Committee for Risk Assessment

RAC

Annex 1

Background document

to the Opinion proposing harmonised classification and labelling at EU level of

carbendazim (ISO); methyl benzimidazol-2-ylcarbamate

EC Number: 234-232-0
CAS Number: 10605-21-7

CLH-O-0000006717-65-01/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

5 December 2019

CLH report

Proposal for Harmonised Classification and Labelling

**Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2**

International Chemical Identification:

carbendazim (ISO);
methyl benzimidazol-2-ylcarbamate

EC Number: **234-232-0**

CAS Number: **10605-21-7**

Index Number: **613-048-00-8**

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ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON CARBENDAZIM (ISO); METHYL BENZIMIDAZOL-2-YLCARBAMATE

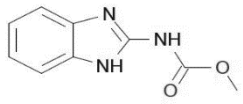
CONTENTS

ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON CARBENDAZIM (ISO); METHYL BENZIMIDAZOL-2-YLCARBAMATE

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	methyl 1H-benzimidazol-2-ylcarbamate
Other names (usual name, trade name, abbreviation)	Carbamic acid, N-1H-benzimidazol-2-yl-, methyl ester
ISO common name (if available and appropriate)	Carbendazim (ISO)
EC number (if available and appropriate)	234-232-0
EC name (if available and appropriate)	Carbendazim
CAS number (if available)	10605-21-7
Other identity code (if available)	CIPAC No.: 263
Molecular formula	$C_9H_9N_3O_2$
Structural formula	
SMILES notation (if available)	COC(=O)Nc1nc2ccccc2[nH]1
Molecular weight or molecular weight range	191.21 g/mol

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	**Concentration range (% w/w minimum and maximum in multi-constituent substances)**	**Current CLH in Annex VI Table 3.1 (CLP)**	**Current self-classification and labelling (CLP)**
Carbendazim methyl benzimidazol-2-ylcarbamate CAS NO: 10605-21-7	< 99.0 %(w/w)	Muta. 1B H340 Repr. 1B H360FD Aquatic Acute 1 H400 Aquatic Chronic 1 H410	

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)	The impurity contributes to the classification and labelling
3-amino-2-hydroxyphenazine (AHP) CAS NO: 4569-77-1	0.00003 %(w/w)	-	**https://echa.europa.eu/information-on-chemicals/annex-iii-inventory/-/dislist/details/AIII-100.121.272**	

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
None					

Table 5: Test substances (non-confidential information) (this table is optional)

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)	Other information	The study(ies) in which the test substance is used

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6:

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H340 H360FD H400 H410	GHS08 GHS09 Dgr	H340 H360FD H410			
Dossier submitters proposal	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	**Add** Skin Sens. 1 **Retain** Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	**Add** H317 **Retain** H340 H360FD H400 H410	**Add** GHS07 **Retain** GHS08 GHS09 Dgr	**Add** H317 **Retain** H340 H360FD H410		**Add** M = 10 (acute) M = 10 (chronic)	
Resulting Annex VI entry if agreed by RAC and COM	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H340 H360FD H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H340 H360FD H317 H410		M = 10 (acute) M = 10 (chronic)	

Table 7: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	Data conclusive but not sufficient for classification	Yes
Flammable gases (including chemically unstable gases)	Hazard class not applicable (solid)	No
Oxidising gases	Hazard class not applicable (solid)	No
Gases under pressure	Hazard class not applicable (solid)	No
Flammable liquids	Hazard class not applicable (solid)	No
Flammable solids	Data inconclusive	Yes
Self-reactive substances	Data inconclusive	Yes
Pyrophoric liquids	Hazard class not applicable (solid)	No
Pyrophoric solids	Data conclusive but not sufficient for classification	Yes
Self-heating substances	Data inconclusive	Yes
Substances which in contact with water emit flammable gases	Data conclusive but not sufficient for classification	Yes
Oxidising liquids	Hazard class not applicable (solid)	No
Oxidising solids	Data conclusive but not sufficient for classification	Yes
Organic peroxides	Data conclusive but not sufficient for classification	Yes
Corrosive to metals	Hazard class not applicable (solid)	No
Acute toxicity via oral route	hazard class not assessed in this dossier	No
Acute toxicity via dermal route	hazard class not assessed in this dossier	No
Acute toxicity via inhalation route	hazard class not assessed in this dossier	No
Skin corrosion/irritation	hazard class not assessed in this dossier	No
Serious eye damage/eye irritation	hazard class not assessed in this dossier	No
Respiratory sensitisation	hazard class not assessed in this dossier	No
Skin sensitisation	harmonised classification proposed	Yes
Germ cell mutagenicity	hazard class not assessed in this dossier	No
Carcinogenicity	hazard class not assessed in this dossier	No
Reproductive toxicity	hazard class not assessed in this dossier	No
Specific target organ toxicity-single exposure	hazard class not assessed in this dossier	No
Specific target organ toxicity-repeated exposure	hazard class not assessed in this dossier	No
Aspiration hazard	hazard class not assessed in this dossier	No

Hazard class	Reason for no classification	Within the scope of public consultation
Hazardous to the aquatic environment	harmonised classification proposed	Yes
Hazardous to the ozone layer	hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Carbendazim is an active substance currently authorized for the use in biocidal products, whereas the authorization for the use in plant protection products has been expired.

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. However, for the appropriate classification of mixtures (products) multiplying factors (M-factors) are needed, generally listed in Annex VI for substances with a harmonised classification.

Currently no harmonised M-factors are available. Hence, the aim of the present CLH dossier is the harmonisation and inclusion of M-factors for carbendazim in Annex VI.

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

The substance is an active substance in the meaning of Regulation EC 1107/2009 and Regulation (EU) No 528/2012. Such substances shall normally be subject to harmonised classification and labelling, and no further justification is required. (Article 36 CLP Regulation).

Carbendazim has a harmonised classification as Muta. 1B and Repr. 1B; H360FD. Classification as Skin Sens. 1 was additionally proposed by the evaluating competent authoritiy during the biocide review program under Regulation (EU) No 528/2012. Hence, skin sensitisation is subject to the present CLH dossier.

Currently no harmonised M-factors are available for the harmonised classification Aquatic Acute 1 and Aquatic Chronic 1. Hence, the aim of the present CLH dossier is the harmonisation and inclusion of M-factors for carbendazim in Annex VI, based on data evaluated within the framework of substance authorisation for the use in biocidal products (referred to as key data).

Valid and reliable data presented in the Draft Re-Assessment Report are presented for information only. These additional studies represent supporting data and have not been evaluated in detail for harmonisation of the M-factors, as they would not change the result.

5 IDENTIFIED USES

The substance is used as an active substance in plant protection and biocidal products in film preservatives, fibre, leather, rubber and polymerised materials preservatives and in construction material preservatives.

6 DATA SOURCES

As of November 2017 there are no active registrations for carbendazim under the REACH regulation. The balance of information included in this report comes from the Competent Authorities Draft Assessment Report (DAR) created under the Biocidal Product Regulation (BPR). The substance has also previously been approved as a plant protection product and further information from the final assessment report have been included.

7 PHYSICOCHEMICAL PROPERTIES

Table 8: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	Sand-coloured, odourless crystalline powder	(Albrecht and Kappes, 1975)	Visual respectively olfactory assessment
Melting/freezing point	No melting point; Decomposition at 217 °C before melting	(Cowlyn, 2011)	OECD Method 102/ EEC Method A.1 (Metal block)
Boiling point	Not applicable (Decomposition at 217 °C before melting)		
Relative density	1.45 at 20 °C	(Ertel, 1976)	OECD 109 equivalent to 92/69/EEC, A.3 (pycnometer method)
Vapour pressure	9 x 10^{-5} Pa at 20 °C	(Grewer, 1987)	OECD 104 equivalent to 92/69/EEC, A.4 (vapour pressure balance)
Surface tension	72.5 mN/m Temperature: at 20 °C; 90 % saturated concentration	(Cowlyn, 2009)	OECD 115 equivalent to 92/69/EEC, A.5 (ring method)
Water solubility	pH 4: 29 mg/l at 24 °C pH 7: 8 mg/l at 24 °C pH 8: 7 mg/l at 24 °C	(Gorbach, 1971)	UV-spectrometric determination
Partition coefficient n-octanol/water	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	(Singh, 1988)	according to OECD 107 equivalent to 92/69/EEC, A.8 (shaking method)
Stability in organic solvents and identity of relevant degradation products			Not relevant: Model formulation is water based.
Dissociation constant	pKa: 4.2	(Appel, 1988)	OECD 112 (Titration method)
Viscosity			This data is only required for liquid substances and carbendazim is a solid.

8 EVALUATION OF PHYSICAL HAZARDS

8.1 Explosives

Table 9: Summary table of studies on explosive properties

Method	Results	Remarks	Reference
92/69/EEC, Method A.14	not explosive	Based on the theoretical assessment of the	Reisinger, T. (2008)

Method	Results	Remarks	Reference
		chemical structure.	

8.1.1 Short summary and overall relevance of the information provided on explosive properties

No tests were performed because explosive properties of the substance can be excluded by an evaluation of the chemical structures:

The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties with reference to the screening procedures in Appendix 6 of the UN-MTC, see Table A6.1.

8.1.2 Comparison with the CLP criteria

Data waiving is acceptable: A substance or mixture shall not be classified as explosive in accordance with section 2.1.4.3 of Annex I to Regulation (EC) No 1272/2008, if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria; […]

8.1.3 Conclusion on classification and labelling for explosive properties

Classification and labelling is not required.

8.2 Flammable gases (including chemically unstable gases)

Hazard class not applicable (solid).

8.3 Oxidising gases

Hazard class not applicable (solid).

8.4 Gases under pressure

Hazard class not applicable (solid).

8.5 Flammable liquids

Hazard class not applicable (solid).

8.6 Flammable solids

Table 10: Summary table of studies on flammable solids

Method	Results	Remarks	Reference
Hoechst internal Directives of 1973-10-01	Not highly flammable	Evaluation: 3 (topical burning or glowing without diffusion)	Albrecht, Lehr, W. (1975) Report No.: A11451

8.6.1 Short summary and overall relevance of the provided information on flammable solids

A study was performed according to a method of the company's internal Directives, which was not included within the report. Discrepancies exist in the Draft Assessment Report, as the study refers to

Directive 92/69/EEC, Method A.10, however the study was performed in 1975, when Method A.10 was not implemented yet to Directive 67/548/EEC.

8.6.2 Comparison with the CLP criteria

A substance (non-metal powder) is classified as a flammable solid when the burning time is less than 45 seconds or the burning rate is more than 2.2 mm/s, by using UN Test N.1 of the UN RTDG, Manual of Tests and Criteria. As the test item could be ignited by an ignition source not further specified, the classification criteria on the burning rate cannot be evaluated because only the burning behavior is mentioned in the test report. Referring to the Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) in section 2.7.4.2., the burning index (referred to as 'class number' in VDI 2263) as obtained from the Burning Behaviour test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) may be used as screening method. If a burning index of 3 or less is found, the substance or mixture should not be classified as a flammable solid and no further testing is required. However, if smouldering or a flame is observed, the full test must be carried out. As the test report has no details on the test procedure it is not possible to come to a conclusion on the classification.

8.6.3 Conclusion on classification and labelling for flammable solids

The data is inconclusive.

8.7 Self-reactive substances

Table 11: Summary table of studies on self-reactivity

Method	Results	Remarks	Reference
Differential scanning calorimetry (DSC) EEC Method A1, OECD Method 102, OECD Method 113	Decomposition starts at 217°C before melting		Cowlyn, N. (2011)

8.7.1 Short summary and overall relevance of the provided information on self-reactive substances

Carbendazim undergoes thermal decomposition in air and nitrogen atmospheres as tests were performed using a differential scanning calorimetry (DSC). Carbendazim started to decompose at 217°C with further thermal effects at approximately 230°C. Decomposition was complete at a temperature of approximately 280°C. However, in the DSC-measurements aluminium crucibles were used with a perforated lid, therefore no exothermic decomposition energy could be determined.

8.7.2 Comparison with the CLP criteria

Data waiving is acceptable in accordance with the given definition of self-reactive substance in section 2.8.2.1 of Annex I to Regulation (EC) No 1272/2008:

(a) they are explosives, according to the criteria given in 2.1;

(b) they are oxidising liquids or solids, according to the criteria given in 2.13 or 2.14, except that mixtures of oxidising substances, which contain 5% or more of combustible organic substances shall be classified as self-reactive substances according to the procedure defined in 2.8.2.2;

(c) they are organic peroxides, according to the criteria given in 2.15;

(d) their heat of decomposition is less than 300 J/g; or

(e) their self-accelerating decomposition temperature (SADT) is greater than 75°C for a 50 kg package (See UN RTDG, Manual of Test and Criteria, sub-sections 28.1, 28.2, 28.3 and Table 28.3.)

8.7.3 Conclusion on classification and labelling for self-reactive substances

Study cannot be used for non-classification as the data is inconclusive. The onset temperature and decomposition energy is required using a suitable calorimetric technique (see Part II, sub-section 20.3.3.3 of the UN RTDG, Manual of Tests and Criteria) to confirm that heat of decomposition is less than 300 J/g.

8.8 Pyrophoric liquids

Hazard class not applicable (solid).

8.9 Pyrophoric solids

8.9.1 Short summary and overall relevance of the provided information on pyrophoric solids

The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.

8.9.2 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for pyrophoric solids need not be applied in accordance with section 2.10.4 of Annex I to Regulation (EC) No 1272/2008, when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)).

8.9.3 Conclusion on classification and labelling for pyrophoric solids

Classification and labelling is not required.

8.10 Self-heating substances

Table 12: Summary table of studies on self-heating substances

Method	Results	Remarks	Reference
Hoechst internal Directives of 1973-10-01	No spontaneous ignition up to 400 °C		Albrecht, Lehr, W. (1975) Report No.: A11454

8.10.1 Short summary and overall relevance of the provided information on self-heating substances

A study was performed according to a method of the company's internal Directives, which was not included within the report. Discrepancies exist in the Draft Assessment Report, as the study refers to Directive 92/69/EEC, Method A.16, however the study was performed in 1975, when Method A.16 was not implemented yet to Directive 67/548/EEC.

8.10.2 Comparison with the CLP criteria

The Guidance on the Application of the CLP Criteria states that EU test method A.16 as described in Regulation (EC) No 440/2008 checks for self-heating properties. However, the method used is generally inappropriate for a sound assessment, and the findings do not lead to a classification. Therefore, special care must be taken if results from EU test method A.16 are interpreted towards a CLP classification for self-heating substances and mixtures. Self-heating is a very complex phenomenon which is influenced by many parameters (some of them being volume, temperature, particle shape and size, heat conductivity and bulk density). Therefore, self-heating behaviour cannot be predicted from any theoretical model. In some cases, properties might even differ between producers of seemingly very similar substances or mixtures. Differences in self-heating behaviour are especially to be anticipated where surface treatment occurs in the production process. Hence, all data sources should be carefully evaluated with regard to reliability and scientific validity.

According to CLP criteria, a self-heating substance is classified in one of the two categories following the results of the UN Test N.4 described in Part III, Sub-section 33.3.1.6 of the UN RTDG, Manual of Tests and Criteria.

8.10.3 Conclusion on classification and labelling for self-heating substances

The data is inconclusive.

8.11 Substances which in contact with water emit flammable gases

8.11.1 Short summary and overall relevance of the provided information on substances which in contact with water emit flammable gases

The study does not need to be conducted because the substance is known to be soluble in water to form a stable mixture.

8.12 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for this class need not be applied in accordance with section 2.12.4 of Annex I to Regulation (EC) No 1272/2008, if:

(a) the chemical structure of the substance or mixture does not contain metals or metalloids; or

(b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or

(c) the substance or mixture is known to be soluble in water to form a stable mixture.

8.12.1 Conclusion on classification and labelling for substances which in contact with water emit flammable gases

Classification and labelling is not required.

8.13 Oxidising liquids

Hazard class not applicable (solid).

8.14 Oxidising solids

Table 13: Summary table of studies on oxidising solids

Method	Results	Remarks	Reference
Expert Statement	Not oxidising		Maier, Rexer, (1990)

8.14.1 Short summary and overall relevance of the provided information on oxidising solids

No tests were performed because oxidizing properties of the substance can be excluded by an evaluation of the chemical structures:

The study does not need to be conducted because the organic substance contains oxygen or halogen atoms which are chemically bonded only to carbon or hydrogen and hence, the classification procedure does not need to be applied.

8.14.2 Comparison with the CLP criteria

Data waiving is acceptable: For organic substances or mixtures the classification procedure for this class shall not apply in accordance with section 2.14.4 of Annex I to Regulation (EC) No 1272/2008, if:

(a) the substance or mixture does not contain oxygen, fluorine or chlorine; or

(b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

8.14.3 Conclusion on classification and labelling for oxidising solids

Classification and labelling is not required.

8.15 Organic peroxides

8.15.1 Short summary and overall relevance of the provided information on organic peroxides

The study does not need to be conducted because the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.

8.15.2 Comparison with the CLP criteria

Data waiving is acceptable in accordance with the given definition of organic peroxides in section 2.15.1.1 of Annex I to Regulation (EC) No 1272/2008:

Organic peroxides mean liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide. Organic peroxides are thermally unstable substances or mixtures, which can undergo exothermic self-accelerating decomposition. In addition, they can have one or more of the following properties:

(i) be liable to explosive decomposition;

(ii) burn rapidly;

(iii) be sensitive to impact or friction;

(iv) react dangerously with other substances.

8.15.3 Conclusion on classification and labelling for organic peroxides

Classification and labelling is not required.

8.16 Corrosive to metals

Hazard class not applicable (solid).

The study does not need to be conducted because there is no established suitable test method for solid substances.

RAC evaluation of physical hazards

Summary of the Dossier Submitter's proposal

The dossier submitter (DS) proposed no classification of carbendazim for physical hazards on the basis of the following data:

Property and Method	Results	Remarks	Reference
Explosives screening procedures in Appendix 6 of the UN-MTC, Table A6.1	Examination of the structure indicates that there are no chemical groups associated with explosive properties. Not explosive	Statement: Based on the theoretical assessment of the chemical structure	Reisinger, 2008
Flammability (solids) Method: Hoechst internal Directives of 1973-10-01 similar to EEC A.10	Not highly flammable	Evaluation: Class 3 (topical burning or glowing without diffusion) Details concerning the used methods and the purity of the tested material is not available	Albrecht and Lehr, 1975
Self-ignition temperature Hoechst internal Directives of 1973-10-01 similar to EEC A.16	No spontaneous ignition up to 400°C	-	Albrecht and Lehr, 1975
Oxidising properties (solids)	Not oxidising	Statement: Based on the theoretical assessment of the chemical structure	Maier and Rexer, 1990
Self-reactive substances	Not self-reactive properties	Statement: Based on the theoretical assessment of the chemical structure	
Pyrophoric solids	Not pyrophoric properties	Statement: Based on experience in manufacturing and handling	

Comments received during public consultation

There were no comments provided.

Assessment and comparison with the classification criteria

Explosives

According to Annex I: 2.1.4.3 of the CLP Regulation a substance is not classified as explosive when there are no chemical groups associated with explosive properties present in the molecule. Taking into account that carbendazim does not contain chemical groups associated with explosive properties it does not warrant classification as an explosive substance.

Flammable solids

Carbendazim was considered as 'not highly flammable' in an experimental study (Albrecht and Lehr, 1975) similar to A.10. Although, the hazard class should be assessed in accordance with the test method described in Part III, sub-section 33.2.1, of the UN RTDG, Manual of Tests and Criteria: powdered, granular or pasty substances shall be classified as readily combustible solids when the time of burning of one or more of the test runs, is less than 45 seconds or the rate of burning is more than 2.2 mm/s.

However, according to chapter R.7.1.10.3 of Guidance on Information Requirements and Chemical Safety Assessment (R.7a): *If available data from an A.10 test method indicate that a classification as a flammable solid does not apply (result: not highly flammable), no more testing is necessary. However, if the A.10 test method has come to the conclusion 'highly flammable', it will be necessary to also determine the influence of the wetted zone as described in the UN Test N.1.* Since the result of test method similar to A.10 performed with carbendazim was 'not highly flammable' the classification as flammable solids is not warranted.

Self-reactive substances

The classification procedures for self-reactive substances and mixtures need not be applied in accordance with section 2.8.4.2 of Annex I to CLP Regulation if there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria.

Taking into account that carbendazim does not contain chemical groups associated with explosive and self-reactive properties it does not warrant classification as a self-reactive substance.

Pyrophoric solids

In accordance with section 2.10.4 of Annex I to CLP Regulation, the classification procedure for pyrophoric solids needs not to be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)).

Carbendazim is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, it does not warrant classification as a pyrophoric solid.

Self-heating substances

No spontaneous ignition up to 400°C was reported in the experimental study (Albrecht and Lehr, 1975) carried out according to a method similar to EEC A.16. The hazard class should be assessed using method N.4 in Part III of the UN RTDG manual of test and procedure, where the substance is heated up to 140°C. If the result of this test is negative no further test is necessary. There is a difference in volume-to-surface ratio (5:1) in the tested sample between the N.4 test (100 mm sample cube) and the A.16 test (20 mm sample cube), and increased volume-to-surface ratio leads to less efficient removal of heat from the centre of the sample. Diversely, in method A.16 the substance is heated up to 400°C. RAC considers that the difference in sample size is compensated by the difference in temperature between the two methods.

Furthermore, according to chapter R.7.1.10.7 of Guidance on Information Requirements and Chemical Safety Assessment (R.7a): *the study (N.4) does not need to be conducted for solids if preliminary results exclude self-heating of the substance up to 400°C and if available data from a test according to method A.16 indicate that a classification as a self-heating substance does not apply, no more testing is necessary. Only in case of positive result with A.16 test method, the appropriate UN test method is required to confirm classification.*

Overall, as carbendazim did not ignite up to 400°C, it does not warrantclassification as a self-heating substance.

Substances which in contact with water emit flammable gases

In accordance with section 2.12.4 of Annex I to CLP Regulation, the classification procedure for this class need not be applied if:

a) the chemical structure of the substance or mixture does not contain metals or metalloids; or
b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or
c) the substance or mixture is known to be soluble in water to form a stable mixture.

Carbendazim fulfils all of the above criteria, therefore it does not warrant classification as a substance which emits flammable gases in contact with water.

Organic peroxides

The substance does not contain peroxide groups, and therefore classification is not warranted.

Oxidising solids

For organic substances or mixtures the classification procedure for this class shall not apply in accordance with section 2.14.4 of Annex I to CLP Regulation, if:

a) the substance or mixture does not contain oxygen, fluorine or chlorine; or
b) the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

Carbendazim fulfils criterion (b), above, therefore it does not warrant classification as an oxidising solid.

In conclusion, RAC supports the proposal of the DS for **no classification of carbendazim as regards physical hazards**.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not assessed in this dossier.

10 EVALUATION OF HEALTH HAZARDS

10.1 Acute Toxicity – oral route

Not assessed in this dossier.

10.2 Acute toxicity - dermal route

Not assessed in this dossier.

10.3 Acute toxicity - inhalation route

Not assessed in this dossier.

10.4 Skin corrosion/irritation

Not assessed in this dossier.

10.5 Serious eye damage/eye irritation

Not assessed in this dossier.

10.6 Sensitisation

10.6.1 Skin sensitisation

10.6.1.1 Non-human information

Table 14: Summary table of relevant skin sensitisation studies with carbendazim

Method Guideline Reliability GLP Deviations if any	**Species (Strain) Sex, no/group**	**Test substance (purity) Positive control Vehicle Concentrations**	**Result**	**Reference**
OECD Guideline TG	Guinea pig (Dunkin/Hartley)	Carbendazim (purity 99.5 %)	Dermal induction and challenge	Anonymous

Method Guideline Reliability GLP Deviations if any	**Species (Strain) Sex, no/group**	**Test substance (purity) Positive control Vehicle Concentrations**	**Result**	**Reference**
406 (Skin sensitisation; (Guinea Pig Maximisation Test)) Reliability: 1 GLP: Yes Deviations: No	10 males/ treatment group 5 males/control group	Positive control: no concurrent Vehicle for induction and challenge: Alembicol D Adjuvant: yes (50 % FCA in water) <u>Induction</u> Day 0 (intradermal injection): 5 % (w/v) carbendazim in vehicle Day 7 (topical, occlusive for 48 h): 62.5 % (w/v) carbendazim in vehicle <u>Challenge</u> Day 21 (topical, occlusive for 24 h): 62.5 % and 31.25 % carbendazim in vehicle	induced slight skin erythema indicative of skin sensitisation in 4 out of 10 treated animals.	(1997)
OECD Guideline TG 406 (Skin sensitisation (Buehler test)) Reliability: 2 GLP: Yes Deviation: 9 inductions, challenge treatment was conducted on day 37 instead of day 27-29	Guinea pig (Pirbright-White) 20 females/ treatment group 10 females/ control	Carbendazim (purity: 99.4 %) Positive control: None Vehicle for induction and challenge: Petrolatum <u>Induction</u> Day 1, 3, 5, 8, 10, 12, 15, 18, 19 (dermal, occlusive for 6 h): 50 % (w/v) carbendazim in vehicle <u>Challenge</u> Day 37 (topical, occlusive for 6 h): 50 % (w/v) carbendazim in vehicle	Carbendazim has no skin sensitizing effect on guinea pigs in the modified Buehler test (9 inductions).	Anonymous (1987)
Non- Guideline (Primary skin irritation and sensitization test on guinea pigs) Reliability: 2 GLP: No Main deviations: test was performed with 10 instead 20 animals, no	Guinea pig (strain not specified) 10 males/treatment group 10/ males control	Carbendazim (purity 98 % %) Positive control: None Vehicle for induction: dimethyl phthalate Vehicle for challenge: Acetone <u>Induction</u> Four intradermal injections, one each week over a period of three weeks: 1 % (w/v) carbendazim in vehicle <u>Challenge</u> After two weeks rest: 40 % and 4 % in vehicle	Carbendazim did not produce dermal irritation or sensitisation in guinea pigs under the conditions tested.	Anonymous (1976b)

Method Guideline Reliability GLP Deviations if any	**Species (Strain) Sex, no/group**	**Test substance (purity) Positive control Vehicle Concentrations**	**Result**	**Reference**
local irritiation was created with sodium lauryl sulphate, challenge was performed after 2 weeks instead of 3 or 4 weeks, no information on the sensitivity and reliability of the experimental technique		(topical)		

*Key study; FCA: Freunds Complete Adjuvans

Guinea Pig Maximisation Test (GPMT) (Anonymous (1997))

In the GLP- and guideline-conform guinea pig maximisation test (GPMT) ten male guinea pigs were intradermally injected on day 0 with 5 % (w/v) carbendazim in the vehicle Alembicol D, Freunds Complete Adjuvans (FCA) and a mixture of both. Six days later the area was pretreated for 24 h with 0.5 ml 10 % sodium lauryl sulphate in petrolatum to produce skin irritation and therefore to enhance penetration. On day 7 topical exposure to 62.5 % carbendazim in vehicle for 48 hours (occlusive) was performed. Five male control animals were treated similarly, but with vehicle alone. The main application scheme and the resulting dermal reactions after induction treatment in test and control animals are summarized in Table 15.

Two weeks after the topical application all animals were challenged with 62.5 % and 31.25 % carbendazim in the vehicle Alembicol D (24 h, occlusive). Evaluation and scoring was performed at 24, 48 and 72 h after patch removal. At the challenge concentration of 62.5 % carbendazim in vehicle 1/10 animals showed a sensitisation reaction 24 hours after the patch test, 4/10 animals after 48 hours and 3/10 animals at 72 hours after the test. At the challenge concentration of 31.25 % carbendazim in vehicle, 0/10 animals showed a sensitisation reaction 24 hours after the patch test, 3/10 animals after 48 hours and still 3/10 after 72 hours after the test (Table 17). No animal of the control group showed any positive reactions at challenge (Table 16). In summary, the test revealed a skin sensitisation reaction in 4 out of 10 test animals.

There was no concurrent positive control but the performance of the assay in the laboratory was periodically checked and revealed the following results: benzocaine: 6/10 animals sensitised; α-hexylcinnamaldehyde: 10/10 animals sensitised; 2-mercaptobenzthiazol: 10/10 animals sensitised. No signs of ill health or toxicity were recorded, body weights increased in all guinea pigs over the period of the study.

Conclusion: Overall carbendazim technical (purity 99.5 %) is considered to be a skin sensitiser in this study.

Table 15: Dermal reactions following the induction applications with carbendazim technical (Anonymous 1997)

Site	Intradermal injection (Day 0)			Topical application (Day 7)		
	Application solution	Test animals	Control animals	Application solution	Test animals	Control animals
1	50 % FCA in water	Necrosis	Necrosis	62.5 % (w/v) carbendazim in vehicle (test animals) or vehicle only (control animals)	Slight erythema	Slight erythema
2	5 % (w/v) carbendazim in vehicle (test animals) or vehicle only (control animals)	Slight irritation	Slight irritation			
3	FCA + carbendazim in vehicle (test animals) or FCA + vehicle (control animals)	Necrosis	Necrosis			

FCA: Freunds Complete Adjuvans

Table 16: Dermal reactions following the challenge applications with carbendazim technical –control animals (Anonymous 1997)

Animal number	E= Erythema O=Oedema	Score					
		24 h		48 h		72 h	
		A	P	A	P	A	P
45	E O	0 0	0 0	0 0	0 0	Not indicated	
46	E O	0 0	0 0	0 0	0 0		
47	E O	0 0	0 0	0 0	0 0		
48	E O	0 0	0 0	0 0	0 0		
49	E O	0 0	0 0	0 0	0 0		

0: No erythema or no oedema;
A: Anterior site exposed to carbendazim technical 62.5 % w/v in Alembicol D
P: Posterior site exposed to carbendazim technical 31.25 % w/v in Alembicol D

Table 17: Dermal reactions following the challenge applications with carbendazim technical (Anonymous 1997)

Animal number	E= Erythema O=Oedema	Score					
		24 h		48 h		72 h	
		A	P	A	P	A	P
50	E O	0 0	0 0	0 0	0 0	0 0	0 0
51	E O	0 0	0 0	0 0	0 0	0 0	0 0
52	E O	0 0	0 0	0 0	0 0	0 0	0 0
53	E O	0 0	0 0	0 0	0 0	0 0	0 0
54 positive	E O	0 0	0 0	1 0	1 0	0 0	1 0
55	E O	0 0	0 0	0 0	0 0	0 0	0 0
56	E O	0 0	0 0	0 0	0 0	0 0	0 0
57 positive	E O	1 1	0 0	1 1	1 0	1 0	1 0
58 positive	E O	0 0	0 0	1 0	1 0	1 0	1 0

Animal number	E= Erythema O=Oedema	Score					
		24 h		48 h		72 h	
		A	P	A	P	A	P
59 positive	E	0	0	1	0	1	0
	O	0	0	1	0	0	0

0: No erythema or no oedema; 1: Slight erythema or slight oedema
A: Anterior site exposed to carbendazim technical 62.5 % w/v in Alembicol D
P: Posterior site exposed to carbendazim technical 31.25 % w/v in Alembicol D

Modified Buehler test (Anonymous (1987))

The skin sensitising properties of carbendazim were also determined in a modified Buehler test based on OECD TG 406. Twenty female guinea pigs were dermally treated with test substance at 50 % in petrolatum (occlusive for 6 hours) on days 1, 3, 5, 8, 10, 12, 15, 18 and 19. Ten control animals were treated similarly but with vehicle only. On day 37 all animals were challenged with 50 % test substance and vehicle (occlusive for 6 hours). Examination at two designated time points (24 and 48 hours after treatment) showed that challenge treatment caused no changes in the treated skin areas in the treatment or control group. Carbendazim technical (purity 99.4 %) is considered not to be a skin sensitiser in this study.

The induction and challenge strategy in this modified Buehler test deviates from the guideline protocol (OECD TG 406) that requires inductions on days 0, 6-8, 13-15 and schedules challenge applications on day 27-29.

Primary skin irritation and sensitiziation test on guinea pigs (Anonymous (1976b))

In a third test the skin sensitising properties of carbendazim were evaluated in a non-guideline primary skin irritation and sensitisation test. Ten male guinea pigs were intradermally injected four times, once each week over a period of three weeks, with 1 % (w/v) carbendazim in dimethyl phthalate (DMP). Topical challenge was performed after a two week rest period with 40 % and 4 % carbendazim in acetone. Control animals received similar topical applications. No animal showed a dermal reaction.

This test method deviates from OECD TG 406 as follows: No husbandry information was contained in the report and the test was performed only with 10 instead of 20 animals. No rationale for the used concentrations was provided and no local irritation was created with sodium lauryl sulphate. Challenge was performed after two weeks instead of three (GPMT) or after four weeks (Buehler test). There is no information documented that the sensitivity and reliability of the experimental technique used is checked every six month.

10.6.1.2 Human information

No information on skin sensitisation in humans is available.

10.6.1.3 Summary and discussion of skin sensitisation

In a reliable guinea pig maximisation test according to OECD TG 406, skin reactions indicative of sensitisation were observed in 4 out of 10 treated animals after 48 h using a challenge concentration of 62.5 % carbendazim in Alembicol D (Anonymous (1997)). Within a modified Buehler test (Anonymous (1987)) and a non-guideline skin irritation and sensitisation study (Anonymous (1976b)) that both deviated from OECD TG 406 no sensitising properties of carbendazim were observed.

Since the Buehler test is considered less sensitive and both, the Buehler test as well as the non-guideline study, present limitations in the study design, classification of carbendazim is proposed based on the positive GPMT.

10.6.1.4 Comparison with criteria

Table 18: Results of skin sensitisation tests in comparison with CLP criteria

Toxicological result	CLP criteria
GPMT: Intradermal induction with 5 % carbendazim in Alembicol D resulted at 48 h after challenge in 4/10 (40 %) of test animals showing signs of allergic reactions in the form of slight erythema. (Anonymous, 1997).	Category 1B (H317): ≥30 % to < 60 % responding at > 0.1 % to ≤ 1 % intradermal induction dose or **≥ 30 % responding at >1 % intradermal induction dose**
Buehler test: Topical induction with 50 % carbendazim in petrolatum did not lead to irritating skin effects in the animals of the treatment or the control group. (Anonymous, 1987).	Category 1B (H317): ≥ 15 % to < 60 % responding at > 0.2 % to ≤ 20 % topical induction dose or ≥ 15 % responding at > 20 % topical induction dose
Test not further specified: Intradermal induction with 1 % carbendazim in DMP resulted in no irritating or sensitising skin effects at the challenge with 4 and 40 % Carbendazim in acetone in the animals of the treatment and of the control group. (Anonymous, 1976b).	Study does not comply with recognised test guidelines.Therefore, CLP criteria cannot be applied.

10.6.1.5 Conclusions on classification and labelling

Carbendazim meets the criteria for skin sensitization. The substance was tested at a concentration of 5 % only. Therefore, no firm conclusion on subcategorisation (1A/1B) can be made. Thus classification with Skin Sens. 1; H317 (May cause an allergic skin reaction) is proposed.

RAC evaluation of skin sensitisation

Summary of the Dossier Submitter's proposal

The DS proposed to classify carbendazim as a skin sensitiser in category 1 without subcategorization on the basis of the results of two guideline and GLP compliant tests (positive Guinea Pig Maximisation Test (GPMT) and negative Buehler assay in guinea pigs). In a third test (primary skin irritation and sensitisation test), no animals showed a dermal reaction. However this test did not comply with recognised test guidelines and the DS considered the study not applicable for comparison with the CLP criteria.

Comments received during public consultation

One Member State Competent Authority (MSCA) agreed with the DS with classification of carbendazim as Skin Sens. 1, H317, based on the positive, reliable, GPMT. Although, MSCA asked for confirmation that the concentration of tested item used for each inducing exposure was the maximum concentration leading to mild to moderate skin irritation and that the concentration used for the challenge exposure corresponded to the highest non-irritant dose, in accordance with the OECD TG 406.

According to DS' response, the concentrations used for both induction and challenge had been selected on the basis of a preliminary test on which no further details had been given in the original study report (Anonymous, 1997). However, it had been stated that the 5% carbendazim applied intradermally for induction was "the highest concentration that caused

irritation but did not adversely affect the animals". The 62.5% concentration used for topical induction and challenge had been described as the "maximum practical concentration that could be prepared and dosed topically and did not give rise to irritation effects". There was no further proof of these statements but, in principle, the previous information was confirmed by the findings in the main study. Slight irritation had been reported to have occurred, as expected, after intradermal induction. In fact, slight erythema had been seen after topical application but it could be also due to the vehicle Alembicol D. In the control animals which had been exposed to carbendazim only during challenge, no dermal reactions had been noted.

Assessment and comparison with the classification criteria

Summary of the main findings reported in the CLH report on animal skin sensitisation studies with carbendazim:

<table>
<tr><th>Study</th><th>Dose level</th><th>Results</th><th>Reference</th></tr>
<tr><td>GPMT
OECD TG 406

Dunkin Hartley guinea pig

10 males/ treatment group

5 males/ control group

GLP</td><td>Carbendazim (purity 99.5%)

Induction: (day 0) intradermal injection - 5% w/v
(day 7) topical application - 62.5% w/v

Challenge: (day 21) - 62.5% w/v and 31.25% w/v

Vehicle: Alembicol D
Adjuvant: 50% FCA in water

Positive control: yes</td><td>Responses at 24, 48, and 72h after path removal

<table><tr><td>Responses at</td><td>24h</td><td>48h</td><td>72h</td></tr><tr><td colspan="4">Challenge 62.5%</td></tr><tr><td>treated</td><td>1/10</td><td>4/10</td><td>3/10</td></tr><tr><td>control</td><td>0/5</td><td>0/5</td><td>0/5</td></tr><tr><td colspan="4">Challenge 31.25%</td></tr><tr><td>treated</td><td>0/10</td><td>3/10</td><td>3/10</td></tr><tr><td>control</td><td>0/5</td><td>0/5</td><td>0/5</td></tr></table>
Conclusion: positive</td><td>Anonymous, 1997</td></tr>
<tr><td>Buehler assay

OECD TG 406

Pirbright-White guinea pig

20 females/ treatment group

10 females/ control group

GLP

Deviations: 9 inductions, challenge treatment was conducted on day 37 instead of day 27-29</td><td>Carbendazim (purity 99.4%)

9 induction applications - day 1, 3, 5, 8, 10, 12, 15, 18, 19
Challenge – day 37

Induction and challenge: 50% w/v

Vehicle: petrolatum

No positive control</td><td>No skin sensitising effects at 24 and 48 h after patch removal.

Conclusion: negative</td><td>Anonymous, 1987</td></tr>
</table>

Primary skin irritation and sensitization test on guinea pigs Non- Guideline, 10 males/treated and control group **Disregarded study** due to the following deficiencies of the method: test was performed with 10 instead 20 animals, no local irritation was created with sodium lauryl sulphate, challenge was performed after 2 weeks instead of 3 or 4 weeks, no information on the sensitivity and reliability of the experimental technique	Carbendazim (purity 98%) Induction: 4 intradermal inductions, one each week over a period of 3 weeks Concentration: 1% w/v Vehicle for induction: dimethyl phthalate Challenge: after 2 weeks rest Concentration: 4 and 40% w/v (topical) Vehicle for challenge: Acetone No positive control	No skin sensitising effects Conclusion: negative	Anonymous, 1976

Since the Buehler test is considered less sensitive and both, the Buehler test as well as the non-guideline study, present limitations in the study design, classification of carbendazim is proposed based on the positive GPMT.

In one reliable GPMT study according to OECD TG 406, skin reactions indicative of sensitisation were observed in 4 out of 10 treated animals (40%) after intradermal induction with 5% of carbendazim in Alembicol D (Anonymous, 1997). Therefore, RAC considers that the CLP criteria for classification as a Cat. 1B skin sensitiser (positive response in ≥ 30% of animals at > 1% intradermal induction dose in GPMT) have been met. It is very unlikely that at lower concentrations the criteria for Cat. 1A (≥ 30% response at ≤ 0.1% intradermal induction dose, or ≥ 60% response at 0.1-1% intradermal induction) would be met, given the fairly low response rate at 5%. However, lower concentrations have not been tested and therefore, Cat. 1A cannot be totally excluded in line with the CLP regulation. As a conclusion, RAC supports the DS' proposal for classification of carbendazim as skin sensitizer in category 1 (Skin Sens. 1; H317 - May cause an allergic skin reaction), without a subcategory.

Specific concentration limit

Carbendazim has, based on existing data, a weak potency of skin sensitisation, therefore, the generic concentration limit should be applied.

10.6.2 Respiratory sensitisation

No data available.

10.7 Germ cell mutagenicity

Not assessed in this dossier.

10.8 Carcinogenicity

Not assessed in this dossier.

10.9 Reproductive toxicity

Not assessed in this dossier.

10.10 Specific target organ toxicity-single exposure

Not assessed in this dossier.

10.11 Specific target organ toxicity-repeated exposure

Not assessed in this dossier.

10.12 Aspiration hazard

Not assessed in this dossier.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Carbendazim is hydrolytically stable at pH 5 and 7. Hydrolysis half-life at pH 9 exceeds 16 days (~ 153 days). The substance is not readily biodegradable and can be assumed to be not inherently biodegradable as well. Half-lifes derived from studies in water-sediment and soil were higher than 16 days (at 12 °C) and mineralization was far below 70 %. 2-AB (2-amino-benzimidazole, CAS Number 934-32-7) was detected as significant hydrolysis product and relevant metabolite (> 10 %) during degradation in soil (= 10 %). Based on the available information carbendazim has to be considered not rapidly degradable.

Table 19: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
OECD 301 B	Not readily biodegradable	< 20 % ThCO2 in 28 days	Voelskow (1990) CLH_11_1_A_7_1_1_2_1-01 RI = 2
SETAC Europe (1995): Procedures for assessing the environmental fate and ecotoxicity of pesticides	$DegT_{50}$-total system: 28.6 and 142.6 days (12 °C) CO_2: 23.0 % and 6.0 % AR Metabolites: Bickenbach: 7 metabolites < 10 % Unter Widdersheim: 4 metabolites < 10 % 2-AB max. 6.3 % AR	Two water-sediment systems tested ("Bickenbach" & "Unter Widdersheim"), 20 ± 2 °C over 149 days	Knoch (2001); Zillgens (2007a) CLH_11_1_4_3_A7_1_2_2_2-01 & -02, RI = 1
OECD 307	DT_{50}: 22.8–260.8 d (12 °C) CO_2: max. 13.7 % Metabolites: 2-AB max. 3.0-10.0 %	six soils (2 x sandy loam, 2 x silt loam, loamy sand, silty clay) 20 ± 2 °C over 120 days	Adam (2012); CLH_11_1_4_3_A7_2_2_1-02, RI = 1
BBA IV 4-1	$DissT_{50}$: 11-78 d at field temperature and soil moisture	four soils (loamy sand, sandy loam, sandy loam, silty sand), 368-381 d	Krebs & Baedelt (1990); CLH_11_1_4_1_A 7_2_2_2-01–04, RI = 2 (all studies)
US EPA Pesticide Assessment Guideline (1982), comparable to OECD no. 111	pH 5 and 7: stable pH 9: mean DT_{50} 153 days (12°C, n=2) hydrolysis product: 2-Aminobenzimidazole (2-AB) (30% of parent)	Half-life was recalculated by DE	Priester (1984) CLH_11_1_3_ A7_1_1_1_1-02 RI = 1
according to: BBA, RL IV 6-1 (1990) US EPA (1982) UBA (1990)	photolytically stable	study not conducted under environmentally relevant conditions (sterile, pH = 5)	Schwab (1992) CLH 11_1_4_4 _A7_1_1_1_2-01 RI = 1

11.1.1 Ready biodegradability

Table 20: Summary of relevant information on ready biodegradability

Method	Results	Remarks	Reference
OECD 301 B ("modified Sturm test)	< 20 % $ThCO_2$* in 28 days	Test substance concentration 10 and 20 mg/L	Voelskow (1990) **CLH_11_1_A_7_1_1_2_1-01** **RI = 2**

* *$ThCO_2$ = theoretical carbon dioxide amount*

A study on ready biodegradability of carbendazim was performed according the Modified Sturm Test (OECD 301 B). Two vessels with inoculum (from municipal sewage sludge) and test substance, two vessels with inoculum and reference compound (benzoic acid) and two control vessels only with inoculum were set up.

The incubation temperature was 22 °C, the concentration of carbendazim was 10 and 20 mg/l. The CO_2 evolution was measured at intervals of 4, 7, 14 and 28 days. Degradation of the reference substance resulted in CO_2 evolution greater than 60 % of the theoretical maximum within 28 days. CO_2 evolution in the control vessels, with inoculum and without test substance, remained less than 50 mg per vessel (3 L). The amount of CO_2 produced in 28 days was less than 20 % of the theoretical CO_2 content. carbendazim is therefore considered as not readily biodegradable.

11.1.2 BOD_5/COD

Not available.

11.1.3 Hydrolysis

Table 21: Summary of relevant information on hydrolysis

Method /Guideline	pH	Temperature [°C]	Initial TS concentration, C_0 [mg L^{-1}]	Reaction rate constant, K_h [d^{-1}]	Half-life, DT_{50} [d]	Coefficient of correlation, r_2	Reference
US EPA Pesticide Assessment Guideline (1982), comparable to OECD no. 111	5	25	0.7×10^{-3}	stable	stable	n. a.	Priester (1984) **CLH_11_1_3_A7_1_1_1_1-02** **RI = 1**
			7×10^{-3}	stable	stable	n. a.	
	7		0.7×10^{-3}	stable	stable	n. a.	
			7×10^{-3}	stable	stable	n. a.	
	9		0.7×10^{-3}	0.014	58	n. a.	
			7×10^{-3}	0.011	50	n. a.	

The study submitted for hydrolysis as a function of pH and identification of breakdown products by Priester (1984) was accepted **(CLH_11_1_3_A7_1_1_1_1-02)**. In the study experimental data obtained at 50 °C and 60 °C were extrapolated to estimate a hydrolysis rate at 22 °C. As the hydrolysis reaction might not have followed the simplified Arrhenius approach assumed, this estimate may not have been entirely accurate.

Table 22: Overview of DT_{50} and hydrolysis rate constants

pH	Initial TS concentration, C0 [mg L-1]	DT_{50} [d]		k_{water} [d^{-1}]
		25°C	12°C(*)	12°C(*)
5		> 1 year	> 2 years	n. a.
7		> 1 year	> 2 years	n. a.

9	0.7×10^{-3}	58	164	4.2×10^{-3}
	7×10^{-3}	50	141	4.9×10^{-3}

(*) calculated by RMS based on values for 25°C and TGD on Risk assessment, Part II (2003) model calculation: chapter 2.3.6.1

The hydrolysis half-lives were recalculated by RMS to reflect an average EU outdoor temperature of 12 °C for fresh water. The above mentioned values for DT_{50} were converted assuming a pseudo first-order rate constant.

In summary, carbendazim is stable at pH 5 and 7. The hydrolysis rates increase at pH 9, mean half-life of around 153 days was calculated. 2-Aminobenzimidazole (2-AB) was determined as significant hydrolysis product and amounted for approximately 30 % of the parent compound.

11.1.3.1 Field investigations and monitoring data (if relevant for C&L)

Four soil field dissipation studies with carbendazim were conducted according to BBA IV 4-1 in Germany **(CLH_11_1_4_1_A 7_2_2_2-01–04, RI = 2 (all studies))** over a period of 368–381 days. In each study the formulation Derosal (carbendazim, water miscible suspension concentrate; 360 g L^{-1}) was applied by spraying to bare soil with an application rate of 0.5 L ha^{-1}. Samples were taken randomly from a depth of 0 – 20 cm at nine sampling time points. The soil samples were extracted with ethylacetate. No metabolites were determined. In all studies the concentration of carbendazim decreased with time to values below the limit of detection (LOD, 0.02 to 0.03 mg kg^{-1}) at the end of the study. The dissipation DT_{50} values, recalculated by Zillgens **(CLH_11_1_4_1_A_7_2-01)**, range between 11 and 78 days at field temperature and soil moisture. Since it could not be demonstrated that dissipation of carbendazim was a result of ultimate degradation, the information provided by these field studies cannot be considered for use for classification purposes.

11.1.3.2 Inherent and enhanced ready biodegradability tests

A test on inherent biodegradability of carbendazim was carried out according to the OECD test guidelines 301F and 302B **(CLH_11_1_4_2_A_7_1_1_2_2-01, RI = 3)**. In the test, which was performed using a formulated product (Derosal®), carbendazim was eliminated to > 95 % within of 3 hours. However, since the test was poorly documented and information about relevant test conditions (source and concentration of the inoculum; degradation of a reference compound) was lacking, it was considered not acceptable.

11.1.3.3 Water, water-sediment and soil degradation data (including simulation studies)

<u>Water-sediment</u>

The dissipation of ^{14}C-carbendazim was studied in two water/sediment systems (Bickenbach, Unter Widdersheim) incubated under aerobic conditions in the dark at 20 ± 2 °C over a period of 149 days **(**Guideline: SETAC Europe (1995): Procedures for assessing the environmental fate and ecotoxicity of pesticides, **CLH_11_1_4_3_A7_1_2_2_2-01 & -02, RI = 1)**.

The substance was rapidly transferred into the sediment, reaching levels of 24.0 % and 9.7 % initial applied radiation (AR) in the water phase at day 28 in the Bickenbach and Unter Widdersheim-System, respectively. At the same time, the total radioactivity increased to 77.4 % (Bickenbach) and 92.3 % (Unter Widdersheim) in the sediment. At the end of the study, 65.6 % AR (Bickenbach) and 93.6 % AR (Unter Widdersheim) were still present in the systems, whereas 60.3 % and 53.7 % AR were found in the fraction of non-extractable residues. $DegT_{50}$ values of 15.1 days (Bickenbach) and 76.8 days (Unter Widdersheim) were calculated for the total system, corresponding to 28.6 and 142.6 days, respectively, when converted to an average EU outdoor temperature of 12 °C. Mineralisation amounted to 23.0 and 6.0 % $^{14}CO_2$ after 149 days.

Throughout the study, six metabolites were detected in the “Bickenbach” water phase, two in the “Unter Widdersheim” water phase. In the sediment extracts, four metabolites were found in the “Bickenbach” test system, three in the “Unter Widdersheim” test system. Three unknown metabolites in the

"Bickenbach" test system were observed in the water phase as well as in the sediment phase, in the "Unter Widdersheim" test system one unknown metabolite was found in both compartments. The metabolite 2-AB was identified in the sediment extracts only (from day 42 on) with an amount of up to 6.3 % of applied radioactivity. With regard to the total system, no metabolite was detected above 10 % of applied radioactivity. A radioactive fraction, which does not move in the TLC analyses, exceeded 10 % of the applied dose in the "Bickenbach" test system on day 28 (13.6 % AR) and day 42 (16.2 % AR), respectively. Most of the unknown fraction was found in the "Bickenbach" water phases. Chromatographic attempts for characterization of the non-moving fraction due to silylation of polar components resulted in a worst-case calculation of 10.5 % AR (day 28) and 8.3 % AR (day 42) for the unknown, non-moving fraction in the "Bickenbach" total test system. The actual number of components in the fraction is not known.

Soil (key study)

The degradation of ^{14}C-radiolabelled carbendazim was further investigated in six soils (2 x sandy loam, 2 x silt loam, loamy sand, silty clay) 20 ± 2 °C over a period of 120 days according to OECD 307 **(CLH_11_1_4_3_A7_2_2_1-02, RI = 1)**. At the end of the incubation (day 120), 5.6–53.6 % of the applied radioactivity were recovered as unchanged test compound. The total recovery of radioactivity was between 90 and 110 % for all soils and sampling time points. DT_{50} values ranged between 12.0–137.5 days (22.8–260.8 days at 12 °C) among the investigated soils. The amount of non-extractable radioactivity (NER) constantly increased during incubation, reaching maximum levels of 40–81 %. Mineralization was generally low with a maximum of 13.7 % in the soil with the highest pH (sandy loam, Speyer 5M), while in three soils even less than 5 % $^{14}CO_2$ were formed. Volatile products other than $^{14}CO_2$ remained below 0.1 % of applied radioactivity. In the soil extracts the metabolite 2-AB was identified. The amount of 2-AB reached maxima of 3.0-10.0 % of the applied radioactivity, in single replicates up to 11.3 %. Two further metabolites were detected in traces but were not identified.

Soil (additional information)

Helweg **(CLH_11_1_4_3_A7_2_1-01, RI = 3)** investigated the degradation of ^{14}C-carbendazim in flow-through soil metabolism systems under aerobic conditions at 25 °C and a moisture content of 45 % of maximum water holding capacity over a period of up to 270 days. A sandy loam (pH 5.9, humus 2.5 %), a mucky loam (pH 7.7, humus 10.2 %) and a loamy sand (pH 7.1, humus 2.9 %) were tested in several small experiments. The study was considered not acceptable because of methodical deficiencies (incomplete mass balance, no half-lives) and missing details in the publication. $^{14}CO_2$ evolution was not determined in both, the sandy loam and mucky loam soil. In the sandy loam, a maximum of 30 % of AR were recovered as $^{14}CO_2$ at day 270 in the experiment using 20 mg/kg carbendazim. Non-extractable residues amounted to 10 and 70 % AR at day 28 in the sandy loam and mucky loam soil, respectively, following harsh extraction procedure (boiling under reflux for 4 hours in MeOH:5N HCl (40:1, v:v) and re-extraction with MeOH). The contents of 2-AB in the extracts were < 10 % (no details available).

Otto (1975) determined the degradation of carbendazim in a sand (pH 6.8, organic carbon content 2.58 %) and in a loamy sand (pH 5.2, organic carbon content 1.0 %), respectively, over a period of up to 480 days **(CLH_11_1_4_3_A7_02_01-03, RI = 3)**. Test conditions were an aerobic atmosphere, 22 ± 2 °C and a moisture content of 40 % of maximum field capacity. For the sand, ^{14}C-carbendazim was used. After an extraction with methanol:glacial acetic acid (9:1), the concentrations of carbendazim in the extracts were measured. For both soils, Otto (1975) observed half lives of 37 days (recalculation done by Zillgens, **CLH_11_1_4_3_A7_2-01**). Metabolites were found in trace concentrations (no details available). The study was considered not acceptable for the endpoint aerobic degradation in soil because of missing details in the publication.

Finally, degradation half live of ^{14}C-carbendazim was determined by Gildemeister et al. **(CLH_11_1_4_3_A7_2_2_1-01, RI = 3)** according to BBA-leaflet guideline no. 36 (1976) in a sandy soil (pH 4.7, organic carbon content 2.7 %) at 15 °C, 20 °C and 25 °C, respectively. The soil was incubated at 40 % of maximum field water capacity for 28 days. The calculated half lives of carbendazim were 34 days (15 °C), 31 days (20 °C) and 26 days (25 °C) (recalculation done by Zillgens, **CLH_11_1_4_3_A7_2-01**). Marginal amounts of unidentified metabolites were found (three at most), but no details were reported. For day 28, NER amounts of 48 % (15 °C); 52 % (20 °C) and 57 % (25 °C)

were reported. However, these values may include the mineralisation as well. The study was considered not acceptable for the endpoint aerobic degradation in soil because of methodical deficiencies (soil properties, study duration too short) and missing details in the publication.

In all simulation studies (water-sediment and soil), $DegT_{50}$ values were higher than 16 days (at 12 °C) and mineralization did not reach 70 % within 28 days. Thus, these results do not support rapid degradability of carbendazim.

11.1.3.4 Photochemical degradation

Table 23: Summary of relevant information on photolysis

Method /Guideline	Initial molar TS concentration	Total recovery of test substance [% of appl. a.s.]	Photolysis rate constant (k^c_p)	Direct photolysis sunlight rate constant (k_{pE})	Reaction quantum yield (Φ^c_E)	Half-life ($t_{1/2E}$)	Reference
according to: BBA, RL IV 6-1 (1990) US EPA (1982) UBA (1990)	4.75 mg/L	90.6 – 106.4	not determined	not determined	not determined	not determined	Schwab (1992) **CLH 11_1_4_4_A7_1_1_1_2-01** **RI = 1**

In the study by Schwab (1992) **(CLH 11_1_4_4_A7_1_1_1_2-01)** carbendazim is photolytically stable over the period of 166 hours corresponding to 35 sunny days under natural conditions at 52° Northern latitude in June. The intensity of the radiation was determined by an uranylsulfate/oxalate actinometer. No transformation products were identified. The study was not conducted under environmentally relevant conditions (sterile, pH = 5).

In general, the photolytic transformation of the a.s. in a natural water will take place solely in the upper centimetres of the water body where solar radiation may penetrate. Regarding the environmental exposure estimation there is currently no standard method available to assess the influence of phototransformation in water in an appropriate way with respect to the depth, mixing, and turbidity of the water systems. Assuming a phototransformation in the whole water body (i.e. taking the rate constant as such) would highly overestimate the degradation potential. Thus, the transferability of the degradation rate constant from laboratory tests to natural water is limited.

11.2 Environmental transformation of metals or inorganic metals compounds

Not relevant.

11.2.1 Summary of data/information on environmental transformation

Not relevant.

11.3 Environmental fate and other relevant information

No other relevant information available.

11.4 Bioaccumulation

Table 24: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
Standard equation (74), TGD on Risk Assessment (2003), Part II, chapter 3.8.3.2	estimated log K_{ow} = 1.5 estimated BCF_{fish} = 3.75 L/kg		CLH_11_4_A7_4_2
US-EPA, similar to OECD 305	Viscera: BCF = 460 L/kg Whole fish: BCF = 27 L/kg	Exposure: 28 d Initial nominal concentrations: 0.018 mg/L and 0.17 mg/L	Anonymus (1984a) CLH_11_4_A7_4_3_3_1_1

11.4.1 Estimated bioaccumulation

An approximation of the aquatic bioaccumulation potential of carbendazim has been performed on the basis of the log K_{ow} by applying the standard equation 74 given in Part II, 3.8.3.2 of the TGD (2003). The measured log K_{ow} of 1.5 leads to a calculated BCF_{fish} of 3.75 L/kg. According to CLP a log $K_{OW} \geq 4$ is used to indicate a potential for bioaccumulation, therefore the log K_{OW} indicates a low potential for bioaccumulation for carbendazim. It has to be noted that the equation 74, which is based on the work by Veith et al., is only validated for substances with a log K_{ow} of 2 – 6 and therefore carbendazim is not within the application range of this QSAR. However, with a log $K_{ow} < 3$ the substance even does not meet the TGD's first screening criterion for bioaccumulation potential. In addition, also the adsorption does not indicate a bioaccumulation potential, with log $K_p < 3$.

11.4.2 Measured partition coefficient and bioaccumulation test data

Despite a log $K_{OW} < 4$ and a low estimated BCF_{fish} which both do not trigger an experimental study on bioconcentration with fish, such a study is available from the EFSA pesticide peer review (Doc III-A 7.4.3.3.1/01). Bioconcentration was determined in a flow-through test on Bluegill sunfish (*Lepomis macrochirus*) with two concentrations of radiolabelled carbendazim (0.018 and 0.17 mg/L). The 28 d exposure was followed by a two week depuration phase. Radioactivity increased rapidly in all tissues on the first day and continued to increase gradually throughout the exposure period. The results were similar at the two exposure concentrations with maximum BCFs of 27 and 23 L/kg at the low and high exposures, respectively. It remains unclear if steady state was approached, since after a plateau between 14 and 21 d, concentrations in fish increased again at day 28. Concentration of ^{14}C-residues was higher in the viscera than in the rest of the fish. However, since the radioactivity in the viscera contained no detectable levels of carbendazim, the BCF for carbendazim would be low. Radiolabelled residues were characterised mostly as a glucuronide conjugate of 5-hydroxy carbendazim (70-80 %), 12-18 % as unidentified polar compounds and 8-12 % as unextracted bound residues. For all tissues, radioactivity declined rapidly during the depuration phase, for both concentrations and all parts of the fish, depuration levels after 3 d decreased by approximately an order of magnitude, therefore it can be assumed that $t_{1/2} < 3$ d. After subsequent depuration period of two weeks in total, 94 % of the maximum tissue concentration was eliminated. The study was considered as acceptable with a reliability of 2. The BCF for fish does not exceed the trigger value of 500 L/kg and therefore indicates a low potential for bioaccumulation.

Terrestrial bioconcentration

The bioconcentration factor $BCF_{earthworm}$ for assessing the potential for bioconcentration in terrestrial organisms was roughly estimated using the equation 82d given in the EU Technical Guidance Document (TGD) on Risk Assessment (2003) and log K_{ow} of 1.5 determined for carbendazim:

$BCF_{earthworm} = (0.84 + 0.012 \times K_{ow}) / (1\ kg/L) = (0.84 + 0.012 \times 1.5) \times L/kg$

$BCF_{earthworm} = 0.858$ L/kg

Based on the calculated $BCF_{earthworm}$ value of 0.858 L/kg, terrestrial bioconcentration potential for carbendazim is considered to be low.

Summary and Conclusion

Based on both experimentally derived aquatic bioconcentration and on estimation of aquatic and terrestrial bioconcentration the substance is not expected to bioconcentrate in aquatic and terrestrial organisms. In conclusion, the bioaccumulation potential for carbendazim is considered low.

11.5 Acute aquatic hazard

Table 25: Summary of relevant information on acute aquatic toxicity

Method	Species	Test material	Results	Remarks	Reference
OECD 203	*C. carpio*	Carbendazim	LC_{50} (96 h) = 0.44 mg/L nominal	static	Anonymous (1988) A40032 CLH_11_5_A7_4_1_1_1

OECD 203	*O. mykiss*	Carbendazim	LC_{50} (96 h) = 0.83 mg/L mean measured	static	Anonymous (1988) A40135 CLH_11_5_A7_4_1_1_2
OECD 204	*O. mykiss*	Carbendazim	LC_{50} (96 h) > 0.56 mg/L nominal NOEC (21 d) = 0.018 mg/L nominal (mortality, weight)	flow-through	Anonymous (1989) A40788 CLH_11_6_A7_4_3_1_1
ASTM	*I. punctatus*	Carbendazim	LC_{50} (96 h) = 0.019 mg/L nominal	static **key study**	Palawski, D.U. (1986) A30119 CLH_11_5_A7_4_1_1_3
ASTM	*O. mykiss*	Carbendazim	LC_{50} (96 h) = 0.87 mg/L nominal	static	Palawski, D.U. (1986) A30119 CLH_11_5_A7_4_1_1_3
ASTM	*L. macrochirus*	Carbendazim	LC_{50} (96 h) > 3.2 mg/L nominal	static	Palawski, D.U. (1986) A30119 CLH_11_5_A7_4_1_1_3
EPA	*C. variegatus*	Carbendazim	LC_{50} (96 h) > 1158 mg/L mean measured	static **supporting data from PPP***	Anonymous (1988) A52917 Carbendazim_07_Vol 3_B9-B10
no guideline stated	*O. mykiss*	Carbendazim	LC_{50} (96 h) = 0.19 mg/L nominal	static **supporting data from PPP***	Anonymous (1976a) A52914 Carbendazim_07_Vol 3_B9-B10
no guideline stated	*O. mykiss*	Carbendazim	LC_{50} (48 h) = 0.34 mg/L nominal	static **supporting data from PPP***	Anonymous (1976a) A33570 Carbendazim_07_Vol 3_B9-B10
no guideline stated	*L. macrochirus*	Carbendazim	LC_{50} (96 h) > 17.25 mg/L nominal	static **supporting data from PPP***	Anonymous (1984b) A52913 Carbendazim_07_Vol 3_B9-B10
OECD 203	*O. mykiss*	Carbendazim	LC_{50} (96 h) = 0.98 mg/L mean measured	semi-static **supporting data from PPP***	Anonymous (1996) SNG44(c)/960465 Carbendazim_07_Vol 3_B9-B10
OECD 202	*D. magna*	Carbendazim	EC_{50} (48 h) = 0.15 mg/L nominal	static	Fischer, R. (1988) A39285 CLH_11_5_A7_4_1_2_1
no guideline stated	*D. magna*	Carbendazim	EC_{50} (48 h) = 0.46 mg/L nominal	static **supporting data from PPP***	Canton, J.H. (1976) A33570 Carbendazim_07_Vol 3_B9-B10
no guideline stated	*D. magna*	Carbendazim	EC_{50} (48 h) = 0.35 mg/L nominal	static **supporting data from PPP***	Hall, C.L., Stahl, R.G. (1985) A52906 Carbendazim_07_Vol 3_B9-B10
OECD 202	*D. magna*	Carbendazim	EC_{50} (48 h) = 0.39 mg/L mean measured	static	Baer, K.N. (1992) A52905

				supporting data from PPP*	Carbendazim_07_Vol 3_B9-B10
OECD 202	*D. magna*	Carbendazim	EC_{50} (48 h) = 0.19 mg/L mean measured	static **supporting data from PPP***	Bell, G. (1996) SNG44(b)/960464 Carbendazim_07_Vol 3_B9-B10
EPA/600/4-85/013	*D. magna*	Carbendazim	EC50 (48 h) = 0.087 mg/L nominal	not valid, daphnids were fed during exposure period*	Hutton, D.G. (1986) A52904 Carbendazim_07_Vol 3_B9-B10
OECD 201	*D. subspicatus*	Carbendazim	E_rC_{50} (72 h) > 8 mg/L nom. conc., max. water solubility	static	Heusel, R. (1991) A46674 CLH_11_5_A7_4_1_3_2
no guideline stated	*C. pyrenoidosa*	Carbendazim	E_rC_{50} (48 h) = 0.34 mg/L nominal	static **supporting data from PPP***	Canton, J.H. (1976) A33570 Carbendazim_07_Vol 3_B9-B10
OECD 201	*P. subcapitata*	Carbendazim	E_rC_{50} (120 h) > 11 mg/L mean measured	static **supporting data from PPP***	Bell, G. (1996) SNG44(a)/960463 Carbendazim_07_Vol 3_B9-B10
OECD 201	*P. subcapitata*	Carbendazim	E_bC_{50} (72 h) = 1.3 mg/L nominal E_bC_{50} (120 h) = 1.6 mg/L nominal	not valid, growth in controls lower than a factor of 10 within 72 h *	Douglas & Handley (1988) A52909 Carbendazim_07_Vol 3_B9-B10

* Study evaluation based on Draft Re-Assessment Report for carbendazim from the EFSA conclusion on pesticide peer review, EFSA Journal 2010; 8(5):1598 (https://www.efsa.europa.eu/de/efsajournal/pub/1598; Annex I Renewal Assessment Report from 29/06/2010 can be obtained via http://dar.efsa.europa.eu/dar-web/provision). Some of the tudies presented in the Draft Re-Assessment Report are considered as supporting data and have not been evaluated in detail for classification, as they would not contribute to the classification decision of carbendazim.

11.5.1 Acute (short-term) toxicity to fish

Two studies on acute toxicity of carbendazim to fish **(CLH_11_5_A7_4_1_1_1** and **CLH_11_5_A7_4_1_1_2)** and furthermore a prolonged study in accordance to OECD TG 204 (**CLH_11_6_A7_4_3_1_1**) have been evaluated in detail. Further studies have already been assessed during evaluation under Regulation (EC) No 1107/2009 and do not contribute to classification of the substance.

CLH_11_5_A7_4_1_1_1: The study by Anonymous (1988) was performed in accordance with OECD TG 203 and GLP requirements in a static system with a study duration of 96 h. The test species *Cyprinus carpio* (Mirror carp) was exposed to carbendazim (99.4 %) using hydrochloric acid or acetone as solvent in an acute test. In total three trials are performed within the test report, the first one based on acetone as solvent and the following ones with hydrochloric acid as solvent and different concentrations of the test substance. Due to difficulties to maintain test concentrations the results based on acetone as solvent have not been considered further and the results of the two other tests have been pooled to extend the concentration range and are described in the following. Ten fish per tested concentration with an age of 11 – 13 month (3.4 – 4.2 cm length and a weight of 1.7 – 3.2 g) were exposed to nominal concentrations of 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg carbendazim/L. Both a control

and a solvent control were performed. A recovery of 58 to 102 % of nominal concentrations was reported after 96 h based on the analytical results for 6 (of 10 in total) treatment levels, but only in the nominal concentration of 0.056 and 0.18 mg/L dropped below 80 % of nominal at 48 and 96 h. Up to 0.18 mg/L no mortality was observed, at 0.32 mg/L 30 % mortality after 96 h and at 0.56 mg/L and higher concentrations between 90 % and 100 %. Contrary to the test report, the LC_{50} has been determined based on nominal instead of mean measured values since the dose-response curve based on the probit method and on mean measured concentrations did not fit the biological results: On the basis of mean measured concentrations a LC_{50} of 0.61 mg/L was derived in the study report with a confidence interval of 0.36 – 1.21 mg/L. However, at the nominal concentration of 0.56 mg/L already a mortality of 90 % was observed. Since measured concentrations of carbendazim during the 96 h of the test were with one exemption within a range of 80 – 120 % of nominal, it was considered as justified to recalculate the LC_{50} on the basis of nominal concentrations and the resulting LC_{50} = 0.44 mg/L matches the steep slope of the dose-response curve observed within the test. Sublethal effects have been observed at 0.32 mg/L and above, some of the fish showed slow reactions, darting movements, equilibrium disturbances, deformations, lateral position, surface swimming, horizontal turns, gulping air and/or head down swimming. The validity criteria according to OECD TG 203 are met. The study was considered as acceptable with a reliability of 1. Based on this study an LC_{50} (96 h) of 0.44 mg carbendazim/L with a 95 % confidence interval of 0.33 – 0.58 mg/L was determined for *C. carpio*.

CLH_11_5_A7_4_1_1_2: The study was performed in 1988 in accordance to OECD TG 203 and GLP requirements following a static acute test design. *Oncorhynchus mykiss* (Rainbow trout, formerly known as *Salmo gairdneri*) was exposed to nominal concentrations of 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10 mg/L in a first test (a) and in a second test (b), with 0.010, 0.018, 0.032, 0.056, 0.10 and 0.18 mg/L of carbendazim 99.4 %, both with acetone as solvent for a duration of 96 h (0.1 mL acetone/L). The test substance precipitated in the test media at concentration levels of 0.32 mg/L and higher, therefore the results refer to mean measured concentrations of the test substance. Ten fish per test substance (age: 6-7 months, mean length 5.03 cm (a) and 5.47 cm (b) and mean weight 1.82 g (a) and 2.66 g (b)) and 20 each in the control and solvent control have been used with one replicate per test concentration / per tank. No deviations from the guideline are noted and pH value, oxygen concentration and temperature were within the range given in the guideline. Sublethal effects have been noted for some of the fish exposed to concentrations of 0.33 mg/L (measured) and above (slow reactions, folded fins, surface swimming, equilibrium disturbances and/or swollen eyes). Based on mean measured concentrations a LC_{50} (96h) = 0.83 mg/L was calculated (with a 95 % confidence interval of 0.55 – 1.97 mg/L). The study fulfils the validity criteria according to OECD TG 203 and a reliability of 1 was given.

Study **CLH_11_6_A7_4_3_1_1** represents a prolonged study according to OECD TG 204 and was further prolonged to cover a period of 21 d. The mean weight of fish was additionally in accordance with OECD TG 215 (initially less than 5 g) and also the sublethal endpoints growth and behaviour were evaluated. The test duration of 21 d was shorter than the 28 d required for OECD TG 215. This study cannot be regarded as a long-term study with regard to CLP requirements, however the NOEC after 21 d supports the available long-term test for the same test species. Nominal test concentrations of 0.0032, 0.0056, 0.010, 0.018 and 0.032 mg/L were used. The lowest test concentration, 0.0032 mg/L, did not reveal any mortality or effects on behaviour. At 0.0056 mg/L and higher concentrations effects on behaviour were noted (staying near outflow). Effects on growth were observed starting from 0.01 mg/L on (weight and length), but only at the highest test concentration of 0.032 mg/L these effects were statistically significant. The study was considered as acceptable with a reliability of 2. The observed effects on behaviour can be sufficiently explained as avoidance and not as a toxic effect and were not considered as relevant for the NOEC. Considering the available early-life stage test with the same species but covering a longer time and more life-stages, a NOEC = 0.018 mg/L (nom.) for the study by Anonymous (1989) can be derived, based on mortality and growth. As the study does not fulfil the prerequisites for a long-term study, at least an acute LC_{50} based on mortality data after 96 h can be derived. As no mortalities occurred up to the highest tested concentration within the first 96 h, consequently a LC_{50} > 0.56 mg/L can be derived from this study.

Furthermore a 96 h acute study from the scientific literature by Palawski (1986) has been evaluated since it provides relevant data for acute toxicity to fish **(CLH_11_5_A7_4_1_1_3)**. Within the study

carbendazim toxicity has been compared based on three different fish species, *Oncorhynchus mykiss* (Rainbow trout), *Ictalurus punctatus* (Channel catfish) and *Lepomis macrochirus* (Bluegill) with 10 fish per test concentration. Furthermore an additional test series has been performed to determine effects of temperature, pH, water hardness and effects on early life stages on *O. mykiss* and *I. punctatus*. The study followed a static test design, analytical monitoring of test substance was not performed and data on validity of the test were not reported. 10 fish per concentration were exposed to the test substance and mortality was recorded every 24 h. Tested concentrations, results for controls and application of test substance were not reported, however the non-GLP study was performed according to the ASTM guideline. The study revealed that *Ictalurus punctatus* is significantly more sensitive than *O. mykiss* and *L. macrochirus*: For *I. punctatus* a LC_{50} (96 h) of 0.019 mg/L (95 % confidence limit = 0.013 – 0.027 mg/L) was reported, for *O. mykiss* a LC_{50} (96 h) of 0.87 mg/L (95 % confidence limit = 0.63 – 1.19 mg/L) and for *L. macrochirus* a LC_{50} (96 h) > 3.2 mg/L, based on nominal concentrations of carbendazim. The results presented in the study are plausible, in fact the results for *O. mykiss* are in good agreement with the corresponding study by Anonymous (1988), which provides a 96-h LC_{50} = 0.83 mg/L for the same species. Considering the level of documentation and the test guideline, the study was considered as acceptable with a reliability of 2. As this study provided the lowest acute effect value for carbendazim for fish with 96 h-LC_{50} = 0.019 mg/L (nom.) for *I. punctatus* this study was chosen as a key study.

Based on the studies and on the additional data presented in the table above it can be concluded that *Ictalurus punctatatus* represents the most sensitive fish species tested. As study CLH_11_5_A7_4_1_1_3 represents the lowest acute effect value, it was furthermore chosen as a key study and provides a 96 h-LC_{50} of nominally 0.019 mg carbendazim/L for *I. punctatus*. It should be noted that no long-term data for this species is available.

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

Acute toxicity to aquatic invertebrates has been assessed based on study **CLH_11_5_A7_4_1_2_1** with *D. magna*. The study was performed in accordance with OECD TG 202 and GLP requirements. Carbendazim (99.4 % purity) was used as test substance in a static acute test system. Immobility and abnormal behaviour was recorded after 24 and 48 h and test substance concentration was monitored for some of the samples. Test ‘a’ was performed with HCl as solvent and nominal concentrations of 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18, 32, 56, 100, 180, 320, 560 and 1000 mg carbendazim/L. Test ‘b’ was performed with acetone as solvent and 0.0010, 0.0018, 0.0032, 0.0056, 0.010, 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg/L. Test ‘c’ represents a repetition of test ‘b’ and for test ‘d’ the same concentration levels as test ‘b’ and ‘c’ have been used with HCl as solvent. Ten daphnia per vessel were used and test ‘a’ was perfomed with 2 vessels per concentration level, tests ‘b’, ‘c’, and ‘d’ with 6 vessels per concentration level and for the controls and solvent controls. The study can only be used to some extend for hazard assessment and classification, since some contamination with the test substance was revealed by the accompanying chemical analysis, both in controls and treatments of test ‘a’. Therefore an increase in carbendazim concentrations during the course of the study has been noted in some replicates. Further trials were therefore performed within the same study, leading to more plausible results, however contaminations in the controls still were observed. Out of these, test series ‘d’ was chosen where chemical analysis leads to plausible and reliable results, especially for the concentration range leading to biological effects and is therefore relevant for EC_{50} derivation. For these concentrations, nominal and measured concentrations were in sufficiently good concordance, allowing to base effect values on nominal concentrations. An EC_{50} (48 h) of 0.15 mg/L was derived from this study (95 % confidence interval: 0.10 – 0.18 mg/L). Based on the above described shortcomings a reduced reliability of 2 could be set. The validity criteria according to the test guideline can be considered as fulfilled.

In summary, for the acute toxicity to aquatic invertebrates an EC_{50} of 0.15 mg/L was considered as relevant and sufficiently reliable. Further, more reliable data with regard to *D. magna* are available at long-term level.

11.5.3 Acute (short-term) toxicity to algae or other aquatic plants

Acute (short-term) toxicity to algae has been assessed based on a study without chemical analysis of test substance concentration (study **CLH_11_5_A7_4_1_3_2**). The study was performed with *Desmodesmus subspicatus* (formerly *Scenedesmus subspicatus*) following OECD TG 201 and in accordance to GLP requirements. Growth inhibition was determined as test parameter by monitoring cell growth at 24, 48 and 72 h. A high concentration range was covered (nom. 1.0, 1.8, 3.2, 5.6, 10,18, 32, 56, 100, 180, 320, 560 and 1000 mg carbendazim/L), and therefore the higher concentrations are exceeding the maximum solubility of 8 mg/L in water, leading to a visible precipitate of the test substance. No monitoring of test substance concentration was performed; it can be assumed that the test substance carbendazim (99.1 %) is sufficiently stable in aquatic systems as demonstrated in other ecotoxicological tests. As the highest concentration without precipitate, 10 mg/L, shows no effects on the test organism and therefore the study can be considered sufficient to demonstrate no effects on algae up to maximum water solubility. The study is valid in accordance to the guideline's quality criteria and controls showed sufficient exponential growth. Results are plausible and the study is considered as reliable (reliability = 1) and a 72 h-E_bC_{50} of 419 mg/L (95 % confidence level = 320 – 560 mg/L) and a NOEC of 10 mg/L were determined. An E_rC_{50} has not been calculated but would also exceed maximal solubility and should therefore not provide any biological relevance. The study was considered as acceptable and reliable for aquatic hazard assessment. It can be concluded that EC_{50} values are higher than the water solubility limit of carbendazim, E_rC_{50} > 8 mg/L.

11.5.4 Acute (short-term) toxicity to other aquatic organisms

No acute (short-term) toxicity studies to other aquatic organisms are considered as relevant for Classification and Labelling.

11.6 Long-term aquatic hazard

Table 26: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
OECD 210	*O. mykiss*	Carbendazim	NOEC (79 d) = 0.011 mg/L mean measured (embryo mortality)	flow-through	Anonymous (1993) A52478 CLH_11_6_A7_4_3_2_1
OECD 202	*D. magna*	Carbendazim	NOEC (21 d) ≥ 0.01 mg/L nominal (reproduction)	semi-static	Fischer, R. (1988) A41208 CLH_11_6_A7_4_3_4_1
US EPA E72-4	*D. magna*	Carbendazim	NOEC (21 d) = 0.0031 mg/L mean measured	semi-static **supporting data**	Baer, K.N. (1992) A52907 Carbendazim_07_Vol 3_B9-B10 *
OECD 202	*D. magna*	Carbendazim	NOEC (21 d) = 0.0015 mg/L mean measured (reproduction)	semi-static **key study**	Kelly et al. (1997) SNG80/970692 CLH_11_6_A7_4_3_4_2
no guideline stated	*D. magna*	Carbendazim	NOEC (18 d) = 0.010 mg/L nominal	static **supporting data**	Canton, J.H. (1976) A33570 Carbendazim_07_Vol 3_B9-B10 *
EPA 850.1300, 72-4	*D. magna*	Carbendazim	NOEC (21 d) = 0.013 mg/L mean measured (reproduction)	not valid, coefficient of variation for reproduction in controls is exceeding 25 % (control: 85.7 %;	Hutton, D.G. (1988) A52908 Carbendazim_07_Vol 3_B9-B10 *

				solvent control: 64.7 %)	
OECD 201	*D. subspicatus*	Carbendazim	NOE_rC (72 h) = 8 mg/L nom. conc., max. water solubility	static	Heusel, R. (1991) A46674 CLH_11_5_A7_4_1_3_2
OECD 201	*P. subcapitata*	Carbendazim	NOE_bC (72 h) = 2.5 mg/L mean measured	static **supporting data**	Bell, G. (1996) SNG44(a)/960463 Carbendazim_07_Vol 3_B9-B10 *
OECD 201	*P. subcapitata*	Carbendazim	NOEC (120 h) = 0.5 mg/L nominal	not valid, growth in controls lower than a factor of 10 within 72 h	Douglas & Handley (1988) A52909 Carbendazim_07_Vol 3_B9-B10 *

* Study evaluation based on Draft Re-Assessment Report for carbendazim from the EFSA conclusion on pesticide peer review, EFSA Journal 2010; 8(5):1598 (https://www.efsa.europa.eu/de/efsajournal/pub/1598; Annex I Renewal Assessment Report from 29/06/2010 can be obtained via http://dar.efsa.europa.eu/dar-web/provision). Some of the tudies presented in the Draft Re-Assessment Report are considered as supporting data and have not been evaluated in detail for classification, as they do not contribute to classification of carbendazim.

Most of the aquatic studies have been performed using either Acetone or HCl (or both of them in parallel) as a solvent for carbendazim due to the low solubility of the test substance.

11.6.1 Chronic toxicity to fish

For the assessment of long-term toxicity to fish, a study with rainbow trout *Oncorhynchus mykiss* (formerly designated as *Salmo gairdneri*) in flow-through system has been evaluated.

Study **CLH_11_6_A7_4_3_2_1** represents a long-term study with *O. mykiss*, an early-life stage test according to OECD TG 210 and GLP requirements. Carbendazim was tested with a flow-through design at nominal concentrations of 0.00053, 0.0015, 0.0043, 0.012, 0.035 and 0.1 mg/L with dimethylformamide (DMF) as solvent (≤ 100 mg/L DMF in test solutions). 40 Rainbow trout eggs were placed approximately 21 h after fertilisation in each embryo cup with 2 replicates per test concentration and during the test after thinning reduced to 15 larvae per replicate. The test was performed with an additional solvent control and 6 treatment levels with carbendazim (90.3 % purity) as test substance. Embryo survival, hatching data and larval mortality were recorded daily, length and weight of fish were measured at the end of the test. Measured concentrations were within a range of 80 – 120 % of nominal concentrations, however test results have been recalculated on the basis of mean measured concentrations (0.00046, 0.0014, 0.0042, 0.011, 0.034, and 0.92 mg/L). During the last week of the test some technical problems occurred: At day 76 the dissolved oxygen concentrations dropped below 60 % of saturation in several concentrations and during the last week temperature was fluctuating between 9.6 and 12.8 °C. This was due to the accumulation of food in the exposure chambers and technical problems and none of these deviations were considered to be biologically significant due to the absence of abnormal effects in the controls. Consequently, the test can be considered as valid and provides reliable results. At the test concentrations of 0.034 and 0.092 mg/L none of the embryos survived to hatch. There were no statistically significant differences in the first and last day of hatching, percent hatch, larval survival, abnormal larvae, standard length, or wet weight in the remaining test concentrations. Based on embryo mortality after 79 d, a NOEC of 0.011 mg/L (mean measured) and a LOEC of 0.034 mg/L were derived. The study was considered as acceptable with a reduced reliability of 2 due to the technical problems in the last week of the test.

The lowest effect value for long-term fish toxicity is provided by study **CLH_11_6_A7_4_3_2_1**, resulting in a NOEC value of 0.011 mg/L. It should be noted that on basis of acute test results *O. mykiss* does not represent the most sensitive fish species, but *I. punctatus*. As only long-term data for *O. mykiss* is available, the hazard assessment cannot cover the acutely most sensitive fish species. It should be noted

that the LC_{50} for *I. punctatus* (LC_{50} = 0.019 mg/L) does not fall below the long-term toxicity to *O. mykiss* (NOEC = 0.011 mg/L).

11.6.2 Chronic toxicity to aquatic invertebrates

A semi-static reproduction study with *Daphnia magna*, study **CLH_11_6_A7_4_3_4_1**, was performed following OECD TG 202 and GLP requirements. The test was conducted with 4 replicates with 10 Daphnia each and HCl as solvent for carbendazim, together with a solvent control. Daphnia have been exposed to nominal concentrations of 0.001, 0.0018, 0.0032, 0.0056 and 0.01 mg/L of carbendazim (purity 99.4 %) and a solvent control has been performed with each 10 animals per vessel and 4 replicates for 21 d. Numbers of immobile parental animals and offspring as well as the development of embryos was determined three times a week. The solvent control showed already 20 % effect on reproduction when compared to the control without solvent, therefore this study should not considered being sufficiently sensitive to detect substance effects within the same order of magnitude. No effects have been observed up to the highest test concentration in relation to the solvent control but it cannot be ruled out that solvent effects interfered with test substance effects. A reduced reliability of 2 was set for this study since measured concentrations exceeded in most cases nominal concentrations (116 – 180 %). Due to the lack of effects observed and because for the highest concentration only a slight exceedance of nominal test substance concentration was measured, a recalculation to mean measured concentrations was not considered necessary and would not change the outcome of the study. A NOEC of ≥ 0.01 mg/L based on nominal concentrations was derived from this study.

Furthermore a semi-static study according to GLP-requirements was considered for classifiation. The study by Baer (1992) was performed with DMF as solvent and 7 replicates with each one adult Daphnia. Concentrations between 0.0015 and 0.1 mg/L were tested and the dose-response curve complies with a "hockey stick graph". A low slope was observed at the lower concentrations (12 – 19 % effects on reproduction at 0.0066 – 0.027 mg/L), whereas the next concentration of 0.05 mg/L showed already 99.9 % effects on reproduction. Since these low effects in the beginning were considered as ecotoxicologically relevant and statistically significant, a 21 d-NOEC of 0.0031 mg/L (based on mean measured concentration) was derived.

Reproduction study **CLH_11_6_A7_4_3_4_2** with *D. magna* was performed in accordance to OECD TG 202 and GLP requirements with a semi-static test design with 4 replicates with 10 Daphnia each. Daphnia were exposed to nominal concentrations of 0.0018, 0.0056, 0.018, 0.056 and 0.18 mg/L carbendazim (purity 99.5 %) for 21 days. Contrary to the other studies available, no solvent has been used. Numbers of immobile parental animals and offspring as well as the development of embryos was determined daily. Measured concentrations are within a range of 68 to 107 % of nominal in freshly prepared and aged solutions, mean measured concentrations within a range of 81 to 106 % of nominal (mean measured test concentrations: 0.0015, 0.0046, 0.015, 0.045 and 0.19 mg/L). After 21 days a NOEC = 0.0015 mg/L for reproduction was derived, based on mean measured concentrations of the test substance. At the next concentration step of 0.0046 mg/L (mean measured) already 100 % effect on reproduction and survival were observed. This study confirms the results from Baer, the dose-response curve showed effects on survival and reproduction at a level of 12 – 23 % over one order of magnitude (0.0046 to 0.045 mg/L mean measured concentration), whereas the next concentrations step revealed 100 % effect. The study was considered as valid according to the guideline and GLP requirements, reliable (reliability = 1) and acceptable without restrictions.

Despite the fact that study **CLH_11_6_A7_4_3_4_2** and the study by Baer show similar results, they were considered as too different to calculate a geometric mean out of both NOEC values: Only one of the studies was performed with DMF as solvent and study designs with respect to replicates differed markedly from one another (4 replicates with 10 Daphnia per vessel vs. 7 replicates with 1 Daphnia per vessel, having therefore different statistical power for the testing of the NOEC). Therefore, only study **CLH_11_6_A7_4_3_4_2** has been selected for long-term toxicity for Daphnia, furthermore representing the key study for chronic toxicity.

11.6.3 Chronic toxicity to algae or other aquatic plants

Acute and chronic toxicity to algae was assessed on basis of the same study and results of the evaluation are presented in the according section of the CLH report.

11.6.4 Chronic toxicity to other aquatic organisms

No chronic toxicity studies to other aquatic organisms are considered as relevant for Classification and Labelling.

11.7 Comparison with the CLP criteria

11.7.1 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 $\mathbf{M_{acute} = 10}$ (considering 0.01 mg/L < $LC_{50} \leq$ 0.1 mg/L).

11.7.2 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 $\mathbf{M_{chronic} = 10}$ (considering 0.001 mg/L < NOEC < 0.01 mg/L for non-rapidly degradable substances).

11.8 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.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

Degradation

Hydrolysis

In the hydrolysis study included in the dossier, rates were calculated for temperatures of 50°C and 60°C to be later extrapolated to 25°C and 12ºC. The Arrhenius equation was used for this extrapolation.

At 12ºC, carbendazim was found to be stable at pH 5 and 7 (>2 years). The mean half-live at pH 9 was around 153 days. 2-Aminobenzimidazole (2-AB) was determined as significant hydrolysis product and amounted for approximately 30% of the parent compound.

Ready biodegradability

A study on the ready biodegradability of carbendazim was performed according to OECD TG 301B. The CO_2 evolution measured after 4, 7, 14 and 28 days was less than 20% of the theoretical CO_2 content. Carbendazim is therefore considered not readily biodegradable by the Dossier Submitter.

Photochemical degradation

In the available study, carbendazim was demonstrated to be photolytically stable over the period of 166 hours corresponding to 35 sunny days under natural conditions at 52° Northern latitude in June. No transformation products were identified. The study was not conducted under environmentally relevant conditions (sterile, pH = 5). Thus, the extrapolation of the degradation rate constant from laboratory tests to natural water is limited.

Water/sediment degradation data

The dissipation of ^{14}C-Carbendazim was studied in two water/sediment systems (Bickenbach, Unter Widdersheim) incubated under aerobic conditions in the dark at 20 ±2°C over a period of 149 days (Guideline: SETAC Europe (1995): Procedures for assessing the environmental fate and ecotoxicity of pesticides).

DT_{50} values of 15.1 days (Bickenbach) and 76.8 days (Unter Widdersheim) were calculated for the total system, corresponding to 28.6 and 142.6 days, respectively, when converted to an average EU outdoor temperature of 12°C. Mineralisation amounted to 23.0 and 6.0% $^{14}CO_2$ after 149 days.

Throughout the study, several metabolites were identified in the water, sediment and whole system, some of them were not identified. With regard to the total system, no metabolite was detected above 10% of applied radioactivity.

Conclusion on degradation

Carbendazim is hydrolytically stable at pH 5 and 7. The Hydrolysis half-life at pH 9 exceeds 16 days (~ 153 days). The substance is not readily biodegradable. Half-lives derived from studies in water-sediment and soil were higher than 16 days (at 12°C) and mineralization was far below 70%. 2-AB (2-amino-benzimidazole, CAS Number 934-32-7) was detected as significant hydrolysis product and relevant metabolite (> 10%) during degradation in soil (= 10%). Based on the available information, the DS considered carbendazim as not rapidly degradable, for classification purposes.

Bioaccumulation

In anonymous (1984a), bioconcentration was determined in a flow-through test on Bluegill sunfish (*Lepomis macrochirus*) with two concentrations of radiolabelled carbendazim (0.018 and 0.17 mg/L) based on EPA Guidelines. The results were similar at the two exposure concentrations with maximum BCFs of 27 and 23 L/kg at the low and high exposures, respectively. It remains unclear if steady state was reached, since after a plateau between 14 and 21d, concentrations in fish increased again at day 28. The study was considered as acceptable with a reliability of 2. The BCF for fish does not exceed the trigger value of 500 L/kg and therefore indicates a low potential for bioaccumulation, for classification purposes.

The estimated log k_{ow} for carbendazim according to OECD TG 107 was estimated to be 1.5. According to CLP, a log $K_{ow} \geq 4$ is used to indicate a potential for bioaccumulation, therefore the log K_{ow} also indicates a low potential for bioaccumulation for carbendazim.

Aquatic toxicity

Acute toxicity

The next table shows information available for acute toxicity. Only valid studies are included here, supporting data included in the CLH dossier is not presented. All studies conducted with technical grade carbendazim (> 90%).

Method	Species	Results	Remarks	Reference
OECD TG 203	*Cyprinus carpio*	LC_{50} (96 h) = 0.44 mg/L nominal	Static	Anonymous, 1988a CLH_11_5_A7_4_1_1_1
OECD TG 203	*Oncorhynchus mykiss*	LC_{50} (96 h) = 0.83 mg/L mean measured	static	Anonymous, 1988b CLH_11_5_A7_4_1_1_2
OECD TG 204	*Oncorhynchus mykiss*	LC_{50} (96 h) > 0.56 mg/L nominal	Flow-through	Anonymous, 1989 A40788CLH_11_6_A7_4_3_1_1
ASTM	***Ictalurus punctatus***	**LC_{50} (96 h) = 0.019 mg/L nominal**	**static**	**Palawski, 1986 CLH_11_5_A7_4_1_1_3 Key study**
ASTM	*Oncorhynchus mykiss*	LC_{50} (96 h) = 0.87 mg/L nominal	static	Palawski, 1986 CLH_11_5_A7_4_1_1_3
ASTM	*Lepomis macrochirus*	LC_{50} (96 h) > 3.2 mg/L nominal	static	Palawski, 1986 CLH_11_5_A7_4_1_1_3
OECD TG 202	*Daphnia magna*	EC_{50} (48 h) = 0.15 mg/L nominal	static	Fischer, 1988 CLH_11_5_A7_4_1_2_1
OECD TG 201	*Desmodesmus subspicatus*	E_rC_{50} (72 h) > 8 mg/L nom. conc., max. water solubility	static	Heusel, 1991 CLH_11_5_A7_4_1_3_2

Two studies on acute toxicity of carbendazim in fish (Anonymous, 1988a,b) and a prolonged study in accordance with OECD TG 204 (Anonymous, 1989) have been evaluated in detail.

In Anonymous (1988a), *Cyprinus carpio* (Mirror carp) was exposed to carbendazim (99.4 %) OECD TG 203. Ten fish per tested concentration with an age of 11 – 13 month (3.4 – 4.2 cm length and a weight of 1.7 – 3.2 g) were exposed to nominal concentrations of 0.018, 0.032, 0.056, 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 mg carbendazim/L. The LC_{50} was 0.44 (0.33 – 0.58) mg/L. The validity criteria according to OECD TG 203 were met. The study was considered by the DS as acceptable with a reliability of 1.

In Anonymous (1988b), *Oncorhynchus mykiss* (Rainbow trout) was exposed to nominal concentrations of 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10 mg/L in a first test (a) and in a second test (b), with 0.010, 0.018, 0.032, 0.056, 0.10 and 0.18 mg/L of carbendazim 99.4 %, both with acetone as solvent for a duration of 96h (0.1 mL acetone/L). The test substance precipitated in the test media at concentration levels of 0.32 mg/L and higher, therefore the results refer to mean measured concentrations of the test substance with an LC_{50} (96h) = 0.83 mg/L calculated (with a 95 % confidence interval of 0.55 – 1.97 mg/L). The study fulfils the validity criteria according to OECD TG 203 and a reliability of 1 was given.

In Palawski (1986), carbendazim toxicity was assessed for three different fish species, *Oncorhynchus mykiss*, *Ictalurus punctatus* (Channel catfish) and *Lepomis macrochirus* (Bluegill) with 10 fish per test concentration and 96h of duration. Furthermore, additional test series were performed to determine effects of temperature, pH, water hardness and effects on early life stages on *O. mykiss* and *I. punctatus*. The study followed a static test design, analytical monitoring of test substance was not performed, and results for controls and data on validity of the test were not reported. However, the non-GLP study was performed according to an ASTM guideline. The study revealed for *I. punctatus* a LC_{50} (96h) of 0.019 mg/L (95 % confidence limit = 0.013 – 0.027 mg/L), for *O. mykiss* a LC_{50} (96h) of 0.87 mg/L (95 % confidence limit = 0.63 – 1.19 mg/L) and for *L. macrochirus* a LC_{50} (96h) > 3.2 mg/L, based on nominal concentrations of carbendazim. The study was considered by the DS as acceptable with a reliability of 2. As this study provided the lowest acute effect value for carbendazim for fish with 96h LC_{50} = 0.019 mg/L (nom.) for *I. punctatus*, this study was chosen as a key study.

Anonymous (1989) represents a prolonged study according to OECD TG 204 and was further prolonged to cover a period of 21 days. In the test no mortalities occurred up to the highest tested concentration within the first 96 h, consequently a LC_{50} > 0.56 mg/L can be derived from this study.

For aquatic invertebrates, Fischer (1988) assessed the toxicity of carbendazim to *Daphnia magna* in a static-acute toxicity test according to OECD TG 202 and following GLP. Four tests (test A, B, C, D) with two different vehicles (HCL and acetone) and with different series of test substance concentrations were performed. Test A had a concentration range from 0.1 to 1 000 mg/L with HCL as a vehicle. In Test B and C, the concentration ranged from 0.001 to 10 mg/L, using acetone as a vehicle. In Test D, test b was replicated using HCl as a vehicle. Out of these, test series 'D' was considered relevant for EC_{50} derivation. An EC_{50} = 0.15 mg/L was obtained based on nominal concentrations (concentrations within the HCL system remain within ± 20 of nominal).

Acute toxicity to algae (Heusel, 1991), was assessed based on a study without chemical analysis of test substance concentration. The study was performed with *Desmodesmus*

subspicatus (formerly *Scenedesmus subspicatus*) following OECD TG 201 and in accordance with GLP. Cell growth was monitored at 24, 48 and 72 h. A high concentration range was covered (nom. 1.0, 1.8, 3.2, 5.6, 10,18, 32, 56, 100, 180, 320, 560 and 1000 mg/L), with the higher concentrations exceeding the maximum solubility of 8 mg/L in water, leading to a visible precipitate of the test substance. The highest concentration without precipitate, 10 mg/L, showed no effects on the test organism. Hence, it can be concluded that EC_{50} values are higher than the water solubility limit of carbendazim, E_rC_{50} > 8 mg/L. The study was considered as acceptable and reliable for aquatic hazard assessment.

Chronic toxicity

The next table shows information available for chronic toxicity. Only valid studies are included here, supporting data included in the CLH dossier is not presented here. All studies conducted with technical grade carbendazim (> 90%).

Method	Species	Results	Remarks	Reference
OECD TG 210	*Oncorhynchus mykiss*	NOEC (79 d) = 0.011 mg/L mean measured	flow-through	Anonymous, 1993 CLH_11_6_A7_4_3_2_1
OECD TG 202	*Daphnia magna*	NOEC (21 d) ≥ 0.01 mg/L nominal	semi-static	Fischer, 1988 CLH_11_6_A7_4_3_4_1
OECD TG 202	***Daphnia magna***	**NOEC (21 d) = 0.0015 mg/L mean measured**	**semi-static**	**Kelly et al. 1997 CLH_11_6_A7_4_3_4_2 Key study**
OECD TG 201	*Desmodesmus subspicatus*	NOE_rC (72 h) = 8 mg/L nom. conc., max. water solubility	static	Heusel, 1991 CLH_11_5_A7_4_1_3_2

Anonymous (1993) investigated long term toxicity to *O. mykiss* according to OECD TG 210 and GLP. Measured concentrations were within a range of 80 – 120 % of nominal concentrations, however test results have been recalculated on the basis of mean measured concentrations (0.00046, 0.0014, 0.0042, 0.011, 0.034, and 0.92 mg/L). Embryo survival, hatching data and larval mortality were recorded daily, length and weight of fish were measured at the end of the test. Based on embryo mortality after 79d, a NOEC of 0.011 mg/L and a LOEC of 0.034 mg/L were derived. The study was considered acceptable, reliability 2, due to the technical problems in the last week of the test.

A semi-static reproduction study with *Daphnia magna* (Fisher, 1988) was performed following OECD TG 202 and GLP. Daphnia were exposed to nominal concentrations of 0.001, 0.0018, 0.0032, 0.0056 and 0.01 mg/L and a solvent control was performed with each 10 animals per vessel and 4 replicates for 21d. Numbers of immobile parental animals and offspring as well as the development of embryos was determined three times a week. A reliability of 2 was given for this study since measured concentrations exceeded in most cases nominal concentrations (116 – 180 %). Due to the lack of effects observed and because for the highest concentration only a slight exceedance of nominal concentration was measured, a recalculation to mean measured concentrations was not considered necessary. A NOEC of ≥ 0.01 mg/L was derived from this study.

The reproduction study with *D. magna* (Kelly *et al*. 1997) was performed in accordance with mean measured concentrations were within a range of 81 to 106 % of nominal: 0.0015, 0.0046, 0.015, 0.045 and 0.19 mg/L. After 21 days a NOEC = 0.0015 mg/L for reproduction was derived, based on mean measured concentrations. The study was considered valid, reliability 1.

In Heusel (1991) (see study summary above), a NOEC = 8 mg/L was obtained for *D. subspicatus.*

DS conclusion on classification

Adequate acute toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants). The fish species *Ictalurus punctatus* LC_{50} = 0.019 mg/L (nominal concentration) was the most acutely sensitive species tested. Based on this value, the DS proposed classification as Aquatic Acute 1 (H400), M = 10 (considering 0.01 mg/L < LC_{50} ≤ 0.1 mg/L).

Carbendazim is considered as not rapidly degradable and has a low potential for bioaccumulation. Adequate chronic toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants). In the available data, invertebrates represent the most sensitive trophic level for chronic toxicity and a NOEC of 0.0015 mg/L for Daphnia magna was considered for classification.

Based on this value, the DS proposed classification as Aquatic Chronic 1, H410, with M = 10 (considering 0.001 mg/L < NOEC < 0.01 mg/L for non-rapidly degradable substances).

Comments received during public consultation

Two MSCAs commented on the CLH proposal. One MS agreed with the proposed classification. The other MS asked for further information to clarify the relevance and reliability of the Palawski (1986) and the use of *Ictalarus punctatus* data for acute classification. In addition, it asked for further clarification on the use of yolk sac fry data for classification.

The DS submitter provided further information on the study (see RCOM) and concluded that it is valid. Furthermore, it indicated within the same study there are further results for *O. mykiss* which perfectly match the results from a GLP-study according to OECD TG 203 from 1988, which was considered as valid (96 h LC_{50} = 0.87 mg/L in Anonymous, 1984, vs. 96 h LC_{50} = 0.83 mg/L in Anonymous, 1988b).

In relation to the yolk sac fry data, the DS does not consider these results relevant for classification.

Assessment and comparison with the classification criteria

Rapid degradability

RAC agrees with the DS and considers the carbendazim to be **not rapidly degradable:** carbendazim is hydrolytically stable at pH 5 and 7. Hydrolysis half-life at pH 9 exceeds 16 days (~ 153 days). The substance is not readily biodegradable. In all simulation studies (water-sediment and soil), DT_{50} values were higher than 16 days (at 12 °C) and mineralisation did not reach 70 % within 28 days.

Bioaccumulation

RAC agrees with the DS and considers carbendazim as **non bioaccumulative**. The measured BCF_{fish} value of 27 L/kg does not exceed the trigger value of 500 L/kg and the measured log k_{ow} = 1.5 does not exceed the trigger value of 4.

Aquatic toxicity

RAC analysed the Palawski (1986) study (also published as Palawski and Knowles, 1986) and recognises that relevant data for its reliability assessment is missing, i.e.: Tested concentrations and control data were not provided and validity criteria cannot be checked.

Despite these shortcomings, RAC agrees with the DS and accepts the endpoint LC_{50} = 0.019mg/L for acute classification and considers the following regarding the acute data for the yolk sac fry endpoints:

- Although the data is not ideal, the acute endpoint is obtained following a standard test (ASTM) comparable to OECD TG 203. Aspects known for RAC such as fish size (1.2 g), temperature (22 ºC), feeding regime (no food was provided 24 hours before the test started and during the test), number of fish (10), observations (done every 24h) and water hardness are all within Guideline Requirements.
- The results presented within the study are plausible, in fact the results for *O. mykiss*, 96h LC_{50} = 0.87 mg/L, are in good agreement with the corresponding study by Fisher (1988), which provides 96h LC_{50} = 0.83 mg/L for the same species.
- RAC considers the yolk sac fry test more comparable with OECD TG 236 Fish Embryo Acute Toxicity (FET). However, with the data available it is difficult to assess the embryo test adequacy. In addition, FET was designed for *Danio rerio* and would need to be adapted for *I. punctatus*. In the *I. punctatus* test, exposure time, life stage, temperature, etc., might not be the adequate.
- FET has uncertainties related to its predictive capacity and its applicability in the Regulatory Context as a substitute of standard tests. For many chemicals, FET sensitivity is lower than the OECD 203 although the reasons why this occurs are unknown. A limit number (thiophanate-methyl among them) exhibited a higher toxicity in FET with an FET/AFT LC_{50} ratio < 0.1. These may represent substances with a mode of action specific for embryonic development. Yet the reasons are unknown. In addition, there are still uncertainties in relation to its applicability domain, etc.

- For the above reasons it is not recommended to use it as a direct one-to-one replacement for OECD TG 203 under REACH, although it can be used in a weight of evidence approach.

Consequently, for acute classification RAC agrees with the DS and considers that adequate acute toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants).

Fish *Ictalurus punctatus* LC_{50} (96h) = 0.019 mg/L

Invertebrates *Daphnia magna*: EC_{50} (48h) = 0.15 mg/L

Algae *D. subspicatus* EC_{50} (72h) > 8 mg/L

The most sensitive species tested in the aquatic compartment is *Ictalurus punctatus* LC_{50} = 0.019 mg/L (nominal concentration). Based on this and considering that 0.01 mg/L < LC_{50} ≤ 0.1 mg/L, the substance fulfils the criterion for Acute classification and warrants classification **Aquatic Acute 1 (H400)**, **M = 10**.

For chronic classification RAC agrees with the DS and considers that adequate chronic toxicity data are available for all three trophic levels (fish, crustacean, algae/aquatic plants):

Fish, *O. mykiss* NOEC (79d) = 0.011 mg/L

Invertebrates*, Daphnia magna* NOEC (21d) = 0.0015 mg/L

Algae, *D. subspicatus* NOE_rC (72h) = 8 mg/L.

Hence, according to the classification criteria the classification for the long term aquatic hazards the substance being not rapidly degradable and with a NOEC of 0.0015 mg/L for *Daphnia magna* (0.001 mg/L < NOEC < 0.01 mg/L), carbendazim warrants classification as **Aquatic chronic 1 (H410), M = 10.**

It should be noted that on the basis of acute test results *O. mykiss* does not represent the most sensitive fish species under acute testing, as *I. punctatus* gives more conservative results. As only long-term data for *O. mykiss* are available, the hazard assessment cannot cover chronic data for the most acutely sensitive fish species. Using the acute data for *I. punctatus* in the surrogate approach, the same classification as that using the chronic invertebrate data (as proposed above) would be obtained.

In summary, RAC agrees with the DS that carbendazim is non-rapidly degradable, non bioaccumulative and warrants classification as Aquatic Acute 1; H400 (M = 10) and Aquatic Chronic 1; H410 (M = 10).

12 EVALUATION OF ADDITIONAL HAZARDS

12.1 Hazardous to the ozone layer

Emission of carbendazim to air can occur during the manufacture or the service life of carbendazim-containing products. In absence of specific effect data, only a qualitative hazard assessment can be carried out for the atmosphere compartment. As carbendazim is only slightly volatile (vapour pressure = 9×10^{-5} Pa at 20 °C) and degrades quickly in the atmosphere with regard to the estimated half life of 1.92 hours for indirect photolysis i.e. the reaction with free radicals, a significant accumulation of carbendazim in the air seems to be unlikely. Direct exposure of air is therefore considered negligible. The derivation of a hazard class is not feasible.

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