CLH report

Proposal for Harmonised Classification and Labelling

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

Substance Name:

5-Chloro-2-(4-chlorophenoxy)-phenol

EC Number: **429-290-0**

CAS Number: **3380-30-1**

Index Number: **605-023-00-5**

Contact details for dossier submitter:

Umweltbundesamt GmbH

on behalf of

AT Competent Authority

Federal Ministry of Agriculture, Forestry, Environment and Water Management

Version number: 3 **Date: 19 December 2014**

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Part A.

Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	***5-Chloro-2-(4-chlorophenoxy)-phenol***
EC number:	***429-290-0***
CAS number:	***3380-30-1***
Annex VI Index number:	***605-023-00-5***
Degree of purity:	***99.1%w/w***
Impurities:	***The manufacturer has requested that all impurities remain confidential since it may provide an indication on the possible method of manufacturing. Information on impurities is provided in the confidential IUCLID section 1.2 (Composition) and in the "confidential" attachment.***

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation
Current entry in Annex VI, CLP Regulation	Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1 H318 H400 H410
Current proposal for consideration by RAC	Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)

	CLP Regulation
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Eye Dam. 1 Aquatic Acute 1 (M=10) Aquatic Chronic 1 (M=10) H318 H400 H410

The proposal contains only information related to the hazard classes and/or differentiations which revise the existing Annex VI entry based on the information available according to ECHA, 2012[1]. This concerns specifically the M-Factor for Environment hazards.

[1] Guidance on the application of the CLP Criteria, http://echa.europa.eu/documents/10162/13562/clp_en.pdf (2013-07-05)

1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or DSD criteria

Table 3: Proposed classification according to the CLP Regulation (including criteria according to 2nd ATP of CLP)

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.2.	Flammable gases	n.a.	n.a.	currently not classified	data lacking
2.3.	Flammable aerosols	n.a.	n.a.	currently not classified	data lacking
2.4.	Oxidising gases	n.a.	n.a.	currently not classified	data lacking
2.5.	Gases under pressure	n.a.	n.a.	currently not classified	data lacking
2.6.	Flammable liquids	n.a.	n.a.	currently not classified	data lacking
2.7.	Flammable solids	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.9.	Pyrophoric liquids	n.a.	n.a.	currently not classified	data lacking
2.10.	Pyrophoric solids	n.a.	n.a.	currently not classified	data lacking
2.11.	Self-heating substances and mixtures	n.a.	n.a.	currently not classified	data lacking
2.12.	Substances and mixtures which in contact with water emit flammable gases	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.13.	Oxidising liquids	n.a.	n.a.	currently not classified	data lacking
2.14.	Oxidising solids	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.15.	Organic peroxides	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
2.16.	Substance and mixtures corrosive to metals	n.a.	n.a.	currently not classified	data lacking
3.1.	Acute toxicity - oral	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
	Acute toxicity - dermal	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
	Acute toxicity - inhalation	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation	Eye dam.1 H318: Causes serious eye damage	n.a.	currently classified	-
3.4.	Respiratory sensitisation	n.a.	n.a.	currently not classified	data lacking
3.4.	Skin sensitisation	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.5.	Germ cell mutagenicity	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.6.	Carcinogenicity	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.7.	Reproductive toxicity	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.10.	Aspiration hazard	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
3.11.	Risk for breast fed babies	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	Aquatic Acute 1 H400: Very toxic to aquatic life Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.	M=10 M=10	currently classified, but without M Factor	
5.1.	Hazardous to the ozone layer	n.a.	n.a.	currently not classified	conclusive but not sufficient for classification

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: (Including criteria according to 2nd ATP of CLP)

GHS Pictograms:

GHS05

GHS09

Signal word: Danger

Hazard statements:
H318 – Causes serious eye damage
H410 – Very toxic to aquatic life with long lasting effects

Precautionary statements:
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P273 – Avoid release to the environment
P308 + P313+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 – Immediately call a POISON Center or doctor/physician.
P391 – Collect spillage
P501 - Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).

Proposed notes assigned to an entry: none

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

The substance was agreed by written procedure in the 13th sending for the written procedure on classification and labelling of dangerous New Substances. Therefore DCPP was not scheduled for discussion at the 16th meeting for C&L New Chemicals on 13-14 May (Environment) or April (Human Health) 2004.

DCPP was listed in a draft 30th ATP in December 2004. Under the Index number 605-023-00-5 DCPP has been included in the 30th ATP (COMMISSION DIRECTIVE 2008/58/EC).

The REACH registration dossier was taken into account: This dossier is a registration update of a previously notified substance which did not reach the next tonnage threshold under the REACH regulation. It was updated because of a change in classification and labelling (creation of dossier: 2011-08-04). The original data from the NONs-file were not examined in detail.

2.2 Short summary of the scientific justification for the CLH proposal

Acute aquatic toxicity: L(E)C50 values ≤1 mg/L for all three trophic levels. Lowest available EC50 value = 0.038 mg/L.

Chronic aquatic toxicity: The active substance is not rapidly degradable and the NOECs are below 0.1 mg/L. Lowest available NOEC = 0.0093 mg/l.

According to the classification criteria of Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 DCPP causes serious eye damage and is very toxic to aquatic life with long lasting effects: The acute effects lead to the classification Aquatic Acute 1 with an M-Factor of 10, the chronic effect data lead to the classification Aquatic Chronic 1 with an M-Factor of 10. The acute lowest toxicity value is >0.01 to < 0.1 mg/L. The reported lowest chronic toxicity value is >0.001 to < 0.01 mg/L and the substance is not rapidly degradable.

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

According to Annex II of Commission Regulation (EC) No 790/2009

Classification: Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1

H318, H400, H410

Labelling: GHS05, GHS09, Dgr

H318, H410

2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

According to Annex V of Commission Regulation (EC) No 790/2009

Classification: Xi; R41 - N; R50-53

Labelling: Xi; N - R: 41-50/53, S: (2-)26-39-60-61

2.4 Current self-classification and labelling

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2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

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2.4.2 Current self-classification and labelling based on DSD criteria

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3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Biocides: No need for justification.

Deviation/amendment to the current harmonised classification concerning environmental hazards and the M-factor.

Part B.

SCIENTIFIC EVALUATION OF THE DATA

Preliminary Note: Doc. III-A (=Document III-A) refers to the key study summary for the respective endpoint of the biocidal draft Competent Authority Report.

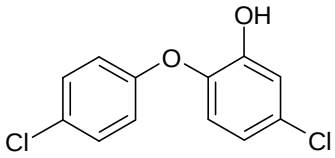
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 4: Substance identity

EC number:	429-290-0
EC name:	-
CAS number (EC inventory):	-
CAS number:	3380-30-1
CAS name:	Phenol, 5-chloro-2-(4-chlorophenoxy)-
IUPAC name:	5-Chloro-2-(4-chlorophenoxy)-phenol
CLP Annex VI Index number:	605-023-00-5
Molecular formula:	$C_{12}H_8Cl_2O_2$
Molecular weight range:	255.1 g/mol

Structural formula:



1.2 Composition of the substance

According to a five batch analysis (Study A2.7/01) the minimum degree of purity of DCPP is 99.1%w/w.

Detailed information on the chemical composition of the active substance as manufactured is confidential (please see ICULID section 1.2)

Current Annex VI entry: no information stated.

No additives

1.2.1 Composition of test material

See confidential information (IUCLID section 1.2) and “confidential” attachment.

1.3 Physico-chemical properties

Table 5: Summary of physico - chemical properties

Property	Method	Results	Reference
Melting point	OECD guideline 102	73.6°C	Doc. III-A 3; Study A3.1/01
Boiling point	OECD guideline 103	359.3°C	Doc. III-A 3; Study A3.1/02
Density	OECD guideline 109 CIPAC MT 186	relative density D^{20}_{4}=1.47 Pour density = 0.45 g/mL; Tap density = 0.61 g/mL.	Doc. III-A 3; Study A3.1/03 Doc. III-A 3; Study A3.1/04
Vapour pressure	OECD guideline 104	$1.2*10^{-06}$ Pa at 25 °C Calculated at 20°C = $4.3*10^{-7}$ Pa.	Doc. III-A 3; Study A3/01
Henry´s Law Constant	Calculation based on QSAR	Results at 25 °C: $6.82*10^{-04}$ $Pa*m^3*mol^{-1}$ (Bond method) $2.53*10^{-03}$ $Pa*m^3*mol^{-1}$ (Group method)	Doc. III-A 3; Study A3.2/02
Physical state	Visual inspection	Crystalline powder	Doc. III-A 3; Study A3.3/01
Colour	Visual inspection	White (pale grey)	Doc. III-A 3; Study A3.3/01

Property	Method	Results	Reference
Odour	Olfactory inspection	Slightly smelling like phenols	Doc. III-A 3; Study A3.3/01
Absorption spectra: UV/VIS	OECD guideline 101	There is an absorption maxima at 277 nm.	Doc. III-A 3; Study A3.4/01
Absorption spectra: IR	The test was performed according to internal standard operation procedures.	DCPP was identified by FTIR-spectrum using a KBR-pellet	Doc. III-A 3; Study A3.4/01
Absorption spectra: NMR	The test was performed according to internal standard operation procedures.	DCPP was identified by ^{1}H-NMR spectrum.	Doc. III-A 3; Study A3.4/01
Absorption spectra: MS	The test was performed according to internal standard operation procedures.	DCPP was identified by MS spectrum.	Doc. III-A 3; Study A3.4/01
Water solubility	OECD guideline 105 HPLC-UV	Solubility at 20°C: 19.5 mg/L; pH 5-6. pH 5 and 10°C 6.3 mg/L; pH 5 and 20°C 10 mg/L; pH 5 and 30°C 14.7mg/L.	Doc. III-A 3; Study A3.5/01 Doc. III-A 3; Study A3.5/02
Dissociation constant	OECD guideline 112	pKa=9.49 (20°C).	Doc. III-A 3; Study A3.6/01
Solubility in organic solvents, including the effects of temperature on stability	HPLC-UV	Solubility in n-hexane: ~ 8.7 mg/L at 10 °C; ~ 18.6 mg/L at 20 °C; ~ 27.0 mg/L at 30 °C Solubility in n-octanol: ~ 36.8 mg/L at 10 °C; ~ 43.7 mg/L at 20 °C; ~ 51.4 mg/L at 30 °C	Doc. III-A 3; Study A3.5/02
Partition coefficient n-octanol/water	OECD guideline 117 Calculation	Log Pow = 3.7 at 20 °C Log Pow = 4.8 at 10 °C Log Pow = 4.6 at 20 °C Log Pow = 4.5 at 30 °C	Doc. III-A 3; Study A3.9/01 Doc. III-A 3; Study A3.5/02
Thermal stability identity of relevant breakdown products	OECD guideline 113	Based on DCS and TGA measurements, it can be concluded that the active substance is stable between 30 and 150°C.	Doc. III-A 3; Study A 3.10/01

Property	Method	Results	Reference
Flammability, including autoflammability and identity of combustion products	EC method A.10, A.12 and A.13	DCPP is not highly flammable. DCPP is not auto-flammable.	Doc. III-A 3; Study A 3.11/01 Doc. III-A 3; Study A 3.11/02
Flash point	Company Statement	Not performed because the active substance is solid.	Company Statement
Surface tension	OECD guideline 115	65 mN/m at 19.7 °C	Doc. III-A 3; Study A3.13/01
Viscosity	Company Statement	Not performed because the active substance is solid	Company Statement
Explosive properties	Company Statement	There is no structural alert for explosive properties..	Company Statement
Oxidizing properties	Company Statement	There is no structural alert for oxidizing properties.	Company Statement
Granulometry		No data available	

2 MANUFACTURE AND USES

2.1 Manufacture

Biocides: Does not need to be specified for the CLH proposal.

2.2 Identified uses

PT1: Human hygiene biocidal products

PT2: Private area and public health area disinfectants and other biocidal products

PT4: Food and feed area disinfectants

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Table 6: Summary table for relevant physico-chemical studies

Property	Method	Results	Reference
Thermal stability identity of relevant breakdown products	OECD guideline 113	Based on DCS and TGA measurements, it can be concluded that the active substance is stable between 30 and 150°C.	Doc. III-A 3; Study A 3.10/01
Flammability, including autoflammability and identity of combustion products	EC method A.10, A.12 and A.13	DCPP is not highly flammable. DCPP is not auto-flammable.	?
Flash point	Company Statement	Not performed because the active substance is solid.	Company Statement
Explosive properties	Company Statement	There is no structural alert for explosive properties..	Company Statement
Oxidizing properties	Company Statement	There is no structural alert for oxidizing properties.	Company Statement

3.1 *[Insert hazard class when relevant and repeat section if needed]*

No classification is proposed based on available data.

3.1.1 Summary and discussion of

No classification is proposed based on available data.

3.1.2 Comparison with criteria

No classification is proposed based on available data.

3.1.3 Conclusions on classification and labelling

No classification is proposed based on available data.

4 HUMAN HEALTH HAZARD ASSESSMENT

No proposal for revision or amendment to the existing harmonised classification is made.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Note: key studies are highlighted **bold**

5.1 Degradation

Summary of relevant information on degradation: please see single subsections

5.1.1 Stability

Hydrolysis

The abiotic degradation of DCPP in the dark (i.e. hydrolysis) was investigated in one study at 50°C in sterile aqueous buffer solutions at pH values of 4, 7 and 9 following the preliminary test of OECD guideline 111 (see **Doc. III-A 7.1.1.1.1, Study A 7.1.1.1.1**). The test vessels with test substance were incubated in the dark for up to 5 days. No degradation of test substance was measured after 5 days at these pH values using HPLC (see table 7). Therefore, DCPP is considered to be hydrolytically stable and to reveal a hydrolysis half-life of more than one year at temperatures up to 25°C and within the range of the tested and environmentally relevant pH levels, as less than 10% of the test substance was degraded during this test.

Table 7: Hydrolysis of DCPP

Guideline / Test method	pH	Temp. [°C]	Initial TS concentration, C_0 [mg/L]	TS concentration after 5 days incubation [mg/L]	Reaction rate constant, K_h [s^{-1}]	Half-life, DT50 [h]	Reference
OECD guideline 111 and following GLP	**4, 7, 9**	**50**	**pH 4: 2.700 and 2.804**	**pH 4: 2.931 and 2.915**	**Not available**	**Not available for 50°C**	**Doc. III-A 7.1.1.1.1, Study A 7.1.1.1.1**
			pH 7: 1.085 and 1.025	**pH 7: 1.195 and 1.157**		**Estimate: > 1year at 25°C**	
			pH 9: 32.0003 and 32.064	**pH 9: 32.829 and 32.958**			

Photolysis in water

A test on the phototransformation of DCPP in water was performed according to "OECD Guideline for Testing of Chemicals, Proposal for a new Guideline, Phototransformation of Chemicals in Water – Direct and Indirect Photolysis, Draft Document, August 2000", which has already been adopted as OECD-guideline 316 (see Doc. III-A 7.1.1.1.2, Study A 7.1.1.1.2/01).

The UV/VIS absorption spectrum of DCPP between 200 nm and 800 nm reveals that DCPP absorbs light only at wavelengths below 400nm. Simulated sunlight from a Hanau Suntest apparatus, equipped with a xenon lamp with filters to remove wavelengths below 290 nm, was used for irradiation. The radiolabelled test item was irradiated at an initial concentration of 0.21 mg/L in sterile buffer solution at pH 7 (at 25°C) over a continuous period of 19 days.

DCPP underwent rapid photolysis with its amount decreasing from 100% of applied initially to 53.0% after 6 hours irradiation. By day 2, it had declined to represent 1.3% of the applied radioactivity, and from day 5 onwards, it was not detectable any more. DCPP remained stable in the dark, still representing 98.5% of the applied radioactivity at the end of the study (day 19). The Suntest half life of DCPP was calculated to be 0.27 days (continuous irradiation, 1 day = 24h at 25°C). The quantum yield for the photochemical reaction was determined to be Φ = 0.986 molecules degraded per photon. Using the quantum yield, the half-life of DCPP in aqueous systems at latitudes between 30°N and 50°N was estimated and shown to range from 0.24 days to 4.86 days depending on latitude and season (calculated by GC SOLAR, version 1.20, U.S. EPA) (see table 8).

Table 8: Phototransformation of DCPP in water

Guideline Test method	**pH**	**Temp. (°C)**	**Initial TS concen-tration, C_0 (mg/L)**	**Photoly-sis rate constant, (k^c_p, $days^{-1}$)**	**Reaction quantum yield, f^cE (molecules degraded per photon)**	**Half-life, DT_{50}, in aqueous systems, (days)**	**Metabolites formed (max. %/at day of irradiation)**	**Reference**
OECD guideline 316 and following GLP	**7**	**24.8 ± 0.2**	**0.21**	**2.607**	**0.986**	**DT_{50}, lab*:** **DCPP: 0.27** **M1: 1.61** **M7: 0.98** **M8: 0.72** **DT_{50}, env**:** **DCPP:** **Latitude 30°N: 0.24 – 0.76** **Latitude 40°N: 0.27 – 1.63** **Latitude 50°N: 0.32 – 4.86**	**M1 (26.3/2)** **M2 (6.5/0.17 and 0.25)** **M4 (14/19)** **M7 (19.9/1)** **M8 (20.4/0.25)** **M16 (42.9/9)** **M17 (36.3/19)**	**Doc. III-A 7.1.1.1.2, Study A 7.1.1.1.2/01** **and Study 7.1.1.1.2/02**

* Suntest half life of DCPP and metabolites (continuous irradiation, 1 day = 24h at 25°C)

**Minima and maxima represent values for summer and winter season, respectively.

Six major photodegradates accounting for more than 10% of the applied radioactivity were formed during the study (M1, M4, M7, M8, M16, and M17) (see **Doc. III-A 7.1.1.1.2, Study A 7.1.1.1.2/01 and Study 7.1.1.1.2/02)**.

M1, M7, and M8 showed a clear curve of formation and decline with maximum mean amounts of 26.3% (day 2), 19.9% (day 1) and 20.4% (day 0.25) of the applied radioactivity, respectively. At the end of the study M1 accounted to 2.3% while M7 and M8 were below detection limit. M4, M16 and M17 reached their maxima at the second last or last sampling interval, accounting for 14% (day 19), 42.9% (day 9) and 36.3% (day 19) of the applied radioactivity, respectively. Besides DCPP and the major metabolites M1, M4, M7, M8, M16, and M17 (> 10%), one fraction (M2) was detected which exceeded levels of 5% of applied. The detected amounts of all other metabolites detected were lower than 4.4% of applied radioactivity.

LC/MS analysis was used for metabolite identification. It could be shown that M1, M16 and M17 are nonhalogenated and highly polar compounds. M2 was identified as 4-chlorocatechol, M7 as monochlordihydroxybiphenylether and M8 as a condensation product. M4 was not identified. The applicant stated that it was not possible to determine it technically. This was not considered to be

conclusive. Regarding the structure of DCPP, a dioxine or another hazardous substance could be a potential degradation product. Therefore, the missing identity of M4 represents a concern.

According to the results of this test the following degradation pathways are assumed:

- Dechlorination most probably with following ring opening/formation of highly polar compounds
- Condensation most probably with following ring opening
- Cleavage of the ether binding and formation of chlorocatechol

Mineralization of the photodegradation products of ^{14}C-DCPP continuously increased with study progress. On day 19 $^{14}CO_2$ accounted for 20.3% of the applied radioactivity. Low amounts of radioactivity were detected in the fraction of organic volatiles not exceeding 2.1% of applied.

The rate of photodegradation of the major photodegradates M1, M7, and M8, were described using simple first order and consecutive first order kinetics, respectively. M1, M7 and M8 are further photolysed with Suntest half-lives of 1.61, 0.98, and 0.72 days, respectively (see table 8).

Phototransformation in air

DCPP is susceptible to photochemical degradation in the gas phase as proven by the estimation according to the methology described in the TGD (EC 2003, part II, p. 51).

The half-life of DCPP in air due to indirect photodegradation, i.e. oxidation with photochemically produced hydroxyl radicals, was calculated using the software programme AOPWIN, v. 1.92. The prediction is based on the chemical structure of the substance and is entered by SMILES notation.

The half-life of DCPP in the troposphere was calculated to be 19.701 hours (0.821 days) with a degradation rate ($kdeg_{air}$) of 0.84 day^{-1} (see table 4.1-3; see **Doc. III-A 7.3.1, Study A 7.3.1)**. These values are based on a 24h day, at 25°C and an OH-radical concentration of 5 x 10^5 radicals/cm^3 (EC 2003, part II, p. 51)**.** Results of the calculation are summarised in table 9.

Table 9 Abiotic degradation: Phototransformation in air

Guideline / Test method	Molecule / radical	Rate constant for reaction with OH-radicals (k_{OH}) [cm^3 $molecule^{-1}$ sec^{-1}]	$kdeg_{air}$* [d^{-1}]	Half-life ($t_{1/2}$) [d]	Reference
Estimation by AOPWIN software	**OH**	**19.5447x10^{-12}**	**0.84**	**0.821**	**Doc. III-A 7.3.1, Study A 7.3.1**

* kdegair= kOH • cOH • 24 • 3600; cOH = 5 x 10^5 OH-radicals/cm^3 according to EC 2003, part II, p. 51

Conclusion: Abiotic degradation

Considering the high hydrolytic stability determined at 50°C for different pH values (preliminary test) it is not expected that hydrolytic processes will contribute significantly to the degradation of DCPP in aquatic systems.

Whereas, the derived photolytic environmental half-lives of DCPP in water range between 0.24 days and 4.86 days (latitudes between 30°N-50°N, considering all seasons) and demonstrate that DCPP is photodegraded rapidly in aquatic systems. Mineralization (formation of CO_2) plays a

significant role in the photolysis process of DCPP. Based on the calculation according to Atkinson, the chemical lifetime of DCPP in the air was assessed to be less than one day.

Based on the vapour pressure (1.2×10^{-6} Pa at 25 °C) and the Henry's Law constant (calculated, 6.82×10^{-4} Pa x m^3/mol (25°C) (Bond method) resp. 2.53×10^{-3} Pa x m^3/mol (25°C) (Group method)), volatility of DCPP and gaseous release is considered to be of minor importance. These data indicate that DCPP is not expected to partition from aqueous phases to air in significant quantities. The degradation of DCPP residues by OH-radicals in air proceeds with a DT_{50} value of 19.701 hours.

5.1.2 Biodegradation

5.1.2.1 Biodegradation estimation

No data available

5.1.2.2 Screening tests

Ready biodegradability

DCPP was investigated for its ready biodegradability in several initial tests:

A CO_2-evolution test according to OECD Guideline 301B was performed with radiolabelled test substance (Diclosan, label: phenole-U-C14) at a concentration of approximately 95 µg/L test substance in five replicates over an extended period of 61 days (**Doc III-A 7.1.1.2.1/01, Study A 7.1.1.2.1/01**). The inoculum was activated sludge form a municipal wastewater treatment plant (Mannheim, Germany). The degradation was monitored via the radioactive carbon dioxide formed by biodegradation of the test substance. The reference control was performed with aniline (20 mg TOC/L), measuring the evolving carbon dioxide as Total Inorganic Carbon (TIC) in the absorption solutions. In addition an inhibition control was run to determine possible toxic effects on the microorganisms. The test passed the validity criteria. No inhibitory effect was observed to the microbial degradation activity at the tested concentration. The test substance was degraded by 40–50% after 28 days, failing the ready biodegradability pass level. After 61 days DCPP was degraded by 52±9%. The distribution of the radioactivity over the compartments CO_2, water and sludge of the test system revealed that water and sludge contained less than 10% TAR (Replicates 3–5). Replicate 2 had a slightly higher proportion (12%), while replicate 1 was considered to be an outlier: 30%). The sludge contained 3–5% TAR (replicates 2-5), while CO_2 contained 43–55% TAR (replicate 1: 23%). The recovery of ^{14}C at test end was between 60% and 70% TAR. The low recovery at test end might be explained by small losses of $^{14}CO_2$ during the sampling processes during the exposure in combination with the low initial test concentration. In additional non-GLP investigations (GC/MS analysis of two replicates), metabolites were not detected above background level. In one replicate traces of DCPP were detected, while DCPP was not detected in the other replicate. Overall, it can be concluded that DCPP is biodegradable under aerobic conditions, but the ready biodegradability pass levels were failed.

A manometric respirometry test (OECD guideline 301F) was performed at a concentration of 100 mg a.s./L) over a period of 28 days (Study A 7.1.1.2.1/02). Ultrasound dispersion was employed for fifteen minutes to obtain a homogenouos suspension of the test item. Incubation was carried out at 22.0 °C with activated sludge collected from a domestic wastewater treatment plant (ARA Ergolz II, Füllinsdorf / Switzerland). The reference control was performed with sodium benzoate, 104

mg/L. During exposure, the Biochemical Oxygen Demand was measured continuously by means of a BOD-meter. Based on this parameter, the biodegradation of DCPP was 0% after 28 days. Although the used test substance concentration was above the EC_{50} value of 8 mg/L determined for STP microorganism's, no inhibitory effect on the biodegradation of the reference item sodium benzoate was determined in the toxicity control containing both the test and the reference item. As the compound has only a water solubility of 19.5 mg/L (at 20 °C) the study was performed above the compound's water solubility.

A test according to the "Japan Chemical Substance Control Law (1974)" (comparable to the modified MITI test, OECD guideline 301C) was performed at 100 mg a.s./L over a period of 28 days (Study A 7.1.1.2.1/03). Incubation was carried out at 25 ± 1 °C with standard activated sludge. The functional control was performed with aniline, 100 mg/L. During exposure, O_2-consumption was quantified. Biodegradation (Biological Oxygen Demand, BOD versus Theoretical Oxygen Demand, ThOD) was -3% (average, n = 3) after 28 days. Based on the results of an additional HPLC analysis, concentration of the test substance in the three test sections of the test substance were detected to 100% compared with initial content. Thus, the percentage biodegradation of the test substance was calculated to be 0% for each of the three test sections. As the compound has only a water solubility of 19.5 mg/L (at 20 °C) the study was performed above the compound's water solubility.

A manometric respirometry test (OECD guideline 301F) was performed at a concentration of 100 µg a.s./L) over a period of 28 days (Study A 7.1.1.2.1/04). Incubation was carried out at 21.5-22.0 °C with a polyvalent inoculum (bacteria collected from activated sludge of a sewage treatment plant, ARA Pro Rheno Basle). The reference control was performed with sodium benzoate (100 mg/L), measuring the Biochemical Oxygen Demand. The degradation of the test item DCPP was monitored by gas-chromatography. Within 28 days of incubation, a complete primary degradation (100 %, concentration of a.s. was below the limit of detection) of DCPP was observed.

Possible metabolites of DCPP (e.g. 4-chlorocatechol, 4-chloro-2-methoxy-1-phenol, Methyl-DCPP, 2-, 3-, and 4-chloroanisole, 2-, 3-, and 4-chlorophenol) have not been found. None of the primary metabolites could be traced above the detection limit of 2.5 µg/L or 2.5%.

The test concentration used was well below the EC_{50} of 8 mg/l determined for STP relevant organism's. Nevertheless, the test design was not suitable to determine ready biodegradability: No data on mineralization of the substance could be provided thus failing to give information on passing the criteria for ready biodegradability. The advice given in Annex II of OECD Guideline 301 regarding evaluation of the biodegradability of chemicals suspected to be toxic to the inoculums was not followed: For substances with EC_{50} values of less than 20 mg/l the use of low test concentrations should be employed necessitating the use of the stringent and sensitive Closed Bottle test or the use of C^{14}-labelled material. Moreover, no data on DCPP elimination from abiotic control were provided, only data regarding oxygen demand: Hence, adsorption processes cannot be excluded in this study as DCPP has shown to have a rather high KOC-value.

None of the submitted studies on DCPP could demonstrate that the criteria according to the definitions given by the OECD guidelines for testing ready biodegradability were passed. Therefore, DCPP has to be regarded as "not readily biodegradable". An assessment of inherent biodegradability was performed.

Inherent biodegradability

A Zahn-Wellens/EMPA test (OECD guideline 302B) was performed at 100 µg a.s./L over a period of 28 days (**Doc III-A 7.1.1.2.2, Study A 7.1.1.2.2**). Incubation was carried out at 20-22 °C with activated sludge collected from a communal wastewater treatment plant (ARA Therwil,

Switzerland). The functional control was performed with Diethylene glycol. DCPP was analysed by GC/MSD methods in water and sludge samples because the concentration of the test substance was too small for DOC analysis. Additionally, for the anticipated metabolites 2-Chlorophenol, 3-Chlorophenol, 4-Chlorophenol, Methoxy-benzene (Anisole) and Methyl-DCPP water and sludge samples were analysed.

As a result, elimination of DCPP was >99% after 14 days according to the water samples. Additionally, the elimination of DCPP within 28 days was observed in the sludge samples, although slower than in the water samples. As no DOC was measured in the DCPP-test, the pass levels for inherent biodegradability could not be passed. Although some adsorption cannot be ruled out, it can be concluded that DCPP is inherently primary biodegradable.

2-Chlorophenol and 3-Chlorophenol could not be detected in water or sludge samples. 4-Chlorophenol and Methoxy-benzene (Anisole) could be quantified in a low amounts in some samples. Nevertheless, these values are considered to be of very limited informative value. Methyl-DCPP could be quantified in the water samples with a maximum on day 7. In the two sludge samples Methyl-DCPP could be quantified with a maximum on day 7 and 14, respectively."

The results of all biodegradation/elimination studies with DCPP are summarized in table 10.

Table 10: Biodegradation/Elimination of DCPP

Guideline / Test method	**Test type[1]**	**Test para-meter**	**Inoculum**			**Test substance concentr.**	**Degradation/Elimination**		**Ref.**
			Type	**Concentration**	**Adaptat.**		**Incubation**	**Degree [%]**	
OECD 301B	**Ready**	**CO_2**	**Activated sludge**	**30 mg/L**	**no**	**95 µg/L**	**28 d** **61d**	**40-50% degradation** **52±9% degradation**	**Doc III-A 7.1.1.2.1/01, Study A 7.1.1.2.1/01**
OECD 301F Manometric respirometry test	Ready	O_2	Activated sludge	30 mg/L	no	100 mg/L	28 d	0% degradation	Study A 7.1.1.2.1/02
Japan Chemical Substance Control Law (1974)*	Ready	O_2 DCPP (HPLC)	Activated sludge	30 mg/L	no	100 mg/L	28 d	0% degradation	Study A 7.1.1.2.1/03
OECD 301F Manometric respirometry test	Ready	DCPP (GC)	Activated sludge	30 mg/L	no	100 µg/L	28 d	100% elimination, no data on ultimate degradation	Study A 7.1.1.2.1/04
OECD 302B Zahn-Wellens test	**Inherent**	**DCPP (GC-MSD)**	**Activated sludge**	**0.49 g/L suspended solids**	**no**	**100 µg/L**	**28 d**	**> 99%, elimination, no data on ultimate degradation**	**Doc III-A 7.1.1.2.2, Study A 7.1.1.2.2**

* Test comparable to OECD 301C, MITI (I)-method

Conclusions to the results of laboratory biodegradation tests

Based on the results of four studies on biodegradability of DCPP which could not demonstrate sufficient mineralisation to pass the criteria given by the OECD guidelines for testing ready biodegradability, DCPP is classified as “not readily biodegradable” according to the definitions. However some studies showed considerable biodegradation of DCPP (40-50% after 28 days). Additionally, an assessment of inherent biodegradability was performed. As no DOC was measured for the test conducted with the test item the test is not able to show ultimate biodegradation of DCPP. The elimination of DCPP within 28 days in water and sludge samples is leading to the conclusion that DCPP is inherently primary biodegradable, although the criteria for inherent biodegradability could not be met due to lack of DOC measurement and amount of adsorption cannot be quantified.

5.1.2.3 Simulation tests

Biological sewage treatment

Aerobic aquatic degradation in STP

An activated sludge simulation test according to OECD Guideline 303 was performed (Study A 7.1.2.1.1/01). No radiolabelled test material was used, hence e.g. adsorption processes cannot be ruled out.

The elimination of the test item DCPP (nominal test substance concentration 40 µg/L) was investigated in two continuously operating test plants running in parallel under identical conditions. The degradation of the synthetic and domestic sewage was followed in two control plants and determined by DOC analysis. The test compound in the influent and effluent was determined with a specific analytical method (GC/MSD). The experiment started with a settling-in period of 14 days in order to stabilize the removal of DOC at > 80%.

An elimination rate of 99.6% was achieved 24 h after start of the test period. During the test period, DCPP and Methyl-DCPP in the treated effluent and activated sludge were determined: In the water samples the maximum value for DCPP was 0.34 µg/l and for methyl-DCPP 1 µg/l. Nevertheless the water sample measurements have some impairments, as Methyl-DCPP was also measured several times in the control effluent. The value of 1 µg/l for Methyl-DCPP was only reached once, while the other 4 quantifiable values are 0.15, 0.19, 0.14 and 0.2 µg/l Methyl-DCPP. In most of the water samples the values gained were below limit of quantification for DCPP as well as for Methyl-DCPP.

In sludge samples the maximum value for DCPP was 3.6 µg/l and for methyl-DCPP 0.8 µg/g: some tendency for higher values towards study end could be observed, which was more pronounced for methyl-DCPP.

Conclusion:

DCPP was extensively removed in activated sludge systems. Removal of more than 99% was achieved within 24 h, measured with substance specific analytical methods. Some DCPP and methyl-DCPP could be detected in the effluent and sludge samples.

No simulation tests with the active substance DCPP are available for other environmental compartments.

5.1.3 Summary and discussion of degradation

DCPP is hydrolytic stable. Whereas, the derived photolytic environmental half-lives of DCPP in water range between 0.24 days and 4.86 days (latitudes between 30°N-50°N, considering all seasons) and demonstrate that DCPP is photodegraded rapidly in aquatic systems. Mineralization (formation of CO_2) plays a significant role in the photolysis process of DCPP.

DCPP is not expected to partition from aqueous phases to air in significant quantities (Henry's Law constant calculated, 6.82 x 10^{-4} Pa x m^3/mol (25°C) (Bond method) resp. 2.53 x 10^{-3} Pa x m^3/mol (25°C) (Group method)). The degradation of DCPP residues by OH-radicals in air proceeds with an estimated DT50 value of 19.701 hours.

Based on the results of four studies on biodegradability of DCPP which could not demonstrate sufficient mineralization to pass the criteria given by the OECD guidelines for testing ready biodegradability, DCPP is classified as "not readily biodegradable" according to the definitions. However some studies showed considerable biodegradation of DCPP (40-50% after 28 days). Additionally, an assessment of inherent biodegradability was performed. As no DOC was measured for the test conducted with the test item the test is not able to show ultimate biodegradation of DCPP. The elimination of DCPP within 28 days in water and sludge samples is leading to the conclusion that DCPP is inherently primary biodegradable, although the criteria for inherent biodegradability could not be met due to lack of DOC measurement and amount of adsorption cannot be quantified.

According to an STP simulation test (OECD 303) DCPP was extensively removed in activated sludge systems. Removal of more than 99% was achieved within 24 h, measured with substance specific analytical methods. Some DCPP and methyl-DCPP could be detected in the effluent and sludge samples. No simulation tests with the active substance DCPP are available for other environmental compartments.

5.2 Environmental distribution

5.2.1 Adsorption/Desorption

Adsorption / desorption in soils

Screening test

The adsorption coefficient K_{oc} of DCPP on soil was estimated using High Performance Liquid Chromatography (HPLC). The test was performed according to OECD Test Guideline 121 and GLP. Six reference standards of known K_{oc} values were analysed on a HPLC system to determine an average capacity factor k'. Sodium nitrate was used to determine the HPLC system dead time (t_0). A regression line was plotted with the determined k' values and the known K_{oc} values (log k' versus log K_{oc}).

The linear regression of measured k' against K_{oc} values yielded a line with a slope of 5.048, an intercept of 0.8916 and a correlation coefficient of $r^2 = 0.9931$. DCPP was analysed on the same HPLC system during the same sample sequence as the reference substances. The capacity factors (log k') gained for DCPP amount to 0.4502 and 0.4464. The adsorption coefficient of the test substance was calculated as **log K_{oc} = 3.1545 (K_{oc} = 1427.25);** further data is given in Table 11 **(Doc. III-A 7.1.3/01, Study A 7.1.3/01).**

Table 11: HPLC retention time data and determination of Koc for DCPP and reference substances

Substance	**t_R Reference mix (min)[1)2)]**	**k'**	**Log k'**	**Log K_{oc}**
Phenol	4.0375	1.2093	0.0825	1.32
Methyl benzoate	4.5925	1.5130	0.1798	1.80
Naphthalene	6.5480	2.5830	0.4121	2.75
1,2,3-Trichlorobenzene	6.5480	2.5830	0.4121	3.16
Phenanthrene	9.6035	4.2550	0.6289	4.09
4,4'-DDT	17.7115	8.6917	0.9391	5.63
DCPP – injection A	6.981	2.8200	0.4502	**3.1545**
DCPP – injection B	6.936	2.7953	0.4464	

1) t_R = average retention time in min for two measurements of the reference mix
2) Dead time for sodium nitrate (t_0) = 1.8275 min (mean of two measurements)

Another non-GLP OECD Test Guideline 121 study using High Performance Liquid Chromatography (HPLC) performed by the same laboratory using the same reference substances and with no obvious differences regarding the study protocol resulted in a considerable lower Koc value of 419 (Study A 7.1.3/02).

Nevertheless, QSAR data for DCPP support the value of the GLP study: According to KOCWIN v2.00 a Koc estimate from Log Kow of 1565 is obtained, from Molecular Connectivity Index (MCI) a Koc estimate of 6470 is obtained.

Conclusion:

Based on the results of a HPLC screening test with the test substance DCPP the K_{oc} value was calculated to be 1427.25. This result was substantiated with QSAR data. It can be assumed to be adsorbed in soils and to be less susceptible for translocation.

5.2.2 Volatilisation

Vapour pressure according to OECD guideline 104: 1.2*10-06 Pa at 25 °C, Calculated at 20°C = 4.3*10-7 Pa (**Doc. III-A 3, Study A3/01**)

5.2.3 Distribution modelling

No data available

5.3 Aquatic Bioaccumulation

Summary of relevant information on aquatic bioaccumulation: please see single subsections

5.3.1 Aquatic bioaccumulation

5.3.1.1 Bioaccumulation estimation

Based on the measured log K_{ow} value of 3.7 a BCF of 278.61 was calculated as recommended in the Technical Guidance Document on Risk Assessment (EC, 2003)[2] (Study A 7.4.2). This value indicates a moderate potential of the test substance to bioaccumulate. However, experimental determined BCF values should be preferred, if available. QSAR values (EPIWIN 4.00[3], BCFBAF v3.01) for DCCP result in a BCF value of 208.2 for a calculated log Kow of 4.02 and 128.3 for a measured log Kow of 3.7.

5.3.1.2 Measured bioaccumulation data

The bioconcentration of DCPP in carp (*Cyprinus carpio*) was experimentally determined following the OECD guideline 305 and the Japanese standard method according to the "Testing Methods for New Chemical Substances" of the Ministry of International Trade and Industry of Japan of 1974 **(Doc. III-A 7.3.3.1, Study A 7.3.3.1).**

The concentrations of the test substance were selected to be 0.02 mg/L and 0.002 mg/L based on an acute toxicity screening pre-test (results of the screening test: 96h-LC50 for *Danio rerio* = 0.86 mg/L). The bioconcentration test was performed under flow-through conditions for 28 days because equilibrium was reached at 7 days after the start of uptake phase. After the end of exposure period, a 1-week depuration phase was performed. The determined mean lipid content before exposure was 3.2% and at termination 3.6%. No trend to gain weight during the test period was observed.

The mean steady-state BCFs obtained for Level 1 (0.02 mg/L) and Level 2 (0.002 mg/L) under the equilibrium were **67.4 and 76.7**, respectively. During the depuration phase more than 95% of the amount of test substance residual in carp was eliminated within 7 days in Level 1 and 2. The metabolites of DCPP were not determined. Test results are summarised in table 12.

The metabolites of DCPP were not determined. Nevertheless, referring to methyl-DCPP, since no measured BCF value is available, the BCF was calculated by the use of SRC EPIWIN 4.00 (BCFBAF Program (v3.01)). The resulting BCF value is 488.2. As the measured data of DCPP were slightly below those of the estimated BCF-values it can be assumed that this estimated BCF value of 488 is in the correct range.

BCF value for DCPP was determined to be in the range of 67 to 77 times, the calculated value on methyl-DCPP would represent a worst case assumption on the possible bioaccumulation.

The study was rated with Klimisch score 2, as the study has some considerable flaws. Particularly, no total organic carbon or suspended solids measurements during the testing took place which could lead to an underestimation of BCF due to adsorption of DCCP. Nevertheless, analytical data provided demonstrated stable DCPP concentration during the test. Moreover, the fish tested at each

[2] http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd/tgdpart2_2ed.pdf

[3] http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm

concentration should have been four instead of two according to OECD guideline No. 305 and the interval for the sampling could have been shorter. Nevertheless, 5 measurements took place supporting the steady state concentration over a period of time.

Table 12: Bioaccumulation of DCPP

Log P_{OW} of a.s.	**Guideline**	**Exposure**	**Initial conc. of a.s.**	**Steady-state BCF**	**Uptake rate constant**	**Depuration time (DT_{90})**	**Reference**
3.7	QSAR calculation method	n.a.	n.a.	278.61	n.a.	n.a.	Study A 7.4.2
3.7	OECD 305; MITI test (Japanese standard)	4 weeks uptake + 1 week depuration	0.02 mg/L	67.4 ± 8.9	n.d.	<1 week	**Doc. III-**A **7.4.3.3.1, Study A 7.4.3.3.1**
			0.002 mg/L	**76.7 ± 6.6**	n.d.	<1 week	

5.3.2 Summary and discussion of aquatic bioaccumulation

DCPP has a log K_{ow} value of 3.7 and may therefore accumulate in organisms. An experimental study with carp (*Cyprinus carpio*) demonstrated the opposite. Mean bioconcentration factors (BCF) of 67.4 and 76.7 were obtained and it was seen to be rapidly eliminated after termination of the exposure. Corrected for a whole body lipid content of 5%, assuming a mean lipid content of 3.4%, the resulting whole body BCFs in fish were 99.1 and **112.8**.

For the metabolite methyl-DCPP a BCF-value of 488.2 was calculated.

5.4 Aquatic toxicity

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

The acute toxicity of DCPP was investigated towards zebra fish (*Danio rerio*) in a 96-hour static test according to the Commission Directive 92/69/EEC, Annex Part C.1, and the OECD Guideline for Testing of Chemicals No. 203 **(Doc. III-A 7.4.1.1/01, Study A 7.4.1.1/01)**. Since the results of pre-tests showed a solubility of about 10-20 mg/L, the highest test concentration was prepared dissolving the test item in the test water and stirring for 3 days to make sure that the test item was completely dissolved. The nominal test concentrations used for the test were 0.46, 1.0, 2.2, 4.6, and 10 mg a.s./L (no solvent was used), and a control was run in parallel. Mortality and symptoms of intoxication were determined. The test medium and the test water in the control were slightly aerated during the test period. The average age/size of the used zebra fish were: mean wet weight: 0.2 ± 0.05 g, mean length: 2.6 ± 0.1 cm. During holding and acclimation until one day before the start of the test the fish were fed *ad libitum* with a commercial fish diet. The fish were acclimated for one week prior to the test start to the test water and temperature. Fish were not fed one day before and during the study. The volume of the glass aquariums (test vessels) contained 3 L test medium. The number of animals per vessel was 7, with one aquarium per concentration. The test was not performed in closed vessels. The test temperature was 21-22°C and the dissolved oxygen was >8.3 mg/L (>60%saturation). The photoperiod was 16 hours light and 8 hours dark.

For the analytical measurements of the test item concentrations duplicate samples from the freshly prepared test media of all test concentrations and the control were taken at the start of the test. For the determination of the maintenance of the test item concentrations during the test period, duplicate samples were taken out of all test media and the control after two days and at the end of the test (Day 4), respectively when all fish were dead in one concentration. All samples were taken from the approximate centre of the aquaria without mixing of the test media, and were deep-frozen (at about -20°C) immediately after sampling. The concentrations of the test item DCPP were analyzed in the duplicate test media samples from the test concentrations of nominal 0.46 to 4.6 mg/L from Day 0, of nominal 0.46 and 1.0 mg/L from Day 2 and Day 4 and of nominal 2.2 mg/L from Day 1 since all fish were dead in this concentration at this time.

The samples from the test concentration of nominal 10 mg/L were not analyzed, since the same high toxic effect was determined in the next lower analyzed samples of nominal 4.6 mg/L. The test concentration of nominal 10 mg/L was therefore not considered as being a relevant part of the concentration-effect relationship. From the control samples only one of the duplicate samples was analyzed from Day 0, Day 2 and Day 4.

The analytical determined mean test item concentrations in the test media varied in the range of 37 to 115% of the nominal values during the whole test period. At the start the mean measured test item concentrations ranged from 110 to 115% of the nominal values. After 48 hours of incubation 37-41% of nominal were found in the low-level samples while after 96 hours of incubation 69-70% of nominal were found in these samples. As the test item is hydrolytically stable and considerably soluble in fat, adsorption and subsequent desorption and re-solution may be a reason for the observed fluctuations. All reported results are related to total mean measured concentrations of the test item which were in the range of 74-112% (calculated as the average over all measurements per test concentration)of the nominal values.

At the total mean measured test item concentration of 0.34 mg/L all fish survived until the end of the test and no symptoms of intoxication were observed. At the next higher test concentrations of total mean measured 0.74 and 2.2 mg/L all test fish showed one or several intoxication symptoms. At the end of the test four of the seven test fish had died at the test concentration of 0.74 mg/L. The fish in the test concentration of 2.2 mg/L had died within one day. At the two highest test concentrations all fish were dead already about 2 hours after introduction into the test media.

The LC50 and the 95% confidence interval at the observation dates were calculated as far as possible by Probit Analysis. The biological results of the test concentration of nominal 10 mg/L were not taken into account at the calculation. The NOEC, LOEC, LC0 and LC100 were determined directly from the raw data. The LC50 at the observation intervals after 2 hours could not be calculated by Probit Analysis or Moving Average Interpolation due to the steep concentration-effect relationship. Instead the LC50-value was determined as the geometric mean value of the two consecutive test concentrations with 0% and 100% mortality, and the 95% confidence intervals for the LC50 as the test concentrations with 0% and 100% mortality.

The 96h-LC_{50} was determined to be **0.70 mg a.s./L,** the NOEC for 96h is **0.34 mg a.s./L.**

The validity criteria for acute fish test according to OECD Guideline 203 regarding the mortality of control animals <10% and the concentration of dissolved oxygen in all test vessels > 60% saturation were fulfilled. The criteria “concentration of test substance >80% of initial concentration during test” could not be met.

The study was rated with the Klimisch score 2 as the study is a GLP study conducted according to an internationally accepted Guideline but the static test conditions were suboptimal as the test concentration could not be maintained > 80% of the nominal concentration. For a substance with high adsorption properties a semi-static or flow-through test system would have been preferable.

Additionally, a screening pre-test on acute toxicity with *Danio rerio* following OECD guideline No. 203 was performed in the course of the study determining bioconcentration of DCPP in carp (*Cyprinus carpio*) following the OECD guideline 305 and the Japanese standard method according to the "Testing Methods for New Chemical Substances" of the Ministry of International Trade and Industry of Japan of 1974 for concentration selection (Doc. III-A 7.4.3.3.1, Study A 7.4.3.3.1). After a two week acclimatisation phase 10 fish (mean body length 3.2 cm; mean body weight: 0.24 g) per test concentration (0.62, 0.69, 0.74, 0.86, 0.98, 1.09) water control and mercuric chloride controls were put into 4 L glass tank. The semistatic approach (renewal of test water after 48 hours) at 23.5°C resulted in a 96h-LC_{50} for *Danio rerio* = 0.86 mg/L based on initial concentration levels measured by HPLC. As only these initial concentration values were available and the data reporting due to the function as a screening pre-test were generally containing a rather rough description of the details this study is not regarded as a key study. The studies are summarised in table 13 below.

Table 13: Acute toxicity of DCPP towards fish

Test substance	**Guideline / Test method**	**Species**	**Exposure**		**Results**	**Reference**
			Test type	**Duration [h]**	**LC_{50} [mg a.s./L]**	
DCPP	Directive 92/69/EEC, Annex Part C.1; OECD 203	*Danio rerio* (zebra fish) (formerly *Brachydanio rerio*)	Static	96	**0.70 (m)**	**Doc. III-A 7.4.1.1/01, Study A 7.4.1.1/01**
DCPP	OECD 203	*Danio rerio* (zebra fish)	Semi-static	96	0.86 (i)	Study A 7.3.3.1

(m): based on mean measured concentrations
(i): based on initial measured concentrations

Conclusion:

The LC_{50} of DCPP after 96 hours in the acute fish toxicity test was **0.70 mg a.s./L**. This value is supported by a 96h-LC_{50} for *Danio rerio* (formerly *Brachydanio rerio*) = 0.86 mg/L from a non-key study screening pre-test.

5.4.1.2 Long-term toxicity to fish

No chronic fish toxicity study is available with DCPP.

It was seen in short-term studies that aquatic invertebrates were slightly more sensitive to DCPP than fish.

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

The acute toxicity of the DCPP to *Daphnia magna* was determined in a 48-hour static test according to the Commission Directive 92/69/EEC, Annex Part C.2, and the OECD Guideline for Testing of Chemicals No. 202 **(Doc. III-A 7.4.1.2/01, Study A 7.4.1.2/01)**.

The nominal concentrations used in the test were 0.1, 0.22, 0.46, 1.0, and 2.2 mg a.s./L (no solvent used), and a control. The test concentrations were selected based on the results of a range-finding test and the results of a pre-experiment on the solubility of the test item. For the preparation of the stock solution the test substance was dissolved in the test water by ultrasonic treatment and then intensively stirred during 3 hours. The dilution water had an alkalinity of 0.8 mmol(L (caCO3 and a hardness of 2.5 mmol/L. The pH value ranged between 7.8 and 7.9. The Ca/Mg ratio was 4:1 (based on molarity) and the Na/K ratio was 10:1 (based on molarity). The test water was aerated until oxygen saturation was reached. The used strain was *Daphnia magna* Straus from the original source of the University of Sheffield. At the start of the test daphnids were 6-24 hours old and were not first brood progeny. The *Daphnia magna* were cultured in reconstituted water of identical quality (regarding pH, main ions and total hardness) and under identical temperature and light conditions as in the tests. *Daphnia* were not fed during the test. The volume of the test vessels was 100 mL glass beakers. The volume per animal was 50 mL per 10 animals. The number of animals/vessel was 10 with 2 replicate vessels per concentration. The test was not performed in closed vessels. The test temperature was 20 to 21°C and the dissolved oxygen was >8.5 mg/L during the test. For the photoperiod 16 hours light and 8 hours dark was selected with a light intensity between 200 and 1200 Lux. The immobility or mortality of the daphnids was determined by visual controls after 24 and 48 hours of exposure. Those animals not able to swim within 15 seconds after gentle agitation of the test beaker were considered to be immobile.

At the start and at the end of the test, the pH-values, the oxygen concentrations and the water temperature were determined in one sample from each test concentration and the control. The appearance of the test media was recorded at the start of the test and after 24 and 48 hours.

For the analytical measurements of the test item concentrations, one sample from the freshly prepared stock solution and duplicate samples from the freshly prepared test media of all test concentrations and the control were taken just before the start of the test (without daphnids).

For the determination of the stability of the test item under the test conditions, respectively the maintenance of the test item concentrations during the test period, sufficient volumes of the freshly prepared test media of all test concentrations and the control were incubated during the test period under the same conditions as in the actual test (but without daphnids). Duplicate samples were taken at the end of the test period. The collecting of samples after 48 hours from the actual test itself was not possible, since the test media volumes in the test were too small for the analytical requirements.

All samples were deep-frozen (at about -20 °C) immediately after sampling.

The concentrations of the test item DCPP were analyzed in the stock solution sample and in the duplicate test media samples from the test concentrations of nominal 0.22 to 0.46 mg/L and both sampling times (0 and 48 hours). The lowest test item concentration of nominal 0.1 mg/L was not analysed, since it was below the 48-hour NOEC. The highest test item concentrations of nominal 1.0 and 2.2 mg/L were not analysed, since after 48-hours the same toxic effect was determined at the next lower test item concentration of nominal 0.46 mg/L. The test item concentration of nominal 1.0 and 2.2 mg/L therefore were considered as being of no biological relevance for the concentration-effect relationship. From the control samples only one of the duplicate samples was analysed from each of both sampling times.

The analytical determined mean test item concentrations in the analysed test media varied in the range from 81 to 87% of the nominal values. In the stock solution sample 87% of the nominal concentration was measured. In the test media the test item DCPP was sufficiently stable during the test period of 48 hours. Therefore, all reported biological results are related to the nominal test item concentrations. The analytical method used was HPLC-UV/VIS.

In the control and up to and including the test item concentrations of nominal 0.46 mg a.s./L no immobility or mortality of the test animals or other signs of intoxication were determined during the test period of 24 hours. After 48 hours of exposure the toxicity of the test item to *Daphnia magna* had increased. The 24h- and 48h-EC_{50} could not be calculated by Probit Analysis or Moving Average Interpolation due to the steep concentration-effect relationship. Instead the EC_{50}-value was determined as the geometric mean value of the two consecutive test concentrations with 0% and 100% mortality, and the confidence intervals for the $EC5_0$ as the test concentrations with 0% and 100% immobility.

The NOEC and LC_{100} were determined directly from the raw data. The 48h-NOEC was at 0.22 mg a.s./L, the EC_{100} was 0.46 mg/L. The study was rated Klimisch score 1. An overview of the test results is presented in table 14.

Table 14: Acute toxicity of DCPP towards aquatic invertebrates

Guideline / Test method	**Species**	**Exposure**		**Results**	**Reference**
		Test type	**Duration [h]**	**EC50 [mg a.s./L]**	
Directive 92/69/EEC, Annex Part C.2; OECD 202	*Daphnia magna* (Waterflea)	Static	48	**0.32 (n) (95%CI 0.22-0.46 mg/L)**	**Doc. III-A 7.4.1.2/01, Study A 7.4.1.2/01**

(n): based on nominal test item concentration

Conclusion:

The EC_{50}-toxicity value obtained for DCPP towards *Daphnia magna* was **0.32 mg a.s./L.**

5.4.2.2 Long-term toxicity to aquatic invertebrates

The influence of the test item DCPP on the reproduction and survival rate of *Daphnia magna* was investigated in a semistatic test over 21 days following the OECD Guidelines for Testing of Chemicals No. 211 **(Doc. III-A 7.4.3.4, Study A 7.4.3.4).**

The nominal test concentrations used in the test were 0.022, 0.046, 0.10, 0.22, and 0.46 mg a.s./L, and a control. Mortality, the number of young born and signs of intoxication were compared with corresponding parameters in the control.

The test was conducted in reconstituted water (purified water with analytical grade salts and additives), "M7". The water hardness was given with 2.5 mmol/L (=250 mg/L) as $CaCO_3$. Before use the dilution water was aerated until oxygen saturation. The initial pH was 7.9 ± 0.3. The test animals (females of a clone of the species *Daphnia magna* Straus) were bred under identical temperature and light conditions as in the test, and in the same kind of test water as used in the test The test organisms were <24 hours old and fed with a food mixture containing one part of green algae of the species Scenedesmus subspicatus (freshly grown in the laboratories of RCC) and one part of fish food suspension. The carbon content of the food suspensions was determined using a Shimadzu TOC 500 Analyser. The food amounts were based on the measured concentration of total

organic carbon (TOC) in the food suspensions. The amounts of TOC fed per test animal and day (Monday to Friday) ranged between 0.1 mg to 0.25 mg TOC.

The test media of all test concentrations and of the control were renewed on Days 2, 5, 7, 9, 12, 14, 16 and 19 of the exposure period (every Monday, Wednesday and Friday). By that, a total of 9 treatments were performed. At these dates the surviving test animals were carefully transferred by glass tubes from the old test vessels into the freshly prepared test media of the corresponding concentrations. Each test animal was kept individually in a 100 mL glass beaker containing 80 mL test medium. The beakers were covered with glass plates. 10 vessels (replicates) per concentration and a control were used. The test temperature ranged between 20 to 21°C, dissolved oxygen was >8.2 mg O2/L during the test. The pH values were 7.6 to 8.0 during the test. The photoperiod was 16 hour/day with an intensity of irradiation of 300 - 800 Lux.

In the samples (nominal test concentrations 0.22 and 0.46 mg/L) including food particles the mean test item concentrations at the end of the renewal periods of 48 and 72 hours decreased to 41 - 63% of the nominal values. Thus, a part of the test item had obviously adsorbed onto the food particles.

As the amount of test substance adsorbed to removed offspring or food (consumed by the offspring), which was not removed daily but only at the renewals, is unclear, the averaged test item concentrations from day 14 and 19, for which the used test media per test concentration were poured together after removal of daphnia and which had included food particles, are considered the more reliable test item concentrations, reflecting actual test conditions. The averaged measured test item concentrations from day 14 and 19 including food particles are 0.094 mg/L for the nominal concentration of 0.22 mg/L, and 0.27 mg/L for the nominal test item concentration of 0.46 mg/L.

Taking into account the survival rates and the reproduction rates of the test animals, the highest concentration of DCPP tested without toxic effects after the exposure period of 21 days (21-day NOEC) was 0.094 mg a.s./L (nominal concentration of 0.22 mg a.s./L, cf. table 15). The lowest concentration tested with toxic effects (21-day LOEC) was determined to be 0.27 mg a.s./L (nominal concentration of 0.46 mg a.s./L) due to the 100% mortality rate of *Daphnia magna* at this test concentration.

Table 15: Chronic toxicity of DCPP to aquatic invertebrates

Guideline/ Test method	**Species**	**Life stage** [age]	**Exposure**		**Results [mg a.s./L]**			**Reference**
			Design	**Treatm. Period**	**EC_{50}**	**LOEC**	**NOEC**	
OECD guideline 211	*Daphnia magna*	<24 h	Semi-static	21 days	0.30 (n)	0.27[1)] (m)	**0.094** (m)	**Doc. III-A 7.4.3.4, Study A 7.4.3.4**

(n) Results are based on nominal concentrations

(m) Results are based on averaged measured concentrations from day 14 and 19, for which the used test media per test concentration were poured together after removal of daphnia and which had included food particles

1) 100% mortality at this concentration

Conclusion:

The NOEC obtained in the chronic toxicity test towards *Daphnia magna* was **0.094 mg a.s./L** based on the 100% mortality of parent animals observed at 0.27 mg a.s./L, when exposed to DCPP.

5.4.3 Algae and aquatic plants

The influence of DCPP on the growth of the green algal species *Desmodesmus subspicatus* (former *Scenedesmus subspicatus*, species CHODAT, Strain No. 86.81 SAG from the "Pflanzenphysiologiches Institut der Universität Göttingen") was investigated in a 72-hour static test according to the Commission Directive 92/69/EEC, Annex Part C.3, and the OECD Guideline for Testing of Chemicals No. 201 **(Doc. III-A 7.4.1.3/01, Study A 7.4.1.3/01)**.

The nominal test concentrations used in the test were 2.2, 4.6, 10, 22, and 46 µg a.s./L, and a control was run in parallel. The test concentrations were selected based on the results of a range-finding test and the results of a pre-experiment to the solubility of the test item. Since the results of pre-tests showed a solubility of about 10-20 mg a.s./L, the highest test concentration was prepared dissolving the test item in the test water and stirring for 3 days to make sure that the test item was completely dissolved.

The algae culture used for the toxicity test was 3 days old and had been maintained under the same conditions as those for the toxicity test. The algae were cultivated and tested in synthetic test water, prepared according to the mentioned test guidelines. Small volumes of the test media and the control (1.0-2.0 mL) were taken out of all test flasks after 24, 48, and 72 hours of exposure and were not replaced. The algae cell densities in the samples were determined by counting with an electronic particle counter with at least two measurements per sample. The initial cell concentration started with a biomass of. 10 000 (= 1 x 10^4) cells per mL of test solution. After the test period of 72 hours, a sample was taken from the control and from the test concentration of nominal 10 µg/L. The shape of the algal cells was microscopically examined.

The volume of the cultured Erlenmeyer flasks was 50 mL with 15 mL algal suspension covered with glass dishes and constant stirring by magnetic stirrers. Incubation was performed under standardised conditions according to the mentioned guidelines. The test was performed under continuous illumination (illumination by fluorescence tubes in a distance of about 35 cm from the test flask). The light intensity during the test was 8147 Lux (mean value, range between: 7820 and 8620 Lux). Three replicates per test concentration and six replicates in the control were investigated. The test temperature was 23 and the pH value ranged from 7.8 to 8.8. The dilution water was not aerated.

For the analytical measurements of the test item concentrations, one sample from the freshly prepared stock solution and duplicate samples from the freshly prepared test media of all test concentrations and from the control were taken just before the start of the test (without algae).

For the determination of the stability of the test item under the test conditions, and for the maintenance of the test item concentrations during the test period respectively, additional flasks with adequate volumes of the freshly prepared test media of all test concentrations and the control were incubated under the same conditions as in the actual test (but without algae) and were sampled in duplicate at the end of the test (after the 72 hours test period). All samples were deep-frozen (at about -20 °C) immediately after sampling.

The concentrations of the test item DCPP were analyzed in the stock solution sample and in the duplicate test media samples from the test concentrations of nominal 10-46 µg/L from both sampling times (0 and 72 hours). From the control samples only one of the duplicate samples was analysed from each of both sampling times (0 and 72 hours). The samples from the test concentrations were below the determined 72-hour NOEC.

The analytically determined test item concentration in the analysed test media ranged from 77 to 124% of the nominal values. The total mean measured test item concentrations were in the range of 95 to 119% of the nominal values. As 80% of the initial test item concentration could not be maintained over all test concentrations trough out test duration the geometric mean was used for determination of the NOEC. The analytical method used was HPLC-UV/VIS. A NOEC of **9.3 µg**

a.s./L could be derived as geometric mean of measured concentrations at the beginning and end of the test.

The E_bC50 and E_rC50 (the concentration of the test item corresponding to 50% inhibition of algal biomass b respectively growth rate µ compared to the control) were calculated by probit Analysis.

For the determination of the NOEC, the calculated mean biomass and the mean growth rate µ at the test concentrations were tested on significant differences to the control values by a Dunnett-test. For the results please see table 16 below.

The validity criteria for algal growth inhibition test according to OECD Guideline 201 concerning the cell concentration in control cultures increased at least by a factor of 16 within 3 days was fulfilled. The concentration of test substance ≥80% of initial concentration during test was not fulfilled.

The study was rated with the Klimisch score 2 because the test is a GLP study conducted according to internationally accepted guidelines but the test item concentrations could not be maintained within 80% of the initial test item concentrations throughout the test duration. Nevertheless, a reliable NOEC of 9.3 µg/L derived as a geometric mean based on measured concentrations at the beginning and end of the test could be obtained, which did not differ in a very considerable amount from the nominal test concentration of 10 µg/L.

Table 16: Effects of DCPP on green algae

Guideline	**Species**	**Test design**	**Results [µg a.s./L]**				**Reference**
			NOE_bC	**E_bC_{50}**	**NOE_rC**	**E_rC_{50}**	
Directive 92/69/EEC, Annex Part C.3; OECD 201	*Desmodesmus subspicatus*	72h static	9.3 (m)	23 (n)	**9.3 (m)**	38 (n)	**Doc. III-A 7.4.1.3/01, Study A 7.4.1.3/01**

(m): based on measured concentration using a geometric mean

(n): based on nominal concentrations

Conclusion:

DCPP was tested towards the green alga species *Desmodesmus subspicatus*. The NOEC obtained for both endpoints biomass and growth rate after 72 h was 9.3 µg a.s./L as geometric mean based on measured concentrations. The endpoint biomass was the most sensitive with a 72h-EC_{50} of 23 µg a.s./L based on nominal concentrations, the E_rC_{50} was determined to be 38 µg a.s./L.

The algae is thus the most sensitive organism from the acute aquatic data set (fish, crustaceans, algae). Based on these results, DCPP is classified for acute aquatic toxicity. Furthermore, this result is the lowest from the chronic toxicity data. Therefore, it is the basis for chronic aquatic toxicity classification.

No test with DCPP towards aquatic plants is available.

5.4.4 Other aquatic organisms (including sediment)

No test with DCPP towards sediment organisms is available.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

CLP:

Aquatic Acute 1:

Aquatic acute toxicity: L(E)C_{50} values for all three trophic levels are below 1 mg/L; Lowest L(E)C_{50} value: E_rC_{50} (algae) =0.038 mg/L

- **è Classification with Aquatic Acute 1**
- **è M factor = 10**

Studies used:

- Doc. III A7.4.1.1/01: Study A 7.4.1.1/01, OECD Guideline No. 203, EEC C.1 (1992) -> **LC_{50} (fish) = 0.70 mg/L**
- Doc. III A7.4.1.2/01: Study A 7.4.1.2/01, OECD 202, Part1 (1992) EEC C.2 (1992) -> **EC_{50} (crustacean) = 0.32 mg/L**
- Doc. III A7.4.1.3/01: Study A7.4.1.3/01, OECD 201 (1984) EEC C.3 (1992) -> **E_rC_{50} (algae) = 0.038 mg/L**

Aquatic Chronic 1:

There are chronic data for two trophic levels and DCPP is not rapidly degradable. DCPP is classified as not readily biodegradable (40-50% biodegradation after 28 days). The inherent biodegradation study failed to show ultimate biodegradation of DCPP. DCPP is hydrolytically stable at pH values between 4 to 9. Photolysis in water yields a DT_{50} =4.9 days (winter), but mineralization after 19 days was only 20%AR[4].

Chronic NOEC values for two trophic levels (daphnia and algae) are below 0.1 mg/L;

Lowest chronic NOEC value: NOE_rC (algae) =0.0093 mg/L

According to Table 4.1.0 (b) (iii) of Regulation (EU) No 286/2011 category chronic 1 is also met by the acute toxicity values for fish (LC50 = 0.70 mg/L, Doc. III A7.4.1.1/01: Study A 7.4.1.1/01).

- **è classification with Aquatic Chronic 1**
- **è M factor = 10**

Studies used:

- Doc. III A7.1.1.2.1/01, Study A7.1.1.2.1/01, OECD 301B (1992), -> **40-50% degradation in 28 days**
- Doc. III A7.1.1.2.2, Study A7.1.1.2.2, OECD 302B (1993) and 87/302/EEC, Part C (1988) ->**99% elimination, no data on ultimate degradation**
- Doc. III A7.1.1.1.1, Study A7.1.1.1.1, OECD 111 (1981) -> **hydrolytically stable at pH 4, 7 and 9 at 50°C**

[4] Applied radioactivity

- Doc. III A7.1.1.1.2, Study A A7.1.1.1.2/01 and Study A7.1.1.1.2/02, OECD 316 -> **DT_{50} = 0.32 - 4.86 days** (latitude 50°N, summer - winter)
- Doc. III A7.4.1.1/01: Study A 7.4.1.1/01, OECD Guideline No. 203, EEC C.1 (1992) -> **LC_{50} (fish) = 0.70 mg/L**
- Doc. III A7.4.3.4, Study A7.4.3.4, OECD guideline 211 (OECD, 1998) -> **NOEC (crustacea) =0.094 mg/L**
- Doc. III A7.4.1.3/01: Study A7.4.1.3/01, OECD 201 (1984) EEC C.3 (1992) -> **NOE_rC (algae) = 0.0093 mg/L**

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

Table 17: Proposed classification and labelling according to Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011

Classification		**Justification**
Classification	Eye Dam. 1	Please see chapter 3 of this document.
	Aquatic Acute 1 (M=10)	L(E)C50 values ≤1 mg/L for all three trophic levels. The lowest available and considerable EC50 value = 0.038 mg/L.
	Aquatic Chronic 1 (M=10)	The active substance is not rapidly degradable and the NOECs are below 0.1 mg/L. Lowest available NOEC = 0.0093 mg/l.
Hazard statements	H318: Causes serious eye damage H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.	According to the classification criteria of Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 DCPP causes serious eye damage and is very toxic to aquatic life with long lasting effects: The acute effects lead to the classification Aquatic Acute 1 with an M-Factor of 10, the chronic effect data lead to the classification Aquatic Chronic 1 with an M-Factor of 10.
Labelling		**Justification**
GHS Pictograms	 GHS05  GHS09	According to the classification criteria of Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 classification of Eye Dam. 1, Aquatic Acute 1, and Aquatic Chronic 1 the labelling with GHS05, GHS09 the signal word "danger", the Hazard statements H318 and H410 and the Precautionary Statements P273, P305, P280, P391 and P 501 have to be put on the label.
Signal words	Danger	

Hazard statements		H318: Causes serious eye damage. H410: Very toxic to aquatic life with long lasting effects.
Precautionary Statements	**General**	-
	Prevention	P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection.
	Response	P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician P391: Collect spillage.
	Storage	-
	Disposal	P501: Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).

6 OTHER INFORMATION

No other information

7 REFERENCES

REFERENCE LIST – SORTED BY SECTION NUMBER

Section No / Reference No	Year	Title/Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection	Owner
A2.7/01	2008a	DCPP: 5 Batch analysis for European Biocide Registration. Date: 2008-03-26; Trace Analysis & Occupational Hygiene (TAOH), Expert Services Business Unit of Ciba Inc., Basle, Switzerland Test No. 08.055 GLP; unpublished	Yes	BASF SE
A3.1/01	1999	Determination of the melting point / melting range of FAT 80'220/A. Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report no.: 711966; GLP:Yes; Published: No	Yes	BASF SE
A3.1/02	1999	Determination of the boiling point / boiling range of FAT 80'220/A. Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report no.: 711977; GLP:Yes; Published: No	Yes	BASF SE
A3.1/03	1999	Determination of the relative density of FAT 80'220/A. Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report no.: 711988; GLP:Yes; Published: No	Yes	BASF SE
A3.1/04	2007	Bulk density of DCPP ex Anupam Rasayan/Indien. Date: 2007-07-11; Ciba Spezialitätenchemie Grenzach GmbH, Grenzach, Germany Report No.: -- GLP:No unpublished	Yes	BASF SE
A3.2/01	1998	Calculation of the vapour pressure of FAT 80'220/A. Date: 1998-11-26 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report No. 711990 GLP: No; unpublished	Yes	BASF SE
A3.2/02	2007	DCPP, Calculation of Henry's Law Constant. Date: 2007-01-26, Dr. Knoell Consult GmbH, Leverkusen, Germany	Yes	BASF SE

Section No / Reference No	Year	Title/Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection	Owner
		Report No: 2007/01/26/UB, GLP: No, unpublished		
A3.3/01	2007	Chemical characterisation of DCPP. Date: 2007-07-13, CONFIDENTIAL Ciba Specialty Chemicals Inc, TAOH (Trace Analysis & Occupational Hygiene), Basle, Switzerland, Report No. 07.204 GLP: Yes, unpublished	Yes	BASF SE
A3.4/01	1999	Report on analytical certification, FAT 80'220/A. Date: 1999-01-15 CONFIDENTIAL, Ciba Specialty Chemicals, Consumer Care, Analytic (GZ5.54), Grenzach-Wyhlen, Germany Report No. A98-1812, GLP: No, unpublished	Yes	BASF SE
A3.5/01	1999	Determination of the water solubility of FAT 80'220/A. Date: 1999-02-01 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report No. 712012; GLP: Yes; Published: No	Yes	BASF SE
A3.5/02	2007	Determination of the solubility of dichlorophenoxyphenol (DCPP) in water and solvents. Date: 2007-07-31 Ciba Specialty Chemicals Inc., Trace Analysis and Occupational Hygiene (TAOH), Basel, Switzerland; Report No. 07.249, GLP: Yes, Published: No	No	BASF SE
A3.6/01	2007	Dissociation constant 2-Hydroxy 4,4'-Dichloro Diphenyl Ether. Date: 2007-06-14 Ciba Specialty Chemicals Inc., Analytics R&D CE, Basel, Switzerland; Report No. 34571GLP: Yes; Published: No	Yes	BASF SE
A3.9/01	1999	Determination of the partition coefficient (n-octanol/water) of FAT 80'220/A. Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report No. 712023 GLP: Yes; Published: No	Yes	BASF SE
A3.10/01	2007	Thermal stability 2-Hydroxy 4,4'-Dichloro Diphenyl Ether. Date: 2007-06-14 Ciba Specialty Chemicals Inc., Analytics R&D CE, Basel, Switzerland; Report No. Study No. 34063 GLP: Yes; Published: No	Yes	BASF SE
A3.11/01	2007	FAT 80220/E (DCPP), Determination of the flammability and evaluation of the flammability in contact with water and pyrophoric properties. Date: 2007-10-30 RCC Ltd., Itingen, Switzerland; Report No. B47283; GLP: Yes; Published: No	Yes	BASF SE

Section No / Reference No	Year	Title/Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection	Owner
A3.11/02	2007	FAT 80220/E (DCPP), Determination of the relative self-ignition temperature. Date: 2007-10-30 RCC Ltd., Itingen, Switzerland; Report No. B47294; GLP: Yes Published: No	Yes	BASF SE
A3.13/01	1999	Determination of the surface tension of an aqueous solution of FAT 80'220/A. Date: 1999-03-19 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report No. 712001 GLP: Yes; Published: No	Yes	BASF SE
A3.17/01	2007	Packaging material for Tinosan® HP 100. Date: 2007-07-02 Ciba Specialty Chemicals Inc., Basel, Switzerland; Report No. -- GLP: No; Published:No	Yes	BASF SE
A3.17/02	2007	-No title- Date: 2007-12-19, CONFIDENTIALCiba Inc. Switzerland, Basel, Switzerland; Report No. --GLP: No Published: No	Yes	BASF SE
A7.1.1.1.1	1999g	Hydrolysis determination of FAT 80'220/A at different pH values Date: 1999-03-01 RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland; Report No. 712260 GLP: Yes; Published: No	Yes	BASF SE
A7.1.1.1.2/01	2008	^{14}C-DCPP Aqueous Photolysis Under Laboratory Conditions and Determination of the Quantum Yield. Date: 2008-12-16 Harlan Laboratories Ltd., Itingen, Switzerland; Report No. B46980 GLP: Yes; Published: No	Yes	Ciba Inc.
A7.1.1.1.2/02	2009	Aqueous Photolysis of DCPP; Metabolite Identification by LC/MS. Date: 2009-01-09 Trace Analysis & Occupational Hygiene (TAOH), Ciba Inc., Basel, Switzerland; Report No. 08.319; GLP: No; Published: No	Yes	Ciba Inc.
A 7.1.1.2.1/02	2012	Reg.No. 5854910 (label: phenole-U-C14) (Radiolabelled Diclosan) - Determination of the Ready Biodegradability in a modified CO_2-Evolution Test at aerobic conditions with radiolabelled test substance. BASF SE, Ludwigshafen, Germany. Report No. 22G0456/11G165, Date: 2012-11-19, BASF SE, Experimental Toxicology and Ecology, Ludwigshafen/Rh., Germany; Report No. 22G0456/11G165, GLP: Yes, Published: No	Yes	BASF SE
A 7.1.1.2.1/02	1999a	Ready biodegradability of FAT 80220/A in a Manometric Respirometry Test. Date: 1999-01-15 RCC Ltd., Itlingen, Switzerland.; Report No. Study Project No.: 712258GLP:Yes; Published: No	Yes	BASF SE

Section No / Reference No	Year	Title/Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection	Owner
A 7.1.1.2.1/03	2000	Biodegradation test of FAT 80220/A by microorganisms Date: 2000-04-13 Institute of Ecotoxicology, Gakushin University, Japan: Report No.: G4-0011.D186.CR, GLP: Yes, Published: No	Yes	BASF SE
A 7.1.1.2.1/04	2002	Ready biodegradability of FAT 80220/B (Manometric Respirometry Test). Date: 2002-11-15, Amended: 2002-12-09Solvias AG, Basle, Switzerland Report No. Solvias Report No. L02-002909GLP:Yes, Published:No	Yes	BASF SE
A 7.1.1.2.2	2001	Inherent biodegradability of FAT 80220/A (Zahn-Wellens/EMPA – Test). Date: 2001-02-02; Solvias AG, Basle, Switzerland. Report No. Test No. G59413, GLP:Yes; Published:No	Yes	BASF SE
A 7.1.2.1.1/01	2002	Activated sludge simulation test for the Biodegradability of FAT 80220/B Date: 2002-01-25; Solvias AG, GLP Test Facility Solvias, Basel, Switzerland, Report No. Test No. L01-002997; GLP:No; Published: No	Yes	BASF SE
A 7.1.3/01	2007b	Determination of Koc of DCPP according to OECD TG121 Date: 2007-04-24 Dep. of Trace Analysis and Occupational Hygiene (TAOH) Ciba Specialty Chemicals Inc., Basle, SwitzerlandReport No. 07.128, GLP:Yes, Published: No	Yes	BASF SE
A 7.1.3/02	2006	Determination of Koc of Methoxytriclosan und DCPP according to OECD TG121 Date: 2006-11-14 Dep. of Trace Analysis and Occupational Hygiene (TAOH) Ciba Specialty Chemicals Inc., Basle, SwitzerlandReport No. 06.498, GLP:No, Published: No	Yes	BASF SE
A.7.3.1	2007a	DCPP. Calculation of indirect photodegradation. Date: 2007-02-02. Dr. Knoell Consult GmbH, Leverkusen, Germany; Report No. KC-PD-01/07; GLP:No; Published:No	Yes	BASF SE
A 7.4.1.1/01	1999b	Acute toxicity of FAT 80'220/A to zebra fish (*Brachydanio rerio*) in a 96-hour static test. Date: 1999-04-06 RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen/Switzerland; Report No. 712170GLP: Yes Published: No	Yes	BASF SE
A 7.4.1.1/02	2000	Acute toxicity of FAT 90'403/A to zebra fish (*Brachydanio rerio*) in a 96-hour semi-static test. Date: 2000-07-03; RCC Ltd., Environmental Chemistry & Pharmanalytics	Yes	BASF SE

Section No / Reference No	Year	Title/Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection	Owner
		Division, Itingen, Switzerland ; Report No. 758946; GLP: Yes, Published: No		
A 7.4.1.2/01	1999c	Acute toxicity of FAT 80'220/A to *Daphnia magna* in a 48-hour immobilization test. Date: 1999-01-20; RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen/Switzerland, Report No. 712203, GLP:Yes, Published:No	Yes	BASF SE
A 7.4.1.3/01	1999d	Acute toxicity of FAT 80'220/A to *Scenedesmus subspicatus* in a 72-hour algal growth inhibition test. Date: 1999-04-06 RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen/Switzerland, Report No. 712225 GLP:Yes, Published:No	Yes	BASF SE
A 7.4.2	2007b	DCPP. Calculation of the Bioconcentration Factor (BCF). Date: 2007-02-12., Dr. Knoell Consult GmbH, Leverkusen, Germany, Report No. KC-BCF-01/07, GLP:No, Published:No	Yes	BASF SE
A 7.4.3.3.1	2000	Bioconcentration test of FAT80'220/A in carp (Cyprinus carpio). Date: 2000-05-08 Institute of Ecotoxicology, Gakushuin University, Japan; Report No. G4-0014 C112 CR; GLP: Yes; Published: No	Yes	BASF SE
A 7.4.3.4	1999	Influence of FAT 80'220/A on survival and reproduction of *Daphnia magna* in a semistatic test over three weeks. Date: 1999-11-02 RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen/Switzerland, Report No. 735322, GLP: Yes, Published: No	Yes	BASF SE

8 ANNEXES

First Draft CAR, Doc II-A, DCPP, RMS AT, 2013

First Draft CAR, Doc III-A, DCPP, RMS AT, 2013

First Draft CAR, Doc II-A and Doc III-A Confidential, DCPP, RMS AT, 2013

First Draft CAR, References, DCPP, RMS AT, 2013