractable radioactivity could be raised from 28 % to 69 % of applied radioactivity. In all extracts only carbendazim was detected.

Four soil field dissipation studies with carbendazim were conducted in Germany. Only the concentration of carbendazim but no metabolites were determined in the extracts. The dissipation DT_{50} values of carbendazim ranged between 11 and 78 days at field temperature (15 - 95 days converted to 12°C average EU outdoor temperature).

Abiotic Degradation

Carbendazim is hydrolytically stable at pH 5 and 7. The hydrolysis rates increase at pH 9, mean half-life of around 153 days was calculated at EU outdoor temperature of 12°C. 2-Aminobenzimidazole (2-AB) was determined as significant hydrolysis product and amounted for approximately 30 % of the parent compound at pH 9.

Carbendazim is photolytically stable. The study was not conducted under environmentally relevant conditions (sterile, pH = 5).

An estimation of photochemical degradation of carbendazim in air resulted in a half-life of 1.919 hours (global 24-hours-mean of $c(OH)_{air}$ = 5 x 10^5 molecules/cm^3).

Distribution / Mobility

Several studies on the adsorption/desorption of carbendazim in soil were submitted. In general, there was a good correlation between the adsorption constants and the organic carbon content. No dependence of the adsorption constant with the clay content, the cation exchange capacity (if reported) or the soil pH was observed. Overall, the adsorption characteristic of carbendazim seems to be adequately described by the Koc concept. The slope 1/n for the adsorption isotherms was on average 0.796. The arithmetic mean of Koc values of 487.2 L/kg (n = 23; range 122 – 2805 L/kg) was chosen as representative value and applied in the environmental exposure assessment. According to McCall et al. (1981) carbendazim is classified as moderately or rather medium mobile in soil.

Summary of relevant input parameters for environmental exposure assessment

To harmonize the input parameters for the environmental exposure assessment, the following parameters including physico-chemical data were agreed upon:

Biodegradation:

- k = 0 h^{-1} for biodegradation in sewage treatment plants;
- k = 7.281 × 10^{-3} $days^{-1}$ for soils (12 °C).

Abiotic degradation is not to be taken into account.

Physico-chemical data:

- melting point: decomposition before melting;
- water solubility: 8 mg/L (pH 7, 24 °C; 6.75 mg L^{-1} at 12 °C);
- vapour pressure: 9 × 10^{-5} Pa (20 °C; 5.06 × 10^{-5} Pa at 12 °C);

Distribution and partition coefficients:

- mean Koc: 487.2 L/kg;
- log Pow: 1.51 (25 °C, pH 7);
- Henry´s Law Constant (calculated, at 12°C): 1.434 × 10^{-3} Pa m^3/mol;

- STP distribution (estimated with SimpleTreat 3.0):

  Fair = 0.0 %, Fwater = 94.3 %, Fsludge = 5.7 %, and Fdegraded = 0.0 %.

Bioaccumulation

Based on both experimentally derived aquatic bioconcentration (BCF_{fish} measured = 27 L/kg) and on estimation of aquatic (BCF_{fish} calc. = 3.75 L/kg) and terrestrial bioconcentration ($BCF_{earthworm}$ calc. = 0.858 L/kg) the active substance is not expected to bioconcentrate in aquatic and terrestrial organisms and to pose an unacceptable risk of biomagnification in the food chain of either compartment. In conclusion, there is no indication of a bioaccumulation potential.

2.2.2.2. Hazard identification and effects assessment

Aquatic Compartment

Both short- and long-term laboratory studies with carbendazim on fish, daphnia and algae were submitted and evaluated. An additional study in sediment in a spiked-water system has been evaluated. As acute and long-term tests with species from three trophic levels are available, an assessment factor of 10 can be applied according to the Guidance on BPR IV ENV B + C (2017).

For the trophic level of predators, acute and chronic toxicity towards fish was observed with a 96 h-LC_{50} = 0.019 mg/L for the channel catfish *Ictalurus punctatus* and a 79 d-NOEC = 0.011 mg/L for the rainbow trout *Oncorhynchus mykiss*. *Daphnia magna* as primary consumer were also sensitive towards carbendazim, acute with a 48 d-LC_{50} = 0.15 mg/L and for reproduction with a 21 d-NOEC = 0.0015 mg/L. Green algae as primary producers showed the lowest sensitivity, 72 h-ErC_{50} > 8 mg/L and 72 h-NOEC = 8 mg/L for *Desmodesmus subspicatus*.

Based on the NOEC from the Daphnia study and an AF of 10 for acute and long term studies for three trophic levels, the $PNEC_{aqua}$ for carbendazim is 150 ng/L.

Inhibition of microbial activity (aquatic)

In a standard activated sludge respiration inhibition test with sludge from a domestic sewage treatment plant, an EC_{50} of > 1000 mg/L was observed. Considering the limit of water solubility, a $PNEC_{microorganism,STP}$ = 0.7 mg/L was derived.

Sediment

No study with spiked sediment is available for carbendazim. The $PNEC_{sediment}$ is derived according to EPM. As the log Kow is < 3, the risk assessment for the sediment is covered by the risk assessment for the aquatic compartment.

Terrestrial Compartment

The effect assessment for the terrestrial environment relies on acute and reproduction studies with earthworms, an acute study with plants and a study with soil microorganisms. An additional study with springtails (*F. candida*) was not considered relevant for PNEC derivation, because toxicity was orders of magnitude lower than for earthworms. With primary producers, consumers and decomposers, different taxonomic groups and three trophic levels are included in the PNEC calculation. Carbendazim shows a high acute and chronic toxicity to earthworms with an EC_{50} = 5.4 mg/kg dw soil for the acute test after 14 d and a 56 d-NOEC = 1 mg/kg dw soil for the chronic test. For plants, only acute data on seed germination and growth were available, the EC_{50} > 100 mg/kg dw soil indicates a lower level of toxicity than towards earthworms. A study on effects on microbial activity did not show relevant effects on rates of C- and N-mineralisation after 28 d, NOEC ≥ 4.25 mg/kg dw soil. In summary, the PNEC will be calculated considering

chronic data for consumers and decomposers and acute data for primary producers, the latter showed at least an order of magnitude lower (acute) sensitivity. Earthworms represent the most sensitive of the tested species therefore NOEC = 1 mg/kg dw soil for *E. fetida andrei* has to be used for $PNEC_{soil}$ calculation; a density of 1.5 g/cm³ for the dry soil can be assumed.

The assessment factor relies on short-term toxicity tests and two NOECs for additional long-term toxicity tests of two trophic levels. The terrestrial risk assessment does not cover long-term data on plants; however it could be demonstrated that primary producers do not belong to the most sensitive taxonomic group. Therefore, in accordance with Guidance on BPR IV ENV B + C (2017) (Table 18, footnote d), an AF = 10 was derived and applied to the lowest NOEC from only two species. Based on the NOEC from the earthworm reproduction study and an AF of 10, the $PNEC_{soil}$ is 0.0882 mg/kg wet weight soil, based on a density of 1700 kg/m³.

Metabolite 2-AB

2-Aminobenzimidazole (2-AB) is considered as a major metabolite for the terrestrial compartment and represents the main degradation product of the active substance in the environment. In the biodegradation study, 2-AB occurred at levels up to 10 %, mostly independent on the type of soil. Chronic aquatic and terrestrial ecotoxicity of carbendazim is driven by its specific mode of action and not via narcosis / baseline toxicity. Carbendazim acts by binding to β-tubulin and subsequent inhibition of microtubule assembly, whereas 2-AB is known not to bind to β-tubulin. Therefore, it can be concluded that 2-AB will not exhibit the specific mode of action of the parent substance and it is justified to assess the ecotoxicological relevance of 2-AB via its baseline toxicity by means of a QSAR estimation as a function of its partition coefficient log K_{ow}. 2-AB exhibits a lower log K_{ow} which results in a lower predicted baseline toxicity than carbendazim (Kowwin version 1.68 estimate: log K_{ow} = 0.88). In consequence, 2-AB is not an ecotoxicological relevant metabolite. Based on the results of the QSAR estimation it can be concluded that 2-AB is less toxic than carbendazim and not relevant for ecotoxicological risk assessment.

2.2.2.3. Exposure assessment and risk characterisation

Exposure Assessment

PT 7

Paints contain carbendazim as film preservative at concentrations between 0.025 and 0.1 %. The formulation of the end product is done by mixing a water based suspension concentrate (10 %) into the paints to the above mentioned final carbendazim concentration. Since these products are ready to use, the concentrations in the paint represent the end-use concentration. For the assessment of the environmental exposure of the biocidal product (b.p.) the following life cycle stages are selected to be relevant:

- production of a.s.
- formulation of b.p. (10 % water-based concentrate)
- formulation of end-use product (paints)
- application by roller & brush (indoor, outdoor)
- application by spray (outdoor)

- service life (indoor, outdoor)

The disposal step is not taken into consideration because emissions are assumed to be of minor relevance compared to releases due to application and use. Furthermore, the ESD for film preservatives (EC DG ENV and RIVM; 2004) states that, in case of landfill, it is very unlikely that the total remaining amount of a.s. in the paints will be released. Additionally, in several countries schemes for controlled treatment of excess/waste are in place. In case of incineration, organic substances will be destroyed and no emissions are expected.

The a.s. is produced outside the EU (imported as a solid). No exposure data with respect to the production step are required. The biocidal product is a water-based suspension concentrate containing 10 % carbendazim. The formulation of b.p. processed at industrial scale is a highly automated process and is performed under insulated/closed conditions. No relevant losses of carbendazim to the environment due to production of a.s. and formulation of b.p. are expected. In addition, the exposure and risk assessment for carbendazim during production of carbendazim and the formulation of the biocidal product should be addressed under other EU legislation.

Formulation of the water-based suspension of carbendazim (10 % a.s.) into the end-use-product (paint) is also processed at industrial scale under closed conditions. Thus, exposure to the environment is also considered negligible.

Application of paints containing carbendazim as a film preservative is carried out by roller and brush or by sprayer. Both are considered to be performed by a non-professional user. Furthermore, according to ESD for PT 10, it is distinguished between the application and use of paints in the city and in the countryside. In a city, losses of paints containing carbendazim during brushing or spray application are likely to fall onto paved ground. The drips may flush with rainwater into the local sewer system. In contrast, losses in the countryside end up directly at the adjacent soil and finally reach the groundwater or could end up in surface water. In case of spray-application an additional receiving compartment of releases is the soil compartment in a distance to a treated house due to spray drift.

For the service life of carbendazim containing film preservatives four major environmental exposure pathways of carbendazim have been identified:

- leaching of carbendazim due to rainwater, the collection of rainwater in the sewer system (city, mixed sewer system) and subsequently the release to the STP, surface water, sediment, soil and finally groundwater;

- leaching of carbendazim due to rainwater, the collection of rainwater in the sewer system (city, separate sewer system) and subsequently the direct release to surface water and finally sediment;

- leaching of carbendazim due to rainwater and the direct emission to soil in rural areas (countryside) and subsequently to groundwater;

- leaching of carbendazim due to rainwater and direct release to surface water and finally sediment (bridge over pond).

For the indoor application of carbendazim containing paints, emission estimates are performed for general public use of decorative paints by non-professionals (according to OECD ESD Number 22, 2009). During service life (indoor use), emission of carbendazim can occur via an open window to air. However, a significant accumulation of carbendazim in the air seems to be unlikely. Direct exposure of air due to indoor use of carbendazim is therefore considered negligible. No exposure and risk assessment of service life are performed regarding the indoor use.

PT 10

For the assessment of the environmental exposure of the biocidal product (b.p.) the following life cycle stages are selected to be relevant:

- production of a.s.
- formulation of b.p. (10 % water-based concentrate)
- formulation of end-use product (plasters)
- application by roller (indoor, outdoor)
- service life (indoor, outdoor)

The disposal step is not taken into consideration because emissions are assumed to be of minor relevance compared to releases due to processing and use.

The active substance is manufactured outside the EU (imported as a solid). Therefore, no exposure data with respect to the production step are required. The biocidal product is a water-based suspension concentrate containing 10 % carbendazim. The formulation of the b.p. at industrial scale is a highly automated industrial process and runs mostly under closed conditions. No releases to the environment are expected due to formulation of b.p. In addition, the exposure and risk assessment for carbendazim during production of carbendazim and the formulation of the biocidal product should be addressed under other EU legislation. The production of the end-use products such as plaster (by mixing the carbendazim-containing biocidal product into the end-use product) is done on an industrial scale. The production is highly automated and exposure to the environment is also considered negligible. The exposure and risk assessment have been done for end-use products with two different concentrations of carbendazim, 0.1 % and 0.02 % respectively.

Regarding application, in-situ treatment by “brushing & rolling” is considered according to the Intended Use. Only non-professionals (amateurs) are considered as worst case for environmental exposure assessment, covering also the application by professionals. The ESD for PT 10 distinguishes between the application and use of masonry preservatives in the countryside and in the city. Losses during in-situ treatment (outdoor) will end up directly in the adjacent soil in the countryside whereas they may be released to the STP or directly to surface waters in a city.

There is no emission scenario available to cover the indoor use and application of carbendazim containing plasters. In addition, cleaning of the hand-held tools like trowels, etc. by use of water is not foreseen. Hence, no release to sewers during application is expected and no exposure and risk assessment are performed regarding the indoor use.

For the service life of carbendazim containing plasters (outdoor) three major environmental exposure pathways of carbendazim have been identified:

- leaching of carbendazim due to rainwater, the collection of rainwater in the sewer system (city, mixed sewer system) and, subsequently, the release to the STP, surface water, sediment, soil and finally groundwater;
- leaching of carbendazim due to rainwater, the collection of rainwater in the sewer system (city, separate sewer system) and, subsequently, the direct release to surface water and finally sediment;
- leaching of carbendazim due to rainwater and the direct emission to soil in rural areas (countryside) and, subsequently, to groundwater.

Regarding indoor use, during service life, emission of carbendazim can occur via an open window to air. However, a significant accumulation of carbendazim in the air seems to be unlikely. Direct exposure of air due to indoor use of carbendazim is therefore considered negligible. No exposure and risk assessment of service life are performed regarding the indoor use.

Aggregated Exposure Assessment

It seems to be realistic that carbendazim is simultaneously leached due to rainwater of the same rain event from façades treated with biocidal products of PT 7 and 10 and that the rainwater is collected in the same sewer system. Therefore, predicted environmental concentrations resulting from the respective service life scenarios of PT 7 and 10 are added up.

Risk Characterisation

PT 7

Aquatic Compartment

Sewage treatment plant

The estimated PEC/PNEC ratios for microorganisms in STP are below one for the in-situ treatment as well as for the service life scenarios. Hence, the use of the carbendazim containing film preservatives does not pose an unacceptable risk for the biological treatment stage of a STP.

Surface water compartment

Application

The PEC/PNEC ratio for the surface water compartment exceeds the value of one for all outdoor in-situ application scenarios in the city (brushing, spraying) for products containing 0.1 % a.s. carbendazim. Therefore, as risk mitigation measure it is recommended to cover the paved soil during application of paints containing carbendazim to avoid flushing the a.s into the sewer system and finally into the surface water. However, regarding in-situ spray application, even with the above recommended risk mitigation measure and an additional reduction of a carbendazim concentration to 0.025 % in the paint, the PEC/PNEC ratio for the surface water compartment exceeds the value of one due to spray drift. Therefore, in case of the assessed paints containing carbendazim as a film preservative, application by spraying should not be allowed.

The assessment of in-situ application of paints near or above surface water bodies reveals PEC/PNEC ratios below one for the surface water compartment for paints containing 0.025 % a.s. carbendazim. For paints containing 0.1 % a.s. carbendazim unacceptable risks were observed. Thus, as no risk mitigation measure exists, their application near or above surface water bodies should not be allowed.

For the indoor application of the assessed carbendazim containing paints, no unacceptable environmental risks are observed.

Service life

The city service-life scenario for paints containing 0.1 % a.s. carbendazim does pose an unacceptable risk to aquatic organisms irrespective of carbendazim containing leachates pass a STP or enter surface water directly. No adequate risk mitigation measure is available to avoid releases in the sewer over a period of 5 years. No leaching test is available to proper assess the service life of paints containing 0.025 % carbendazim.

Regarding the assessment of service-life of paints applied near or above surface water bodies, the estimated PEC/PNEC ratios for the surface water compartment are below one for products

containing 0.1 % a.s. carbendazim if biodegradation in surface water with a DT_{50} value of 145.6 days (at 12°C, see Doc II, chapter 4.1.1.3.1) is considered. Hence the use of treated articles which are treated with carbendazim containing paints near or above surface water does not pose unacceptable risks for the aquatic compartment.

Because the $PNEC_{sediment}$ is derived according to EPM, the PEC/PNEC ratios for the sediment are the same as for the surface water, i.e. the risk assessment for the sediment is already covered by the risk assessment for the surface water.

Terrestrial Compartment including Groundwater

Application:

Regarding in-situ application of houses located in the city with paints containing 0.1 % carbendazim, the PEC/PNEC ratios for the soil compartment (after a.s. emission to STP and sewage sludge application to soil) are below 1 for both brush and spray application. This indicates that no unacceptable risk for the terrestrial compartment exists due to brush and spray application in the city.

The in-situ application (brush or spray) of houses situated in a rural area exhibits a PEC/PNEC ratio greater than 1 for products containing 0.1 % a.s. carbendazim. It is recommended to protect the soil against losses of a.s. by covering the soil during application. With the above recommended risk mitigation measure, the PEC/PNEC ratio for the distant soil compartment is below 1 (tier 2 assessment of spray application). This indicates that no unacceptable risk for the terrestrial compartment exists due spray application in the countryside for paints containing 0.1 % a.s. carbendazim if the above recommended risk mitigation measure is applied.

For the indoor application of the assessed carbendazim containing paints, no unacceptable risks are observed for the soil compartment (after a.s. emission to STP and sewage sludge application to soil).

Service life:

Regarding the use of film preservatives onto house façades located in the city, no unacceptable risk for the soil compartment (after a.s. emission to STP and sewage sludge application to soil) was identified, since the PEC/PNEC ratio for the service life of the assessed a.s. containing paints is below 1.

In case of direct emission to soil (treated houses situated in the countryside) the PEC/PNEC ratio exceeds the value of one in case of TIME 2. However, refinement of $PEClocal_{Soil}$ TIME 2 by taking degradation into account results in a PEC/PNEC ratio lower than 1. Therefore, no unacceptable risk for the terrestrial compartment exists due to the use of the assessed paints containing carbendazim as film preservative in the countryside.

Groundwater:

Regarding the in-situ treatment scenarios in the countryside (brush&roller and spray application) the legally admissible threshold for biocides in the groundwater is exceeded for carbendazim, respectively. For the city scenarios this is only the case for the assessment of the spray application (tier I). These unacceptable risks would be mitigated due to the recommended risk mitigation measure “covering the adjacent ground/soil during application” and the general restriction regarding spray application. No unacceptable risks for the groundwater are observed for the indoor application of carbendazim containing paints.

For the service-life of carbendazim containing paints, no unacceptable risk were identified due to indirect emission to soil via the STP in the city scenario. As a consequence of the direct emission to soil (countryside), unacceptable risks occur in TIME 1 as well as in TIME 2 calculations (service life) even after taking biodegradation into account.

Therefore, a refinement of the groundwater assessment has been carried out for the service life scenario countryside TIME 2. All $PECloca l_{groundwater}$ values calculated with FOCUS PEARL 4.4.4 are below 1 x 10^{-4} µg L^{-1} and, therefore, considerably below the limit value of 0.1 µg L^{-1}. The results indicate that no unacceptable risk for the groundwater exists for the service life scenarios of the assessed carbendazim containing film preservatives with 0.1 % a.s..

Metabolite 2-Aminobenzimidazole (2-AB)

The metabolite 2-AB is identified as a relevant metabolite in soils. Additional information about the persistency and ecotoxicology of 2-AB indicate that a preliminary risk assessment for this major metabolite can be performed by assuming similar persistency and ecotoxicology than carbendazim. Therefore, local PECs of 2-AB in soil are not calculated. The exposure and risk assessment of the metabolite in soil are assumed to be covered by the assessment of carbendazim.

A groundwater assessment for 2-AB is done using FOCUS PEARL 4.4.4. The estimation of the groundwater concentration is performed for the use of paints containing carbendazim as film preservative onto a house in the countryside (service life, over a period of 5 years). Further scenarios are assumed to be covered by this assessment. All $PECloca l_{groundwater}$ values of 2-AB calculated with FOCUS PEARL are below 1 x 10^{-4} µg L^{-1} and, therefore, considerably below the limit value 0.1 µg L^{-1}. This indicates that, regarding 2-AB, no unacceptable risk for the groundwater exists for the assessed products.

Atmosphere

During service-life, emission of carbendazim to air can occur, especially regarding the indoor use of carbendazim containing paints. As carbendazim is only slightly volatile (vapour pressure = 9 × 10^{-5} Pa at 20 °C) and degrades quickly in the atmosphere by reaction with OH radicals, a significant accumulation of carbendazim in the air seems to be unlikely. Direct exposure of air is therefore considered negligible and an exposure as well as a risk assessment for the atmosphere is not performed.

PT 10

Aquatic Compartment

Sewage treatment plant

The estimated PEC/PNEC ratios for microorganisms in STP are below the trigger value (< 1) for the application as well as for the service life scenario (outdoor). Hence, the application of carbendazim containing plasters and their outdoor use do not pose unacceptable risks for the biological treatment stage of a STP.

Surface water compartment

The PEC/PNEC ratio for the surface water compartment exceeds the value of 1 for all in-situ application scenarios (city scenario, outdoor) for end-use products (plasters) containing 0.1 % a.s. as well as 0.02 % carbendazim. Therefore, as risk mitigation measure, it is recommended to cover the ground/soil during application of carbendazim containing plasters.

The PEC/PNEC ratio for the surface water compartment exceeds the value of 1 for all service life scenarios (outdoor) for end-use products (plasters) containing 0.1 % a.s. as well as 0.02 % carbendazim. This indicates that the use of the assessed carbendazim containing plasters pose an unacceptable risk to aquatic organisms irrespective of carbendazim containing leachates pass a STP or enter surface water directly. No adequate risk mitigation measure is available to avoid releases in the sewer over a period of 25 years.

Because the $PNEC_{sediment}$ is derived according to EPM, the PEC/PNEC ratios for the sediment are the same as for the surface water, i.e. the risk assessment for the sediment is already covered by the risk assessment for the surface water.

Terrestrial Compartment including Groundwater

Application:

Regarding in-situ application in the countryside (outdoor), the PEC/PNEC ratios for both concentrations of carbendazim in plasters exceed the value of 1, so that it is recommended to protect the soil against losses of a.s. by covering the soil during application. Although there are no unacceptable risks identified for soil organisms due to application of sewage sludge in the city scenario (outdoor), the ground/soil has also to be covered during application of carbendazim containing plasters in the city because of identified unacceptable risks for aquatic organisms.

Service life:

In case of indirect emission to soil via the STP during service-life (city scenario, outdoor), the PEC/PNEC ratios for the soil compartment are below the trigger value (< 1) for both concentrations of carbendazim in plasters. This indicates that no unacceptable risk for the terrestrial compartment exists due to the outdoor use of the assessed carbendazim containing plasters in urban areas.

In case of direct emission to soil (countryside), for a concentration of a.s. in the plaster of 0.1 %, a PEC/PNEC ratio of 1.7 for TIME 1 calculation indicates an unacceptable risk for the terrestrial compartment regarding the initial time period. Also for TIME 2, there is an unacceptable risk (PEC/PNEC =1.21) for a concentration of 0.1 %, even after taking biodegradation into account.

Using a concentration of 0.08 % of a.s. in the plaster, no unacceptable risks are identified for TIME 2 at least. Therefore, it may be recommended to restrict the maximum concentration of a.s. in plasters to 0.08 % to avoid unacceptable risks for terrestrial organisms during service-life.

Groundwater:

For the application stage of carbendazim containing plasters (outdoor) the legally admissible threshold for biocides in the groundwater is exceeded for carbendazim. However, these unacceptable risks will be mitigated by covering the ground/soil during application.

There is no unacceptable risk identified for service-life due to indirect emission to soil via the STP in the city scenario (outdoor) for plasters containing 0.02 % carbendazim. However, for concentration of 0.1 % carbendazim in plasters an unacceptable risk could be identified.

As a consequence of the direct emission to soil (countryside), PEC values in groundwater exceed the limit value of 0.1 µg L^{-1} in TIME 1 as well as in TIME 2 calculations for all assessed concentrations of carbendazim in plasters. A refinement of the groundwater assessment has been carried out for the service life scenario countryside in TIME 2 (plasters containing 0.1 % carbendazim) using FOCUS PEARL 4.4.4 which covers also further service life scenarios with identified unacceptable risks. All $PEClocal_{groundwater}$ values calculated with FOCUS PEARL are below the limit value of 0.1 µg L^{-1}. A refinement of the groundwater assessment for TIME 1 has not been carried out.

In sum, the results indicate that no unacceptable risk for the groundwater exists due to the outdoor use of the assessed carbendazim containing plasters during service life.

Metabolite 2-Aminobenzimidazole (2-AB)

The metabolite 2-AB is identified as a relevant metabolite in soils. Additional information about

the persistency and ecotoxicology of 2-AB indicate that a preliminary risk assessment for this major metabolite can be performed by assuming similar persistency and ecotoxicology than carbendazim. Therefore, local PECs of 2-AB in soil are not calculated. The exposure and risk assessment of the metabolite in soil are assumed to be covered by the assessment of carbendazim.

A groundwater assessment for 2-AB is done using FOCUS PEARL 4.4.4. The estimation of the groundwater concentration is performed for the service life scenario countryside TIME 2 (plasters containing 0.1 % carbendazim). Further scenarios are assumed to be covered by this assessment.

All $PEClocal_{groundwater}$ values of 2-AB calculated with FOCUS PEARL are below the limit value of 0.1 µg L^{-1}. This indicates that, regarding 2-AB, no unacceptable risk for the groundwater exists for the assessed products.

Atmosphere

During service-life, emission of carbendazim to air can occur. As carbendazim is only slightly volatile (vapour pressure = 9×10^{-5} Pa at 20 °C) and degrades quickly in the atmosphere by reaction with OH radicals, a significant accumulation of carbendazim in the air seems to be unlikely. Direct exposure of air is therefore considered negligible by the eCA and an exposure as well as a risk assessment for the atmosphere is not performed.

Aggregated Risk Assessment

In the aggregated risk assessment, the simultaneous leaching of carbendazim due to rainwater from façades treated with biocidal products of PT 7 and 10 and the collection of the rainwater in the same sewer system during the same rain event is assessed. In case of passing a STP, the estimated aggregated PEC/PNEC ratios for microorganisms in STP and the terrestrial compartment are below one. The estimated aggregated PEC/PNEC ratios for the surface water compartment and for groundwater (tier 1) are above one in case of passing a STP. However, considering the calculated refinements of groundwater assessment using FOCUS PEARL 4.4.4, it is assumed that no unacceptable risk is expected for the groundwater compartment due to the simultaneous use of biocidal products in PT 7 and 10. In case of direct rainwater discharge to the surface water (separate sewer system), an aggregated PEC/PNEC ratio above one indicates an unacceptable risk for the aquatic compartment (surface water and sediment) as well.

Non Compartment Specific Effects Relevant to the Food Chain (Secondary Poisoning)

According to the Guidance on BPR IV ENV B + C (2017), concern for a bioaccumulation potential of a chemical only exists when a substance has a log Kow ≥ 3 or is highly adsorptive (or belongs to a structural class of substances that is known to bioaccumulate) and there is no mitigation property such as hydrolysis (half-life less than 12 hours). Data on bioconcentration indicate that carbendazim neither bioconcentrate in aquatic biota nor bioaccumulates in the food chain of terrestrial organisms (cf. Doc II-A, chapter 4.1.2). Consequently, carbendazim has only a very low potential for a concern for secondary poisoning of non-target animals.

Summary

PT7

The outdoor in-situ application of the end-use product (carbendazim containing paints with 0.1 % a.s.) by brushing & rolling as well as by spraying poses an unacceptable risk to aquatic and terrestrial organisms in all scenarios (city and rural areas). Therefore, it is necessary that the ground/soil adjacent to the treated object is covered during application. For the city scenario an unacceptable risk persists for aquatic organisms due to spray application although risk mitigation

measures were taken into account. Consequently, in case of the assessed paints containing carbendazim as a film preservative, application by spraying should not be allowed. Regarding the “bridge over pond” scenario, the PEC/PNEC ratio for the surface water compartment exceeds the value of one for the in-situ application by non-professionals for products containing 0.1 % carbendazim. Thus, as no risk mitigation measure exists, application of these paints containing carbendazim as a film preservative near or above surface water bodies should not be allowed. However, for paints containing 0.025 % a.s. carbendazim, the assessment of in-situ application of paints near or above surface water bodies reveals PEC/PNEC ratios below one for the surface water compartment.

For the indoor application of the assessed carbendazim containing paints, no unacceptable environmental risks are observed.

Regarding the use phase (service-life, outdoor) carbendazim released by leaching does not pose an unacceptable risk to the microorganisms in the STP, to the aquatic compartment (in case of bridge over pond scenario), to the soil compartment and the groundwater. Assessing the use of carbendazim containing paints (0.1 % a.s.) in the city (outdoor) unacceptable risks for the compartments surface water and sediment were observed in all cases (via passing a STP, via STP bypass and via direct emission of rainwater to surface water (separate sewer system)). This indicates that the use of the assessed carbendazim containing paints pose an unacceptable risk to aquatic organisms irrespective of carbendazim containing leachates pass a STP or enter surface water directly. No adequate risk mitigation measure is available to avoid releases in the sewer over a period of 5 years. Therefore, the risk assessment reveals that overall the outdoor use of the assessed carbendazim containing paints pose an unacceptable risk to the environment.

Direct exposure of air due to indoor use of carbendazim is considered negligible by the ECA and an exposure as well as a risk assessment for the indoor use is not performed. Consequently, the indoor use of Carbendazim containing paints does not pose an unacceptable risk to the environment.

The metabolite 2-aminobenzimidazole (2-AB) is identified as a relevant metabolite in soils. The exposure and risk assessment of the metabolite in soil are assumed to be covered by the assessment of carbendazim. The risk assessment for groundwater indicates no unacceptable risk for 2-AB for the assessed products.

PT 10

The outdoor in-situ application of the end-use product (carbendazim containing plasters with 0.1 and 0.02 % a.s., respectively) by brushing and rolling poses an unacceptable risk to aquatic and terrestrial organisms. Therefore, it is necessary that the ground/soil adjacent to the treated object is covered during application.

Regarding the use phase (service-life, outdoor) carbendazim released by leaching does not pose an unacceptable risk to the microorganisms in the STP and the groundwater. In contrast, for concentrations of 0.1 % a.s. there is an unacceptable risk for the soil compartment after direct releases to soil for TIME 1 (30 days) and TIME 2 (25 years) calculations, even after considering biodegradation for the longer assessment period of 25 years. These unacceptable risks are mitigated if carbendazim containing plasters are restricted to concentrations of not more than 0.08 % a.s. in the end-use products.

However, for the aquatic compartment, the PEC/PNEC ratio exceeds the value of 1 for all service life scenarios (outdoor) for end-use products (plasters) containing 0.1 % a.s. as well as 0.02 % carbendazim. This indicates that the use of the assessed carbendazim containing plasters pose an unacceptable risk to aquatic organisms irrespective of carbendazim containing leachates pass a STP or enter surface water directly. No adequate risk mitigation measure is available to avoid

releases in the sewer over a period of 25 years.

The metabolite 2-Aminobenzimidazole (2-AB) is identified as a relevant metabolite in soils. The exposure and risk assessment of the metabolite in soil are assumed to be covered by the assessment of carbendazim. The risk assessment for groundwater indicates no unacceptable risk for 2-AB for the assessed products.

Summarizing, the risk assessment reveals that the outdoor use of the assessed carbendazim containing plasters pose an unacceptable risk to the environmental since no adequate risk mitigation measure is available to avoid releases in the sewer over a period of 25 years.

No emission scenario is available to cover the indoor use and application of carbendazim containing plasters. In addition, cleaning of the hand-held tools like trowels, etc. by use of water is not foreseen. Hence, no release to sewers during application is expected and no exposure and risk assessment are performed regarding the indoor use. Consequently, the indoor use of carbendazim containing plasters does not pose an unacceptable risk to the environment.

Referring to secondary poisoning of non-target animals, carbendazim has only a very low potential for a concern relating to the use in PT 7 and PT 10, respectively.

In the aggregated risk assessment, the simultaneous leaching of carbendazim due to rainwater from façades treated with biocidal products of PT 7 and 10 and the collection of the rainwater in the same sewer system during the same rain event is assessed. In case of passing a STP as well as in case of direct rainwater discharge to the surface water (separate sewer system), an aggregated PEC/PNEC ratio above one indicates an unacceptable risk for the aquatic compartment (surface water and sediment).

2.2.2.4. PBT and POP assessment

PBT / vPvB

The PBT- and vPvB-Assessment for carbendazim is performed according to the guidance given in the Guidance on BPR IV ENV B + C (2017) as described in chapter 3.11 as well as in the new REACH legislation:

- P criterion: Half life > 40 d in freshwater (> 60 d in marine water) or

  > 120 d in freshwater sediment (> 180 d in marine sediment) or

  > 120 d in soil (according to the new REACH legislation)
- B criterion: BCF > 2000 L/kg
- T criterion: Chronic NOEC < 0.01 mg/L or CMR or endocrine disrupting effects

<u>P criterion</u>

Carbendazim is not readily biodegradable. In two water-sediment systems, a worst case DT_{50} value of 145.6 days (at 12°C) was observed for the total system. Since the DT_{50} value exceeds the trigger value for freshwater as well as for freshwater sediments, carbendazim fulfils the P-criterion in the aquatic system. Regarding the vP-criterion (> 60 d in freshwater or > 180 d in freshwater sediment) no definite statement can be made for carbendazim on the basis of the

available data.

For soils a geomean DT_{50} value of 95.2 days at 12°C was calculated. According to this DT_{50} value, carbendazim is not persistent in soil by definition (DT_{50} < 120 d). However, taking into account (a) the clear link between the high extent of non-extractable radioactivity (NER) and DT_{50} value in soil and (b) further experimental results which indicate that at least a part of NER in soil is unchanged carbendazim, the label “not persistent in soil” seems not to reflect reality.

Based on QSAR estimations using EPIWEB 4.1 the metabolite 2-AB (relevant in soil) potentially fulfils the (v)P-criterion (BIOWIN 2: 0.3124; BIOWIN 3: 2.7700; BIOWIN 6: 0.1126) and further information is warranted. For soil acceptable half-lives could be calculated for 2-AB from at least four soils and both label-positions by simulating the fate of carbendazim and 2-AB by simultaneous analysis of carbendazim and 2-AB (SFO-SFO), resulting in a geometric mean of 55.4 days (12°C, n=4). Based on this, 2-AB is not persistent in soil.

B criterion

On the basis of the physico-chemical properties of carbendazim a significant bioaccumulation potential can be excluded as log K_{ow} of 1.5 does not exceed the screening criterion of log K_{ow} > 4.5 and estimated BCF values are 3.75 L/kg for aquatic and 0.858 L/kg for terrestrial organisms. Furthermore the BCF_{fish} value of 27 L/kg based on laboratory bioconcentration test does not exceed the B and vB criteria (B: BCF > 2000 L/kg; vB: BCF > 5000). Therefore it can be concluded that carbendazim does not fulfil the B-criterion.

Based on QSAR estimation (Kowwin version 1.68: log K_{ow} = 0.88), it can be concluded that the metabolite 2-AB does not fulfil the B-criterion

T criterion

From a long-term test with *Daphnia magna* a NOEC value of 0.0015 mg/L for carbendazim was derived. Therefore, the T-criterion is fulfilled.

No effect data to conclude on the T-criterion for 2-AB is available and no classification is listed in the ECHA C&L inventory. Based on the assessment scheme (REACH Guidance on Information Requirements R.11), no further assessment of T is necessary if P and B are not confirmed and effect data is lacking, which is the case for 2-AB. 2-AB should therefore be considered as ‘potentially T’.

Conclusion

In conclusion, carbendazim fulfils two of three criteria (P and T) but is not a PBT or a vPvB-substance. Regarding the vP-criterion (aquatic system) no definite statement can be made on the basis of the available data. The metabolite 2-AB, relevant for soil, is not considered to fulfil the P-criterion in soil but potentially fulfils the (v)P-criterion in the aquatic compartment based on QSAR estimations. 2-AB does not fulfil the B-criterion but potentially fulfils the T-Criterion. Therefore, 2-AB potentially fulfils two of three criteria (P and T).

POP

Carbendazim fulfils two of three PBT criteria (P and T) but the long range transport criterion according to the Stockholm convention (half-life in air of more than two days) is not fulfilled. Therefore, carbendazim does not fulfil the POP criteria.

2.2.3. Assessment of endocrine disruptor properties

According to the document "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[2], for reports submitted before 1 September 2013 the provisions of the BPD apply. Furthermore, a maximum approval period of five years is foreseen for substances that fulfil the ED criteria. Since the applicant has no obligation to provide lacking data with respect to the endocrine disruption properties of the active substance, the competent authority has to conclude on the data already provided by the applicant. In case the data is insufficient, the eCA may not be able to draw a comprehensive conclusion on the endocrine disruptor properties of that substance.

Since the evaluation of carbendazim for PT 7 and 10 was submitted before 1 September 2013, requesting additional data would only lead to a delay without being able to finally conclude on the ED properties. Furthermore, carbendazim already fulfils the exclusion criteria, thus, the regulatory outcome will not change. That means that in line with Article 19(4) of Regulation (EU) No 528/2012, any biocidal products containing carbendazim will not be authorised for making available on the market for use by the general public. Furthermore, products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. Thus, an assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted. The endocrine disrupting properties will be assessed in full detail in the scope of the renewal of the approval, where all relevant information can be requested from the applicant.

2.3. Overall conclusion.

The outcome of the assessment for carbendazim in product-type 7 and 10 is specified in the BPC opinion following discussions at the 25th and 33th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

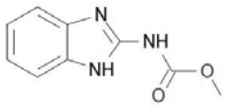
[2] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details)

Appendix I: List of endpoints

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

Active substance (ISO Name)	carbendazim
Product-type	7 and 10

Identity

Chemical name (IUPAC)	Methyl-benzimidazol-2-ylcarbamate
Chemical name (CA)	Carbamic acid, *N*-1*H*-benzimidazol-2-yl-, methyl
CAS No	10605-21-7
EC No	234-232-0
Other substance No.	CIPAC No.: 263
Minimum purity of the active substance as manufactured (g/kg or g/l)	990 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	2,3-Diaminophenazine, CAS-no. 655-86-7 < 0.00023 %w/w 3-Amino-2-hydroxyphenazine, CAS-no. 4569-77-1) < 0.00003 %w/w
Molecular formula	$C_9H_9N_3O_2$
Molecular mass	191.21 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	No melting point; Decomposition at 217°C before melting (purity 99 % (w/w))
Boiling point (state purity)	Not applicable (decomposition)
Thermal stability / Temperature of decomposition	Decomposition above 217°C before melting
Appearance (state purity)	Sand-coloured, odourless crystalline powder (technical AS)
Relative density (state purity)	1.45 at 20°C (purity ≥ 99 %)
Surface tension (state temperature and concentration of the test solution)	72.5 mN/m at 20 °C (c = 7 mg/l)
Vapour pressure (in Pa, state temperature)	9×10^{-5} Pa at 20 °C

Henry's law constant (Pa m^3 mol^{-1})	3.17 x 10^{-3} Pa m^3/mol (24°C)
Solubility in water (g/l or mg/l, state temperature)	pH 4: 29 mg/l at 24 °C pH 7: 8 mg/l at 24 °C pH 8: 7 mg/l at 24 °C
Solubility in organic solvents (in g/l or mg/l, state temperature)	ethanol: 300 mg/l at 24 °C benzene: 36 mg/l at 24 °C hexane: 0.5 mg/l at 24 °C ethyl acetate: 135 mg/l at 24 °C methylene chloride: 68 mg/l at 24 °C methanol: 480 mg/l at 20 °C
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant: Model formulation is water based.
Partition coefficient (log P_{OW}) (state temperature)	pH 5: logPow 1.38 at 25 °C pH 7: log Pow 1.51 at 25 °C pH 9: logPow 1.49 at 25 °C
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5: stable (25°C)
	pH 7: stable (25°C)
	pH 9: 50 – 58 d (25 °C) corresponding to 141 – 164 d (12 °C)
Dissociation constant	$pK_a = 4.49$ pK_b = 10.62(Purity 99 %)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption > 290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	photolytically stable under sterile conditions, pH = 5 In the absence of photo sensitizers and at pH 5 in aqueous buffer, carbendazim is stable over the period of 166 hours, corresponding to 35 sunny days at 52° Northern latitude in June.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No study
Flammability or flash point	Not highly flammable; No spontaneous ignition up to 400°C.
Explosive properties	Not explosive

Classification and proposed labelling

with regard to physical hazards	-

with regard to human health hazards	Muta. 1B Repr. 1B Skin Sens.1	H340 H360FD H317
with regard to environmental hazards	Aquatic Acute 1; H400 (M-factor=10) Aquatic Chronic 1; H410 (M-factor=10)	

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Pure and technical carbendazim can be analysed with Reversed phase HPLC method with Nucleosil C18 column (250 x 4mm, 5 µm) as stationary phase at isocratic conditions with UV/VIS detection (wavelength: 282 nm).
Impurities in technical active substance (principle of method)	A reversed phase HPLC method with Hypersil ODS column (125 x 4 mm, 3 µm) as stationary phase using isocratic conditions and Fluorescence detection (excitation wavelength: 430 nm; emission wavelength: 552nm) was used for the determination of AE F069662 (DAP = 2, 3-diaminophenazine) and AE F070535 (HAP =3-amino-2-hydroxyphanazine). The validation of the method covers specificity, linearity, precision and LOD/LOQ. Further informations are given in the confidential Documents Doc IIA and Doc IIIA4.1.

Analytical methods for residues

Soil (principle of method and LOQ)	carbendazim (active substance) HPLC-UV (280 nm, C18 column) LC-MS (C18 column, APCI+, m/z 192) LOQ: 0.02 mg/kg
Air (principle of method and LOQ)	method is not required for the intended use, which excludes spraying (see section 2.1.1)

Water (principle of method and LOQ)	carbendazim (active substance) in drinking water LC-MS/MS (SRM, m/z 192→160/ m/z 192→132) LOQ: 0.1 µg/L carbendazim (active substance) in surface water HPLC-UV (286 nm, C8 and C18 column) LOQ: 1 µg/L carbendazim (active substance in drinking water, ground water, surface water LC-MS/MS (C18 column, ESI+, m/z 192→160) LOQ: 0.1 µg/L
Body fluids and tissues (principle of method and LOQ)	carbendazim (active substance) in plasma: LC-MS/MS (phenyl-hexyl column, ESI+, m/z 192→160) confirmation by ion ratio of m/z 192 →160/ 192→132) LOQ: 1 µg/L carbendazim (active substance) in milk, egg, meat, fat LC-MS/MS (C8 column, ESI+, m/z 192→160) LOQ: 0.05 mg/kg
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	not required

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapidly absorbed (ca. 80 % within 72 h based on urinary excretion and metabolites in faeces)

Rate and extent of dermal absorption*:	[redacted] based solvent-free paint formulation containing 0.1 % (w/w) a.s., based on human skin *in vitro* at 10µl/cm^2: 0.6 % [redacted] containing 10.6 % (w/w) a.s., based on human skin *in vitro* at 10µl/cm^2: 1.0 % Untested solvent-free paint formulations equivalent to [redacted]*:* linear "pro rata" extrapolation according to EFSA, 2012 (e.g. for a respective paint formulation containing 0.025 % (w/w) a.s.: 2.4 %) Other untested formulations, based on EFSA, 2012: 25 or 75 % default value at > or ≤ 50 g/L, resp. for liquids and 50 g/kg for solids.
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation, highest residues in liver (> 0.5 %)
Metabolism	Extensively metabolised, mainly to 5-hydroxymethyl benzimidazole carbamate (5-HBC); conjugated as either glucuronides or sulfates
Rate and extent of excretion:	Rapidly excreted, predominantly in urine (54-66 %)
Toxicologically significant metabolite(s)	None

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	> 10,000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5.8 mg/L air (4 h, nose only, highest attainable concentration)

Skin corrosion / irritation	Not irritant
Eye irritation	Not irritant
Respiratory tract irritation	No data
Skin sensitisation (test method used and result)	Sensitiser (GPMT) **H317**
Respiratory sensitisation (test	No data - not required

method used and result)	
Repeated dose toxicity	
Subchronic	
Species / target / critical effect	**Rat, Dog (oral):** Feed intake, bw, bw gain ↓ Liver: histopathology, clinical chemistry, weight ↑ Testis: weight ↓, desquamation of seminiferous tubular epithelium; azoospermia at high doses **H360-F** **Rabbit (dermal, local):** Skin: mild irritation
Relevant oral NOAEL / LOAEL	30-d, rat: 40 mg/kg bw/d (400 ppm) 90-d, dog: 2.7 mg/kg bw/d (100 ppm)
Relevant dermal NOAEL / LOAEL	10-d (7 d/wk) & 21-d (5d/wk), rabbit (overall): Local: 10 mg/kg bw/d; LOAEL: 50 mg/kg bw/d (mild irritation) Systemic: 2000 mg/kg bw/d
Relevant inhalation NOAEL / LOAEL	No data - not required

Short term	
Species/ target / critical effect	No data
Relevant oral NOAEL / LOAEL	No data
Relevant dermal NOAEL / LOAEL	No data
Relevant inhalation NOAEL / LOAEL	No data

Long term	
Species/ target / critical effect	**Rat / mouse / dog:** General observations: mortality (dog, mouse), bw ↓, Liver (wt ↑, histological findings, clinical chemistry)
Relevant oral NOAEL / LOAEL	Mouse 18-mo: 22.5 mg/kg bw/d (150 ppm) Rat, 2-yr: 22 mg/kg bw/d (500 ppm) Dog, 2-yr: 2.6 mg/kg bw/d (100 ppm)
Relevant dermal NOAEL / LOAEL	No data
Relevant inhalation NOAEL / LOAEL	No data

Genotoxicity	1) Numerical chromosome aberrations both in vitro and in vivo as a result of the interference with mitotic spindle proteins; Threshold concentration in vitro for aneugenic activity: 0.2 – 0.6 µg/ml; NO(A)EL for aneuploidy induction in vivo:

	50 mg/kg bw **H340** 2) Frame shift mutations in vitro by the impurities 2,3-diaminophenazine and 2-amino-3-hydroxy-phenazine

Carcinogenicity

Species/type of tumour	**Mouse (CD1, Swiss):** Liver: adenoma, combined adenoma + carcinoma **Rat / mouse (NMRKf):** no tumours observed
Relevant NOAEL/LOAEL	CD1 mice: LOAEL: 81 mg/kg bw/d, lowest dose tested Swiss mice: LOAEL: 45 mg/kg bw/d, lowest dose tested

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Maternal: **Rat:** bw gain ↓, abortions **Rabbit:** bw gain ↓, abortions Developmental: **Rat:** high resorption rate, foetal wt ↓, skeletal variations ↑, skeletal malformations, at higher doses: hydrocephalus, anophthalmia **Rabbit:** implantation ↓, resorptions ↑, live litter size ↓, skeletal malformations
Relevant maternal NOAEL	**Rat:** 30 mg/kg bw/d **Rabbit:** 20 mg/kg bw/d
Relevant developmental NOAEL	**Rat:** 10 mg/kg bw/d **Rabbit:** 10 mg/kg bw/d **H360-D**

Fertility

Species/critical effect	Adults: bw gain ↓ Reproduction and fertility: infertility in male rats, sperm numbers ↓, testicular atrophy and absence of spermatogenesis Offspring: bw ↓
Relevant parental NOAEL	100 mg/kg bw/d (2000 ppm)
Relevant offspring NOAEL	100 mg/kg bw/d (2000 ppm)
Relevant fertility NOAEL	100 mg/kg bw/d (2000 ppm; infertility) < 50 mg/kg bw/d (sperm count ↓) **H360-F**

Neurotoxicity

Species/ target/critical effect	**Hen (single dose):** Delayed neurotox: no evidence up to 5000 mg/kg bw Acute neurotoxicity: ataxia, leg weakness Systemic toxicity: salivation
Relevant neurotoxicity NOAEL(s)	**$NOAEL_{delayed\ neurotoxicity}$: 5000 mg/kg bw** **$NOAEL_{neurotoxicity}$: 2500 mg/kg bw** **$NOAEL_{systemic\ toxicity}$: < 500 mg/kg bw**

Developmental Neurotoxicity

Species/ target/critical effect	No data - not required

Immunotoxicity

Species/ target/critical effect	No data - not required

Developmental Immunotoxicity

Species/ target/critical effect	No data - not required

Other toxicological studies

Hepatic enzyme induction	Induction of phase I and phase II enzymes in rats and mice
Mechanistic studies on genotoxic effects	Interaction with microtubules, inhibition of polymerisation: NOAEL: 50 mg/kg bw
Genotoxicity studies on impurities	2,3-diaminophenazine: Ames test: positive 2-amino-3-hydroxyphenazine: Ames test: positive

Medical data

Medical surveillance data	No adverse effects in manufacturing personnel reported
Case reports	One poisoning incident reported in open literature (reversible neurotoxicity); four confirmed cases (irritation) with products containing carbendazim and further active ingredients reported by PSD

Summary

	Value	Study	Safety factor
$AEL_{long\text{-}term}$	0.03	Developmental: rat, rabbit	300

$AEL_{medium-term}$	0.03	Developmental: rat, rabbit	300
$AEL_{short-term}$	0.03	Developmental: rat, rabbit	300
ADI[3]	Not required - No residues expected		
ARfD[3]	Not required - No residues expected		
$NOAEC_{dermal}$	Not determined		
$AEC_{inhalation}$	Not determined		

MRLs

Relevant commodities	Residues in food and feed not expected

Reference value for groundwater

According to BPR Annex VI, point 68	Refer to chapter 4 Fate and Behaviour in the Environment.

Dermal absorption

Study (*in vitro/vivo*), species tested	Refer to section Absorption, distribution, metabolism and excretion in mammals; Rate and extent of dermal absorption
Formulation (formulation type and including concentration(s) tested, vehicle)	Refer to section Absorption, distribution, metabolism and excretion in mammals; Rate and extent of dermal absorption
Dermal absorption values used in risk assessment	0.6 % from [redacted] based solvent-free paint formulation containing 0.1 % (w/w) a.s for all relevant scenarios

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	yes
pH 5	pH 5: stable (25 °C)
pH 9	pH 9: 50 – 58 d (25 °C) corresponding to 141 – 164 d (12 °C), metabolite 2-AB: 30 %
Other pH: *[indicate the value]*	pH 7: stable (25 °C)

[3] If residues in food or feed.

Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	photolytically stable under sterile conditions, pH = 5 In the absence of photo sensitizers and at pH 5 in aqueous buffer, carbendazim is stable over the period of 166 hours, corresponding to 35 sunny days at 52° Northern latitude in June.
Readily biodegradable (yes/no)	Not readily biodegradable
Inherent biodegradable (yes/no)	-
Biodegradation in freshwater	-
Biodegradation in seawater	-
Non-extractable residues	-Bickenbach system: maximum 63.4 % of applied radioactivity (day 62), 60.3 % (end of study, day 149) -Unter Widdersheim system: maximum 59.4 % of applied radioactivity (day 120), 53.7 % (end of study, day 149)
Distribution in water / sediment systems (active substance)	**Water phase (dissipation)** residues of a. s. (% of applied): -Bickenbach system: <0.5 % (from day 98 on) -Unter Widdersheim system: 1.1 % (day 98) **DissT$_{50}$ (20°C)** -Bickenbach system: 10.8 days -Unter Widdersheim system: 3.9 days **DissT$_{50}$ (12°C)** -Bickenbach system: 20.5 days -Unter Widdersheim system: 7.4 days **Sediment (dissipation)** residues of a. s. (% of applied): -Bickenbach system: maximum 14.9 % (day 14/21), 3.8 % (day 120) -Unter Widdersheim system: maximum 68.0 % (day 28), 33.4 % (end of study, day 149) **DissT$_{50}$ (20°C)** -Bickenbach system: 34.5 days -Unter Widdersheim system: 99.8 days **DissT$_{50}$ (12°C)** -Bickenbach system: 65.4 days -Unter Widdersheim system: 189.3 days **Whole system (degradation)** **DT$_{50}$ (20°C)** -Bickenbach system: 15.1 days -Unter Widdersheim system: 76.8 days **DT$_{50}$ (12°C)** -Bickenbach system: 28.6 days -Unter Widdersheim system: 145.6 days

Distribution in water / sediment systems (metabolites)	-Bickenbach system: 7 metabolites <10 % of applied radioactivity, only 2-AB identified -Unter Widdersheim system: 4 metabolites <10 % of applied radioactivity, only 2-AB identified Maxima observed (% of applied radioactivity): **2-AB (only in sediment):** -Bickenbach system: 1.3 % (day 42), -Unter Widdersheim system: 6.3 % (day 76)

Route and rate of degradation in soil

Mineralization (aerobic)	In percent of applied radioactivity: **^{14}C-carbendazim (phenyl ring)** -Speyer 2.3 (DE, Sandy Loam): 4.3 % (day 120) -Speyer 2.2 (DE, Loamy Sand): 2.0 % (day 120) -Am Fischteich_a (DE, Silty Loam): 3.8 % (day 120) -Fislis (FR, Silty Clay) 5.9 % (day 120) -Speyer 5M (DE, Sandy Loam) 13.7 % (day 120) **^{14}C-carbendazim (benzimidazole ring)** -Am Fischteich_b (DE, Silty Loam) 4.3 % (day 120)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	**DT_{50} modelling for PEC calculation:** carbendazim: 95.2 days (geomean, n=6, at 12°C) 2-AB: 56.9 days (12°C) currently agreed
DT_{50lab} (20°C, aerobic):	**DT_{50lab} (20°C, aerobic):** **^{14}C-carbendazim (phenyl ring)** -Speyer 2.3 (DE, Sandy Loam): 56.1 days (SFO) -Speyer 2.2 (DE, Loamy Sand): 103.0 days (SFO) -Am Fischteich_a (DE, Silty Loam): 126.1 days (SFO) -Fislis (FR, Silty Clay): 33.3 days (SFO) -Speyer 5M (DE, Sandy Loam): 12.0 days (SFO) **^{14}C-carbendazim (benzimidazole ring)** -Am Fischteich_b (DE, Silty Loam): 137.5 days (SFO)

DT_{90lab} (20°C, aerobic):	**DT_{90lab} (20°C, aerobic):** **^{14}C-carbendazim (phenyl ring)** -Speyer 2.3 (DE, Sandy Loam): 186.4 days (SFO) -Speyer 2.2 (DE, Loamy Sand): 342.1 days (SFO) -Am Fischteich_a (DE, Silty Loam): 418.9 days (SFO) -Fislis (FR, Silty Clay): 110.6 days (SFO) -Speyer 5M (DE, Sandy Loam): 40.0 days (SFO) **^{14}C-carbendazim (benzimidazole ring)** -Am Fischteich_b (DE, Silty Loam): 456.7 days (SFO)
DT_{50lab} (10°C, aerobic):	-
DT_{50lab} (20°C, anaerobic):	-
degradation in the saturated zone:	-
Field studies (state location, range or median with number of measurements)	Not applied for refinement
DT_{50f}:	**DT_{50f} (Average air temp.)** -Frankfurt –Schwanheim (DE, Loamy Sand): 78 days -Gersthofen (DE, Sandy Loam): 11 days -Bornheim (DE, Sandy Loam): 18 days -Stelle (DE, Silty Sand): 16 days **DT_{50} (converted to 12°C average EU outdoor temp./10 kPa)** -Frankfurt –Schwanheim (DE, Loamy Sand): 95 days -Gersthofen (DE, Sandy Loam): 15 days -Bornheim (DE, Sandy Loam): 25 days -Stelle (DE, Silty Sand): 19 days
DT_{90f}:	**DT_{90f}: (Average air temp.)** -Frankfurt –Schwanheim (DE, Loamy Sand): 257 days -Gersthofen (DE, Sandy Loam): 36 days -Bornheim (DE, Sandy Loam): 59 days -Stelle (DE, Silty Sand): 54 days
Anaerobic degradation	-
Soil photolysis	-

Non-extractable residues	In percent of applied radioactivity: **^{14}C-carbendazim (phenyl ring)** -Speyer 2.3 (DE, Sandy Loam): maximum 69.6 % (day 120) -Speyer 2.2 (DE, Loamy Sand): maximum 43.2 % (day 120) -Am Fischteich_a (DE, Silty Loam): maximum 46.8 % (day 120) -Fislis (FR, Silty Clay): maximum 73.4 % (day 100) Speyer 5M (DE, Sandy Loam): maximum 81.1 % (day 100) **^{14}C-carbendazim (benzimidazole ring)** -Am Fischteich_b (DE, Silty Loam): maximum 39.5 % (day 120)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	In percent of applied radioactivity: **2-Aminobenzimidazole (2-AB):** **^{14}C-carbendazim (phenyl ring)** -Speyer 2.3 (DE, Sandy Loam): maximum 4.6 % (day 28) -Speyer 2.2 (DE, Loamy Sand): maximum 10.0 % (day 100) -Am Fischteich_a (DE, Silty Loam): maximum 3.8 % (day 28) -Fislis (FR, Silty Clay): maximum 8.8 % (day 100) -Speyer 5M (DE, Sandy Loam): maximum 3.5 % (day 14) **^{14}C-carbendazim (benzimidazole ring)** -Am Fischteich_b (DE, Silty Loam) maximum 3.0 % (day 28)
Soil accumulation and plateau concentration	-

Adsorption / desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Koc value: 487.2 L kg^{-1} (arithmetic mean, n = 23, range 122 – 2805 L kg^{-1}) 1/n for the adsorption isotherms: 0.796 (average) No pH dependence **2-Aminobenzimidazole (2-AB):** Koc value: 344.3 L kg^{-1} (determined with QSAR model EPI Suite 4.11)

Fate and behaviour in air

Direct photolysis in air	No study
Quantum yield of direct photolysis	No study

Photo-oxidative degradation in air	Tropospheric half-life 1.919 h (according to Atkinson, reaction with OH radicals, concentration: 5 x 10^5 OH/cm^3, related to 24-h day)
Volatilization	Slightly volatile (vapour pressure = 9 × 10^{-5} Pa at 20 °C)

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg L^{-1}

Monitoring data, if available

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Ictalurus punctatus	96 h, static	LC50	0.019 mg/L (nom)
Oncorhynchus mykiss	79 d, flow-through	NOEC	0.011 mg/L (mm)
Invertebrates			
Daphnia magna	48 h, static	EC50	0.15 mg/L (nom)
Daphnia magna	21 d, semi-static	NOEC	0.0015 mg/L (mm)
Algae			
Desmodesmus subspicatus	72 h, static	E_rC_{50} NOEC	> 8 mg/L (nom) 8 mg/L (nom)
Microorganisms			

Activated sludge from sewage treatment plant (treating predominantly domestic sewage)	3 h, static	respiration inhibition	EC_{50} > 1000 mg/L (nominal) NOEC ≥ 1000 mg/L (nominal)

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworm (*Eisenia foetida*)	14 d: LC_{50} = 5.4 mg/kg dry weigh soil
Reproductive toxicity to to earthworm (*Eisenia fetida andrei*)	56 d: NOEC = 1.0 mg/kg dry weight soil
Acute toxicity to plants (*Avena sativa* and *Lactuca sativa*)	14 d: EC_{50} > 100 mg/kg dry weight soil

Effects on soil micro-organisms

Nitrogen mineralization	28 d: NOEC ≥ 2.0 mg/kg dry weight soil NOEC ≥ 4.25 mg/kg dry weight soil (organic matter content converted to standard soil)
Carbon mineralization	28 d: NOEC ≥ 2.0 mg/kg dry weight soil NOEC ≥ 4.25 mg/kg dry weight soil (organic matter content converted to standard soil)

Effects on terrestrial vertebrates

Acute toxicity to mammals	Refer to mammalian toxicity package
Acute toxicity to birds	No data
Dietary toxicity to birds	No data
Reproductive toxicity to birds	No data

Effects on honeybees

Acute oral toxicity	No data
Acute contact toxicity	No data

Effects on other beneficial arthropods

Acute oral toxicity	No data
Acute contact toxicity	No data
Acute toxicity to ……..	No further data

Bioconcentration

Bioconcentration factor (BCF)	BCF_{fish} calc. = 3.75 L/kg

	BCF_{fish} measured = 27 L/kg (whole fish) $BCF_{earthworm}$ calc. = 0.858 L/kg
Depration time (DT_{50})	n.d.
Depration time (DT_{90})	n.d.
Level of metabolites (%) in organisms accounting for > 10 % of residues	70-80 % glucuronide conjugate of 5-hydroxy carbendazim, 12-18 % unidentified polar compounds, 8-12 % not extracted bound residues.

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Object and/or situation	Product Name	Organisms controlled	Formulation		Application			Applied amount per treatment			Re marks:
			Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g $a.s./m^2$ min max	
MG 2 / PT 7 Film preservation (paints)	Water-based model formulation	Fungi	SC	≤ 10%	The biocidal product containing ≤10% carbendazim is added to the paint in an automated process before packaging the paint.			The concentration of carbendazim in the products to be preserved (paints) is 0.025-0.1 %			The treatment of the end-use products with the biocidal product is done by professionals in industrial settings. The application of the carbendazim-treated end-use product is done by professionals and non-professionals.
MG 2 /PT10 Preservation of plaster	Water-based model formulation	Fungi	SC	≤ 10%	The biocidal product containing ≤10% carbendazim is added to the plaster in an automated process.			The concentration of carbendazim in the products to be preserved (plaster) is 0.02-0,1 %			The treatment of the end-use products with the biocidal

Object and/or situation	Product Name	Organisms controlled	Formulation		Application			Applied amount per treatment			Re marks:
			Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g $a.s./m^2$ min max	
											product is done by professionals in industrial settings. The application of the carbendazim-treated end-use product is done by professionals and non-professionals.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II A 3.1	[redacted]	1986	The fate of 14C-carbendazim in the rat, Xenobiotica 1986 16(9):809-815	No	-
Doc II A 3.6	Anon.	2005	US EPA HPV challenge program: robust summaries for carbamic acid, 1H-benzimidazol-2-yl-, methyl ester (CAS No. 10605-21-7). Published: yes	No	-
Doc II A 3.6	Aardema, M.J., Albertini, S., Arni, P., Henderson, L.M., Kirsch-Volders, M., Mackay, J.M., Sarrif, A.M., Stringer, D.A., Taalman, R.D.	1998	Aneuploidy: a report of an ECETOC task force. Mutat Res 410:3-79 Published: yes	No	-
Doc II A 3.6	Kirsch-Volders, M., Aardema, M., Elhajouji, A.	2000	Concepts of threshold in mutagenesis and carcinogenesis. Mutat Res 464(1):3-11 Published: yes	No	-
Doc II A 3.6	Parry, J.M., Jenkins, G.J., Haddad, F., Bourner, R., Parry, E.M.	2000	In vitro and in vivo extrapolations of genotoxin exposures: consideration of factors which influence dose-response thresholds. Mutat Res 464(1):53-63 Published: yes	No	-
Doc II A 3.10	Uludag, B., Tarlaci, S., Yuceyar, N., Arac, N.	2001	A transient dysfunction of the neuromuscular junction due to carbendazim intoxication. J Neurol Neurosurg Psychiatry 70:563-564 GLP: no; Published: yes	No	-

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II A 4	EC	2003	Technical Guidance Document (TGD) on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003	No	-
Doc II A 4	EC	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Publication
Doc II A 4	FOCUS Work Group on Degradation Kinetics, EC	2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration; EC Document Reference Sanco/10058/2005 version 2.0	No	Publication
Doc II A 4	Boudina, A. et al.	2003	Photochemical behaviour of carbendazim in aqueous solutions, Chemosphere, Vol. 50 (5): 649-655, Non GLP, published	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II A 4	[redacted]	1988	Static acute toxicity of carbendazim technical to Sheepshead minnow, Cyprinodon variegatus Report No. A52917 GLP, unpublished IV A7.4.1.1/821-003	Yes	-
Doc II A 4	Canton, J.H.	1976	The toxicity of benomyl, thiophanat-methyl and BCM to four freshwater organisms Bulletin of Environmental Contamination and Toxicology, Vol. 16 (2): 214-218 Non GLP, published IV A7.4.1.1/892-004	No	Publication
Doc II A 4	Baer, K.N.	1992	Static, acute, 48-hour EC50 of DPX-E965-299 (Carbendazim, MBC) to Daphnia magna Report No. A52905 GLP, unpublished IV A7.4.1.2/822-002	Yes	-
Doc II A 4	Hutton, D.G.	1988	Static acute 48-hours EC50 of carbamic acid, 1H-benzimidazol-2-yl-, methyl ester to fed Daphnia magna Report No. A52904 GLP, unpublished IV A7.4.1.2/822-003	Yes	-
Doc II A 4	Hutton, D.G.	1988	Chronic toxicity of Carbamic acid, 1H-benzimidazol-2-yl, methyl ester to Daphnia magna Report No.: A52908 GLP, unpublished IV A7.4.3.4/827-002	Yes	-
Doc II A 4	Baer, K.N.	1992	Chronic toxicity of DPX-E965-299 (Carbendazim, MBC) to Daphnia magna Report No.: A52907 GLP, unpublished IV A7.4.3.4/827-003	Yes	-

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II A 4	Ellis, S.R. Hodson, M.E. Wege, P.	2007	The influence of different artificial soil types on the acute toxicity of carbendazim to the earthworm *Eisenia fetida* in laboratory toxicity tests European Journal of Soil Biology, 43, 239-245 Not GLP; (published) IV A7.5.1.2/892-003	No	Publication
Doc II A 4	Lührs, U.	2002, 2003	Effects of Derosal SC360 on reproduction and growth of earthworms Eisenia fetida in artifical soil and 1st Amendment to final report IBACON GmbH, Rossdorf, Germany Project No.: 15071022; C039272 GLP, unpublished IV A7.5.2.1/833-001	Yes	-
Doc II A 4	Lührs, U.	2001	Carbendazim/Flusilazole (DPX-N7872) SE (1:2): Effects on reproduction and growth of the earthworm Eisenia fetida (Savigny 1826), in artificial soil Project No. 10111022, C039273 GLP, unpublished IV A7.5.2.1/833-004	Yes	-
Doc II A 4	Lührs, U.	2001	Effects of Derosal SC 360 on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil; IBACON, Rossdorf, Germany Report No. 9801022, C039275 GLP, unpublished IV A7.5.2.1/833-005	Yes	-

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II A 4	Heusel, R.	1993	Carbendazim -substance technical (Hoe 017411 00 ZD99 0010). Effect of Folsomia candida (springtails) in a 28 day test in artificial soil (method OECD/ISO draft) Report No. CE92/037, A51540 GLP, unpublished IV A7.5.2.1/835-001	Yes	-
Doc II A 4	Ramakrishna, C. Gowda, T.K.S. Sethunatahan, N.	1979	Effect of benomyl and its hydrolysis products, MBC and AB on nitrification in a flooded soil Bulletin of Environmental Contamination Toxicology, 21 (1979): 328-333 Non GLP, published IV A7.5.2.1/892-005	No	Publication
Doc II A 4	Davidse, L.E., Flach, W.	1978	Interaction of thiabendazole with fungal tubulin Biochimica et Biophysica Acta, 543 (1978) 82-90 Non GLP, published	No	Publication
Doc II B 8	EC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II B 8	CA	2010	Guidance note on leaching rate estimations for substances used in biocidal products in Product Types 07, 09 and 10, adopted March 2010.	No	Publication
Doc II B 8	DWA	2005	Planung, Bau und Betrieb von Anlagen zur Versickerung von Niederschlägen, Arbeitsblatt DWA-A 138, Deutsche Vereinigung für Wasserwirtschaft, Abwasser und Abfall e.V., p. 59.	No	Publication
Doc II B 8	OECD	2003	Emission Scenario Document for Wood Preservatives, OECD Series on Emission Scenario Documents, Number 2, p. 215.	No	Publication
Doc II B 8	OECD	2008	Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropodes for Household and Professional Uses, OECD Series on Emission Scenario Documents, Number 18, p. 188.	No	Publication
Doc II B 8	OECD	2009	Emission Scenario Document on Plastic Additives, OECD Series on Emission Scenario Documents, Number 3, p. 141.	No	Publication
Doc II B 8	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publication
Doc II B 8	EC	1998	Drinking Water Directive (DWD), Council Directive 98/83/EC on the quality of water intended for human consumption	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II B 8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publication
Doc II B 8	Klein, M.	2011	Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessment, FKZ: 360 04 035 Umweltbundesamt Dessau-Roßlau	No	UBA
Doc II B 8	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publication
Doc II B 8	ECB	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publication
Doc II B 8	Technical Meeting	2012	BIP6.7 Decision Tree Agg Expo: document: TM III 2012 ENV-item 3f (follow up of TM I 2012 ENV-item 5e); developed in the ongoing UBA project FKZ 3711 63 412 (10/2011 – 04/2014)	No	No owner
Doc II B 8	Statistisches Bundesamt	2009	Umwelt, Öffentliche Wasserversorgung und Abwasserbeseitigung 2007, Fachserie 19 Reihe 2.1, Wiesbaden, p. 54.	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II B 13	EC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publication
Doc II B 13	OECD	2009	Emission Scenario Document on Plastic Additives, OECD Series on Emission Scenario Documents, Number 3, p. 141.	No	Publication
Doc II B 13	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publication
Doc II B 13	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publication
Doc II B8	CA Finland	April 2006	Cleaning after brushing: Competent Authority Report for Tolylfluanid (PT 8) prepared according to Art. 11(2) of Directive 98/8/EC	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II B8	EC	2002	TNsG Human Exposure Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002“ http://ecb.jrc.it/biocides]	No	Publication
Doc II B8	EC	2007	TNsG Human Exposure Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation	No	Publication
Doc II B8	Garrod A.N.I., Guiver, R., Rimmer, D.A.	2000	BEAT model Garden timber treatment Potential exposure of amateurs (consumers) through painting wood preservative and antifoulant preparations. Annals of Occupational Hygiene (44) 421-426.	No	Publication
Doc II B8	Human Exposure Expert Group (HEEG)	2008	HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, Agreed at TM I08, http://ecb.jrc.ec.europa.eu/documents/Biocides/TECHNICAL_NOTES_FOR_GUIDANCE/TNsG_ON_HUMAN_EXPOSURE/HEEG_OPINIONS/HEEG%202008_Mixing%20Loading%20model%207%20alternatives.pdf	No	Publication

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
Doc II B8	Roff M.	1997	BEAT model Roff - Fences Brushing (water) Dermal exposure of amateur or non-occupational users to wood preservative fluids applied by brushing outdoors. Annals of Occupational Hygiene (41) 297-311.	No	Publication

Doc IIIA

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.1.1/01	Ertel	1976	Hoe 17411 – Melting point Report No.: A11440 Not GLP; (unpublished) Doc. No. 112-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.1.2/01	Röchling	1988	Carbendazim substance, pure – Boiling point Report No.: A37922 Not GLP; (unpublished) Doc. No. 112-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.1.3/01	Ertel	1976	Hoe 17411 – Density Report No.: A11441 Not GLP; (unpublished) Doc. No. 113-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.1.3/02	Albrecht Rexer	1979	Carbendazim technical – Density Report No.: A18679 Not GLP; (unpublished) Doc. No. 113-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.2.1/01	Weller, O.	1991	Volatility from water / Henry-constant Report No.: A46097 Not GLP; (unpublished) Doc. No. 115-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.2/01	Grewer	1987	Determination of the vapor pressure of Hoe 17411 of ZB99 0004 as a function of the temperature Report No.: A38118 Not GLP; (unpublished) Doc. No. 115-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.3.1/01	Ertel	1975	Physical appearance – Hoe 17411 Report No.: A11450 Not GLP; (unpublished) Doc. No. 111-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.3.1/02	Albrecht Kappes	1975	Carbendazim activ ingredient, technical grade - State Report No.: A03118 Not GLP; (unpublished) Doc. No. 111-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.3.2/01	Ertel	1975	Hoe 017411 - Colour Report No.: A11448 Not GLP; (unpublished) Doc. No. 111-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.3.2/02	Albrecht Kappes	1975	Carbendazim activ ingredient, technical grade - Colour Report No.: A03110 Not GLP; (unpublished) Doc. No. 111-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.3.3/01	Ertel	1975	Hoe 17411 - Odour Report No.: A11449 Not GLP; (unpublished) Doc. No. 111-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.3.3/02	Albrecht Kappes	1975	Carbendazim activ ingredient, technical grade - Odour Report No. A03111 Not GLP; (unpublished) Doc. No. 111-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.4/01	Wink, O.	1984	UV-VIS Spectrum Report No.: A30160 Not GLP; (unpublished) Doc. No. 117-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.4/02	Wink, O. Voigt, J.	1984	Infrared (IR) – Absorption-Spectrum Report No.: A30161 Not GLP; (unpublished) Doc. No. 117-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.4/03	Wink, O.	1984	H-NMR-Spectrum Report No.: A30158 Not GLP; (unpublished) Doc. No. 117-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.4/04	Wink, O. Winterscheidt, G.	1984	Mass-Spectrum Report No.: A30159 Not GLP; (unpublished) Doc. No. 117-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.4/05	Anonymous	2009	Representative UV-Spectra of technical Carbendazim from Sinon Corporation, Taiwan at three pH-levels Bayer Crop Science, Taiwan Not GLP; unpublished Doc. No. 117-005 & Appendices 1-3	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.4/06	Anonymous	2009	UV spectrum of carbendazim technical from production site in Taicang (China) Bayer Crop Science, China, Taicang Not GLP; unpublished Doc. No. 117-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.5/01	Gorbach	1971	Hoe 17411 – Solubility of W 17411 in water at different ph-values and in different organic solvents at 24°C Report No.: A11383 Not GLP; (unpublished) Doc. No. 114-001 **Also cited in A3.7**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.6/01	Appel, M.	1988	Hoe 017411/carbendazim - Determination of the dissociation constants (pk values) Report No.: A42938 Not GLP; (unpublished) Doc. No. 115-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)
A3.6	Sinning, D.	2002	Physical and Chemical Characteristics of Carbendazim Technical: color, physical state, odor, stability, pH, UV visible absorption, melting point, bulk denisty, dissociation constant, octanol/water partition coefficient, solubility and vapour pressure. Report No.: 650-48 GLP; (unpublished)	Yes	Troy Chemical Company BV

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.7/01	Albrecht Rexer, K.	1985	Carbendazim substance, pure - Solubility Report No.: A032199 Not GLP; (unpublished) Doc. No. 114-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.9/01	Dorn, E.	1979	Hoe 17411 (Carbendazim) Partition coefficient (P) in the system n-octanol/water Report No. A18088 Not GLP; (unpublished) Doc. No. 114-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.9/02	Singh, H.	1988	n-octanol/water partition coefficient determination of carbendazim at pH 5, pH 7, and pH 9 Report No.: A52841 GLP; (unpublished) Doc. No. 114-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.10/01	Mullee, M.	1992	BCM Technical grade (HOE 17411) Accelerated Storage Stability Safepharm Laboratories Limited, Derby, England Report No.: 121/180 GLP; unpublished Doc. No. 146-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Chemical Company BV
A3.10/02	Cowlyn, N.	2010	Carbendazim – thermal stability (OECD Method 113) Report No.: ZNB0011 GLP; unpublished Doc. No.: 141-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Chemical Company BV
A3.10/03	Cowlyn, N.	2011	Carbendazim – thermal behaviour Report No.: ZNB0079 GLP; unpublished Doc. No.: 141-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Chemical Company BV

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.11/01	Albrecht Lehr, W.	1975	Carbendazim technical - Combustibility Report No.: A11451 Not GLP; (unpublished) Doc. No. 142-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.11/02	Albrecht Lehr, W.	1975	Carbendazim technical – Ignition point Report No.: A11454 Not GLP; (unpublished) Doc. No. 142-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.13/01	Cowlyn, N.	2009	Carbendazim – surface tension Report No.: ZNB0010 GLP; (unpublished) Doc. No.: 116-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Chemical Company BV

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.15/01	Albrecht Lehr, W.	1975	Carbendazim technical – Capability of dust explosion Report No.: A11452 Not GLP; (unpublished) Doc. No. 141-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.15/02	Albrecht Lehr, W.	1975	Carbendazim technical – Sensitivity to percussion Report No.: A11453 Not GLP; (unpublished) Doc. No. 141-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A3.15/03	Reisinger, T.	2008	Statement related to the explosive properties of carbendazim SCC GmbH, Wendelsheim, Germany Report No.: 833-008 Not GLP; (unpublished) Doc. No. 141-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Chemical Company BV

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.16/01	Maier Rexer, K.	1990	Carbendazim substance, technical - Corrosiveness Report No.: A43167 Not GLP; (unpublished) Doc. No. 143-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.1/01	Cichy, M. Fey, G.	2003	Analytical Method - Determination of Carbendazim (AE F017411) in the technical and pure active substance by HPLC– AE F017411 (Carbendazim) Bayer Crop Sciences GmbH, Germany Analytical Method No. AL020/02-0 Report No.: Study No. C033927; Not GLP; unpublished Doc. No. 411-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.1/02	Cichy, M. Santois, A.	2003	Validation of the Analytical Method AL118/96-1 for the Determination of AE F037197 and AE F033008 in Technical and Pure Carbendazim (AEF017411) by HPLC Bayer Crop Sciences GmbH, Germany; Report No.: PA02/019 Not GLP; unpublished Doc. No. 411-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.1/03	Cichy, M. Guebert, C.	2008	Validation of HPLC - Method AL089/99-2 Determination of the Impurities AE F069662 (DAP) and AE F070535 (HAP) in Technical Carbendazim (AE F017411) by High Performance Liquid Chromatography (HPLC) Bayer Crop Sciences GmbH, Germany Report No.: PA08/070 Not GLP; unpublished Doc. No. 411-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.1/04	Cichy, M. Fey, G.	2003	Analytical Method - Determination of the impurities AE F037197 and AE F033008 in technical Carbendazim (AE F017411) by HPLC – AE F017411 (Carbendazim) Bayer Crop Sciences GmbH, Germany Analytical Method No. AL118/96-1 Report No.: C033928 Not GLP; unpublished Doc. No. 411-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.1/05	Cichy, M. Guebert, C.	2004	Analytical Method - Determination of the impurities AE F069662 (DAP) and AE F070535 (HAP) in technical Carbendazim (AE F017411) by HPLC – AE F017411 (Carbendazim) Bayer Crop Sciences GmbH, Germany Analytical Method No. AL089/99-2 Not GLP; unpublished Doc. No. 411-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.2a/01	Brookey, F.M. Crowe, C.D. McNally, M.E.	1991	A High-Performance Liquid Chromatographic Method for the Determination of Benomyl (as MBC), MBC, and 2-AB Residues in Soil E. I. d Du Pont de Nemours and Company, Du Pont Agricultural Products Report No.: A52851 Not GLP; (unpublished) Doc. No. 434-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.2a/02	Saito, S.	2001	Validation Study of the Analytical Method for the Determination of Thiophanate-methyl and Its Degradation Product MBC in Soil (Method No. TM-S2); Report No. NCAS 01-008; GLP; (unpublished) Doc.No:434- 002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	BASF
A4.2b/01	Buerstell, H. Uhl, A. Werner, H-J.	1992	Determination of Hoe 017411 (carbendazim) in air by means of HPLC; Hoechst C Produktentwicklung Oekologie 2, Frankfurt, Germany Report No.: A48577 Not GLP; (unpublished) Doc. No. 436-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.2c/01	Burger, K.	1988	Multiple method for ultra trace determination: Pesticide active ingredients in ground and drinking water analyzed by TLC/AMD (Automated Multiple Development) Zentrale Analytik Bayer, Dormagen, Germany; Pflanzenschutz-Nachrichten, 41: 175-228 Report No.: A445915 Not GLP; (published) Doc. No. 435-001	No	N.R.
A4.2c/02	Taylor, N.W.	2000	Enforcement Method with Validation for Surface Water by HPLC – Carbendazim (AE F017411). GLP; (unpublished) Doc. No. 435-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A4.2c/03	Kobayashi, S.	2004	Development and Validation of the Analytical Method for the Determination of Thiophanate-methyl and Carbendazim in Water; Nippon Soda Co., Ltd, Odawara Labs. Japan Report No.: NCAS 03-296; GLP; (unpublished) Doc. No. 435-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Nippon Soda Co., Ltd.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.2d/01	Kirkland, J.J.	1973	Method for High-Speed Liquid Chromatographic Analysis of Benomyl and/or Metabolite Residues in Cow Milk, Urine, Feces and Tissues E. I. du Pont de Nemours and Company, Du Pont Agricultural Products, Wilmington, Delaware, USA Journal of Agricultural and Food Chemistry, 21(2), 171-177 Report No.: A52853 Not GLP; (published) Doc. No. 433-001	No	N.R.
A4.2d/02	McClory, J.P.	2005	A Confirmation Method for the Analysis of Carbendazim in Plasma; E. I. du Pont de Nemours and Company, DuPont Crop Protection, Global Technology Division; Stine-Haskell, Research Centre, Newark, Delaware GLP; (unpublished) Doc.-No.: 433-002;	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	E. I. du Pont de Nemours and Company
A4.2d/03	Duan, L., Lyon D., et al.	1999	14C-Benomyl: Assay Validation for Metabolites in Rat, Rabbit, Dog, and Monkey Plasma using LC/MS/MS; E. I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware Identification Number: DuPont-1387; GLP; (unpublished) Doc.-No.: 433-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	E. I. du Pont de Nemours and Company

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.2d/04	Knoch, E.	2004	Method Validation: Determination of Carbendazim in Matrices of Animal Origin (Milk, Egg, Muscle and Fat); XXXXXX GLP; (unpublished); Doc.-No.: 433-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	BASF
A5.3.1/01 (PT7)	Heuer, T.	2008	Test of fungicidal efficacy Carbendazim according to EN 15457 Troy Technical Center Europe, Troy Chemie GmbH, Seelze Deutschland Study No.: D070564FIL II Not GLP; unpublished Doc. No.: 336-0701	Yes	Troy Chemical Company BV
A5.3.1/03 (PT10)	Heuer, T.	2008	Test of fungicidal efficacy carbendazim Troy Technical Center Europe Study No.: D00169, D030659 Not GLP, unpublished Doc. No. 336-1002	Yes	Troy Chemical Company BV
A6.1.1/01*	[redacted]	1975	Oral LD50 limit test (fasted male and female rats). Material tested: 2-benzimidazolecarbamic acid, methyl ester E.I. Du Pont de Nemours and Co., Inc. Haskell Laboratory, Newark, Delaware, USA Report No.: A52861 Not GLP; (unpublished) Doc. No. 521-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.1/02*	[redacted]	1972	Acute oral toxicity of methyl-2-benzimidazole carbamate to the rat BASF, Germany Report No.: A52510 / 72/012 Not GLP; (unpublished) Doc. No. 521-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.1.2	[redacted]	1974	Material Tested: 2-Benzimidazolecarbamic acid, methyl ester. Skin Absorption Limit test like study E.I. DuPont de Nemours and Co., Inc.,Haskell Laboratory, Newark, USA Report No. A52865, HLR 798-74, MR No. 2046-001 Registration No. TOX95-51411 Non GLP, unpublished Doc. No. 522-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.1.2/01*	[redacted]	1971	Carbendazim (HOE 17411 OF) Toxicological examination Hoechst AG, Pharmaceuticals Research, Toxicology Section, Frankfurt, Germany Report No.: A00936 Not GLP; (unpublished) Doc. No. 522-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.3/01*	[redacted]	1981	Determination of the acute inhalation toxicity LC50 Reg. No. 67 054 Dust Aerosol Study during 4-hour exposure on Sprague-Dawley rats BASF, Germany; Report No.: A52509 ! 81/299 Not GLP; (unpublished) Doc. No. 523-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.1.4/01*	[redacted]	1972	Carbendazim (HOE 17411 OF, batch 496/I) - Toxicological examination Hoechst AG, Pharmaceuticals Research, Toxicology Section, Frankfurt, Germany Report No.: A00935 Not GLP; (unpublished) Doc. No. 565-001 **Also cited in A6.11**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.1.4/02*	[redacted]	1974	Federal Hazardous Substances Act – Eye irritation test in rabbits E.I. DuPont de Nemours and Co., Inc., Haskell Laboratory, Newark, Delaware, USA Report No.: A52869 ! 799-74 Not GLP; (unpublished) Doc. No. 566-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.5/01*	[redacted]	1987	Carbendazim – active ingredient technical (code: HOE 017411 OF ZD99 0009). Testing for sensitising properties in the Pirbright-white guinea pig according to the technique of Buehler Hoechst Pharma, Germany Report No.: A36804 ! 87.0509 GLP; (unpublished) Doc. No. 567-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.1.5/02	[redacted]	1976	Primary skin irritation and sensitization tests on guinea pigs E.I. DuPont de Nemours and Co., Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware, USA Report No.: A52867 ! 698-76 Not GLP; (unpublished) Doc. No. 567-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.2/01*	[redacted]	1990	Metabolism of [Phenyl(U)-14C]Carbendazim in Rats E.I. Du Pont de Nemours and Co., Inc., Agricultural Products Department, Research and Development Division, Experiment Station, Wilmington, Delaware, USA and Battelle Columbus Division, Ohio, USA Report No.: A52858 ! AMR 1141-88 GLP; (unpublished) Doc. No. 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.2/02*	[redacted]	1993	Dose-excretion study with the fungicide carbendazim in volunteers TNO Medical Biological Lab., Rijswijk Report No.: A50719 Not GLP; (unpublished) Doc. No. 511-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.2/03*	[redacted]	1980	Carbendazim (60% WP) absorption via the skin in rats Hoechst AG, Anal. Lab. and RCL; Frankfurt, Germany Report No.: A48605 ! (B) 134/80 Not GLP; (unpublished) Doc. No. 511-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.2/04	[redacted]	1994	Carbendazim: Rates of penetration through human and rat skin using an in vitro system Hazleton Europe, Harrogate, UK Report No.: A52209 ! 550/16-1011 GLP; (unpublished) Doc. No. 511-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.2/05*	De Ligt, R.A.F.; Maas, W.J.M.	2009	In vitro percutaneous absorption of [14C]Carbendazim, formulated in a paint, through human skin membranes using flow-through diffusion cells; TNO Quality of Life, Zeist, the Netherlands; TNO study code 8190/05; Doc No. 511-001 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation
A6.2/06*	De Ligt, R.A.F.	2009	In vitro percutaneous absorption of [14C]Carbendazim, formulated as a pre-mix, through human skin membranes using flow-through diffusion cells; TNO Quality of Life, Zeist, the Netherlands; TNO study code 8334/04; Doc No. 511-006 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation
A6.3.1/01*	[redacted]	1972	W 17411 = 2-Carbomethoxyaminobenzimidazole. Toxikologische Prüfung. Range-finding-test (30 Tage) an Ratten Hoechst AG, Pharmacology Research, Toxicology Section, Frankfurt, Germany Report No.: A00011 Not GLP; (unpublished) Doc. No. 532-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.3.1/02*	[redacted]	1971	Tentative (28-day) feeding study with W17411 in beagle dogs Central Institute for Nutrition and Food Research (TNO), the Hague, Netherlands Report No. A00015 ! R3659 Not GLP; (unpublished) Doc. No. 532-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.3.2/01*	[redacted]	1975	Ten-day subacute exposure of rabbit skin to 2-Benzimidazolecarbamic acid, Methyl Ester (MBC) (INE-965) DuPont Haskell Lab. Toxicology, Newark, United States Report No. A52873 ! 836-74 Not GLP; (unpublished) Doc. No. 531-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.4.1*	[redacted]	1973	BCM toxicity to rats during dietary administration for thirteen weeks followed by a recovery period of six weeks Huntingdon Research Centre Report No. A01359 Registration No. TOX95-51431 Non GLP, unpublished Doc. No. 533-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.4.1	[redacted]	1987	Report on the study of the sub chronic toxicity of methyl benzimidazole-2-carbamate (MCB) in beagle dogs on oral administration BASF AG, Germany Report No. A52507, RZ-NO 87/090 Registration No. TOX95-51434 Non GLP, unpublished Doc. No. 533-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.4.1	[redacted]	1970	Three-month feeding study on dogs with 2-benzimidazolecarbamic acid, methyl ester (INE-965) E.I DuPont de Nemours and Co. Inc., Haskell Laboratory, Newark, USA Report No.: A52871, HLR 283-70 Registration No. TOX95-51429 Non GLP, unpublished Doc. No. 533-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	E. I. du Pont de Nermours and Company
A6.4.1/01*	[redacted]	1973	Report on a subchronic feeding experiment (93 days) with technical active substance HOE 17411 OF Hoechst Pharma Research Toxicology, Germany Report No. A00409 Not GLP; (unpublished) Doc. No. 533-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.4.1/02	[redacted]	1985	Addendum to report of a subchronic feeding study with HOE 17411 OF, active ingredient technical, in rats. Hoechst AG, Pharma Research Toxicology, [redacted] Report No.: A45408 ! GT85.0607 Not GLP; (unpublished) Doc. No. 533-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.4.1/03*	[redacted]	1972	Sub-chronic (90-day) toxicity study with W17411 in beagle dogs TNO, The Hague, Netherlands Report No.: A00292 ! R3920 Not GLP; (unpublished) Doc. No. 533-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5	[redacted]	1982	Repeated dose (24-month) feeding study for determination of the carcinogenic effect of HOE 17411 OFAT204 (carbendazim) in mice Hoechst AG, Pharmaceuticals Research, Toxicology Section, Frankfurt, Germany Report No. A24749, 643/82 Non GLP, unpublished Doc No. 537-009 Also cited in A6.7	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.5/01*	[redacted]	1972	Long-term feeding studies in rats and dogs with 2-benzimidazolecarbamic acid, methyl ester (INE-965) E. I. DuPont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware, USA Report No.: A52903 ! 195-72 Not GLP; (unpublished) Doc. No. 537-004 **Also cited in A6.7, A6.8.2**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5/02*	[redacted]	1971	2-benzimidazolecarbamic acid, methyl ester (INE-965) – Two year feeding study – ChR-CD rats DuPont, USA Report No.: A52992 ! 36-71 Not GLP; (unpublished) Doc. No. 537-005 **Also cited in A6.7**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5/03*	[redacted]	1978	2-benzimidazolecarbamic acid, methyl ester (INE-965) – Two year feeding study – ChR-CD rats DuPont, USA Report No.: A52993 ! 82-77 Not GLP; (unpublished) Doc. No. 537-006 **Also cited in A6.7**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.5/04*	[redacted]	1985	Carbendazim (INE-965): Additional comments; Supplement 3 of HLR 195-72. Suppl. to Reference No. TOX95-51382 DuPont, Haskell Lab. for Toxicology and Industrial Medicine, Newark, Delaware, USA Report No.: A53125 Not GLP; (unpublished) Doc. No. 537-007 **Also cited in A6.7**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5/05*	[redacted]	1976	Long-term (two-year) toxicity study with Carbendazim in Beagle dogs CIVO/TNO, Zeist, The Netherlands Report No.: A06583 ! R 5023 Not GLP; (unpublished) Doc. No. 537-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5/06*	[redacted]	1984	Addendum to report R5023 (TOX95-51543). Long-term (two-year) toxicity study with Carbendazim in Beagle dogs CIVO/TNO, Zeist, The Netherlands Report No. A29341 Not GLP; (unpublished) Doc. No. 537-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.5/07*	Anonymous	1984	Appendices belonging to Report No. R 5023. Long-term (two-year) toxicity study with Carbendazim in Beagle dogs. Individual data CIVO/TNO, Zeist, The Netherlands Report No. A29340 Not GLP; (unpublished) Doc. No. 537-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.5/08*	[redacted]	1988	Chronic toxicity study with INE 965. Two-year feeding study in dogs, Supplement Report No. A53120 E. I. DuPont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware, USA Report No. A53120! HLR 195-72 Not GLP; (unpublished) Doc. No. 537-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.1/01*	Stammberger, I.	1992	HOE 017411, substance technical (Code: HOE 17411 00 ZD99 0008) - Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli* Hoechst Toxicology, Germany Report No.: A47583 ! 92.0153 GLP; (unpublished) Doc. No. 557-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.1/02*	Donovan, S.D. Irr, J.D.	1982	Mutagenicity evaluation in *Salmonella typhimurium* DuPont, Haskell Laboratory, Newark, Delaware, USA Report No.: A52878 ! 710-82 Not GLP; (unpublished) Doc. No. 557-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.1/03	Krul, C.A.M.	2002	Bacterial reverse mutation test with Carbendazim, TNO Nutrition and Food Research, Department of Explanatory Toxicology, Zeist, the Netherlands Report No.: V 3405/18 Doc. No 557-019 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation
A6.6.1/04*	Sokolowski, A.	2011	Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay with Carbendazim Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany. Report No.: 1424402 Doc. No. 557-022 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.2/01*	Marshall, R.	1996	Carbendazim: Induction of aneuploidy in cultured human peripheral blood lymphocytes Corning Hazleton Harrogate, England Report No.: A67199 GLP; (unpublished) Doc. No. 557-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.2/02*	Banduhn, N. Obe, G.	1985	Mutagenicity of methyl 2-benzimidazole carbamate, diethylstilbestrol and estradiol: Structural chromosomal aberrations, sister-chromatid exchanges, C-mitoses, polyploidies and micronuclei Univ. Berlin, Germany; Mutation Research, 156: 199-218 Report No.: A33450 Not GLP; (published) Doc. No. 592-029	No	N.R.
A6.6.2/03	Parry, J.M. Parry, E.M. Ellard, S. Warr, T. O´Donovan, J. Lafi, A.	1993	The detection, definition and regulation of aneugenic chemicals Vig, B.K. (ed.), Chromosome segregation and aneuploidy, Springer-Verlag, Berlin and Heidelberg Report No.: A52022 Not GLP; (published) Doc. No. 592-013	No	N.R.
A6.6.2/04	Elhajouji, A. van Hummelen, P. Kirsch-Volders, M.	1995	Indications for a threshold of chemically-induced aneuploidy in vitro in human lymphocytes Env Molec Mutagen, 26: 292-304 Not GLP (published) Doc. No. 592-026	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.2/05	Elhajouji, A. Tibaldi, F. Kirsch-Volders, M.	1997	Indication for thresholds of chromosome non-disjunction versus chromosome lagging induced by spindle inhibitors in vitro in human lymphocytes Mutagenesis, 12: 133-140 Not GLP; (published) Doc. No. 592-027	No	N.R.
A6.6.2/06	[redacted]	2002	Chromosomal aberration test with Carbendazim in cultured Chinese hamster ovary cells TNO Nutrition and Food Researrch, Department of Explanatory Toxicology, Zeist, the Netherlands Report No.: V 3402/13 Doc. No. 557-020 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation
A6.6.2/07*	Bohnenberger, S.	2011	Chromosome aberration test in human lymphocytes in vitro with Carbendazim Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Report No.: 1424401 Doc. No.: 557-023 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Troy Corporation

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.3	[redacted]	1981	Evaluation of Hoe 17411 0F AT204 in the Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay; Litton Bionetics, Inc. Report No. A22464, 21001, 563/81A Registration No. TOX95-51456 GLP, unpublished Doc. No. 557-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.3	[redacted]	1983	Mutagenicity Evaluation of Hoe 17 411 0F AT 204 in the Mouse Lymphoma Forward Mutation Assay Litton Bionetics, Inc. Report No. A26176, 6663 Registration No. TOX95-51466 GLP, unpublished Doc. No. 557-014	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.3/01	[redacted]	1983	L5178Y mouse lymphoma cell assay for mutagenicity DuPont de Nemours & Co., Haskell Laboratory, Newark, Delaware, USA Report No.: A52885 Not GLP; (unpublished) Doc. No. 557-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.4/01*	[redacted]	1992	Classification of DPX-T1991-599 (Carbendazim, MBC) induced micronuclei in mouse bone marrow erythrocytes using immunofluorescent antikinetochore antibodies DuPont Haskell Laboratory, Newark, Delaware Report No.: A48879 ! HLR 569-92 GLP; (unpublished) Doc. No. 557-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.4/02*	[redacted]	1983	Mutagenicity testing of methyl-2-benzimidazolecarbamate (carbendazim) in vivo and in vitro Rocz Panstw Zakl Hig. Report No.: A34511 Not GLP; (unpublished) Doc. No. 557-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.4/03*	[redacted]	1975	Test report on the mutagenic effect of 2-(methoxycarbonylamino)-benzimidazole (MCB) on rats after a single oral administration (chromosomal examinations) BASF, Germany Report No. A17489 Not GLP; (unpublished) Doc. No. 557-009	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.4/04*	Seiler, J.P.	1976	The mutagenicity of benzimidazole and benzimidazole derivatives. Cytogenetic effects of benzimidazole derivatives in the bone marrow of the mouse and the Chinese hamster Mutation Research, 40(4): 339-347 Report No.: 19877 Not GLP; (published) Doc. No. 592-014 **Also cited in A6.10.3**	No	N.R.
A6.6.4/05*	[redacted]	1990	HOE 017411 – substance, technical and a mixture of HOE 017411 + HOE 093049 – substance, technical. Micronucleus test in male and female NMRI mice after oral administration Hoechst Pharma Research Toxicology and Pathology, Frankfurt, Germany Report No. A42889 GLP; (unpublished) Doc. No. 557-011 **Also cited in A6.10.3**	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.4/06*	[redacted]	1980	Testing of HOE 17411 – active ingredient (code HOE 17411 OF AT 204) for mutagenicity in the micronucleus test following oral administration to NMRI mice Hoechst Pharma Forschung Toxikologie, Frankfurt, Germany Report No.: A29765 Not GLP; (unpublished) Doc. No. 557-012	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.4/07*	[redacted]	1980	Testing of HOE 17411 – active ingredient (Code HOE 17411 OF AT207) for mutagenicity in the micronucleus test following oral administration to NMRI mice Hoechst Pharma Forschung Toxikologie, Frankfurt, Germany Report No.: A28150 Not GLP; (unpublished) Doc. No. 557-013	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.4/08	Seiler, J.P.	1976	Evaluation of some pesticides for mutagenicity Proc. Eur. Soc. Tox., 17: 398-404 Not GLP; (published) Doc. No. 592-021 **Also cited in A6.10.3**	No	N.R.
A6.6.4/09	Seiler, J.P.	1977	Apparent and real thresholds: A study on two mutagens; In Progress in Genetic Toxicology Elsevier, North-Holland Biomedical Press: 233-238 Report No. A49436 Not GLP; (published) Doc. No. 592-015 **Also cited in A6.10.3**	No	N.R.
A6.6.4/10	Seiler, J.P.	1980	Evaluation of some pesticides for mutagenicity; Pesticide Mutagenicity Section for Plant Protection, Swiss Federal Research Station, Waedenswil, Switzerland Report No.: A19875 Not GLP; (published) Doc. No. 592-016	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.6/01*	[redacted]	1973	Report on the testing of MCB (methyl-2-benzimidazole carbamate) for mutagenicity following intraperitoneal injection to the male mouse BASF Medizinisch-Biologische Forschungslaboratorien Gewerbehygiene und Toxikologie, Germany Report No.: A01398 Not GLP; (unpublished) Doc. No. 557-016	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.6/02*	[redacted]	2001	Mouse sperm-FISH assay with carbendazim; GSF - National Research Centre for Environment and Health GSF -National Research Centre for Environment and Health, Institute of Experimental Genetics, Neuherberg, Germany Report No.: C015455! GSF No. F-76628 GLP; (unpublished) Doc. No. 557-017	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.6.6/03*	De Stoppelaar, J.M. Van de Kuil, T. Bedaf, M. Verharen, H.W. Slob, W. Mohn, G.R. Hoebee, B. Van Benthem, J.	1999	Increased frequencies of diploid sperm detected by multicolour FISH after treatment of rats with carbendazim without micronucleus induction in peripheral blood erythrocytes Mutagenesis, 14: 621-631 Not GLP; (published) Doc. No. 592-022	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.6/04*	Matsuo, F. Nakai, M. Nasu, T.	1999	The fungicide carbendazim induces meiotic micronuclei in the spermatids of the rat testis J Vet Med Sci, 61: 573-576 Not GLP; (published) Doc. No. 592-023	No	N.R.
A6.6.6/05*	Jeffay, S.C. Libbus, B.L. Barbee, R.R. Perreault, S.D.	1996	Acute exposure of female hamsters to carbendazim (MBC) during meiosis results in aneuploid oocytes with subsequent arrest of embryonic cleavage and implantation Reprod. Toxicol., 10: 183–189 Not GLP; (published) Doc. No. 592-024	No	N.R.
A6.7/01*	[redacted]	1982	Long-term feeding study with 2-benzimidazol-carbamic acid, methyl ester (MBC, INE-965) in mice (Parts I and II) E.I. DuPont de Nemours & Co., Haskell Lab. for Toxicology and Industrial Medicine, Delaware Report No. A25245 ! Not GLP; (unpublished) Doc. No. 555-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/02*	[redacted]	1980	Long-term feeding study in mice with 2-benzimidazol-carbamic acid, methyl ester (INE-965; H-11, 201; MBC) DuPont Haskell Lab. Toxicology, USA Report No.: A53128 Not GLP; (unpublished) Doc. No. 555-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/03*	[redacted]	1980	Preliminary report of hepatic neoplasms 2-benzimidazol-carbamic acid, methyl ester (INE-965). Chronic feeding oncogenicity study – ChR-CD-1 mice DuPont Haskell Lab. Toxicology, USA Report No: A53129 Not GLP; (unpublished) Doc. No. 555-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/04*	[redacted]	1981	Carbamic acid, 1H-benzimidazol-2-yl-, methyl ester (INE-965, MBC) preliminary report of histomorphological changes in hepatic tissues (liver and gallbladder). Chronic feeding oncogenicity study - CD-1 mice DuPont Haskell Lab. Toxicology, USA Report No.: A53130 Not GLP; (unpublished) Doc. No. 555-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/05*	[redacted]	1981	Carbamic acid, 1H-benzimidazol-2-yl-, methyl ester (INE-965, MBC). Two-year feeding study in CD-1 mice DuPont Haskell Lab. Toxicology, USA Report No.: A53131 Not GLP; (unpublished) Doc. No. 555-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/06*	[redacted]	1990	Oncogenicity studies with benomyl and MBC in mice: Supplemental peer review DuPont Haskell Lab. Toxicology, USA Report No.: A52982 GLP; (unpublished) Doc. No. 555-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/07*	[redacted]	1990	Oncogenicity studies with benomyl and MBC in mice. Peer-review of liver neoplasms Experimental Pathology Laboratories, Research Triangle Park, North Carolina, USA Report No.: A52981 GLP; (unpublished) Doc. No. 555-011	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/08*	Anonymous	1982	EPA request for mouse historical control liver tumour data DuPont Haskell Lab. Toxicology, USA Report No.: A52980 Not GLP; (unpublished) Doc. No. 555-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/09*	[redacted]	1976	Carcinogenicity study with carbendazim in mice CIVO/TNO, Zeist, The Netherlands Report No.: A08129; R4936 Not GLP; (unpublished) Doc. No. 555-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/10*	Anonymous	1976	Appendices belonging to Report No. R 4936, Ref. No. TOX95-51444. Carcinogenicity Study with Carbendazim in Mice. Individual Data Part I CIVO/TNO, Zeist, The Netherlands Report No.: A 29342 Not GLP; (unpublished) Doc. No. 555-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/11*	Squire, R.A. Levitt, M.H.	1975	Report of a Workshop on Classification of Specific Hepatocellular Lesions in Rats National. Canc. Inst., USA: Cancer Research 53, 3214-3223 Report No.: A52593 Not GLP; (published) Doc. No. 592-017	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/12*	[redacted]	1980	Carcinogenicity Study with Carbendazim in Mice Commentary on the CIVO-Report No. R 4936 Hoechst Pharma Research, Toxicology, Germany Report No.: A20324 Not GLP; (unpublished) Doc. No. 555-009	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/13*	[redacted]	1977	Review of liver sections from mice and rats fed with carbendazim Department of Experimental Pathology, Medical School, Hannover, Germany Report No.: A19223 Not GLP; (unpublished) Doc. No. 555-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.7/14*	Turusov, V.S. Day, N.E. Tomatis, L. Gati, E. Charles, R.T.	1973	Tumors in CF-1 mice exposed for six consecutive generations to DDT J. Natl. Cancer Inst., 51(3): 983–997 Report No.: A52515 Not GLP; (published) Doc. No. 592-018	No	N.R.
A6.7/15*	Frith, C.H. Ward, J.M.	1980	A morphologic classification of proliferative and neoplastic hepatic lesions in mice University of Arkansas and National Cancer Inst., USA; J Environ Pathol Toxicol. 3(1-2):329-351 Report No.: A52442 Not GLP; (published) Doc. No. 592-019	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/16*	Maronpot, R.R. Haseman, J.K. Boorman, G.A. Eustis, S.E. Rao, G.N. Huff, J.E.	1987	Liver lesions in B6C3F1 mice: The National Toxicology Program, experience and position Natl. Inst. Environ. Health Sci., Res. Triangle Park, North Carolina, USA; Arch. Toxicol. Suppl., 10: 10–26 Report No.: A49432 Not GLP; (published) Doc. No. 592-020	No	N.R.
A6.8.1/01*	[redacted]	1987	Teratogenicity study of INE-965 (carbendazim) in rats. Report No. MR-7976-001 HLR 281-87 DuPont, Haskell Laboratory, Newark, Delaware, USA Report No.: A52957 GLP; (unpublished) Doc. No. 551-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.8.1/02*	[redacted]	1985	Developmental toxicity study of carbendazim administered via gavage to New Zealand White rabbits Argus Research Laboratories, Inc., Horsham, Pennsylvania, USA Report No.: A52938 GLP; (unpublished) Doc. No. 551-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

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A6.8.2/01*	[redacted]	1976	Multigeneration study with carbendazim in rats TNO, The Netherlands Report No.: A10295, R5024 Not GLP; (unpublished) Doc. No. 553-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.8.2/02*	[redacted]	1984	Appendices belonging to report no. R 5024. Multigeneration study with carbendazim in rats TNO, The Netherlands Report No.: A29338 Not GLP; (unpublished) Doc. No. 553-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.8.2/03	[redacted]	1983	Notebook 892 / 906 (animal weight data, reproduction study). Supplement to HLR 195-72 DuPont, USA Report No.: A53122 Not GLP; (unpublished) Doc. No. 553-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.8.2/04	[redacted]	1970	2-benzimidazolecarbamic acid, methyl ester INE-965 MR-1149 H-5793. Two-year feeding, reproduction study DuPont, USA Report No.: A53121 ! HLR 195-72 Not GLP; (unpublished) Doc. No. 553-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex +I.)	Bayer CropScience AG
A6.9/01*	[redacted]	1978	Neurotoxicity study in hens International Research & Development Corp., USA Report A52939 ! HLO-0027-79 Not GLP; (unpublished) Doc. No. 541-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.1/01*	[redacted]	1966	Material tested: 2-benzimidazolecarbamic acid, methyl ester. Acute oral test DuPont Haskell Lab. Toxicol. USA Report No.: A52864 ! 99-66 MR. No. 581 Not GLP; (unpublished) Doc. No. 553-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.1/02*	Carter, S.D. Hess, R.A. Laskey, J.W.	1987	The fungicide methyl 2-benzimidazole carbamate causes infertility in male Sprague-Dawley rats Biol. Reprod., 37: 709-717 Report No.: A49423 Not GLP; (published) Doc. No. 592-010	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.10.1/03 *	Gray, L.E. Ostby, J. Sigmon, R. Ferrell, J. Rehnberg, G. Linder, R. Cooper, R. Goldman, J. Laskey, J.	1988	The development of a protocol to assess reproductive effects of toxicants in the rat Reprod. Toxicol., 2, 3/4: 281-287 Report No.: A49520 Not GLP; (published) Doc. No. 592-025	No	N.R.
A6.10.1/04 *	Gray, L.E. Ostby, J. Linder, R. Goldman, J. Rehnberg, G. Cooper, R.	1990	Carbendazim-induced alterations of reproductive development and function in the rat and hamster Fundam Appl. Toxicol., 15: 281-297 Report No.: A44321 Not GLP; (published) Doc. No. 592-011	No	N.R.
A6.10.2	[redacted]	1982	Carbendazim-technical grade (Code: Hoe 17411 0F AT 204) 59-Day enzyme induction study in rats TNO, Bilthoven, Netherlands Report No.: A26007, V 82.348/211328 Registration No. TOX95-51589 GLP, unpublished Doc. No. 513-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.2/01 *	[redacted]	1981	Enzyme induction with DuPont compounds H 11, 201-02 and H 10, 962-02 Center in Environmental Toxicology and Department of Biochemistry, Vanderbilt University, School of Medicine Nashville, Tennessee, USA Report No.: A52976 ! HLO-850-81 Not GLP; (unpublished) Doc. No. 512-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

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A6.10.2/02 *	[redacted]	1982	Carbendazim - technical grade (code: HOE 17411 OF AT 204) 60-day enzyme induction study in mice TNO, the Netherlands Report No.: A26008 ! V 82.347/202272 Not GLP; (unpublished) Doc. No. 512-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.3/01 *	De Brabander, M. Van de Veire, R. Aerts, F. Geuens, S. Hoebeke, J.	1976	A new culture model facilitating rapid quantitative testing of mitotic spindle inhibition in mammalian cells Journal of the National Cancer Institute, 56(2): 357-363 Report No.: A49425 Not GLP; (published) Doc. No. 592-001	No	N.R.
A6.10.3/02 *	Friedman, P.A. Platzer, E.G.	1978	Interaction of anthelmintic benzimidazoles and benzimidazoles derivatives with bovine brain tubulin Biochim Biophys Acta, 544: 605-614 Report No.: A33718 Not GLP; (published) Doc. No. 592-002	No	N.R.
A6.10.2	Falke, H. E. Beems, R. B. Spit, B.	1982	Carbendazim-technical grade (Code: Hoe 17411 0F AT 204) 59-Day enzyme induction study in rats TNO, Bilthoven, Netherlands Report No.: A26007, V 82.348/211328 Registration No. TOX95-51589 GLP, unpublished Doc. No. 513-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

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A6.10.3/03	Davidse, L.C.	1973	Antimitotic activity of methyl benzimidazol-2-yl carbamate (MBC) in *Aspergillus nidulans* Pestic Biochem Physiol, 3: 317-325 Report No.: A33560 Not GLP; (published) Doc. No. 592-003	No	N.R.
A6.10.3/04	Hammerschlag, R.S. Sisler, H.D.	1973	Benomyl and methyl-2-benzimidazole (MBC): Biochemical, cytological, and chemical aspects of toxicity to *Ustilago maydis* and *Saccharomyces cerevesia* Pestic Biochem Physiol, 3: 42-54 Report: A33558 Not GLP; (published) Doc. No. 592-004	No	N.R.
A6.10.3/05	[redacted]	1984	Carbendazim - Evaluation of the mitotic spindle inhibition T. N. O. Laboratory of Phytopathology, Agricultural University, Wageningen, The Netherlands Report No.: A28730 Not GLP; (unpublished) Doc. No. 584-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.3/06	Davidse, L.C. Flach, W.	1977	Differential binding of methyl benzimidazol-2-yl carbamate to fungal tubulin as a mechanism of resistance to this antimitotic agent in mutant strains of *Aspergillus nidulans* J Cell Biol, 72: 174-193 Report No.: A33785 Not GLP; (published) Doc. No. 592-005	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.10.3/07	Davidse, L.C. Flach, W.	1978	Interaction of thiabendazole with fungal tubulin Biochim Biophys Acta, 543: 82-90 Report No.: A49517 Not GLP; (published) Doc. No. 592-006	No	N.R.
A6.10.3/08	[redacted]	1984	Translation of Doc. No. A30889: Evaluation of mitotic inhibition by Carbendazim Höchst, Pharma Research Toxicology Report: A45447 Not GLP; (unpublished) Doc. No. 581-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.3/09	Aufderheide, M. Ramm, D. Steinmann, J. Kohler, M. Riebe, M. Mohr, U.	1989	The use of image analysis for the evaluation of data from autoradiography of intestinal tissue Acta Stereol., 8(2): 193-198 Report No.: A49445 Not GLP; (published) Doc. No. 592-007	No	N.R.
A6.10.3/10	Aufderheide, M. Kohler, M. Hamann, S. Riebe, M.	1989	Effects of Carbendazim on the mitotic activity of the small intestine in rat Zentralbl. Hyg. Umweltmed., 189: 62 Report No.: A49521 Not GLP; (published) Doc. No. 592-008	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.10.3/11	[redacted]	1993	Comments on autoradiographic examination of the small intestine in the rat treated with Carbendazim (MBC), and general aspects on its toxicological significance Hoechst, Pharma Development Central Toxicology Report No.: A51240 Not GLP; (unpublished) Doc. No. 584-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.3/12	[redacted]	1982	Evaluation of the genotoxicity studies on carbendazim (MBC), Benomyl and Thiophanate-methyl Univ. Mainz, Germany Report No.: A24389 Not GLP; (unpublished) Doc. No. 584-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.10.3/13	Seiler, J.P.	1977	Nitrosation in vitro and in vivo by sodium nitrite and mutagenicity of nitrogenous pesticides Mutation Research, 48: 225-236 Report No.: n.a. Not GLP; (published) Doc. No. 592-028	No	N.R.

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A6.10.3/14	[redacted]	1993	In vitro effects of carbendazim technical on the mitotic spindle Hoechst L Toxikologie Report No.: A51927 Not GLP; (unpublished) Doc. No. 557-018	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.12.1/01	Griffiths, P.J.	1989	Benefit/ risk evaluation for Du Pont benomyl and carbendazim in agriculture Report No.: A46357 Not GLP; (unpublished) Doc. No. 567-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A6.12.5/01	Anonymous	1992	Evaluation of fully approved or provisionally approved products. Carbendazim evaluation on July 1992. Food and Environment Protection Act 1985, part III Control of Pesticides Regulations 1986., 58, 1992 Report No.: *A53261* Not GLP; (published) Doc. No. 592-009	No	N.R.

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A7.1.1.1.1 /01	Görlitz, G. Klöckner, Ch.	1982	Behaviour of plant protection agents in water Hoechst Analytical Laboratory, Frankfurt, Germany Report No.: A47455 Not GLP; (unpublished) Doc. No. 711-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.1.1.1.1 /02	Priester, T.M.	1984	Hydrolysis of Carbendazim [2-14C] E.I. du Pont de Nemours and Company Inc., Agricultural Chemicals Department, Research Division Experimental Station, Wilmington, Delaware Report No.: A52842 Not GLP; (unpublished) Doc. No. 711-002	Yes	Bayer CropScience AG
A7.1.1.1.2 /01	Schwab, W.	1992	HOE 017411-(Carbendazim)-14C, Photoabbau im Wasser Hoechst C Produktentwicklung Oekologie 1, Frankfurt, Germany Report No.: A47539 GLP; (unpublished) Doc. No. 712-001	Yes	Bayer CropScience AG
A7.1.1.2.1 /01	Voelskow, H.	1990	Testing the biodegradability of Carbendazim Hoechst Umweltschutz, Frankfurt, Germany Hoechst Umweltschutz, Frankfurt, Germany Report No.: A47420! V 89-0464-A1B GLP; (unpublished) Doc. No. 713-002	Yes	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.1.1.2.2 /01	Wellens	1984	Biological degradation of HOE 017411, active ingredient in Derosal Hoechst Umweltschutz, Frankfurt, Germany Report No.: A47513 Not GLP; (unpublished) Doc. No. 713-001	Yes	Data owner Bayer CropScience AG
A7.1.2.2.2	Gildemeister, D.	1988	Degradation of Carbendazim (HOE 017411) in two aerobic aquatic systems Report No.: A37801! RCC 088132! 88/0150; WAS95-00191 GLP; (unpublished) Doc. No.: 715-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.1.2.2.2	Kley, C.	2002	Kinetic evaluation of a water/sediment study with Carbendazim using TopFit 2.0 Report No.: C020880 WAS2002-16 not GLP; (unpublished) Doc. No.: 715-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.1.2.2.2 /01	Knoch, E.	2001	Degradability and Fate of [U-14Cphenyl], Hoe 017411 -Carbendazim in the Aquatic Environment (Water/Sediment System) Institut Fresenius Chemische und Biologische Laboratorien GmbH, Herten, Germany Report No.: C 017201, IF-99/23071-00 GLP; (unpublished) Doc. No. 715-001	Yes	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.1.3/01	Görlitz, G. Klöckner, C.	1986	HOE 017411, Adsorption/desorption in the soil/water system Hoechst Analytical Laboratory, Frankfurt, Germany Report No.: A40783 Not GLP; (unpublished) Doc. No. 731-001	Yes	Bayer CropScience AG
A7.1.3/02	Gawlik, B.M., Kettrup, A.and Muntau, H	2000	Estimation of soil adsorption coefficients of organic compounds by HPLC screening using the second generation of the European reference soil set; Chemosphere 41 (9): 1337-1347; Doc. No. 792-003; (published)	No	Not applicable, study is a publication
A7.1.3/03	Nemeth-Konda, L., Füleky, Gy., Morovjan, Gy. and Csokan, P.	2002	Sorption behaviour of acetochlor, atrazine, carbendazim, diazinon, imidacloprid and isoproturon on Hungarian agricultural soil; Chemosphere 48 (5): 545-552; Doc. No. 792-004; (published)	No	Not applicable, study is a publication
A7.1.3/04	Paszko T.	2006	Sorption behavior and kinetics of carbendazim in mineral soils; Polish Journal of Environmental Studies 15 (3): 449-456; Doc. No. 792-005; (published)	No	Not applicable, study is a publication
A7.1.3/05	Gawlik, B.M. et al.	1998	Application of the European reference soil set (EUROSOILS) to a HPLC-screening method for the estimation of soil adsorption coefficients of organic compounds; Chemosphere 36 (14): 2903-2919; Doc. No. 792-006; (published)	No	Not applicable, study is a publication

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A7.1.3/06	Dios, G, Romero, E.; Sánchez-Rasero, F.	1991	Adsorción de Carbendazima, Cianzina y Etirimol por suelos; Suelo y Planta 1: 239-249 (1991); Doc. No. 792-007; (published)	No	Not applicable, study is a publication
A7.2.1/01	Helweg, A.	1977	Degradation and adsorption of carbendazim and 2-aminobenzimidazole in soil State Lab. Soil Crop Res.; Lyngby, Denmark Pestic. Sci. 8, (1977), 71-78 Report No.: A09825 Not GLP; (published) Doc. No. 792-001 **Also cited in A7.2.2.3**	No	N.R.
A7.2.1/02	Bürkle, W.L.	1989	Carbendazim-Degradation of the metabolite 2-Amino-benzimidazole in soil State Lab. Soil Crop Res.; Lyngby, Denmark Report No.: A47459 ! UE89/189 Not GLP; (unpublished) Doc. No. 721-003	Yes	Bayer CropScience AG
A7.2.1/03	Otto, S.	1975	Verhalten des Pflanzenschutzmittelwirkstoffes im Boden. BASF Aktiengesellschaft, Landwirtschaftliche Versuchsstation, Limburgerhof, Germany; A22991; Doc. No. 721-006; (unpublished)	Yes	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.2.2.1	Anonym	1975	Verhalten des Pflanzenschutz-mittelwirkstoffes im Boden Report No. A22991 BOD95-00445 not GLP; (unpublished) Doc. No. 721-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.2.2.1/01	Gildemeister, H. Jordan, H.J. Remmert, U.	1981	Behaviour of the plant protection product HOE 17411 of AT 102 (Carbendazim) in soil SS 2.2 at 15°C, 20°C and 25°C Hoechst Analyt. Labor., Frankfurt, Germany Report No.: A47457 Not GLP; (unpublished) Doc. No. 721-002	Yes	Bayer CropScience AG
A7.2.2.1/02	Adam, D	2012	^{14}C-Carbendazim – Degradation and Metabolism in Five Soils Incubated under Aerobic Conditions. Innovative Environmental Services (IES) Ltd., Witterswil, Switzerland, study identification 303 01 034, Doc.-No. 721-006, 14th June 2012, (unpublished)	Yes	Troy Chemical Company BV
A7.2.2.2/01	Krebs, B. Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen Hoechst C Produktentwicklung Oekologie 2; Frankfurt, Germany Report: A42435 ! DEU88F10641 Not GLP; (unpublished) Doc. No. 723-001	Yes	Bayer CropScience AG

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A7.2.2.2/02	Krebs, B. Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen Hoechst C Produktentwicklung Oekologie 2; Frankfurt, Germany Report No.: A42436 ! DEU88F10631 Not GLP; (unpublished) Doc. No. 723-002	Yes	Bayer CropScience AG
A7.2.2.2/03	Krebs, B. Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen Hoechst C Produktentwicklung Oekologie 2; Frankfurt, Germany Report No.: A42437 ! DEU88F10631 Not GLP; (unpublished) Doc. No. 723-003	Yes	Bayer CropScience AG
A7.2.2.2/04	Krebs, B. Baedelt, H.	1990	Untersuchung des Abbaues im Boden unter Freilandbedingungen Hoechst C Produktentwicklung Oekologie 2; Frankfurt, Germany Report No.: A42438 ! DEU88F10611 Not GLP; (unpublished) Doc. No. 723-004	Yes	Bayer CropScience AG
A7.2.2.3/01	Otto, S.	1976	Crop rotation studies with lettuce and radishes on soil containing aged residues of Carbendazime (2-Methoxycarbonylamino-benzimdazole) Report No.: A07562 Not GLP; (unpublished) Doc. No. 721-001	Yes	Bayer CropScience AG

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A7.2.2.3/02	Süss A. Pritzl E.	1977	Sorption, Abbau und Pflanzenverfügbarkeit von Carbendazim. Zeitschrift für Pflanzenkrankheiten und Pflanzenschutz Zeitschrift für Pflanzenkrankheiten und Pflanzenschutz – Journal of Plant Diseases and Protection: 84 (6): 352-362 Not GLP; (published) Doc. No. 792-002	No	N.R.
A7.2.3.2	Spitzer, T. Bürkle, W.L.	1990	HOE 017411-14C/HOE 093049-14C (Carbendazim/Diethofencarb) - Leaching test in LUFA standard soils 2.1, 2.2 and 2.3 in accordance with BBA-Richtlinie IV, 4-2 Report No.: A47460, BOD96-004545 GLP; (unpublished) Doc. No. 732-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.2.3.2/01	Gildemeister, H. Jordan, H.J.	1981	Versickerungsverhalten des Pflanzenbehandlungsmittels Derosal flüssig (Hoe 17411 0F CI 020) Hoechst Analytical Laboratory, Frankfurt, Germany Report No.: A20913 (B) 10/81 Not GLP; (unpublished) Doc. No. 721-004	Yes	Bayer CropScience AG

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A7.3.1/01	Reisinger, T.	2008	Estimation of the atmospheric residence time of carbendazim using the Atkinson method Scientific Consulting Company, Chemisch-Wissenschaftliche Beratung GmbH, 55234 Wendelsheim, Germany Not GLP; (unpublished) Doc. No. 743-001	Yes	Troy Chemical Company BV
A7.4.1.1	[redacted]	1988	Static acute toxicity of carbendazim technical to Sheepshead minnow, Cyprinodon variegatus Report No. A52917 GLP, unpublished Doc. No. 821-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.4.1.1	Canton, J.H.	1976	The toxicity of benomyl, thiophanat-methyl and BCM to four freshwater organisms Bulletin of Environmental Contamination and Toxicology, Vol. 16 (2): 214-218 Non GLP, published Doc. No. 892-004 **Also cited in A7.4.1.2, A7.4.1.3, A7.4.3.4**	No	N.R.
A7.4.1.1/01	[redacted]	1988	The effect of Carbendazim – substance technical (identification code: Hoe 017411 0F ZD99 0010) to *Cyprinus carpio* (Mirror carp) in a static-acute toxicity test Report No.: A40032 GLP; (unpublished) Doc. No. 821-002	Yes	Bayer CropScience AG

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A7.4.1.1/02	[redacted]	1988	The effect of Carbendazim – substance technical (identification code: Hoe 017411 0F ZD99 0010) to *Salmo gairdneri* (rainbow trout) in a static acute toxicity test Hoechst Pflanzenschutzforschung Biologie, Frankfurt, Germany Report No.: A40135 GLP; (unpublished) Doc. No. 821-001	Yes	Bayer CropScience AG
A7.4.1.2	Baer, K.N.	1992	Static, acute, 48-hour EC50 of DPX-E965-299 (Carbendazim, MBC) to Daphnia magna Report No. A52905 GLP, unpublished Doc. No. 822-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.4.1.2	Hutton, D.G.	1988	Static acute 48-hours EC50 of carbamic acid, 1H-benzimidazol-2-yl-, methyl ester to fed Daphnia magna Report No. A52904 GLP, unpublished Doc. No. 822-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

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A7.4.1.2/01	Fischer, R.	1988	The effect of Carbendazim – substance technical (identification code: Hoe 017411 0F ZD 0010) to *Daphnia magna* (waterflea) in a static-acute toxicity test Hoechst Pflanzenschutz Forschung Biologie, Frankfurt, Germany Report No.: A39285 GLP; (unpublished) Doc. No. 822-001	Yes	Bayer CropScience AG
A7.4.1.3	Heusel, R.	1991	Carbendazim - substance technical (HOE 017411 00 ZD99 0010) Effect to Scenedesmus subspicatus (Green alga) in a growth inhibition test (method OECD) Report No.: A46674 GLP, unpublished Doc. No. 823-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.4.1.3/01	Douglas, M.T. Handley, J.W.	1988	The algistatic activity of Carbendazim tech Report No.: A52909 GLP; (unpublished) Doc. No. 823-001	Yes	Bayer CropScience AG
A7.4.1.3/02	Heusel, R.	1991	Carbendazim-substance technical (HOE 017411 00 ZD99 0010) Effect to Scenedesmus subspicatus (Green alga) in a growth inhibition test (method OECD); Report No. CE91/037, A46674; Doc. No. 823-002; (unpublished)	Yes	Bayer CropScience AG

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A7.4.1.4/01	Seyfried, B.	2005	Toxicity of mergal BCM powder to activated sludge in a respiration inhibition test RCC Ltd., Environmental Chemistry & Pharmanalytics, Itingen, Switzerland Report No.: 854921 GLP; (unpublished) Doc. No. 842-001	Yes	Troy Chemical Company B.V.
A7.4.3.1/01	[redacted]	1988	The effect of Carbendazim – substance technical (identification code: Hoe 017411 0F ZD99 0010) to *Salmo gairdneri* (Rainbow Trout) in a 21-days prolonged toxicity test Hoechst Produktentwicklung Ökologie, Frankfurt, Germany Report No.: A40788 GLP; (unpublished) Doc. No. 826-001	Yes	Bayer CropScience AG
A7.4.3.2/01	[redacted]	1993	Early life-stage toxicity test of DPX-E965-299 (Carbendazim, MBC) with Rainbow Trout (*Oncorhynchus mykiss*) E.I. du Pont de Nemours and Co. Haskell Laboratory for Tox. & Industrial Medicine, Newark, Delaware Report No.: A52478 GLP; (unpublished) Doc. No. 826-002	Yes	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.4.3.3.1 /01	[redacted]	1984	Laboratory Studies of [2-14 C] Carbendazim bioconcentration in Bluegill sunfish E.I. du Pont de Nemours and Co., Inc. Haskell Lab. for Tox. and Industrial Medicine, Newark, Delaware Report: A52919 Not GLP; (unpublished) Doc. No. 872-001	Yes	Bayer CropScience AG
A7.4.3.4	Baer, K.N.	1992	Chronic toxicity of DPX-E965-299 (Carbendazim, MBC) to Daphnia magna Report No.: A52907 GLP, unpublished Doc. No. 827-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.4.3.4	Hutton, D.G.	1988	Chronic toxicity of Carbamic acid, 1H-benzimidazol-2-yl, methyl ester to Daphnia magna Report No.: A52908 GLP, unpublished Doc. No. 827-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.4.3.4/01	Fischer, R.	1988	The effect of carbendazim - substance technical (identification code: Hoe 017411 0F ZD99 0010) to *Daphnia magna* (Waterflea) in a 21-day reproduction test (method OECD) Hoechst, Frankfurt, Germany Report: A41208 GLP; (unpublished) Doc. No. 827-001	Yes	Bayer CropScience AG
A7.4.3.5.1/01	Sowig, P. Gosch, H.	2002	Chronic toxicity to the sediment dwelling chironomid larvae *Chironomus riparius*-Carbendazim; water miscible suspension Aventis CropScience GmbH Ökotoxikologie, Frankfurt,Germany Report No.: CE01/093, C018793 GLP; (unpublished) Doc. No. 828-001	Yes	Bayer CropScience AG
A7.5.1.1	Ramakrishna, C. Gowda, T.K.S. Sethunatahan, N.	1979	Effect of benomyl and its hydrolysis products, MBC and AB on nitrification in a flooded soil Bulletin of Environmental Contamination Toxicology, 21 (1979): 328-333 Non GLP, published Doc. No. 892-005	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.1.1/01	McMurray, A.	1999	Carbendazim-Suspension concentrate 500 g/L: A laboratory assessment of the effects of AE F01741100 SC42 A205 on soil microflora respiration and nitrogen transformation Chemex International plc., Cambridge, UK Report No.: ENV4576!C005934, BMF2000-7 GLP; (unpublished) Doc. No. 841-001	Yes	Bayer CropScience AG
A7.5.1.2	Ellis, S.R. Hodson, M.E. Wege, P.	2007	The influence of different artificial soil types on the acute toxicity of carbendazim to the earthworm *Eisenia fetida* in laboratory toxicity tests European Journal of Soil Biology, 43, 239-245 Not GLP; (published) Doc. No. 892-003	No	N.R.
A7.5.1.2/01	Vonk, J.W. Adema, D.M.M. Barug, D.	1986	Comparison of the effects of several chemicals on microorganisms, higher plants and earthworms Contaminated Soil; Assink, J.W., van den Brink, J. (eds.), 191-201 Report No.: ARW96-00048 Not GLP; (published) Doc. No. 892-001 **Also cited in A7.5.1.3**	No	N.R.
A7.5.1.3/01	Vonk, J.W., Adema, D.M.M., Barug, D.	1986	Comparison of the effects of several chemicals on microorganisms, higher plants and earthworms; In: Contaminated Soil, Assink, J.W., van den Brink, J. (eds.), 191-201; Report No.: ARW96-00048; Doc. No. 828-001; (published)	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.2.1	Lührs, U.	2003	Effects of Derosal SC360 on reproduction and growth of earthworms Eisenia fetida in artifical soil and 1st Amendment to final report IBACON GmbH, Rossdorf, Germany Project No.: 15071022; C039272 GLP, unpublished Doc. No. 833-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.5.2.1	Lührs, U.	2001	Carbendazim/Flusilazole (DPX-N7872) SE (1:2): Effects on reproduction and growth of the earthworm Eisenia fetida (Savigny 1826), in artificial soil Project No. 10111022, C039273 GLP, unpublished Doc. No. 833-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.5.2.1	Lührs, U	2001	Effects of Derosal SC 360 on reproduction and growth of earthworms Eisenia fetida (Savigny 1826) in artificial soil; IBACON, Rossdorf, Germany Report No. 9801022, C039275 GLP, unpublished Doc. No. 833-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG

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A7.5.2.1	Heusel, R.	1993	Carbendazim -substance technical (Hoe 017411 00 ZD99 0010). Effect of Folsomia candida (springtails) in a 28 day test in artificial soil (method OECD/ISO draft) Report No. A51540 GLP, unpublished Doc. No. 835-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bayer CropScience AG
A7.5.2.1/01	Lührs, U.	2001	Effects of Derosal SC360 on Reproduction and Growth of Earthworms *Eisenia fetida* in artificial soil IBACON, GmbH, Rossdorf, Germany Report No.: 12621022 GLP; (unpublished) Doc. No. 833-002	Yes	Bayer CropScience AG
A7.5.2.1/02	Van Gestel, C.A.M. et al.	1992	Comparison of sublethal and lethal criteria for nine different chemicals in standardized toxicity tests using the earthworm *Eisenia andrei*; Ecotoxicology and Environmental Safety, 23, 206-220 Report No.: ARW96-00039 Not GLP; (published) Doc. No. 892-002	No	N.R.

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.2.1/03	Sowig, P.	2001	Effects on growth and reproduction of earthworms (*Eisenia fetida*) Carbendazim; water miscible suspension concentrate; 500 g/L Aventis CropScience GmbH Ökotoxikologie, Frankfurt, Germany Report No.: CE01/041, ARW2001-53 GLP; (unpublished) Doc. No. 833-003	Yes	Bayer CropScience AG

*key study

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Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/ No)	Owner
B4.1/01	Anonymous	1982	CIPAC Method- Carbendazim CIPAC 263/TC/M/-, Handbook E: 61-66, Not GLP.; published Doc. No. 421-001	No	N.R.
B7.1.1/01	Klamer, M. Venås, T.M.	2008	Field Leaching Study of Carbendazim from Painted Wood Surfaces Exposed to Outdoor Conditions (natural rain) – up to 720 mm rainfall Danish Technological Institute, Taastrup, DK Project: 1006657-17, Ordner No.: 194447-1 Not GLP; (unpublished) Doc. No. 732-004	Yes	Troy Chemical Company BV
B7.1.1/01	Venås, T.M.	2009	Field Leaching Study of Carbendazim from Painted Wood Surfaces Exposed to Outdoor Conditions (natural rain) – up to 951 mm rainfall; Danish Technological Institute, Taastrup, Denmark Project: 1006657-17, Ordner No.: 194447-1 Not GLP; (unpublished) Doc. No. 732-005	Yes	Troy Chemical Company BV
B7.1.1/01	Klamer, M.	2012	Field Leaching Study of Carbendazim from Painted Wood Surfaces Exposed to Outdoor Conditions (natural rain) – up to 2836 mm rainfall Danish Technological Institute, Taastrup, DK Project: 1006657-26, Ordner No.: 194447-1 Not GLP; (unpublished) Doc. No. 732-008 (update of the report Doc. No. 732-004	Yes	Troy Chemical Company BV