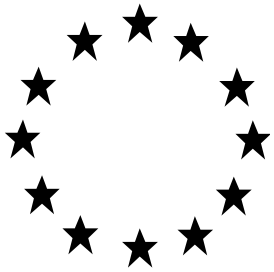
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



DCPP

Product-types PT 1, 2 & 4
(Human hygiene biocidal products, Private area and public health area disinfectants, Food and feed area disinfectants)

January 2015

Austria

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of 5-Chloro-2-(4-chlorophenoxy)-phenol (short: DCPP) as product-type 1, 2 and 4 (Disinfectants for Human hygiene; Disinfectants and algaecides not intended for direct application to humans or animals; Disinfectants for Food and feed area), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 1, 2 and 4 containing DCPP that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive. Those requirements and common principles are very similar to those laid down in Article 19(1), (2) and (5) and Annex VI of Regulation (EU) No 528/2012. At the time of finalisation of this assessment report, there was no indication that the conclusions regarding compliance with Directive 98/8/EC would not be valid for the purpose of establishing compliance with the requirements of Regulation (EU) No 528/2012.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of DCPP for product-type 1, 2 and 4, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 1,2 and4 that contain DCPP. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of 5-Chloro-2-(4-chlorophenoxy)-phenol (short: DCPP) as product-type 1, 2 and 4 (Disinfectants for Human hygiene; Disinfectants and algaecides not intended for direct application to humans or animals; Disinfectants for Food and feed area), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.

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

DCPP (CAS no. 3380-30-1) was notified as an existing active substance, originally by Ciba Spezialitätenchemie Grenzach GmbH. In the context of the acquisition of Ciba by BASF, BASF SE, hereafter referred to as the applicant, continued to act as applicant with regard to DCPP in product-type PT 1, 2 and 4. This change over of responsibility took place on 1 July 2009.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.
In accordance with the provisions of Article 7(1) of that Regulation, CA-Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for DCPP as an active substance in Product Type 1, 2 and 4 was 31 July 2007, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 31 July 2007, Austrian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 Jannuary 2008. On 19 February 2013, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 28 February 2013. The competent authority report included a recommendation for the inclusion of DCPP in Annex I to the Directive for product-type 1, 2 and 4.

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

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.
In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on [date].

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

2. OVERALL SUMMARY AND CONCLUSIONS

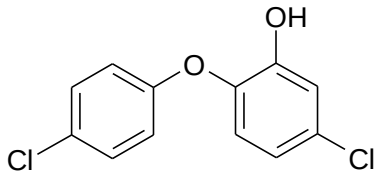
2.1. Presentation of the Active Substance

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

The active substance 5-Chloro-2-(4-chlorophenoxy)-phenol (short: DCPP) is attributed the CAS-No 3380-30-1 and the EC-No 429-290-0. The molecular formula is $C_{12}H_8Cl_2O_2$, and the molecular weight is 255.1 g/mol. The minimum degree of purity is 99.5%w/w.

DCPP contains certain amounts of dioxin impurities. It is therefore proposed to set a maximum limit of 2 pg $TEQ_{WHO-2005}$/g for dioxin impurities of DCPP. This limit value is acceptable from a toxicological and ecotoxicological point of view.

Structural formula:



The structure of DCPP is confirmed by all spectra (IR, NMR, UV/VIS and MS).

The physico–chemical properties are studied for the purified active substance of stated specification (min. 99.5%w/w 5-Chloro-2-(4-chlorophenoxy)-phenol [short: DCPP]) according to the demands of the data requirements. DCPP is a white, crystalline powder, has a slightly smelling like phenols. Its melting point is 73.6°C, and the boiling point is 359.3°C. The relative density is 1.47 at 20.1°C. The calculated vapour pressure is $4.3*10^{-7}$ Pa at 20°C and $1.2*10^{-06}$ Pa at 25°C. The Henry's law constant calculated with bond method is $6.82*10^{-04}$Pa m^3 mol^{-1} at 25°C and calculated with group method is $2.53*10^{-03}$Pa m^3 mol^{-1} at 25°C.

The water solubility of the test item is 19.5 mg/L (20°C, pH 5-6), and at pH 5: 6.3mg/L at 10°C, 10 mg/L at 20°C and 14.7 mg/L at 30°C; the solubility of DCPP increases with the temperature The dissociation constant (pKa) is determined to be pKa=9.49 at 20°C.The solubility of DCPP in hexane is ~ 8731 mg/L at 10 °C; ~ 18638 mg/L at 20 °C and~ 27049 mg/L at 30 °C; and in n-octanol ~ 368228 mg/L at 10 °C; ~ 436764 mg/L at 20 °C; ~ 513828 mg/L at 30 °C.

The active substance as manufactured does not contain any organic solvent. The partition coefficient n-octanol-water is 3.7 at 20°C, and the calculated partition coefficient n-octanol-water is 4.8 at 10°C; 4.6 at 20°C and 4.5 at 30°C. The substance is regarded not to be surface active (surface tension is 65 mN/m at 19.7°C.) The viscosity is not performed because the active substance is a solid. No flash point study was performed because DCPP is a solid; DCPP is not auto flammable and DCPP is not highly flammable.

Based on measurements it can be concluded that the active substance is stable between 30 and 150 °C. It is not considered to be reactive to container material (Polyethylene canister).

The analytical methods for the determination of the active substance and impurities in the active substance as well as the analytical methods for the determination of active substance residues in environmental matrices have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

- The assay of DCPP in the active substance as manufactured is determined using a capillary gas chromatograph equipped with a flame ionisation detector. The quantification is done by external standard method.

- The analytical method for the determination of impurities in the active substance as manufactured is performed using a capillary gas chromatograph equipped with a mass detector.

- The determination of residues in water and soil can be performed by HPLC/MS.

- The vapour pressure of DCPP is $1.2x10^{-06}$ Pa at 25 °C which is clearly below the trigger value. Furthermore no spray application is foreseen within the intended uses described in this CAR. Therefore a method for air is not necessary.

As DCPP is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.

The active substance is used in a manner that may not result in a significant increase in the risk for human health. Therefore an analytical method for the determination of residues of DCPP in or on food or feedstuffs would not have been necessary. However, an analytical method for the determination of active substance residues in a fatty food stimulant - sunflower oil - was developed.

Physico-chemical properties of the METABOLITE: Methyl-DCPP

Tab. 2.1.1-1: Physical and chemical properties of methyl-DCPP

Property	**Method**	**Purity/Specification**	**Results**	**Reference**
Melting point	Company Statement	n.a.	The substance is a degradation metabolite which does not manufacture and market therefore the study does not need to be performed.	Company Statement
Boiling point	Calculation based on EPI Suite v4.11 Calculation based on SciFinder	n.a. n.a.	343.7°C 347.1°C (<t 1013 hPa)	Doc. III-A 3; Study A3.1.02 EPISuite, M-DCPP Doc. III-A 3; StudyA3.1.02. SciFinder, M-DCPP

Property	Method	Purity/Specification	Results	Reference
Density	Calculation based on SciFinder	n.a.	1.294 kg/m^3at 20°C	Doc. III-A 3; StudyA3.1.03. SciFinder, M-DCPP
Vapour pressure	Calculation based on EPI Suite v4.11 Calculation based on SciFinder	n.a. n.a.	$3.58*10^{-3}$ Pa at 25°C $1.47*10^{-2}$ Pa	Doc. III-A 3; Study A3.2/01. EPISuite, M-DCPP Doc. III-A 3; StudyA3.2/02 SciFinder, M-DCPP
Henry´s Law Constant	Calculation based on QSAR	n.a.	Results at 25 °C: 0.388 Pa*m^3*mol^{-1} (Bond method) 16.8 Pa*m^3*mol^{-1} (Group method)	Doc. III-A 3; Study A3.2/01. EPISuite, M-DCPP
Physical state	Visual inspection	n.a.	powder	Doc. III-A 3; Study A3.5 M-DCPP
Colour	Visual inspection	n.a.	white	Doc. III-A 3; Study A3.5 M-DCPP
Absorption spectra: IR	The test was performed according to internal standard operation procedures.	99.7% [redacted]	Methyl DCPP was identified by FTIR-spectrum using a KBR-pellet	Doc. III-A 3; Study A3.4 M-DCPP
Absorption spectra: NMR	The test was performed according to internal standard operation procedures.	99.7% [redacted]	The structure of methyl-DCPP was confirmed by NMR measurements.	Doc. III-A 3; Study A3.4 M-DCPP
Absorption spectra: MS	The test was performed according to internal standard operation procedures.	99.7% [redacted]	The structure of methyl- DCPP can be assigned to the El mass spectrum of the sample.	Doc. III-A 3; Study A3.4 M-DCPP

Property	Method	Purity/Specification	Results	Reference
Water solubility	OECD guideline 105	99.7% [redacted]	0.322 mg/L at 20 °C (pH=6.95)	Doc. III-A 3; Study A3.5 M-DCPP
Dissociation constant	Company Statement	n.a.	The substance does not contain any ionisable functional groups therefore the study does not need to be performed	Company Statement
Partition coefficient n-octanol/water	Calculation based on EPI Suite v4.11 Calculation based on SciFinder	n.a. n.a.	LogPow=4.58 at 25°C LogPow=4.84 at 25°C	Doc. III-A 3; A3.9.EPISuite, M-DCPP Doc. III-A 3;A3.9.SciFinder, M-DCPP
Flammability, including autoflammability and identity of combustion products	Company Statement	n.a.	The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.	Company Statement
Flash point	Company Statement	n.a.	The substance is a solid therefore the study does not need to be performed.	Company Statement
Surface tension	Company Statement	n.a.	Methyl-DCPP is not surface-active.	Company Statement
Viscosity	Company Statement	n.a	The substance is a solid therefore the study does not need to be performed.	Company Statement
Explosive properties	Company Statement	n.a.	There is no structural alert for explosive properties.	Company Statement

Property	Method	Purity/Specification	Results	Reference
Oxidizing properties	Company Statement	n.a.	There is no structural alert for oxidizing properties.	Company Statement

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying products, establishes that the products may be expected to be efficacious. For PT1 DCPP is used as bactericidal active substance for use in liquid soap formulations for hand disinfection. Tests according EN 1040 showed a basic bactericidal activity ≥ 0.02 % a.s. Test according EN 1276 showed bactericidal activity at concentration ≥ 0.144% active substance.

PT2 products containing DCPP are intended to be used as surface disinfectants. For PT 4 DCPP is intended to be used in dishwashing liquids. Tests reported by [redacted] (2007) showed at least bacteriostatic efficacy for the intended in-use concentrations (i.e. PT2 = 0.004%, PT4 = 0.0004%).
Based on the available information it cannot be excluded that resistance and cross resistance to antibiotics may occur.

2.1.3. Classification and Labelling of the active substance

As no specific concentration limits are included in the harmonised classification shown below the inclusion of the following Specific Concentration Limits (SCL)s are proposed based on the provisions of Directive 1999/45/EC and Directive 2006/8/EC. The proposed classification and labelling for the use of Directive 1999/45/EC are laid down in Table 2.1.3-1 (by the RMS).

As the classification according to Reg. (EC) No 1272/2008 and Reg. (EU) No 286/2011 foresees the establishment of M-Factors as well as to base the classification for chronic aquatic toxicity on available chronic toxicity data the following classification and labelling shown in Table 2.1.3-2 is proposed by the RMS.

For toxicological endpoints the proposed classification is the same as the current classification. It should be noted that a concern for inhalation toxicity of triclosan has been raised by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2009) under the Australian Government3. Based on the results of a 21-day rat inhalation study in which a mixture of triclosan and ethanol was tested, the following classification was proposed for triclosan: R23, toxic by inhalation and R37, irritating to the respiratory system according to the dangerous substances regulation 67/548/EEC or Acute tox. 3, H330: Toxic if inhaled and STOT SE 3, H335: May cause respiratory irritation according to the CLP regulation (EC) No 1272/2008. Because in this study triclosan was tested in a mixture with ethanol it is not considered relevant for the classification of triclosan or DCPP as pure substances. However, this finding should be considered when evaluating products containing mixtures of triclosan or DCPP and ethanol

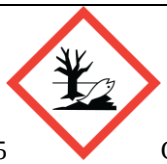
3 http://www.nicnas.gov.au/publications/car/pec/pec30/pec_30_full_report_pdf.pdf

Tab. 2.1.3-1: Proposed classification and labelling according to Annex VI of Directive 67/548/EEC and Directive 1999/45/EC (proposed by RMS)

Classification			Justification
Hazard symbol:	Xi, N		DCPP is irritating to eyes, very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. With regard to its toxicological and ecotoxicological properties, the active substance is classified as irritant and dangerous for the environment and has to be labelled with the hazard symbols Xi and N and the R-phrases R41-50/53.
Indication of danger:	**Irritant** **Dangerous for the environment**		
Labelling symbol			
R-phrases + SCL:	R41: Risk of serious damage to eyes. R50: Very toxic to aquatic organisms. R53: May cause long-term adverse effects in the aquatic environment SCL: N; R50-53: $C_n \geq 2.5\%$; N, R51-53: $0.25\% \leq C_n < 2.5\%$; R52-53: $0.025\% \leq C_n < 0.25\%$;	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	All acute toxicity values are <1 mg/L and the substance is not rapidly biodegradable. The lowest considerable $L(E)C_{50}$ is 0.038 mg/l resulting in the given Specific Concentration Limits
S-phrases:	S2: Keep out of the reach of children S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 39: Wear eye/face protection. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/Safety data sheets.		According to the classification with N; R50-53 and the labelling with N; R50/53 S-phrases S 60-61 have to be put on the label.

Table 2.1.3-2: Proposed classification and labelling according to Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 (proposed by RMS)

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 EC_{50} value = 0.038 mg/L.
	Aquatic Chronic 1 (M=10)	The active substance is not rapidly biodegradable 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).	

2.1.4. Classification and labelling of the representative product for PT1, PT2, PT4

Table 2.1.4-1: Classification and labelling according to Directive 1999/45/EC (proposed by the RMS)

Hazard symbol		Justification
Class of danger	Irritant	
R phrases	R36/R38 Irritating to eyes, irritating to skin	Sum of skin and eye irritating co-formulants and seriously eye damaging active substance is higher than 20%.
	R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment	$L(E)C_{50}$ values of DCPP in the range between 0.01 and 0.1 mg/L (-> SCL: R52-53: 0.025% $\leq C_n <$ 0.25%;) and concentration in the product 0.2 %.
S phrases	S2 keep out of the reach of children S24 avoid contact with eyes S26: in case of contact with eyes, rinse immediately with plenty of water and seek medical advice S37: wear suitable gloves S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions / safety data sheet. S64: if swallowed, rinse mouth with water (only if person is conscious)	
Classification	R 52-53	
Labelling	R: 52/53 S: 60-61	

Table 2.1.4-2: Classification according to Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 (proposed by RMS)

Classification		Justification
Classification	Skin irritation 2	Sum of skin irritating co-formulants is higher than 10%.
	Eye irritation 2	Sum eye irritating co-formulants and seriously eye damaging active substance is higher than 10%.
	Aquatic chronic 3	M=10 and DCPP content in biocidal product is 0.2%
Hazard statements	H315 – causes skin irritation H319 – causes serious eye irritation	See above
	H412 - Harmful to aquatic life with long lasting effects	See above

Table 2.1.4-3: Labelling according to Regulation (EC) No 1272/2008 and Reg. (EU) No 286/2011 (proposed by RMS)

Labelling		
GHS Pictograms		 GHS07
Signal word		Warning
		H315 – causes skin irritation
		H319 – causes serious eye irritation
		H412 – Harmful to aquatic life with long lasting effects
Precautionary Statements	**General**	
	Prevention	P264 - Wash hands thoroughly after handling. P 280 - Wear protective gloves/eye protection/face protection. P273 – Avoid release to the environment
	Response	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: IF EYE IRRITATION PERSISTS: Get medical advice/ attention. P332+P313: IF SKIN IRRITATION OCCURS, Get medical advice/ attention. P362: Take off contaminated clothing and wash before reuse.
	Storage	
	Disposal	P501 - Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

The active substance displays neither explosive nor oxidizing properties. No flash point study was performed because DCPP is a solid; DCPP is not auto flammable and DCPP is not highly flammable.

In conclusion, no physico-chemical hazards and therefore also no risk could be identified for the active substance.

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

DCPP is structurally closely related to the antibacterial active substance triclosan (2,4,4'-trichloro-2'-hydroxy-diphenyl ether, CAS No. 3380-34-5).

The available data base for DCPP is incomplete. Therefore this evaluation is based on read across from the structurally similar substance triclosan to DCPP. This read across is essentially supported by toxicokinetic studies (hamster) and repeated dose studies which are available for both substances. Read across was used for the endpoints carcinogenicity and reproductive toxicity and the evaluation of the relevance of potential endocrine disrupting properties of triclosan for DCPP.

Toxicokinetics and metabolism

Comparative ADME studies of triclosan and DCPP in hamsters showed that the toxicokinetics of the two substances are comparable. While the half-life of DCPP was slightly longer than for triclosan, the AUC value for DCPP was 3-fold lower than for triclosan. The pattern of metabolites of both substances is very similar: Although differing by the presence of one chlorine atom the main metabolites of both substances are glucuronated and sulphonated parent compound. Unmodified triclosan is less abundant in urine than unmodified DCPP, the rate of urinary excretion and the distribution of radioactivity between urine and faeces are nonetheless very similar.

Overall it can be summarised that absorption and distribution of DCPP and triclosan is fast. The AUC after single oral administration of DCPP in male hamsters (females were not tested) is ~ 3-fold lower than for triclosan. This could indicate that read across from triclosan data to DCPP represents a worst case assumption. No toxicokinetic analyses were carried out after application of DCPP to rats and mice, however, the AUC after administration of triclosan to both species was higher compared to DCPP in hamsters.

Pharmacokinetic data in hamsters indicate that triclosan is well-absorbed following oral administration (68-89%). Also in mice and rat studies oral absorption of triclosan is high (about 70%) due to inclusion of bile measurements. Two C_{max} values are seen in mice and rats (at 1 and 4 hours), indicating enterohepatic recirculation, which does not occur in hamsters or humans. In hamsters, the C_{max} has been reported to occur after 1 hour following administration of the dose of triclosan.

While data for single doses of triclosan show that the plasma AUC, as well as the half-life of elimination, in hamsters is greater than in mice or rats, plasma data from repeated-dose studies and from the chronic bioassays in these species have shown that the mouse experiences higher (2- to 5-fold) circulating levels of triclosan compared to the rat or

hamster. Based on tissue distribution data following single and repeated dosing, there is no evidence of bioaccumulation/bioretention of triclosan in rats and hamsters.

The metabolism of triclosan is similar between rodents and humans. In all species tested, the formation of glucuronide and sulphate conjugates predominates, with the relative extents to which glucuronide and sulphate conjugates are formed varying with the type of dosing (i.e., single-dose versus repeated doses) and with species under study. The excretion of triclosan in hamsters, primates, and humans is primarily via the urine, while excretion is primarily faecal in both mice and rats. There is evidence for the existence of enterohepatic circulation in mice and rats, but not in hamsters. The overall conclusion from a comparison of the rodent and human metabolism data is that there is no qualitative difference between the species with regards to levels of parent triclosan and conjugates in plasma, which indicates that enterohepatic circulation does not contribute significantly to the amount of free triclosan in plasma.

There are no data for DCPP in humans.

Triclosan is very well absorbed following oral ingestion in humans. However, limited absorption (approximately 5 to 10% of the dose) occurs following normal toothpaste use (i.e., brushing, expectoration, and rinsing) or following percutaneous application in personal care products.

Regardless of the formulation, only trace amounts of the parent compound are detected in the plasma following exposure to triclosan-containing products. Due to a pronounced first-pass effect, there is a near total conversion of absorbed triclosan to glucuronic and sulphuric acid conjugates. The relative proportions of these metabolites vary depending on the plasma steady-state concentration of total triclosan, with higher concentrations resulting in a shift from predominantly glucuronide- to predominantly sulphate-conjugates. The half-life of elimination for orally administered triclosan was reported to range from approximately 14 hours (single dose) to 20 hours (repeated doses).

Following ingestion, percutaneous application, or intravenous administration, the predominant route of excretion of triclosan is through the urine. In urine, triclosan is present as the glucuronide conjugate. In contrast, triclosan excreted in the faeces is present as the free unchanged compound. Pharmacokinetic data, in particular AUC values after single or repeated oral exposures to triclosan (e.g., through toothpaste use), as well as plasma triclosan levels following percutaneous exposure (e.g., soap use), indicate a lack of bioaccumulation potential.

Comparisons between animal and clinical data have shown that humans are exposed to much lower levels of triclosan through normal daily use of consumer products compared to exposure levels in animals in non-clinical toxicology studies. Percutaneous absorption is higher in rats, as expected, compared to humans. Numerous *in vitro* studies have demonstrated that human systemic exposure to triclosan through the dermal route is minimal (10 to 20%). A new in vitro dermal absorption study according to OECD 428 with DCPP supports a dermal absorption rate of 10% and 44% for 0.5 hours and 24 hours, respectively. The study was carried out with 30 µg/cm^2 DCPP as a 0.3% solution in an oil/water emulsion on pig skin samples.

Acute Toxicity

The oral and dermal LD_{50} values in the rat are greater than 2000 mg/kg body weight. These data indicate that DCPP is not acutely toxic to animals *via* the oral or dermal routes of administration.

DCPP is neither volatile (vapour pressure 1.2×10^{-6} Pa at 25°C) nor are the present formulations application that generate respirable aerosols. Inhalation toxicity studies were therefore not conducted.

It should be noted that based on a 21-day repeated dose inhalation study in rats, in which a mixture of triclosan and ethanol was tested, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)4 under the Australian Government proposed to assign the risk phrase R23 for the active substance triclosan. In contrast, the present evaluation comes to the conclusion that it is not justified to apply R23 for the pure substances triclosan or DCPP. However, the results of the 21-day study should be considered for formulations containing triclosan or DCPP and ethanol.

Irritation and Corrosivity

DCPP was tested on the skin of rabbits. No signs of skin irritation were noted.

In the eye irritation test with DCPP the ocular reactions were not fully reversible within the 21-day observation period. Thus, one criterion for assigning R41 is met.

It should be noted that based on a 21-day repeated dose inhalation study in rats, in which a mixture of triclosan and ethanol was tested, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the Australian Government proposed to assign the risk phrase R37 for the active substance triclosan. In contrast, the present evaluation comes to the conclusion that it is not justified to apply R37 for the pure substances triclosan or DCPP. However, the results of the 21-day study should be considered for formulations containing triclosan or DCPP and ethanol.

Proposed classification according to Council Regulation (EC) No. 1272/2008: Eye Dam. 1, H318: Causes serious eye damage

Proposed classification according to Council Directive 67/548/EEC: Xi, R41: Risk of serious damage to eyes.

Sensitisation

DCPP has been tested in an adjuvant guinea pig maximisation test. The results provided no evidence of sensitisation by DCPP following induction exposures of up to 50% in PEG 400. This relatively high induction/challenge concentration was non-irritant to the skin of guinea pigs. These studies demonstrated that DCPP is not a sensitizer in animals.

Repeated Dose, Sub-Chronic, and Chronic Toxicity

DCPP was tested in a sub-acute and a sub-chronic gavage study and a sub-acute dermal study in rats. In the gavage studies the kidneys, the liver and the blood system were identified as main target organs of toxicity. Most of the effects were reversible after the recovery period, with the exception of some blood values in the 28 days study and morphological changes in the stomach and the kidneys in the 90 day study. Hypertrophy and hyperplasia/hyperkeratosis in the oesophagus and (fore)-stomach are indicative of the irritant nature of DCPP in these gavage studies.

In the 28 day dermal study with DCPP no adverse effects were observed up to concentrations of 30mg/kg bw/day.

Several sub-acute, sub-chronic and chronic studies in rats, mice, hamsters and dogs are available for triclosan. The effects of DCPP and triclosan can be directly compared in the 90 day studies carried out for both substances. Differences between the two studies are limited to the mode of administration (DCPP was administered by gavage, triclosan was

4 http://www.nicnas.gov.au/publications/car/pec/pec30/pec_30_full_report_pdf.pdf

administered via diet) and different dose spacing. The results are, however, very similar. Adaptive hepatocellular hypertrophy was noted along with alterations in urinalysis parameters indicative of an impaired renal function as well as slight reduction of red blood cell counts. The sub-chronic NOAEL based on the DCPP gavage study is 20 mg/kg bw/day. From the 13-week feeding study with triclosan, a NOAEL for triclosan can be transformed to 61 mg/kg bw/day DCPP equivalents. The quantitative difference between the LOAELs/NOAELs found in the two studies might arise from a difference in bioavailability associated with the different application techniques. Differences in dose spacing might be another explanation.

Similar effects seen in the other sub-chronic and chronic studies with triclosan in rats, mice and hamsters further support the toxicological similarities of triclosan and DCPP.

Hepatic effects were marked in mice, and included biochemical changes measured in blood or plasma, liver weight changes, and histopathologic changes. In contrast, liver changes were seen less frequently and with decreased severity in rats and hamsters.

The results of pivotal, GLP-compliant subchronic and chronic studies for orally administered triclosan in rodents affected haematological parameters following up to 104 weeks of dosing. Statistical significant effects were seen at doses as low as 12 mg/kg bw for e.g. red blood cell count and clotting time. However the effects were not consistent between dosing groups and time intervals, and the effects were only transient and not biologically significant, as no anaemic conditions were seen in any of the animals. It is therefore assessed that haematological effects are only relevant at doses ≥127 mg/kg bw, with no adverse effects at 40 mg/kg bw/day (NOAEL) for chronic exposure.

The most critical effects in the hamster were related to nephrotoxic events and reproductive parameters. These effects included polyuria, increased blood urea nitrogen and nephropathy seen with higher doses of triclosan, as well as morphological effects on and reduced numbers of spermatozoa and germ cells. Hamsters are seasonal breeders and undergo spontaneous regression of testicular tissue when conditions are suboptimal for breeding. In the 13 week study effects on spermatozoa and regression of testes were seen in most dosed animals as well as control animals. These animals were most likely in the suppressed phase of the breeding cycle which is why data from this study are difficult to use for evaluation of effects on male reproductive organs. In the chronic hamster study there were statistically significant effects on male reproductive parameters at 250 mg/kg dose group, coinciding with high mortality and a poor clinical condition. Therefore, the applicant proposed that spontaneous regression is again likely to have occurred in this group of males. However this explanation is not fully conclusive. The chronic NOAEL is set at 75 mg/kg bw/day on the basis of effects on blood parameters, male reproductive organs and nephrotoxicity.

No systemic effects were seen in the GLP-compliant 90-day toxicity study using the dermal route of administration in rats. The dermal NOAEL for triclosan is 80 mg/kg bw/day, which was the highest dose tested.

The leading NOAEL taken forward to the AEL derivation comes from the 90 day gavage study with DCPP in rats. The NOAEL = 20mg/kg bw/day, based on clinical signs (breathing noise), reduced red blood cells in males, polyuria, presence of amorphous and hepatocellular hypertrophy at the LOAEL of 100mg/kg bw/day

Genotoxicity

DCPP was negative, with and without activation, in the in vitro tests in bacteria and mammalian cells. The in vitro chromosomal aberration assay in V79 cells produced equivocal results. However, the occurrence of chromosomal damage is unlikely to represent a relevant genotoxic event. This appraisal is confirmed by two in-vivo assays, one micronucleus assay in murine bone marrow and a UDS assay in primary rat hepatocytes. Both assays were clearly negative.

Carcinogenicity

No carcinogenicity studies have been carried out for DCPP. It is proposed to evaluate the endpoint carcinogenicity based on read across from triclosan to DCPP.

Triclosan showed no tumourigenic potential in lifetime cancer bioassays in rats and hamsters. In contrast, triclosan induced hepatic effects in a mouse carcinogenicity assay, starting at the lowest dose tested of 10 mg/kg bw/day, with liver tumour development observed starting at a dose of 30 mg/kg bw/day.

Triclosan did not produce tumours in rats (doses of 12 to 127 or 17 to 190 mg/kg bw/day in males and females, respectively) nor in hamsters (doses of 12 to 250 mg/kg bw/day). The chronic NOAEL for both the rat lifetime bioassay and the hamster study was based on non-neoplastic effects, and in rats determined to be 40 mg/kg bw/day for males and 56 mg/kg bw day for females, while the NOAEL for hamsters was 75 mg/kg bw/day.

In assessing the data and interpreting the findings from all of the carcinogenicity studies, it was important to further evaluate the differences between the rodent species, specifically mice, rats, and hamsters. Biochemical responses in the liver, cell proliferation and morphological responses to triclosan were investigated in a series of studies in all 3 rodent species. Triclosan showed peroxisome proliferator-type effects in the liver of mice (*e.g.*, induction of large increases in peroxisomal fatty acid beta-oxidation, 11- and 12-hydroxylation of lauric acid, and levels of CYP4A proteins, together with increases in the numbers and size of peroxisomes), but not in rat or hamster livers at the doses tested.

It is notable that triclosan induced hepatic cell proliferation in the mouse, but not in the hamster or rat, in investigational studies of replicative DNA synthesis. Taking into account the results from these special investigations, sub-chronic toxicity data indicating an increased sensitivity in mice to triclosan's hepatic effects, and pharmacokinetic data showing greater exposure levels to triclosan in mice compared to rats or hamsters, there is strong evidence that triclosan has peroxisome proliferator effects in mouse liver, but not in rat or hamster liver.

Given the association of peroxisome proliferation, cell proliferation, and tumour induction reported in the mouse, but no effects of these types in rats and hamsters, it was concluded that the mouse is uniquely sensitive to triclosan in the liver.

Importantly, it is generally accepted that chemicals which induce peroxisome proliferation and result in rodent hepatocarcinogenicity do not pose a health risk to humans. Without any tumours in other tissues, with the detection of liver tumours in mice only, and the establishment of peroxisome proliferation as inducer of liver tumours in mice, triclosan is presumed to be of no substantive cancer risk to man.

This conclusion is supported by the absence of effects of triclosan in a wide variety of *in vitro* and *in vivo* genotoxicity assays.

In order to support the read across from triclosan to DCPP for carcinogenicity similar mechanistic studies as performed for tricosan would be useful. In the absence of such tests the observed liver associated changes in blood biochemistry, hepatocellular hypertrophy and increases in liver weights seen in rats after DCPP application support the similarity between the two substances with regard to the endpoint carcinogenicity. Like triclosan, DCPP has been demonstrated to be non-genotoxic by an appropriate battery of in vitro and in vivo tests. The carcinogenicity studies as well as the mechanistic studies on triclosan are therefore considered also relevant for DCPP.

Reproductive Toxicity

No reproductive toxicity studies have been carried out for DCPP. It is proposed to evaluate the endpoint reproductive toxicity based on read across from triclosan to DCPP.

Triclosan was evaluated for reproductive toxicity in studies conducted with mice, rats and rabbits. In summary, the NOAEL for fertility and reproduction from the reproductive toxicity studies was 3000 ppm (238/285 mg/kg bw/day, ♂/♀), the highest dose tested in the two-generation rat study with triclosan administered in the diet. The overall NOAEL for foetal effects of triclosan was 50 mg/kg bw/day, based on foetal variation effects of delayed ossification observed at the high dose that also produced maternal toxicity in the rat oral gavage study. The NOAEL for post-natal effects of triclosan was 1000 ppm (152/76 mg/kg bw/day, ♂/♀) as tested in rats in the two-generation study with triclosan in the diet. It is important to note that the selection of the foetal NOAEL was based on foetal variation effects that were most likely secondary to general maternal toxicity, and not direct effects of triclosan per se.

It should also be noted, that the two-generation reproduction study in rats was conducted with a number of deficiencies, extended mating period and no sperm samples being the most aggravating, giving the endpoint reproduction, reduced impact. Therefore, care should be taken when making conclusions based on data from this study. The prolonged mating period could however pose a problem and is borderline to a classification for reproductive toxicity with Repr. 2 H361f / Xn R62, but has been found not sufficient for this classification as there was no indication of effects on the gonads and epididymis in the chronic/carcinogenicity study in rats.

The investigation of the potential endocrine disruptive effects is on-going under REACH, and consideration should be paid to the further progress.

2.2.2.2. Effects assessment

For the assessment of DCPP one dermal and one gavage 28 day study in rats and one gavage 90 day study in rats are available. Additionally to these data the applicant submitted a range of repeated dose studies from sub-chronic to chronic in which triclosan was tested.

The 28 day and 90 day gavage study in rats in which DCPP was tested was used for AEL derivation. By using this study the need for read across from triclosan is avoided and the AEL can be derived based on data from DCPP itself. In this 90 day study a NOAEL of 20mg DCPP/kg bw/day could be determined based on haematological effects, polyurea

and morphological changes in the liver seen at 100 mg DCPP/kg bw/day (= LOAEL). Similar effects were seen in an oral 90 day rat study in which triclosan was tested. Different effect levels observed in the two studies can be eplained by different administration forms (i.e. gavage vs. diet). It is noteworthy that the oral absorption of triclosan in rats is about 70% as determined in the available toxicokinetic studies including bile measurements. Because no toxicokinetic studies are available for DCPP in rat an oral absorption value of 70% is proposed, based on similar toxicokinetic behaviour of triclosan and DCPP in hamsters.

The standard assessment factors of 10 times 10, for interspecies and intraspecies uncertainty were applied: The AEL short term was derived from the rat 28 day study NOAEL of 150 mg/kg bw day multiplied by 0.7 and divided by 100 = 1 mg/kg bw day. However the effects seen in the 28 day rat study are not considered as severe. The AEL medium term was derived from the rat 90 day study NOAEL of 20 mg/kg bw day (effects on kidneys, liver and the blood system) multiplied by 0.7 and divided by 100 = 0.14 mg/kg bw day; the AEL long term was derived from the same sub-chronic study NOAEL of 20 mg/kg bw day and the same assessment factors, since (1) it is the lowest NOAEL of all available studies for DCPP and triclosan, (2) the NOAELs/LOAELs of the available sub-chronic and chronic studies with triclosan are in the same range (3) the AUC from the kinetic study with triclosan is higher than the AUC for DCPP supporting that triclosan NOAELs should be a conservative estimate for DCPP NOAELs.

2.2.2.3. Exposure assessment

PT 1- Human Hygiene Product

The main routes of human exposure towards 5-Chloro-2-(4-chlorophenoxy)-phenol originating in the application as antimicrobial active substance for use in liquid soap formulations for hand disinfection (PT 1) are listed in the table below.

Table 2.2.2.3-1: Main paths of human exposure to DCPP via use for PT 1

Exposure path	Primary (direct) exposure, during use of b.p.		Secondary (indirect) exposure Incidental contact after application	Via the environment
	Professional use	General public	General Public	General Public
Inhalation	Not relevant	Not relevant	Not relevant	Not relevant[1]
Dermal	Yes	Not relevant	Not relevant	Not relevant[1]
Oral	Not relevant	Not relevant	Not relevant	Not relevant[1]

1 From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food. These scenarios are not considered relevant in this case.

DCPP-containing antimicrobial soaps are intended for use by professional health care personnel and consumers (general public). These soaps are designed and used as rinse-

off products. The suds are left on skin for a short time and then rinsed off with water. Due to the intended use, dermal exposure of users is expected. Exposure via the inhalation route is considered to be not relevant based on the intrinsic properties of DCPP (low volatility of DCPP; vapour pressure: $1.2x10^{-6}$ Pa at 25°C). Oral exposure would be conceivable via hand-to-mouth contact, but the amount of substance taken up is considered to be not relevant, as the soaps are rinsed off with water and intense hand-to-mouth contact is not expected to be likely.

Secondary exposures and exposures via the environment (e.g. via being touched by persons, who have applied these soaps) are expected to be low in comparison to the exposure levels of users. Therefore, potential scenarios are assumed to be not relevant and to be covered by the primary exposure scenarios.

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

PT 2- Private Area and public health area disinfectant

The main routes of human exposure towards 5-Chloro-2-(4-chlorophenoxy)-phenol originating in the use for surface disinfection (PT 2) are listed in the table below.

Table 2.2.2.3-2: Main paths of human exposure to DCPP via use for PT 2

Exposure path	**Primary (direct) exposure, during use of b.p.**		**Secondary (indirect) exposure Incidental contact after application**	**Via the environment**
	Professional use	**General public**	**General Public**	**General Public**
Inhalation	Not relevant	Not relevant	Not relevant	Not relevant[1]
Dermal	Yes	Yes	Yes	Not relevant[1]
Oral	Not relevant	Not relevant	Yes	Not relevant[1]

[1] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food. These scenarios are not considered relevant in this case.

DCPP is used in microbicidal surface disinfectants, which are intended for the cleaning of surfaces in hospitals and private areas by professional and non-professional users. Exposure via the inhalation route is considered to be not relevant as no aerosols are formed during the expected activities and DCPP reveals a low volatility (only low concentrations of gaseous releases possible: vapour pressure: $1.2x10^{-6}$ Pa at 25°C). Oral exposure to DCPP is considered to be unlikely for users (adults), if no misuse is expected and the tasks are performed carefully. Therefore, dermal contact with the active substance is considered to be the only relevant source of exposure during application (e.g. during mopping and wiping of surfaces).

Secondary exposure is assumed to be unlikely in the case of adults, as inhalation exposure is regarded to be low and intense contact with treated surfaces to be unlikely

(referring to dermal and oral route). Oral and dermal exposures are possible considering infants (hand-to-mouth contact with treated surfaces).

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

PT 4- Food and feed area disinfectants

The main routes of human exposure towards 5-Chloro-2-(4-chlorophenoxy)-phenol originating in the use as ingredient for liquid dishwashing detergent concentrates (PT 4) are listed in the table below.

Table 2.2.2.3-3: Main paths of human exposure to DCPP via use for PT 4

Exposure path	Primary (direct) exposure, during use of b.p.		Secondary (indirect) exposure Incidental contact after application	Via the environment
	Professional use	General public	General Public	General Public
Inhalation	Not relevant	Not relevant	Not relevant	Not relevant[1]
Dermal	Yes	Yes	Not relevant	Not relevant[1]
Oral	Not relevant	Not relevant	Yes	Not relevant[1]

[1] From TNsG on Human Exposure, 2007: "Exposure via the environment is an element of secondary exposure. It includes bystanders and consumers, including children, who are inadvertently exposed to biocides by inhalation of plumes drifting off-site and ingesting contaminated food. These scenarios are not considered relevant in this case.

DCPP is an antimicrobial active ingredient for use in liquid dishwashing detergent concentrates and intended for manual dishwashing by professional and non-professional users. Exposure via the inhalation route is considered to be not relevant as no aerosols are formed during the expected activities and DCPP reveals a low volatility (only low concentrations of gaseous releases possible: vapour pressure: 1.2×10^{-6} Pa at 25°C). Oral exposure to DCPP is considered to be unlikely for users (adults), if no misuse is expected and the tasks are performed carefully. Therefore, dermal contact with the active substance is considered to be the only relevant source of exposure during application (manual dishwashing).

Secondary exposure via the inhalation route is considered to be low and not relevant due to the low volatility of DCPP (see 4.1.3.1). Secondary exposure via the dermal route is expected to be not relevant, as intense dermal contact with the washed dishes/surfaces is not assumed to be likely. Furthermore, the concentration of dried residues on these surfaces is also considered to be low, therefore contact with large areas would be necessary to result in relevant levels. Touching wet surfaces is expected to be covered by the primary exposure scenarios describing manual dishwashing. Secondary oral exposure is assumed to be more relevant than dermal exposure, although the expected uptake is also considered to be low for the same reasons as for dermal exposure. Possible scenarios are dissolvation and release of residues (e.g. on plates, drinking vessels) to food or direct uptake of residues (e.g. on cutlerly), which are dislodged by saliva and ingested.

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

2.2.2.4. Risk characterisation

Risk for systemic effects – PT1

DCPP-containing antimicrobial soap is intended for use by professional health care personnel. These soaps are designed as rinse-off products. The suds are left on the skin for a short period of time and then rinsed off with water. Due to the intended use, dermal exposure is expected. Oral and inhalation exposure can be neglected. Secondary exposure and exposure via the environment are expected to be low in comparison to the exposure levels of users. Based on the expected exposure pattern (e.g. persons caring for sick members of their family), exposure levels of non-professionals are considered to be lower or at least not higher than those of professionals. Risk from hand and forearm disinfection before surgical work is estimated assuming 7 g soap to 2000 cm^2 skin for 5 minutes, 10 applications per day. However the 44% dermal absorption value used in the estimation is derived from a 24 hours continuous exposure experiment and total exposure time is estimated as 10 times 5 minutes, i.e. 50 minutes per day. Therefore the tier one estimate using 44% dermal absorption was considered as sufficient. It is also considered that this estimate covers potential risk from just hand disinfection of health care personnel, i.e. 3g to 860 cm^2 for less than 5 minutes.

The resulting MOE and exposure/AEL-ratio are listed in Table 1.3.1-1 and appear clearly acceptable.

Table 1.3.1-1: Professional Use: health care personnel, antibacterial soap – Primary Exposure PT1

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 1	7g soap to 2000cm^2 skin, 5 minutes, then rinsed off with water; 10 applications per day, 44% dermal absorption	n.r.	0.103	n.r.	**0.103**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) / 0.14	100	**135**	**0,74**

At the TM IV 2013 the concern was raised that the dermal exposure estimate provided above may not adequately cover the dermal penetration of DCPP with repeated applications that may amount to 10 times 7g soap (7µg/cm^2 DCPP) per day: If the dermal absorption is calculated in terms of percent and furthermore residues in and on the skin after washing were taken into consideration – the absorption value in terms of 44% derived from the experimental condition of continuous application of a single dose of 30 µg/cm^2 DCPP over 24 hours may not be the worst case.

Therefore in addition to the calculation above also a reversed exposure estimate was calculated considering flux. This estimation supports an acceptable risk for 21 applications for pre-surgical hand and forearm disinfection per day. For details see doc IIB, chapter 4.1.3.1

Risk for local effects – PT1

No detailed risk assessment for local effects is presented here, since the representative product is a dummy product. The formulation of the dummy product is classified for skin and eye irritation, not due to the DCPP content (0.2%), but due to the dummy co-formulants. The major exposure route is dermal, but additional eye exposure may result from splashes to the eye and hand to eye transfer. Respiratory exposure is not considered as relevant. The intended application by professionals is very frequent (daily, 8 times per day) and intensively on bare skin (liquid soap, washing of hands). Consequently this dummy formulation would represent an unacceptable risk. New product formulations may overcome this risk.

Risk for systemic effects – professionals PT2:

Disinfectant cleaner: all-purpose cleaner product is intended for the cleaning of surfaces in hospitals and private areas. Exposure via the inhalation route is considered to be not relevant as no aerosols are formed during the expected activities and DCPP reveals a low volatility. Oral exposure to DCPP is considered to be unlikely for users (adults), when misuse is not considered. Therefore dermal contact is considered to be the only relevant source of exposure during application.

Secondary exposure is possible for infants via dermal and oral routes, i.e. hand-to-mouth contact with treated surfaces.Dermal and oral exposures of pets (e.g. cats and dogs) are assumed to reveal a comparable pattern and situation in comparison to the secondary exposure scenario derived for infants (low body weight, direct oral uptake from floor and transfer from skin to mouth). Therefore, exposure of pets is also assumed to be low and in the same order of magnitude.

The Tier 2 exposure estimate for professionals considers the use of PPE. The resulting MOEs and exposure/AEL-ratios are listed in Table 2.2.2.4-2.

As secondary exposure is expected to be minimal regarding the derived calculations, aggregate exposure is not considered.

Table 2.2.2.4-2: Use of surface disinfection products by professionals – primary exposure PT2

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 2* with gloves	mixing & loading and cleaning of surfaces; professional cleaning personnel (large areas) and professional health care personnel (small areas); 44% dermal absorption	n.r.	0.052	n.r.	**0.052**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) 0.14	100	**269**	**0.37**

*Tier 1 corresponds to tier 1 non-professionals without gloves, see below

Risk for local effects – professionals PT2:

No detailed risk assessment for local effects is presented here, since the representative product is a dummy product. The formulation of the dummy product is classified for skin and eye irritation (not due to the DCPP content (0.2%), but due to the dummy co-formulants), and applying the general classification limits for mixtures (≥ 10 %) the 1:10 in use dilution (reasonable worst case) would be considered as borderline to skin and eye irritating. The major exposure route is dermal, but additional eye exposure may result from splashes to the eye and hand to eye transfer. Respiratory exposure is not considered as relevant.

The mixing and loading of the representative product for preparing the in use dilutions may be considered as daily for professionals, but it is likely below 1 hour per day and the proper use of gloves may be assumed. Therefore the respective risk is considered as acceptable.

The intended application of the in use dilution is frequent (daily washing of surfaces) and intensively (potential exposure to in use dilution under gloves for 6 hours). As for all wet-work specific operators training and skin-health surveillance is necessary. Careful evaluation of the final product and in use solution is necessary at product authorisation stage to decide on the acceptability of risk for local effects.

Risk for systemic effects – non-professionals PT2:

The Tier 1 exposure estimate for non-professionals considers no gloves and no protective clothing. The assumption that exposure to the bare skin (no protective clothing) is considered and the frequency of use, i.e. 1 use per day, render this scenario rather conservative. Also the long term AEL is very conservative, since a low oral absorption of

11% was assumed to calculate the internal AEL. The resulting MOEs and exposure/AEL-ratios for primary exposure are listed in Table 2.2.2.4-3.The MOE value and exposure/AEL-ratio for secondary exposure of infants are listed in Table 2.2.2.4-4. As secondary exposure is expected to be minimal regarding the derived calculations, aggregate exposure is not considered.

Table 2.2.2.4-3: Use of surface disinfection products by non-professionals – primary exposure PT2

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 1	mixing & loading, 44% dermal absorption	n.r.	0.00015	n.r.	**0.00015**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) / 0.14	100	**93333**	**0.001**
Tier 1	Cleaning of surfaces, 44% dermal absorption	n.r.	0.028	n.r.	**0.028**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) / 0.14	100	**500**	**0.2**

Table 2.2.2.4-4: Secondary exposure as a result of DCPP use in surface cleaning products (PT2)

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 1	Intense contact with treated surfaces and potential oral and dermal exposure of infants; it is assumed that the total amount on skin is taken up, either by dermal or oral route.	$4.8*10^{-4}$	n.r.	n.r.	**$4.8*10^{-4}$**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) / 0.14	100	**29167**	**0.003**

It is concluded that the risk for systemic effects from the application of DCPP-containing surface cleaning products by professionals and non-professionals is acceptable. Secondary exposure of infants is minimal.

Risk for local effects – non-professionals, primary and secondary exposure PT2:
No detailed risk assessment for local effects is presented here, since the representative product is a dummy product. The dummy product would need classification for skin and eye irritation, (not due to the DCPP content (0.2%), but due to the dummy co-formulants). On the basis of the CLP classification limits the 1:10 in use dilution (reasonable worst case) would be considered as borderline to skin and eye irritating. However use by non-professionals may be considered as less frequent compared to use by professionals. Careful evaluation of the final product and in use solution is necessary at product authorisation stage to decide on the acceptability of risk for local effects taking into consideration also background risk from wet work and standard detergent use.

In conclusion it is possible that the use of DCPP as surface disinfectant by professionals and the general public results in an acceptable risk. Careful evaluation of the final product is required for this conclusion.

Risk for systemic effects – PT4
The PT4: disinfectant cleaner: dishwashing liquid is intended for manual dishwashing by professionals and non-professionals. Non-professional exposure considers mixing and loading, dishwashing as well as misuse of the product as hand soap. Exposure via the inhalation route is considered to be not relevant as no aerosols are formed during the expected activities and DCPP reveals a low volatility. Oral exposure to DCPP is considered to be unlikely for users (adults), when misuse is not considered. Therefore dermal contact is considered to be the only relevant source of exposure during application.

Automated dishwashing is assumed to be predominant in the restaurant business. Manual dishwashing might be applied only occasionally. In the absence of specific data it is assumed that the scenario for non-professionals also covers the exposure of professionals.

Secondary dermal and oral exposure is possible via small amounts of dried residues on the surface of washed dishes.

The resulting MOEs and exposure/AEL-ratios are listed in Table 2.2.2.4-5 and Table 2.2.2.4-6 for primary and secondary exposure, respectively.

Though the calculated MOE and exposure/AEL ratios for secondary exposure refer to adults, the high MOE indicate that also the risk from secondary exposure to infants is acceptable.

Oral exposures of pets (e.g. cats and dogs) are possible, if bowls intended for pets (food, water) are washed with DCPP-containing dishwashing detergents. This situation is considered to be comparable to the secondary exposure scenario determining potential oral uptake of humans. As low exposure levels were identified in the latter case, exposure and risk of pets is also assumed to be very low.

As secondary exposure is expected to be very low, aggregate exposure is not considered in the current assessment for PT4.

Overall it can be concluded that the risks resulting from the use and misuse of DCPP containing dishwashing liquid are acceptable.

Table 2.2.2.4-5: Use of dishwashing products by non-professionals and professionals – primary exposure PT4

Exposure Scenario:		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
Application of the biocidal product		Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 1	Mixing & Loading and Dishwashing: 44% dermal absorption	n.r.	0.037	n.r.	0.037	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) 0.14	100	**378**	**0.26**
Tier 1	Misuse as liquid soap: 10% dermal absorption	n.r.	0.0098	n.r.	0.0098	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) 0.14	100	**1429**	**0.07**

Table 2.2.2.4-6: Secondary exposure to small amounts of dried residues on the surface of washed dishes as a result of DCPP use in dishwashing products (PT4)

Exposure Scenario:	Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL ---------- AEL long term [mg/kg b.w/day]	AF MOE ref	MOE	Exposure / AEL
dermal and oral exposure to small amounts of dried residues on the surface of washed dishes	Estim. oral uptake	Estim. dermal uptake	Estim. Inhal. uptake	Estim. total uptake (combined exposure)				
Tier 1*, oral absorption 70%	$9.8*10^{-7}$	n.r.	n.r.	**$9.8*10^{-7}$**	NOAEL: 20 $NOAEL_{corr}$: 14 (70% absorption) 0.14	100	**14 285 714**	**$7*10^{-6}$**

*AEL corrected for oral absorption (70%) is compared with oral uptake estimate also considering 70% oral absorption.

Indirect exposure via the dermal route is expected to be not relevant, as the concentration of residues on surfaces, which were in contact with treatment solution (reasonable worst case: 0.02% DCPP) is considered to be low. However a reverse estimate indicates that (depending on the oral and dermal absorption rates) more than

0.95m^2 contaminated surface (e.g. washed dishes ect.) would be necessary to achieve doses near to the AEL $_{long\ term}$ of 0.14 mg/kg bw day.

Risk for local effects – PT4
No detailed risk assessment for local effects is presented here, since the representative product is a dummy product. The formulation of the dummy product is classified for skin and eye irritation (not due to the DCPP content (0.2%), but due to the dummy co-formulants), but the 1:10 in use dilution (reasonable worst case) would be considered as borderline to skin and eye irritating. The major primary exposure route is dermal, but additional eye exposure may result from splashes to the eye and hand to eye transfer. Respiratory exposure is not considered as relevant. The use scenarios, use frequencies and exposure intensity may be considered comparable or less compared to the PT2 application. Careful evaluation of the final product and in use solution is necessary at product authorisation stage to decide on the acceptability of risk for local effects taking into consideration also background risk from wet work and standard detergent use.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Biodegradation:

Ready biodegradability:
DCPP is classified as "not readily biodegradable": (40-50% biodegradation after 28 d in a manometric respirometry test (OECD guideline 301F) performed at a concentration of 100 µg a.s./L). After 61 days DCPP was degraded by 52±9%. The recovery of ^{14}C at test end was between 60% and 70% of Total Applied Radioactivity. No metabolites were identified.

A manometric respirometry test (OECD guideline 301F) and a test according to "Japan Chemical Substance Control Law (1974)" (comparable to the modified MITI test, OECD guideline 301C) were conducted at a concentration of 100 mg/L showing no biodegradation.

Another manometric respirometry test (OECD guideline 301F) performed at a concentration of 100 µg a.s./L indicated complete primary degradation by observation of the decline of the test item by gas-chromatography. As no O_2 was measured the test was not able to show ultimate biodegradation. 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%.

A modified Sturm test (OECD guideline 301B) was performed at two different initial concentrations (10 or 20 mg a.s./L) over a period of 28 days with the structurally related compound triclosan resulting in 18-37% biodegradation after 28 days. No biodegradation was shown in a modified MITI test (OECD guideline 301C) performed at 100 mg triclosan/L over a period of 28 days.

Based on the results of a study on ready biodegradability (OECD guideline 301F) with the metabolite methyl-DCPP, the pass levels for ready biodegradability given by the OECD guidelines were not met. 48% elimination of methyl-DCPP was obtained after 28 days.

Inherent biodegradability:

DCPP is inherently primary biodegradable, as elimination > 99% of DCPP was observed. The test design was not able to show ultimate biodegradation of DCPP (lack of DOC-measurement), so the criteria for inherent biodegradability were not passed.

The possible metabolites 2-Chlorophenol and 3-Chlorophenol could not be detected in water or sludge samples. 4-Chlorophenol and Methoxy-benzene (Anisole) could be quantified in low amounts in some samples. 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."

Degradation in STP:

DCPP was extensively biodegraded and 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.

This removal rate is substantiated by data on the behaviour of triclosan, a structural analogue to DCPP using radiolabelled test substance. For triclosan, biodegradation also was found to play the major role in dissipation of the test item in a municipal STP with 98.2 to 99.3% removal in the effluent. 73.9% - 76.7% of the dissipation was due to complete mineralisation. Besides, 14.2% to 17.1% remained unextractable with the solids, 3.2% to 4% were sorbed to solids and 4% to 5.9% of the radioactivity were measured in the effluent as parent or a metabolite.

Besides triclosan, mainly polar breakdown products could be identified in the effluents or sorbed onto solids. However, all breakdown products observed occurred at low amounts: The average concentration (over all concentrations tested) of the metabolite (unidentified), which was found in the highest concentration in the effluent, was 2%: The average concentration value (over all concentrations tested) of the metabolite (unidentified), which was found in the highest concentration in the sludge, was 1.2%.

Also a second test conducted with triclosan revealed extensive removal: Removal of the parent compound exceeded 98.5%. The amount of triclosan sorbed to the activated sludge and leaving the unit with the wasted slugde equalled 1.5-4.5% of the total ^{14}C dosed to the influent. Primary degradation (i.e. converted to metabolites, biodegradation or incorporation into biomass) of triclosan exceeded 94% whereas complete degradation (i.e. biodegradation or incorporation into biomass) exceeded 80% of the dosage in the influent.

Anaerobic degradation in sewage sludge

No test is available with DCPP on anaerobic aquatic degradation. Due to the similarity of triclosan with DCPP a study conducted with triclosan was taken into consideration. As the bridging data with triclosan indicated that triclosan was not biodegraded in sewage sludge under anaerobic conditions, it can be assumed that the structurally similar DCPP will not be biodegraded under anaerobic conditions.

Degradation in a water/sediment system:

No test is available with DCPP on degradation in water/sediment systems. Due to the similarity of triclosan with DCPP a water/sediment study conducted with triclosan was

taken into consideration. A similar fate and behaviour of both substances is to be expected:

A mean degradation half-life (DT50) for triclosan of about one day was calculated for both the river and pond water phases. In the sediment, the parent compound was degraded more slowly with DT_{50} values of 56 days for both aquatic systems. When normalised to 12 °C, this corresponds to 106 days. Dissipation half-lives for the total system were 41 (river) and 58 (pond) days, corresponding to 78 days (river) and 110 days (pond) when normalised to 12 °C (TGD, 2003).

Degradation of ^{14}C-triclosan in both compartments proceeded via formation of numerous minor metabolites, one of which was identified as methyl-triclosan, to formation of high amounts of bound residues (32.4-33%) and significant radioactive carbon dioxide (21-29%). The concentration of methyl-triclosan was rising during the study (highest concentrations of 4.8% and 3.4%), as well as no or only a slight concentration drop was observed for the not identified metabolite M8.

Degradation in soil:

No test is available with DCPP on degradation in soil. Due to the similarity of triclosan with DCPP two aerobic soil degradation studies conducted with triclosan were taken into consideration: The half-lives vary from 4.7- 99.6 days at 12 °C (geometric mean = 19.8 days, n=6) at Tier I level and the half-lives vary from 4.7- 95 days at 12 °C (geometric mean = 19.3 days, n=6) at Tier II level. The two studies give half-lives that differ by a factor of 10. The difference is not attempted explained by the applicant. Since both studies are valid and the difference in half-lives cannot be explained, both studies are considered key studies. Using the geometric mean of **19.3** days the results from both studies will be used for the risk assessment.

The degradation of ^{14}C-triclosan in soil incubated under aerobic conditions proceeds primarily via the formation of methyl-triclosan and significant amounts of bound residues. A noteworthy mineralisation of the radioactive residues is observed (>5%-16% of applied radioactivity at study termination).

Methyl-triclosan, a structural analogue for methyl-DCPP, was confirmed as major breakdown product, accounting for up to 24% of the applied radioactivity. However, its concentration decreased steadily until study termination. Half-lives for methyl-triclosan at 12 °C were calculated to be 74 to 290 days depending on the soil (corresponding to 39 to 153 days at 20°C). Methyl-DCPP potentially fulfils the P and vP criteria.

As Triclosan including its metabolite methyl-Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the results of this substance evaluation according to REACH have to be taken into account.

In any case, at the renewal stage for the re-evaluation of the persistence criterium of the metabolite methyl-DCPP at least a surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test, performed at 12°C) with methyl-DCPP or the read across substance methyl-triclosan or a water sediment study (OECD Test Guideline No. 308: Aerobic and anaerobic transformation test in aquatic sediment systems surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test) with methyl-DCPP needs to be available at the time point of re-evaluation. The applicant needs to consult with the eCA in due time prior the renewal

stage on this issue: The eCA needs to have enough time to potentially consult the PBT expert group on this matter.

Abiotic degradation:

Hydrolysis:

DCPP is hydrolytically stable in sterile aqueous buffer solutions at pH 4, 7 and 9 at 50°C (preliminary test of OECD guideline 111). No (significant) degradation was measured after 5 days in the dark. As less than 10% of the initial amount were degraded, DCPP is considered to be hydrolytically stable and to reveal a hydrolysis half-life of more than one year under environmentally relevant conditions (temperatures below 25°C, pH-levels from 4 to 7).

Photolysis in water:

The UV/VIS absorption spectrum of DCPP between 200 nm and 800 nm reveals that DCPP absorbs light at wavelengths below 400nm. DCPP was photolytically degraded in sterile buffer solutions with a DT_{50} value of 0.27 days according to OECD-guideline 316. Simulated sunlight from a Hanau Suntest apparatus, equipped with a xenon lamp and filters to remove wavelengths below 290 nm, was used for the irradiation of the samples. The blank samples remained stable in the dark (no hydrolysis of DCPP). 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).

Six major photodegradates accounting for more than 10% of the applied radioactivity were formed during the study (M1, M4, M7, M8, M16, and M17). Besides DCPP and the major metabolites, one fraction (M2) was detected which exceeded levels of 5% of applied radiactivity. The detected amounts of all other metabolites detected were lower than 4.4% of applied radioactivity. 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. Referring to the found formation pathways of photolysis metabolites, most relevant reactions are considered to be: dechlorination, condensation and ring opening of DCPP. Therefore, M4 is not expected to be a higher chlorinated DCPP derivative or (higher chlorinated) dioxin.

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.

Photo-oxidation in air:

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} (applied computer model: AopWin v1.92**)**. 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)**.**

Using AOPWin v 1.92, the half-life of methyl DCPP in the troposphere was calculated to be 28.03 hours (1.17 days). 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)**.** Referring to these results, accumulation DCPP and methyl-DCPP in the air are not expected.

Distribution:

Based on the results of a HPLC screening test with the test substance DCPP the Koc 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.

QSAR data on the metabolite methyl-DCCP revealed Koc-estimates of 3718 and 3228 suggesting higher adsorption to soil and less susceptibility for translocation.

Accumulation:

DCPP has a log P_{ow} value of 3.7 and may therefore accumulate in organisms. However, an experimental study with carp (*Cyprinus carpio*) demonstrated a rather low potential for bioaccumulation. 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.

The metabolite methyl-DCPP has a calculated log K_{ow} value of 4.6. An experimental study with *Danio rerio* revealed high Bioconcentration factors: Kinetic BCF values of 23804 and 16738 were obtained, resulting in lipid corrected values of 17505 and 12129. Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517 were obtained. Based on the criteria for PBT/vPvB substances, methyl-DCPP has to be regarded as very bioaccumulative (vB).

2.2.3.2. Effects assessment

Aquatic compartment (fish, daphnids, algae, aquatic plants, micro-organisms, sediment dweller):

Fish DCPP:

DCPP is acutely toxic as indicated by a 96h-LC_{50} of 0.70 mg a.s./L and a NOEC for 96h of 0.34 mg a.s./L based on total mean measured concentrations of the test item from a 96-hour static test with zebra fish (*Danio rerio*). This value is supported by a 96h-LC_{50} for *Danio rerio* = 0.86 mg/L from a non-key study screening pre-test.

No test is available with DCPP on chronic toxicity towards fish. Due to the similarity of triclosan with DCPP (see justification) an early life-stage toxicity study with triclosan was taken into consideration. The obtained NOEC corrected for the molecular weight of DCPP was a measured value of 0.03 mg a.s./L (corresponds to 0.0341 mg triclosan/L) for rainbow trout. This value is based on the effects of triclosan on the most sensitive endpoint (survival) at a corrected test concentration of 0.0628 mg DCPP/L (corrected for molecular weight of DCPP; corresponds to 0.0713 mg triclosan/L) after 96 days of continuous exposure (lack of hatch and growth effects).

Fish metabolite methyl-DCPP:

For the metabolite methyl-DCPP the LC_{50} was > 0.091 mg methyl-DCPP/L (measured, based on geometric mean) from a static test. In another semi-static test with methyl-DCPP an LC_{50} of > 0.48 mg methyl-DCPP/L (measured) was obtained. In a screening with test methyl-DCPP the observed LC_{50} value was > 1.0 mg methyl-DCPP/L (nominal), although sign of toxicity (e.g. calmness) were observed at the highest test concentration of 1 mg/L. A study on the structural analogue methyl-triclosan (see justification) revealed an LC_{50} value of 3.87 mg/L (corrected for the molecular weight of methyl-DCPP).

For methyl-DCPP also no test is available on chronic toxicity towards fish. Due to the similarity of triclosan with methyl-DCPP a test with triclosan was taken into consideration (see justification). Corrected to the molecular weight of methyl-DCPP a NOEC of 0.032 mg methyl-DCPP/L was determined.

Invertebrates DCPP:

DCPP is acutely toxic to *Daphnia magna* with an acute EC_{50} of 0.32 mg a.s./L.

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 in a 21-day reproduction study.

Invertebrates metabolite methyl-DCPP:

For the metabolite methyl-DCPP the EC_{50}- value obtained towards *Daphnia magna* was > 0.046 mg methyl-DCPP/L. In a screening study an EC_{50}-value of > 0.3 mg methyl-DCPP/L was gained. The EC_{50}-value of a study with structural analogue methyl-triclosan was > 0.16 mg methyl-DCPP/L (corrected for the molecular weight of methyl-DCPP).

The NOEC obtained in the chronic toxicity test towards *Daphnia magna* was < 0.0049 mg methyl-DCPP/L based on the reproductive output per parent animal in the start of the test which did not inadvertently or accidently die during test. For methyl-DCPP daphnia are most sensitive species. As no NOEC could have been established, no $PNEC_{water}$ could be derived for methyl-DCPP.

Algae and aquatic plants DCPP:

DCPP is highly toxic to algae as shown by a test with the green alga species *Desmodesmus subspicatus* (former *Scenedesmus subspicatus*). The NOEC obtained for both endpoints biomass and growth rate after 72 h was 0.0093 mg a.s./L as geometric mean based on measured concentrations. The endpoint biomass was the most sensitive with a 72h-EC_{50} of 0.023 mg a.s./L based on nominal concentrations. E_rC_{50} was determined to be 0.038 mg a.s./L.

For DCPP, the alga is thus the most sensitive organism from the acute and chronic aquatic data set.

No test is available with DCPP on toxicity towards aquatic plants. Due to the similarity of triclosan with DCPP a 7day test with *Lemna gibba* with triclosan resulting into an EC_{50} above the highest concentration tested of 0.0625 mg triclosan/L, which corresponds to 0.0551 mg DCPP/L corrected for the molecular weight of DCPP, was taken into consideration. But due to serious deficiencies like the lack of monitoring of test substance concentration the study is rated with a reliability indicator of 3 and will not be used for environmental risk assessment.

Algae and aquatic plants metabolite methyl-DCPP:

The metabolite methyl-DCPP revealed a 72-h NOE_rC of 0.013 mg/L in a GLP-Study conducted with *Desmodesmus subspicatus* and a 72-h NOE_bC of 0.008 mg/L. Both the 72-h E_bC_{50} and the 72-h E_rC_{50} are estimated to be 0.020< 72-h EC_{50} <0.18mg/L. Due to the low recovery values the EC_{50}-values could only be estimated as a range.

A screening study with methyl-DCPP showed no inhibition up to 0.03 mg methyl-DCPP/L. A study performed with the structural analogue methyl-triclosan revealed NOEC and EC_{50} values in the same range: The 72-h NOEC was 0.035 mg/L, the E_rC_{50} was 0.15 mg/L and the E_bC_{50} was 0.11 mg methyl-DCPP/L (values corrected for the molecular weight of methyl-DCPP).

Micro-organisms DCPP:

Based on the inhibition of oxygen consumption by aerobic sewage bacteria the EC_{50} of DCPP is 8 mg a.s./L, indicating that DCPP inhibits the respiration of activated sludge in the aquatic environment.

Micro-organisms metabolite methyl-DCPP:

Concerning the inhibition of oxygen consumption by aerobic sewage bacteria the NOEC of methyl-DCPP is 0.322 mg methyl-DCPP/L based on the water solubility of 0.322 mg methyl-DCPP/L and based on no observed effects in a limit test at 56.8 mg methyl-DCPP/L.

Sediment dwelling organisms DCPP:

No test with sediment organisms is available for DCPP. Due to the similarity of triclosan with DCPP a test with triclosan was taken into consideration (see justification). Due to the absence of toxicity of triclosan at the highest concentration tested towards sediment dwellers (midge in its larval stage), the nominal 28d-NOEC for *Chironomus riparius* was determined to be > 88.1 mg DCPP/kg dry sediment (corrected for the molecular weight of DCPP, corresponds to 100 mg triclosan/kg dry sediment). The results are based on the emergence ratio and the development rate of midges.

For methyl-DCPP also no test with sediment organisms is available. Due to the similarity of triclosan with methyl-DCPP a test with triclosan was taken into consideration (see justification). Corrected to the molecular weight of methyl-DCPP a **NOEC of > 92.9 mg methyl-DCPP/kg dry sediment** was determined for the toxicity towards the sediment dwelling organism *Chironomus riparius.*

Air compartment:

The vapour pressure of DCPP was measured to be 1.2 x 10^{-6} Pa at 25°C. Henry's Law Constant was estimated to be 6.82 x 10^{-4} Pa x m^3/mol (25°C) based on the Bond method and 2.53 x 10^{-3} Pa x m^3/mol (25°C) based on the Group method (Doc. III-A 3.2). Because of these low values, low volatilisation and thus no significant amounts of gaseous DCPP are expected to be in air.

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} (applied computer model: AopWin v1.92**)**. 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)**.** Referring to these results, an accumulation of DCPP in the air is not expected.

Terrestrial compartment:

Earthworms DCPP:

The 14d-LC_{50} of DCPP towards *Eisenia fetida* based on mortality effects was determined to be 693 mg a.s./kg dw soil. Taking into account the high organic matter of the artificial soil (10%) the LC_{50} converted to standard soil is 236 mg a.s./kg soil dry weight. The NOEC (14d) based on earthworm weight mg a.s./kg soil dry weight was determined to be 171 mg a.s./kg dw soil, which corresponds to the converted to standard soil NOEC of 58.1 mg a.s./kg soil dry weight.

Earthworms metabolite methyl-DCPP:

For the metabolite methyl-DCPP also no test is available regarding toxicity towards earthworms. Due to the similarity of triclosan with methyl-DCPP a chronic test with triclosan was taken into consideration (see justification). Corrected to standard soil organic matter content, and the molecular weight of methyl-DCPP a NOEC of > 28.5 mg methyl-DCPP/kg dry soil was determined for the chronic toxicity towards earthworms.

Micro-organisms DCPP:

No tests are available with DCPP on the toxicity towards terrestrial microorganisms. Due to the similarity of triclosan with DCPP the tests with triclosan were taken into consideration. No adverse effects to the soil carbon and nitrogen cycle could be determined at the highest test concentration of 1.8 mg DCPP/kg dry soil (corrected for the molecular weight of DCPP, corresponds to 2 mg triclosan/kg dry sediment).

Converting this value to standard soil a value of 3.4 mg DCPP/kg soil dry weight is obtained.

Micro-organisms metabolite methyl-DCPP:

For the metabolite methyl-DCPP no tests are available on the toxicity towards terrestrial micro-organisms. Due to the similarity of triclosan with methyl-DCPP tests with triclosan were taken into consideration (see justification). Corrected to standard soil organic matter content, and the molecular weight of methyl-DCPP a NOEC of > 3.6 mg methyl-DCPP/kg dry soil was determined for the toxicity towards terrestrial micro-organisms.

Plants DCPP:

No test is available with DCPP on the toxicity towards terrestrial plants. Due to the similarity of triclosan with DCPP three available toxicity tests with triclosan were taken into consideration.

The test examining vegetative vigour and performed in quartz sand with six different species, reported the lowest NOECs, and it was shown that cucumbers (post-emergent) were the most sensitive species to triclosan. According to OECD TG 208 quartz sand is an acceptable test substrate for non-agricultural chemicals. A NOEC for shoot length of 1.219 mg DCPP/kg dw soil, based on time-weighted average, and corrected for the molecular weight of DCPP as well as to standard soil organic matter content) was obtained.

The two other studies assessed seedling emergence and growth: One study included only one plant species which is not sufficient to cover this endpoint in the sense of the BPD. The third_study was carried out according to OECD no 208 and tested six species including cucumber, but resulted in higher NOEC values.

Plants metabolite methyl-DCPP:

For the metabolite methyl-DCPP also no test is available regarding toxicity towards terrestrial plants. Due to the similarity of triclosan with methyl-DCPP tests with triclosan were taken into consideration (see justification). Corrected to standard soil organic matter content, and the molecular weight of methyl-DCPP a NOEC (cucumber, shoot length, TWA) of 1.29 mg methyl-DCPP/kg dw soil was obtained.

Predatory mite:

No test with an predatory mite is available for DCPP. Due to the similarity of triclosan with DCPP the tests with triclosan were taken into consideration.

A 14-d NOEC of 1.15 mg DCPP/kg soil dry weight (mean measured, corrected to standard soil organic matter content and molecular weight of DCPP, corresponding to a

derived NOEC for triclosan of 1.3 mg triclosan/kg dw soil) in a reproduction study of the soil predatory mite *Hypoaspis aculeifer* according to OECD 226 was gained.

Predatory mite metabolite methyl-DCPP:

For methyl-DCPP in a reproduction study of the soil predatory mite *Hypoaspis aculeifer* (OECD 226), the 14-d NOEC and EC_{50} for reproduction, corrected for standard soil, were 3.4 and 64.5 (53.1-78.3) mg methyl-DCPP/kg dry soil, respectively (95% CI in parentheses). The 14-d NOEC and 14-d LC_{50} for mortality were determined to be 1000 and >1000 mg methyl-DCPP/kg dry soil, respectively, which corresponds to 680 and >680 mg/kg dry soil, respectively, based on standard soil.

Birds DCPP:

No test regarding avian toxicity is available for DCPP. Due to the similarity of triclosan with DCPP the tests with triclosan were taken into consideration. Low acute toxicity to birds was observed: No mortalities or other signs of toxicity occurred in the mallard acute oral study (highest dose tested: 1894 mg DCPP/kg bw, corrected for molecular weight of DCPP, corresponds to 2150 mg triclosan/kg bw). In the acute oral bobwhite quail study a LD_{50} of 759.3 mg DCPP/kg bw (corrected for the molecular weight of DCPP, corresponds to 862 mg triclosan/kg bw) was obtained. As slightly clinical effects (small amounts of diarrhea) were observed at the lowest concentration tested, a NOEL could not be established in the test.

In a bobwhite quail short-term dietary tests a NOEC of 1101 mg DCPP/kg feed (corrected for molecular weight of DCPP, corresponds to 1250 mg triclosan/kg feed) was obtained based on mortality. The LC_{50} in this test was determined to be > 4404 mg DCPP/kg feed (corrected for molecular weight of DCPP, corresponds to > 5000 mg triclosan/kg feed.

Birds metabolite methyl-DCPP:

Also for the metabolite methyl-DCPP no dietary toxicity test is available. Due to the similarity of triclosan with methyl-DCPP the test with bobwhite quail triclosan with was taken into consideration (see justification). Corrected for the molecular weight of methyl-DCPP this results into an LC_{50} of > 4646 mg methyl-DCPP/kg bw.

2.2.3.3. PBT/vBvP assessment

Persistence:

Ready biodegradability:

DCPP is not readily biodegradable (40-50% biodegradation after 28 d).

Inherent biodegrdabality:

DCPP does not pass the criteria for inherent biodegradability also substance specific analysis revealed high elimination rates (> 99% after 14 days according to the water samples). The amount of adsorption cannot be quantified.

Water/sediment:

In a water/sediment degradation study with the structurally related triclosan DT_{50} values (first order) for the entire system were 41.1 (river) and 58.3 (pond) days at 20°C. Triclosan dissipates very fast from the water phase with a DT_{50} value dissipation of 1.2 (river) and 1.4 (pond) days. High amounts of bound residues were found in the sediment (32.4% in river, 33% in pond).

DT_{50} values of 56 were obtained in the sediment. Conversion to standard European conditions (12°C) resulted in a DT_{50} value of 106 days. Conversion to standard European conditions (12°C) regarding the higher value for the entire pond system resulted in a DT_{50} value of 110 days.

P-criterion: $T_{1/2}$ >120 days in fresh sediment – DT_{50} =110 days (12°C) => not P

Soil:

In two aerobic degradation studies in soil with the structurally related triclosan DT50 values between 2.46 and 35.2 days were obtained. Conversion to standard European conditions (12°C) resulted in a highest DT_{50} value of 95 days. High amounts of bound residues were found: 60.8-75.8% after 124 days (20 ± 2 °C); 59.6% after 124 days (10 ± 2 °C); 37.7-59.7% after 64 days.

P-criterion: $T_{1/2}$ >120 days in soil – DT_{50} =95 days (12°C) => not P

At the moment the persistence assessment is inconclusive and considered not to meet the P/vP-criteria. Yet, as Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the conclusions of this substance evaluation according to REACH are required to confirm the persistence status.

Bioaccumulation:

DCPP has a log Pow value of 3.7 and may therefore accumulate in organisms. Nevertheless, an experimental study with carp (*Cyprinus carpio*) demonstrated mean Bioconcentration Factors (BCF) of 67.4 and 76.7. 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.

B-criterion: BCF < 2000 => not B

DCPP does not meet the B-criterion.

Toxicity:

The toxicological studies for genotoxicity, (sub)chronic toxicity, carcinogenicity and reproductive toxicity did not lead to a classification for CMR or STOT RE. Data on reproductive toxicity result in some inconclusive indications for effects.

The substance is not listed in Annex 13 (List of 146 substances with endocrine disruption categorizations prepared in the Expert meeting) and 15 (List of 66 Category 1 substances with categorisation high, medium or low exposure concern) of the Endocrine disrupter website of the European Commission:

However read across from triclosan is supported for several endpoints and the investigation of the potential endocrine disruptive effects of triclosan is on-going under the REACH Regulation.

Fish: NOEC 0.03 mg DCCP/L (corresponds to 0.0341 mg triclosan/L)

Daphnia: NOEC: 0.094 mg a.s./L.

Algae: NOErC: 0.0093 mg a.s./L.

T-criterion: NOEC < 0.01 mg/L => T

Because of the high toxicity of DCPP to algae, the T-criterion is met.

Conclusion:

According to the available data DCPP is toxic, but not bio-accumulative.

At the moment the persistence assessment is inconclusive and considered not to meet the P/vP-criteria. Yet, as Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the conclusions of this substance evaluation according to REACH are required to confirm the persistence status.

As DCPP is not bio-accumulative, DCPP is neither a vPvB, nor a PBT substance.

Metabolite methyl-DCPP

Persistence:

Water/sediment:

Based on the results of a study on ready biodegradability (OECD guideline 301F) with the metabolite methyl-DCPP, the pass levels for ready biodegradability given by the OECD guidelines were not met. 48% elimination of Methyl-DCPP was obtained after 28 days.

In studies on inherent biodegradability and in an STP study the occurrence of methyl-DCPP in water and sludge samples was confirmed. In two studies on ready biodegradability the metabolite methyl-DCPP was not detected.

A study regarding degradation in a water/sediment system with the structurally related triclosan revealed that the metabolite methyl-Triclosan (structural analogue to methyl-DCPP) was below detection limit in the water phase. Up to 4.8% (river) and 3.4 % (pond) were found in the sediment extracts increasing until study end. High amounts of bound residues were found (32.4% in river, 33% in pond). No DT_{50}-values for methyl-Triclosan were obtained.

Soil:

In an aerobic degradation study in soil with the structurally related triclosan DT_{50} values for methyl-triclosan, a structural analogue to methyl-DCPP was confirmed as a major breakdown product, accounting for up to 24% of the applied radioactivity. DT_{50} values ranged from 39.2 to 153 days for three soils performed at 20°C. Conversion to standard European conditions (12°C) resulted in DT_{50} values of 74 to 290 days (geometric mean: 157.8 days).

Nevertheless, DT_{50} values for methyl-triclosan were gained in a simulation study with triclosan and not in a simualtion test with methyl-triclosan.

High amounts of bound residues were found: 60.8-75.8% after 124 days (20 ± 2 °C); 59.6% after 124 days (10 ± 2 °C); 37.7-59.7% after 64 days.

P-criterion: $T_{1/2}$ >120 days in soil: DT_{50} =290 days (12°C) => potentially P

vP-criterion: $T_{1/2}$ >180 days in soil: DT_{50} = 290 days (12°C) => potentially vP

As Triclosan including its metabolite methyl-Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the results of this substance evaluation according to REACH have to be taken into account. In any case, at the renewal stage for the re-evaluation of the persistence criterium of the metabolite methyl-DCPP at least a surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation

Biodegradation Test, performed at 12°C) with methyl-DCPP or the read across substance methyl-triclosan or a water sediment study (OECD Test Guideline No. 308: Aerobic and anaerobic transformation test in aquatic sediment systems surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test) with methyl-DCPP needs to be available at the time point of re-evaluation. The applicant needs to consult with the eCA in due time prior the renewal stage on this issue: The eCA needs to have enough time to potentially consult the PBT expert group on this matter.

Bioaccumulation:

The use of SRC EPIWIN 4.00 (BCFBAF Program (v3.01)) resulted in a BCF value of 488.

Nevertheless, an experimental study with *Danio rerio* revealed high Bioconcentration factors: Kinetic BCF values of 23804 and 16738 were obtained, resulting in lipid corrected values of 17505 and 12129. Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517 were obtained.

B-criterion: BCF > 2000 => B

B-criterion: BCF > 5000 => vB

Methyl-DCPP does meet the B and vB-criterion.

Toxicity:

Chronic toxicity data for methyl-DCPP are available for daphnia and algae.

The NOEC value for algae is 0.013 mg/L. The NOEC for daphnia is < 0.0049 mg/L.

T-criterion: NOEC < 0.01 mg/L => T

Because of the high toxicity of methyl-DCPP to daphnia, the T-criterion is met.

Conclusion:

As methyl-DCPP revealed high BCF-values it has to be considered to meet the B and vB criterion.

Due to its high toxicity revealed in a chronic daphnia test methyl-DCPP has to be considered to meet the T-criterion.

Methyl-DCPP potentially fulfils the P/vP-criteria. Two out of three PBT criteria are definitely met.

As Triclosan including its metabolite methyl-Triclosan is currently assessed under substance evaluation according to REACH with the special concerns of endocrine disrupting properties and PBT/vPvB properties and many data are from read across studies to Triclosan, the results of this substance evaluation according to REACH have to be taken into account. In any case, at the renewal stage for the re-evaluation of the persistence criterium of the metabolite methyl-DCPP at least a surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test, performed at 12°C) with methyl-DCPP or the read across substance methyl-triclosan or a water sediment study (OECD Test Guideline No. 308: Aerobic and anaerobic transformation test in aquatic sediment systems surface water simulation test (OECD Test Guideline No. 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test) with methyl-DCPP needs to be available at the time point of re-evaluation. The applicant needs to consult with the eCA in due time prior the renewal

stage on this issue: The eCA needs to have enough time to potentially consult the PBT expert group on this matter.

2.2.3.4. Exposure assessment

The biocidal product DCPP is an antimicrobial active ingredient for use in liquid soap formulations for hand disinfection used by professional and private users (PT 1), for professional and private surface disinfection (PT 2) and as dishwashing liquid (PT 4).

The environmental exposure assessment has been performed in accordance with the available Emissions Scenario Documents relevant for each Product Type as well as the Technical Guidance Document (TGD II, European Commission 2003)[5] and the EUSES Background report (EC 2004)[6] and is based on information relating to the intended use (Chapter 3 of Doc II B).

The exposure assessment has been performed for the substance DCPP and its metabolite methyl-DCPP.

In the ESD for PT 1, PT 2 and PT 4 it is generally assumed that disinfection cleaners used indoors will generally not reach directly the environmental compartments, only the sewage treatment plant will be the direct receiving compartment for DCPP emissions. DCPP is dispensed onto hands and forearms and after a short contact time the product is rinsed off with tap water (PT 1), it is used for disinfection of surfaces by mopping or manual wiping with a soaked cloth (PT 2) and for manual and automated dishwashing (PT 4). All these uses lead to emissions to the sewer system.

Subsequent to the use of the biocidal product secondary poisoning may occur. Therefore, the concentration of contaminated food (e.g. earthworms or fish) via ingestion by birds and/or mammals is calculated according to the TGD II (EC 2003). The exposure values relevant for risk characterization are presented in the following chapter.

2.2.3.5. Risk characterisation

PT 1: Disinfectant cleaner (liquid hand soap)

DCPP-containing antimicrobial soaps are intended for use by professional health care personnel only. These soaps are used as rinse-off products. The suds are left on skin for a short time and then rinsed off with water. DCPP is used in liquid disinfectant antimicrobial hand soaps which contain max. 0.2% DCPP w/w.

The environmental risk assessment is performed for the active substance DCPP and its metabolite methyl-DCPP.

[5] EC (2003)Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II.

6 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

Aquatic Compartment (incl. Sediment)

STP micro-organisms

The sewage treatment plant will be the direct receiving compartment for DCPP due to its use as "rinse off" product (soaps).

The PEC_{STP} was calculated according to Simple Treat (Tier 1) and 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2). According to the applicant´s information the calculations were performed for professional use only. (see Doc. II-B).

The PNEC for aquatic micro-organisms for DCPP was determined with 0.08 mg/L and for the metabolite methyl-DCPP it was determined with 0.0322 mg/L (see Doc. II-A).

The PEC/PNEC ratio for STP is calculated by dividing the PEC_{STP} by the $PNEC_{aquatic\ micro-organisms}$ (see table 2.1.1.1-1).

Risk characterisation for DCPP

Table 2.2.3.5-1: PEC/PNEC ratios for STP micro-organisms for DCPP

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro-organisms}$= 0.08 mg a.s./L	
Professional use only (10 uses/d)		
Tier 1 (Simple Treat assuming 0% degradation in STP)	0.0238	0.2975
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	1.68E-03	2.10E-02

Conclusion

The PEC/PNEC ratios are below 1 indicating that the intended use of DCPP in PT 1 products containing 0.2% DCPP pose an acceptable risk to STP micro-organisms.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-2: PEC/PNEC ratios for STP micro-organisms for methyl-DCPP

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro-organisms}$= 0.0322 mg a.s./L	
Professional use only (10 uses/d)		
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	1.68E-03	5.22E-02
Tier 2 (2% of $C_{inf,DCPP}$ =Ceffl,methyl-DCPP, 1.2% of Csludge,DCPP=Csludge,methyl-	5.60E-04	1.74E-02

DCPP)		
Tier 3 (0.5% of $C_{inf,DCPP}$ =Ceffl,methyl-DCPP, 1% of Csludge,DCPP=Csludge,methyl-DCPP)	1.40E-04	4.35E-03

Conclusion

The PEC/PNEC ratios are below 1 indicating that the metabolite methyl-DCPP in PT 1 poses no unacceptable risk to STP micro-organisms.

Aquatic organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to surface water. However the aquatic environment can be affected via effluents of waste water treatment procedures. The PEC/PNEC ratios for the aquatic ecosystem have been calculated taking into account the PEC_{SW} for the emission episode.

The PEC_{SW} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2). The calculations were performed for professional use only (see Doc. II-B). The PNEC for aquatic organisms for DCPP is $9.3x10^{-4}$ mg a.s./L (see Doc. II-A).

Risk characterisation for DCPP

Table 2.1.1.1-3: PEC/PNEC ratios for aquatic organisms for DCPP

Exposure type	**$PEC_{surface\ water}$ (mg a.s./L)**	**$PEC/PNEC_{SW}$**
	$PNEC_{aquatic\ organisms}$= $9.3x10^{-4}$ mg a.s./L	
	Professional use only (10 uses/d)	
Tier 1 (Simple Treat assuming 0% degradation in STP)	2.38E-03	2.56
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	1.68E-04	0.181

PEC/PNEC ratios calculated for the emission episode is above the trigger of 1 in Tier 1 calculations concerning the parent substance DCPP, though Tier 2 calculations show a RCR well below 1.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning the aquatic organisms were performed.

Sediment dwelling organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to sediment. However the aquatic environment can be affected via effluents of waste water treatment procedures.

The PNEC for sediment dwelling organisms for DCPP is > 0.881 mg a.s./kg dry sediment (see Doc A-II).

The PEC_{SED} was calculated according to Simple Treat (0% degradation in the STP: Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2). The calculations were performed for professional use only (see Doc. II-B).

Risk characterisation for DCPP

Table 2.1.1.1-4: PEC/PNEC ratios for benthic organisms for DCPP

Exposure type	$PEC_{sediment}$ (mg a.s./kg_{dwt})	$PEC/PNEC_{sed}$
	$PNEC_{sed}$ = 0.881 mg a.s./kg_{dwt}	
	Professional use only (10 uses/d)	
Tier 1 (Simple Treat assuming 0% degradation in STP)	0.348	0.395
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	2.54E-02	0.029

The PEC/PNEC ratios are below 1. Thus the intended use of DCPP in the PT 1 products containing 0.2% DCPP will not pose a risk to sediment dwelling organisms.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning the benthic organisms were performed.

Persistence in sediment

In the sediment of a laboratory water/sediment system triclosan, a structural analogue to DCPP, showed a DT_{50} dissipation of 56 days at 20°C, which is below the threshold value of a DT_{50} >6 months at 20°C.

Non-extractable residues between 32.4 and 33% TAR were formed in the water/sediment system after 104 days, which is below the threshold value >70% of the initial dose after 100 days.

The mineralization rate was between 21.4 and 29.1% TAR after 104 days, which is above the value of < 5% in 100 days.

The consequences or effects on non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion

DCPP is not persistent in sediment and does therefore not fulfil the Annex I exclusion criteria.

Atmosphere

Only a qualitative environmental risk characterisation can be done for the air compartment due to the lack of specific effect data.

The vapour pressure of DCPP is $1.2x10^{-06}$ Pa at 25°C. Henry's Law Constant was estimated based on QSAR and determined to be low ($6.82x10^{-04}$ Pa*m3*mol-1(Bond method); $2.53*10^{-03}$ Pa*m3*mol-1 (Group method)). Because of these very low values, no volatilisation and thus no significant amounts of DCPP are expected to be in air

referring also to the intended use and expected exposure levels. The photochemical oxidative degradation of DCPP was calculated using the computer simulation software AopWin v1.92. An overall OH rate constant of $19.5x10^{-12}$ cm3/molecule-sec was determined, resulting in an estimated half-life in air of 19.7 hours ($5x10^5$ OH/cm3) at 25°C. According to these results, an accumulation of DCPP in the air and a contamination by wet or dry deposition is not expected to be relevant and to represent a risk.

Terrestrial compartment

Terrestrial organisms

Due to the indoor use of DCPP, no (relevant) direct emissions to the environment via the pathway soil occurs. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs for the soil compartment were calculated according to TGD (2003) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP (see Doc. II-B): The PEC_{Soil} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2). The calculations were performed for professional use only (see Doc. II-B).

The PNEC for soil organisms for DCPP is 0.102 mg a.s./kg_{wwt} and for methyl-DCPP it is 0.114 mg a.s./kg_{wwt} (see Doc. II-A, chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil is calculated by dividing the PEC_{soil} by the $PNEC_{soil}$ (see table 2.1.3.1-1).

Risk characterisation for DCPP

Table 2.1.1.1-5: PEC/PNEC ratios for terrestrial organisms for DCPP

Exposure scenario	**PEC_{soil} (mg a.s./kg wet soil)**	**$PEC/PNEC_{soil}$**
	$PNEC_{terrestrial\ organisms}$= 0.102 mg a.s./kg wet soil	
	Professional use only (10 uses/d)	
Arable land, 30 days **Tier 1** (Simple Treat, no degradation in STP and soil)	0.026	0.255
Arable land, 30 days **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	0.0128	0.125

Conclusion

All PEC/PNEC ratios in Tier 1 and Tier 2 calculations are <1. Hence, the ratios indicate that the intended use of DCPP in PT 1 products containing 0.2% DCPP pose an acceptable risk to soil organisms.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-6: PEC/PNEC ratios for terrestrial organisms for methyl-DCPP

	Exposure scenario	**PEC_{soil} (mg a.s./kg wet soil)**	**$PEC/PNEC_{soil}$**
		$PNEC_{terrestrial\ organisms}$= 0.114 mg a.s./kg wet soil	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	Arable land, 30 days Tier 1	0.024	0.211
Tier 2 (2% of $C_{inf,DCPP}$ =Ceffl,methyl-DCPP, 1.2% of Csludge,DCPP=Csludge,methyl-DCPP)	Arable land, 30 days Tier 2	4.51E-03	0.040
Tier 3 (0.5% of $C_{inf,DCPP}$ =Ceffl,methyl-DCPP, 1% of Csludge,DCPP=Csludge,methyl-DCPP)	Arable land, 30 days Tier 3	4.27E-03	0.037

Conclusion

All PEC/PNEC ratios in Tier 1, Tier 2 and Tier 3 calculations are <1. Hence, the ratios indicate that the metabolite methyl-DCPP in PT 1 pose no unacceptable risk to soil organisms.

Persistence in soil

In two laboratory aerobic degradation study the persistence of triclosan, a structural analogue to DCPP, in was assessed: In a study performed at 23-27.5°C a DT50 of 17.4, 29.1 and 35.2 were obtained. In another study at 20°C DT50 values between 2.46 and 3.28 days were shown. All these values are below the threshold value of a DT50 >6 months at 20°C.

Non-extractable residues (NER) were formed between 37.7-59.7% after 64 days (at 23-27.5°C), 60.8-75.8% after 124 days (at 20°C) and 59.6% after 124 days (at 10°C). The mineralization rate was between 11.9-20.1% after 64 days (study performed at 23-27.5°C), between 11.5-16.2% TAR after 124 days (study performed at 20°C) and 5.1% at 10°C. The mineralisation rates for the studies performed at 23-27.5°C and 20°C are above the value of < 5% in 100 days. For the test performed at 10°C a mineralization rate of < 5% in 100 days has to be assumed.

For all the soil tested both of the criteria (NER >70% of the initial dose after 100 days + < 5% in 100 days) both criteria were not fulfilled at the same time.

No field simulations tests are available.

The consequences or effects on soil non-target organisms have been assessed in the risk assessment above and are acceptable.

Conclusion

Taking into account the data on triclosan DCPP can be assumed to be not persistent in soil and does therefore not fulfil the Annex I exclusion criteria.

Groundwater

Due to the indoor use of DCPP, no (relevant) direct emissions of the environment via the pathways soil and ground water occur. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The concentration in pore water of an agricultural soil averaged over 180 days is taken as an indication for potential groundwater concentrations. This is a worst case assumption, neglecting transformation, adsorption and dilution in deeper soil layers. The $PEC_{groundwater}$ values are 0.868 µg a.s./L (Tier 1) and 0.127 µg a.s./L (Tier 2), assuming 10 applications per day.

The values in Tier 1 and Tier 2 assuming 10 applications per day are above the limit value of 0.1 µg/L of the Groundwater Directive (Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration). In Tier 1 calculations a DT50soil of 300 days is assumed and again, no biodegradation, transformation and dilution in deeper soil layers are taken into account by EUSES groundwater calculations. The more realistic Tier 2 approach takes the measured DT50soil of DCPP of 19.3 days (standardised to 12°C) into consideration and shows a concentration of 0.127 $\mu g.L^{-1}$. According to the ESD for PT 87, substances with a Koc > 500 L.kg-1 and a DT50soil < 21 days may not leach to ground water. For DCPP both criteria are applicable (Koc = 1427.25 $L.kg^{-1}$, DT50soil = 19.3 d) and therefore no refined groundwater calculations using FOCUS Pearl were performed.8

The intended use of DCPP in PT 1 products containing 0.2% DCPP pose no unacceptable risk to groundwater.

Risk characterisation for the metabolite methyl-DCPP

The potential groundwater concentrations of 0.266 $\mu g.L^{-1}$ (Tier 1) overstep the threshold value of 0.1 $\mu g.L^{-1}$ of the Groundwater Directive (Directive 2006/118/EC). Tier 2 and Tier 3 calculations result in a groundwater concentration of 0.016 $\mu g.L^{-1}$ and 0.013 $\mu g.L^{-1}$, respectively. Therefore, no unacceptable risk to groundwater is expected. These values are well below the threshold of 0.1 $\mu g.L^{-1}$ of the EU Directive.

Non Compartment Specific Effects Relevant To The Food Chain (Secondary Poisoning)

The logKow of 3.7, which is greater than or equal to 3 indicates that the active substance DCPP may bioaccumulate. The same applies to the metabolite methyl-DCPP: the logKow is in this case 4.58. Therefore, methyl-DCPP may bioaccumulate as well. Moreover, DCPP is adsorptive and similar to triclosan, a substance with known potential to accumulate. On the other hand, the low available bioconcentration factors of 99.1 and 112.8

7 Emission Scenario Document for Wood Preservatives, Part 1, OECD Series on Emission Scenario Documents, Number 2

8 Please note, that at BPC WGII 2014 a further cut-off-criteria was agreed: the standard cut-off criteria (DT50 <21 d at 20°C and Koc >500 L/kg) could be used for biocide application rates up to 100 kg a.s./ha per year. If biocide uses result in high soil loadings >100 kg a.s./ha per year, it is proposed that a formal FOCUS groundwater assessment may need to be performed. In the case of DCPP, the application rates are far away from this new cut-off-criteria of 100 kg/ha per year.

(corrected for a whole body lipid content of 5%) indicate that there is no risk of secondary poisoning to top predators. The bioconcentration factor for fish of methyl-DCPP is 17505, which suggests that secondary poisoning is a topic for methyl-DCPP.

Risk to fish-eating predators

The risk to the fish-eating predators is calculated as the ratio between the concentration in their food (fish) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$). The concentration of DCPP in fish has been calculated from the PEC for surface water, the measured bioconcentration factor for fish and the biomagnification factor (see Doc II-B).

The PNEC values for oral intake by birds and by mammals have been discussed in Doc II-A (see $PNEC_{oral}$).

Risk characterisation for DCPP

Table 2.1.1.1-7: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for DCPP

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.47 mg a.s./kg diet	
	Professional use only (10 uses/d)	
Mammals feeding on fish **Tier 1** (Simple Treat assuming 0% degradation in STP)	0.134	9.12E-02
Mammals feeding on fish **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	9.48E-03	6.45E-03

Conclusion

The PEC/PNEC ratios for secondary poisoning of fish-eating predators concerning the parent compound DCPP are well below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-8: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for methyl-DCPP

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.55 mg a.s./kg diet	
	Professional use only (10 uses/d)	
Mammals feeding on fish **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP} = C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP} = C_{sludge,\ methyl\text{-}DCPP}$)	14.60	9.42

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
Mammals feeding on fish **Tier 2** (2% of $C_{inf,DCPP}$ $=C_{effl,methyl-DCPP}$, 1.2% of $C_{sludge,DCPP}=C_{sludge,methyl-DCPP}$)	4.88	3.15
Mammals feeding on fish **Tier 3** (0.5% of $C_{inf,DCPP}$ $=C_{effl,methyl-DCPP}$, 1% of $C_{sludge,DCPP}=C_{sludge,methyl-DCPP}$)	1.22	0.79

Conclusion

The PEC/PNEC ratio regarding Tier 3 calculations for secondary poisoning of fish-eating predators concerning the metabolite methyl-DCPP is well below 1 and thus no unacceptable risk is expected.

Risk to worm-eating predators

The risk to the earthworm-eating predators is calculated as the ratio between the concentration in their food (earthworm) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$, see Doc. II-A). The concentration of DCPP in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm (see Doc. II-B).

Risk characterisation for DCPP

Table 2.1.1.1-9: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for DCPP

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.47 mg a.s./kg diet	
	Professional use only (10 uses/d)	
Mammals feeding on earthworm **Tier 1** (Simple Treat assuming 0% degradation in STP)	0.296	0.201
Mammals feeding on earthworm **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	0.0434	2.95E-02

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the parent compound DCPP are below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-10: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for methyl-DCPP

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.55 mg a.s./kg diet	
	Professional use only (10 uses/d)	
Mammals feeding on earthworm **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	0.0556	0.036
Mammals feeding on earthworm **Tier 2** (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	3.33E-03	2.15E-03
Mammals feeding on earthworm **Tier 3** (0.5% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	2.77E-03	1.79E-03

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the metabolite methyl-DCPP are below 1 and thus acceptable.

PT2: Disinfectant cleaner (all purpose cleaner)
DCPP is used as surface disinfectant, which is intended for the cleaning of surfaces in hospitals and private areas by professional and non-professional users. Regarding the intended use, it is indicated, that the biocidal product is diluted typically 1:50 with water to give the final cleaning solution (0.004% w/w as in final in use concentration). The final cleaning solution as intended has only bacteriostatic efficacy. A dilution of 1:10 with water corresponding to 0.02% w/w a.s. is assumed as reasonable worst case in the human exposure section. In order to ensure a consistency among the human exposure assessment and the environmental exposure assessment calculations the same dilution is also applied for the environmental risk assessment.

The environmental risk assessment is performed for the active substance DCPP and its metabolite methyl-DCPP.

Aquatic Compartment (incl. Sediment)

STP micro-organisms
The sewage treatment plant will be the direct receiving compartment for DCPP. The PEC_{STP} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d, Tier 2, see Doc. II-B).

The PNEC for aquatic micro-organisms for DCPP was determined with 0.08 mg/L and for the metabolite methyl-DCPP it was determined with 0.0322 mg/L (see Doc. II-A).

Risk characterisation for DCPP

Table 2.1.1.1-11: PEC/PNEC ratios for STP micro-organisms for DCPP

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.08 mg a.s./L	
	Professional + private use (general purpose + lavatory)	
Tier 1 (Simple Treat assuming 0% degradation in STP)	9.14E-03	0.114
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	6.45E-04	8.06E-03

Conclusion

The PEC/PNEC ratios are below 1 indicating that the intended use of DCPP in PT 2 products containing 0.2% DCPP pose an acceptable risk to STP micro-organisms.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-12: PEC/PNEC ratios for STP micro-organisms for methyl-DCPP

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.0322 mg a.s./L	
	Professional + private use (general purpose + lavatory)	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	6.45E-04	2.00E-02
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{inf,DCPP}$ =$C_{sludge,methyl\text{-}DCPP}$)	2.15E-04	6.68E-03
Tier 3 (0.5% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1% of $C_{inf,DCPP}$ =$C_{sludge,methyl\text{-}DCPP}$)	5.38E-05	1.67E-03

Conclusion

The PEC/PNEC ratios are below 1 indicating that the metabolite methyl-DCPP in PT 2 poses no unacceptable risk to STP micro-organisms.

Aquatic organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to surface water. However the aquatic environment can be affected via effluents of waste water treatment procedures.

The PEC/PNEC ratios for the aquatic ecosystem have been calculated taking into account the PEC_{SW} for the emission episode and the annual average (see Doc. II-B) and using the PNEC for aquatic organisms of $9.3x10^{-4}$ mg a.s./L (see Doc. II-A).

The PEC_{SW} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2).

Risk characterisation for DCPP

Table 2.1.1.1-13: PEC/PNEC ratios for aquatic organisms for DCPP

Exposure type	$PEC_{surface\ water}$ (mg a.s./L)	$PEC/PNEC_{SW}$
	$PNEC_{aquatic\ organisms}$= $9.3x10^{-4}$ mg a.s./L	
	Professional + private use (general purpose + lavatory)	
Tier 1 (Simple Treat assuming 0% degradation in STP)	9.12E-04	0.981
Tier 2 (Refinement assuming 74% degradation, 20% directed	6.44E-05	6.92E-02

Exposure type	$PEC_{surface\ water}$ (mg a.s./L)	$PEC/PNEC_{SW}$
to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)		

Conclusion

PEC/PNEC ratios calculated for emission period for the combined risk assessment of professional and private use are below the trigger of 1 for Tier 1 as well as for Tier 2 indicating no risk for these combined uses. Therefore, the intended use of DCPP in PT 2 products containing 0.2% DCPP pose an acceptable risk to aquatic organisms.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning the aquatic organisms were performed.

Sediment dwelling organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to sediment. However the aquatic environment can be affected via effluents of waste water treatment procedures.

The PNEC for sediment dwelling organisms for DCPP is > 0.881 mg a.s./kg dry sediment (see Doc A-II). The PEC_{SED} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2, see Doc B-II).

Risk characterisation for DCPP

Table 2.1.1.1-14: PEC/PNEC ratios for benthic organisms for DCPP

Exposure type	$PEC_{sediment}$ (mg a.s./kg_{dwt})	$PEC/PNEC_{sed}$
	$PNEC_{sed}$ = 0.881 mg a.s./kg_{dwt}	
	Professional + private use (general purpose + lavatory)	
Tier 1 (Simple Treat assuming 0% degradation in STP)	0.1334	0.151
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	9.29E-03	1.05E-02

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations are below 1. Thus the intended use of DCPP in the PT 2 products containing 0.2% DCPP will not pose a risk to sediment dwelling organisms.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning benthic organisms were performed.

Persistence in sediment
Please refer to PT1 chapter 2.2.3.5. for the assessment of persistence in sediment.

Atmosphere
Please refer to PT1 chapter 2.2.3.5. for the assessment of the atmosphere.

Terrestrial compartment

Terrestrial organisms

Due to the indoor use of DCPP, no (relevant) direct emissions of the environment via the pathway soil occurs. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs for the soil compartment were calculated according to TGD (2003) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP (see Doc. II-B): The PEC_{Soil} was calculated according to Simple Treat (Tier 1) and 74% degradation, 6% directed to water and 20% directed to sludge in the STP and a $DT50_{soil}$ of 19.3 d (Tier 2).

The PNEC for soil organisms for DCPP is 0.102 mg a.s./kg_{wwt} and for methyl-DCPP it is 0.114 mg a.s./kg_{wwt} (see Doc. II-A, chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil is calculated by dividing the PEC_{soil} by the $PNEC_{soil}$ (see table 2.3.1-1).

Risk characterisation for DCPP

Table 2.1.1.1-15: PEC/PNEC ratios for terrestrial organisms for DCPP

Exposure scenario	PEC_{soil} (mg a.s./kg wwt)	$PEC/PNEC_{soil}$
	$PNEC_{terrestrial\ organisms}$= 0.102 mg a.s./kg wet soil	
	Professional + private use (general purpose + lavatory)	
Arable land, 30 days **Tier 1** (Simple Treat, no degradation in STP and soil)	9.99E-03	9.82E-02
Arable land, 30 days **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	4.90E-03	4.81E-02

Conclusion

All PEC/PNEC ratios assuming the combined risk assessment of professional and private use in Tier 1 and Tier 2 calculations are well below 1, indicating that for combined approach DCPP in the PT 2 products containing 0.2% DCPP will not pose a risk to soil organisms.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-16: PEC/PNEC ratios for terrestrial organisms for methyl-DCPP

	Exposure scenario	**PEC_{soil} (mg a.s./kg wet soil)**	**$PEC/PNEC_{soil}$**
		$PNEC_{terrestrial\ organisms}$= 0.114 mg a.s./kg wet soil	
		Professional + private use(general purpose + lavatory)	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ Methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ Methyl\text{-}DCPP}$)	Arable land, 30 days	9.20E-03	0.081
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{inf,,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	Arable land, 30 days	1.73E-03	0.015
Tier 3 (0.5% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1% of $C_{inf,DCPP}$ =$C_{sludge,methyl\text{-}DCPP}$)	Arable land, 30 days	1.64E-03	0.014

Conclusion

All PEC/PNEC ratios assuming the combined use of professionals and non-professionals in Tier 1, Tier 2 and Tier 3 calculations are well below 1, indicating that for professional and private use methyl-DCPP will not pose a risk to soil organisms.

Persistence in soil

Please refer to PT1 chapter 2.2.3.5. for the assessment of persistence in soil.

Groundwater

Due to the indoor use of DCPP, no (relevant) direct emissions of the environment via the pathways soil and ground water occur. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The concentration in pore water of an agricultural soil averaged over 180 days is taken as an indication for potential groundwater concentrations. This is a worst case assumption, neglecting transformation, adsorption and dilution in deeper soil layers. The $PEC_{Groundwater}$ values are 0.33 µg a.s./L in Tier 1 and 0.049 µg a.s./L in Tier 2 for combined professional and private use.

The concentration in groundwater in Tier 1 calculation for combined professional and private use is above the limit value of 0.1 µg/L of the Groundwater Directive (Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration). In Tier 1 calculations a DT50soil of 300 days is assumed and again, no

biodegradation, transformation and dilution in deeper soil layers are taken into account by EUSES groundwater calculations. The more realistic Tier 2 approach takes the measured DT50soil of DCPP of 19.3 days (standardised to 12°C) into consideration. According to the ESD for PT 89, substances with a Koc > 500 L.kg-1 and a DT50soil < 21 days may not leach to ground water. For DCPP both criteria are applicable (Koc = 1427.25 $L.kg^{-1}$, DT50soil = 19.3 d) and therefore no refined groundwater calculations using FOCUS Pearl were performed.

In Tier 2 the values are below 0.1 µg/L indicating that the intended use of DCPP in PT 2 products containing 0.2% DCPP pose no unacceptable risk to groundwater.

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Risk characterisation for the metabolite methyl-DCPP

The groundwater concentration value in Tier 1 is 0.102 µg/L and therefore slightly above the threshold of 0.1 µg/L of the EU-Groundwater Directive. Tier 2 and Tier 3 calculations are well below of the limit value of 0.1 µg/L (6.13E-03 µg/L and 5.12E-03 µg/L) of the Groundwater Directive (Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration) indicating that methyl-DCPP pose no unacceptable risk to groundwater.

Non Compartment Specific Effects Relevant To The Food Chain (Secondary Poisoning)

The log Kow of 3.7, which is greater than or equal to 3 indicates that the substance may bioaccumulate. Moreover DCPP is adsorptive and similar to triclosan, a substance with known potential to accumulate. On the other hand, the low available bioconcentration factors of 99.1 and 112.8 (corrected for a whole body lipid content of 5%) indicate that there is no risk of secondary poisoning to top predators.

Risk to fish-eating predators

The risk to the fish-eating predators is calculated as the ratio between the concentration in their food (fish) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$). The concentration of DCPP in fish has been calculated from the PEC for surface water, the measured bioconcentration factor for fish and the biomagnification factor (see Doc II-B). The PNEC values for oral intake by birds and by mammals have been discussed in Doc II-A (see $PNEC_{oral}$).

Risk characterisation for DCPP

Table 2.1.1.1-17: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for DCPP

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.47 mg a.s./kg diet	
	Professional + private use (general purpose + lavatory)	
Mammals feeding on fish **Tier 1** (Simple Treat assuming 0% degradation in STP)	5.14E-02	3.50E-02
Mammals feeding on fish **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	3.63E-03	2.47E-03

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations for secondary poisoning of earthworm-eating predators concerning the parent compound DCPP are below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-18: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for methyl-DCPP

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.55 mg a.s./kg diet	
	Professional + private use (general purpose + lavatory)	
Mammals feeding on fish **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP} = C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP} = C_{sludge,\ methyl\text{-}DCPP}$)	5.05	3.26
Mammals feeding on fish **Tier 2** (2% of $C_{inf,DCPP} = C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{inf,,DCPP} = C_{sludge,methyl\text{-}DCPP}$)	1.87	1.21
Mammals feeding on fish **Tier 3** (0.5% of $C_{inf,DCPP} = C_{effl,methyl\text{-}DCPP}$, 1% of $C_{inf,DCPP} = C_{sludge,methyl\text{-}DCPP}$)	4.69E-01	3.03E-01

Conclusion

The PEC/PNEC ratio in Tier 1 and Tier 2 calculations for secondary poisoning of fish-eating predators concerning the metabolite methyl-DCPP are > 1. The PEC/PNEC ratio in Tier 3 calculations indicates an acceptable risk for secondary poisoning of fish-eating predators.

The risk to the earthworm-eating predators is calculated as the ratio between the concentration in their food (earthworm) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$, see Doc. II-A). The concentration of DCPP in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm (see Doc. II-B).

Risk characterisation for DCPP

Table 2.1.1.1-19: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for DCPP

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.47 mg a.s./kg diet	
	Professional + private use (general purpose + lavatory)	
Mammals feeding on earthworms **Tier 1** (Simple Treat assuming	0.1137	7.73E-02

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
0% degradation in STP)		
Mammals feeding on earthworms **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	1.67E-02	1.14E-02

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the parent compound DCPP are below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Table 2.1.1.1-20: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for methyl-DCPP

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.55 mg a.s./kg diet	
	Professional + private use (general purpose + lavatory)	
Mammals feeding on earthworms **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	2.13E-02	1.37E-02
Mammals feeding on earthworms **Tier 2** (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	1.28E-03	8.26E-04
Mammals feeding on earthworms **Tier 3** (0.5% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1% of $C_{inf,DCPP}$ =$C_{sludge,methyl\text{-}DCPP}$)	1.07E-03	6.90E-04

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the metabolite methyl- DCPP are below 1 and thus acceptable.

PT4: DISINFECTANT CLEANER (DISHWASHING LIQUID)

DCPP is an antimicrobial active ingredient for use in liquid dishwashing detergent concentrates. The exemplary product for which the exposure and risk characterisation is presented in this dossier contains 0.2% DCPP w/w. Regarding the intended use, it is indicated, that the biocidal product is diluted typically 1:500 with water to give the final cleaning solution (0.0004% w/w as in final in use concentration). The final cleaning solution as intended has only bacteriostatic efficacy. A dilution of 1:10 with water corresponding to 0.02% w/w a.s. is assumed as reasonable worst case in the human exposure section. In order to ensure a consistency among the human exposure assessment and the environmental exposure assessment calculations the same dilution is also applied for the environmental risk assessment.

The environmental risk assessment is performed for the active substance DCPP and its metabolite methyl-DCPP.

Aquatic Compartment (incl. Sediment)

STP micro-organisms

The sewage treatment plant will be the direct receiving compartment for DCPP.

The PEC_{STP} was calculated according to Simple Treat (Tier 1) and assuming 48% removal (35% degradation + 13% fractioned to sludge) in STP, $DT50_{soil}$=19.3 d, $DT50_{surface\ water}$=2.7 d and a $DT50_{sediment}$=106 d (Tier 2, see Doc. II-B).

The PNEC for aquatic micro-organisms was determined with 0.08 mg/L (see Doc. II-A), chapter 4.2.1 Aquatic compartment).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-13: PEC/PNEC ratios for STP micro-organisms for DCPP based on consumption approach

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.08 mg a.s./L	
Tier 1 (Simple Treat assuming 0% degradation in STP)	6.80E-03	8.50E-02
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	4.80E-04	6.00E-03

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations are below 1 indicating that, concerning the consumption approach, the intended use of DCPP in PT 4 products containing 0.2% DCPP pose an acceptable risk to STP micro-organisms.

Calculations based on tonnage approach

Table 2.2.3.5-14: PEC/PNEC ratios for STP micro-organisms for DCPP based on tonnage approach

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.08 mg a.s./L	
Tier 1 (Simple Treat assuming 0% degradation in STP)	6.62E-03	0.083
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	4.68E-04	0.006

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations are below 1 indicating that, concerning the tonnage approach, the intended use of DCPP in PT 4 products containing 0.2% DCPP pose an acceptable risk to STP micro-organisms.

Risk characterisation for the metabolite methyl-DCPP

Calculations based on consumption approach

Table 2.2.3.5-15: PEC/PNEC ratios for STP micro-organisms for methyl-DCPP based on consumption approach

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.0322 mg a.s./L	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	4.80E-04	1.49E-02
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	1.60E-04	4.97E-03

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations are below 1 indicating that, concerning the consumption approach, the metabolite methyl-DCPP poses an acceptable risk to STP micro-organisms.

Calculations based on tonnage approach

Table 2.2.3.5-16: PEC/PNEC ratios for STP micro-organisms for methyl-DCPP based on tonnage approach

Exposure scenario	PEC_{STP} (mg a.s./L)	$PEC/PNEC_{STP}$
	$PNEC_{STP\ micro\text{-}organisms}$= 0.0322 mg a.s./L	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	4.68E-04	0.015
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	1.56E-04	0.005

Conclusion

The PEC/PNEC ratios in Tier 1 and Tier 2 calculations are below 1 indicating that, concerning the tonnage approach, the metabolite methyl-DCPP poses an acceptable risk to STP micro-organisms.

Aquatic organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to surface water. However the aquatic environment can be affected via effluents of waste water treatment procedures.

The PEC/PNEC ratios for the aquatic ecosystem have been calculated taking into account the PEC_{SW} for the emission episode and the annual average (see Doc. II-B): The PEC_{STP} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP in STP and a $DT50_{soil}$ of 19.3 d (Tier 2).

The PNEC for aquatic organisms for DCPP is $9.3x10^{-4}$ mg a.s./L (see Doc. II-A).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-17: PEC/PNEC ratios for aquatic organisms for DCPP based on consumption approach

Exposure type	$PEC_{surface\ water}$ (mg a.s./L)	$PEC/PNEC_{SW}$
	$PNEC_{aquatic\ organisms}$= $9.3x10^{-4}$ mg a.s./L	
Tier 1 (Simple Treat assuming 0% degradation in STP)	6.79E-04	0.730
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	4.79E-05	0.052

Conclusion

All PEC/PNEC ratios are < 1 indicating that, concerning the consumption approach, the intended use of DCPP in the PT 4 products containing 0.2% DCPP will not pose a risk to aquatic organisms.

Calculations based on tonnage approach

Table 2.2.3.5-18: PEC/PNEC ratios for aquatic organisms for DCPP based on tonnage approach

Exposure type	$PEC_{surface\ water}$ (mg a.s./L)	$PEC/PNEC_{SW}$
	$PNEC_{aquatic\ organisms}$= 9.3x10^{-4} mg a.s./L	
Tier 1 (Simple Treat assuming 0% degradation in STP)	6.61E-04	0.711
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	4.67E-05	0.050

Conclusion

All PEC/PNEC ratios are < 1 indicating that, concerning the tonnage approach, the intended use of DCPP in the PT 4 products containing 0.2% DCPP will not pose a risk to aquatic organisms.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning the aquatic organisms were performed.

Sediment dwelling organisms

Due to the indoor use of DCPP, there are no direct emissions of DCPP to sediment. However the aquatic environment can be affected via effluents of waste water treatment procedures.

The PNEC for sediment dwelling organisms for DCPP is > 0.881 mg a.s./kg dry sediment (see Doc A-II).

The PEC_{SED} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP in STP and a $DT50_{soil}$ of 19.3 d (Tier 2, see Doc II-B).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-19: PEC/PNEC ratios for benthic organisms for DCPP based on consumption approach

Exposure type	$PEC_{sediment}$ (mg a.s./kg_{dwt})	$PEC/PNEC_{sed}$
	$PNEC_{sed}$ = 0.881 mg a.s./kg_{dwt}	
Tier 1 (Simple Treat assuming 0% degradation in STP)	0.0994	0.113
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	6.99E-03	7.93E-03

Conclusion

All PEC/PNEC ratios are < 1 indicating that, concerning the consumption approach, the intended use of DCPP in the PT 4 products containing 0.2% DCPP will not pose a risk to sediment dwelling organisms.

Calculations based on tonnage approach

Table 2.2.3.5-20: PEC/PNEC ratios for benthic organisms for DCPP based on tonnage approach

Exposure type	$PEC_{sediment}$ (mg a.s./kg_{dwt})	$PEC/PNEC_{sed}$
	$PNEC_{sed}$ = 0.881 mg a.s./kg_{dwt}	
Tier 1 (Simple Treat assuming 0% degradation in STP)	0.097	0.110
Tier 2 (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	6.81E-03	7.73E-03

Conclusion

The PEC/PNEC ratios are below 1. Thus the intended use of DCPP, concerning the tonnage approach, in the PT 4 products containing 0.2% DCPP will not pose a risk to sediment dwelling organisms.

Risk characterisation for the metabolite methyl-DCPP

No risk assessment and therefore no risk characterization for methyl-DCPP concerning the benthic organisms were performed.

Persistence in sediment

Please refer to PT1 chapter 2.2.3.5. for the assessment of persistence in sediment.

Atmosphere

Please refer to PT1 chapter 2.2.3.5. for the assessment of the atmosphere.

Terrestrial compartment

Terrestrial organisms

Due to the indoor use of DCPP, no (relevant) direct emissions to the environment via the pathway soil occurs. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The PECs for the soil compartment were calculated according to TGD (2003) for arable soil and grassland as the average concentrations over certain time-periods in agricultural soil fertilized with sludge from a STP (see Doc. II-B): The PEC_{Soil} was calculated according to Simple Treat (Tier 1) and assuming 74% degradation, 6% directed to water and 20% directed to sludge in the STP in STP and a $DT50_{soil}$ of 19.3 d (Tier 2).

The PNEC for soil organisms for DCPP is 0.102 mg a.s./kg_{wwt} and for methyl-DCPP it is 0.114 mg a.s./kg_{wwt} (see Doc. II-A, chapter 4.2.3 Terrestrial compartment).

The PEC/PNEC ratio for soil is calculated by dividing the PEC_{soil} by the $PNEC_{soil}$ (see table 2.3.3.1-1).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-21: PEC/PNEC ratios for terrestrial organisms for DCPP based on consumption approach

Exposure scenario	PEC_{soil} (mg a.s./kg wet soil)	$PEC/PNEC_{soil}$
	$PNEC_{terrestrial\ organisms}$= 0.102 mg a.s./kg wet soil	
Arable land, 30 days **Tier 1** (Simple Treat, no degradation in STP and soil)	2.73E-03	2.68E-02
Arable land, 30 days **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	3.64E-03	3.57E-02

Conclusion

All PEC/PNEC ratios are <1. Hence, the ratios indicate that the intended use of DCPP, concerning the consumption approach, in PT 4 products containing 0.2% DCPP pose an acceptable risk to soil organisms.

Calculations based on tonnage approach

Table 2.2.3.5-22: PEC/PNEC ratios for terrestrial organisms for DCPP based on tonnage approach

Exposure scenario	PEC_{soil} (mg a.s./kg wet soil)	$PEC/PNEC_{soil}$
	$PNEC_{terrestrial\ organisms}$= 0.102 mg a.s./kg wet soil	
Arable land, 30 days **Tier 1** (Simple Treat, no degradation in STP and soil)	7.26E-03	7.12E-02
Arable land, 30 days **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	3.55E-03	3.48E-02

Conclusion

All PEC/PNEC ratios are < 1. Hence, the ratios indicate that the intended use of DCPP, concerning the tonnage approach, in PT 4 products containing 0.2% DCPP pose an acceptable risk to soil organisms.

Risk characterisation for the metabolite methyl-DCPP

Calculations based on consumption approach

Table 2.2.3.5-22: PEC/PNEC ratios for terrestrial organisms for methyl-DCPP based on consumption approach

	Exposure scenario	**PEC_{soil} (mg a.s./kg wet soil)**	**$PEC/PNEC_{soil}$**
		$PNEC_{terrestrial\ organisms}$= 0.114 mg a.s./kg wet soil	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	Arable land, 30 days	6.85E-03	0.060
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	Arable land, 30 days	1.28E-03	0.011

Conclusion

All PEC/PNEC ratios are <1. Hence, the ratios indicate that the metabolite methyl-DCPP in PT 4, concerning the consumption approach, pose an acceptable risk to soil organisms.

Calculations based on tonnage approach

Table 2.2.3.5-23: PEC/PNEC ratios for terrestrial organisms for methyl-DCPP based on tonnage approach

	Exposure scenario	**PEC_{soil} (mg a.s./kg wet soil)**	**$PEC/PNEC_{soil}$**
		$PNEC_{terrestrial\ organisms}$= 0.108 mg a.s./kg wet soil	
Tier 1 (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	Arable land, 30 days	6.68E-03	6.19E-02
Tier 2 (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	Arable land, 30 days	1.25E-03	1.16E-02

Conclusion

All PEC/PNEC ratios are <1. Hence, the ratios indicate that the metabolite methyl-DCPP in PT 4, concerning the tonnage approach, pose an acceptable risk to soil organisms.

Persistence in soil

Please refer to PT1 chapter 2.2.3.5. for the assessment of persistence in soil.

Groundwater

Risk characterisation for DCPP

Calculations based on consumption approach

Due to the indoor use of DCPP, no (relevant) direct emissions of the environment via the pathways soil and ground water occur. However, indirect exposure of agricultural soils through fertilization with sludge from a STP is considered relevant.

The concentration in pore water of an agricultural soil averaged over 180 days is taken as an indication for potential groundwater concentrations. This is a worst case assumption, neglecting transformation, adsorption and dilution in deeper soil layers. The potential groundwater concentration, calculated on the basis of the consumption approach, of 2.73 $\mu g.L^{-1}$ following Tier 1 calculations overstep the threshold value of 0.1 $\mu g.L^{-1}$ of the Groundwater Directive (Directive 2006/118/EC). In Tier 1 calculations a DT50soil of 300 days is assumed and again, no biodegradation, transformation and dilution in deeper soil layers are taken into account by EUSES groundwater calculations. The more realistic Tier 2 approach takes the measured DT50soil of DCPP of 19.3 days (standardised to 12°C) into consideration. According to the ESD for PT 810, substances with a Koc > 500 L.kg-1 and a DT50soil < 21 days may not leach to ground water. For DCPP both criteria are applicable (Koc = 1427.25 $L.kg^{-1}$, DT50soil = 19.3 d) and therefore no refined ground water calculations using FOCUS Pearl were performed.11

The Tier 2 calculations the potential groundwater concentration is 0.036 $\mu g.L^{-}1$ and therefore well below of the limit value of 0.1 µg/L of the Groundwater Directive (Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration) indicating that the intended use of DCPP in PT 4 products containing 0.2% DCPP pose no unacceptable risk to groundwater.

Calculations based on tonnage approach

The potential groundwater concentrations, calculated on the basis of the tonnage approach, of 0.242 $\mu g.L^{-1}$ following Tier 1 calculations overstep the threshold value of 0.1 $\mu g.L^{-1}$ of the Groundwater Directive (Directive 2006/118/EC). In Tier 1 calculations a DT50soil of 300 days is assumed and again, no biodegradation, transformation and dilution in deeper soil layers are taken into account by EUSES groundwater calculations. The more realistic Tier 2 approach takes the measured DT50soil of DCPP of 19.3 days (standardised to 12°C) into consideration and shows a concentration of 0.035 $\mu g.L^{-1}$. This

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11 Please note, that at BPC WGII 2014 a further cut-off-criteria was agreed: the standard cut-off criteria (DT50 <21 d at 20°C and Koc >500 L/kg) could be used for biocide application rates up to 100 kg a.s./ha per year. If biocide uses result in high soil loadings >100 kg a.s./ha per year, it is proposed that a formal FOCUS groundwater assessment may need to be performed. In the case of DCPP, the application rates are far away from this new cut-off-criteria of 100 kg/ha per year.

concentration is well below of the limit value of 0.1 µg/L of the Groundwater Directive (Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration) and thus represents no unacceptable risk for groundwater regarding DCPP.

Non Compartment Specific Effects Relevant To The Food Chain (Secondary Poisoning)

The log Kow of 3.7, which is greater than or equal to 3, indicates that the substance may bioaccumulate. Moreover DCPP is adsorptive and similar to triclosan, a substance with known potential to accumulate. On the other hand, the low available bioconcentration factors of 99.1 and 112.8 (corrected for a whole body lipid content of 5%) indicate that there is no risk of secondary poisoning to top predators.

Risk to fish-eating predators

The risk to the fish-eating predators is calculated as the ratio between the concentration in their food (fish) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$). The concentration of DCPP in fish has been calculated from the PEC for surface water, the measured bioconcentration factor for fish and the biomagnification factor (see Doc II-B). The PNEC values for oral intake by birds and by mammals have been discussed in Doc II-A (see $PNEC_{oral}$).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-24: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for DCPP based on consumption approach

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.47 mg a.s./kg diet	
Mammals feeding on fish **Tier 1** (Simple Treat assuming 0% degradation in STP)	0.0383	2.61E-02
Mammals feeding on fish **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	2.70E-03	1.84E-03

Conclusion

The PEC/PNEC ratios for secondary poisoning of fish-eating predators concerning the parent compound DCPP following the consumption approach are well below 1 and thus acceptable.

Calculations based on tonnage approach

Table 2.2.3.5-25: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for DCPP based on tonnage approach

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.47 mg a.s./kg diet	
Mammals feeding on fish **Tier 1** (Simple Treat assuming 0% degradation in STP)	0.0373	0.025
Mammals feeding on fish **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	2.63E-03	0.002

Conclusion

The PEC/PNEC ratios for secondary poisoning of fish-eating predators concerning the parent compound DCPP following the tonnage approach are well below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Calculations based on consumption approach

Table 2.2.3.5-26: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for methyl-DCPP based on consumption approach

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.55 mg a.s./kg diet	
Mammals feeding on fish **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	4.18	2.697
Mammals feeding on fish **Tier 2** (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	1.39	0.897

Conclusion

The PEC/PNEC ratio for secondary poisoning Tier 2 calculations of fish-eating predators concerning the metabolite methyl-DCPP following the consumption approach is below 1 and thus acceptable.

Calculations based on tonnage approach

Table 2.2.3.5-27: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for methyl-DCPP based on tonnage approach

Exposure scenario	PEC_{FISH} (mg a.s./kg wet fish)	PEC/PNEC
	PNECoral = 1.55 mg a.s./kg diet	
Mammals feeding on fish **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	4.07	2.626
Mammals feeding on fish **Tier 2** (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	1.36	0.877

Conclusion

The PEC/PNEC ratio for secondary poisoning Tier 2 calculations of fish-eating predators concerning the metabolite methyl-DCPP following the tonnage approach is below 1 and thus no unacceptable risk is expected.

Risk to worm-eating predators

The risk to the earthworm-eating predators is calculated as the ratio between the concentration in their food (earthworm) and the predicted no-effect concentration for oral intake ($PNEC_{oral}$, see Doc. II-A). The concentration of DCPP in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm (see Doc. II-B).

Risk characterisation for DCPP

Calculations based on consumption approach

Table 2.2.3.5-28: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for DCPP based on consumption approach

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.47 mg a.s./kg diet	
Mammals feeding on earthworms **Tier 1** (Simple Treat assuming 0% degradation in STP)	9.28E-03	6.31E-03
Mammals feeding on earthworms **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	0.0124	8.44E-03

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the parent compound DCPP following the consumption approach are below 1 and thus acceptable.

Calculations based on tonnage approach

Table 2.2.3.5-29: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for DCPP based on tonnage approach

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.47 mg a.s./kg diet	
Mammals feeding on earthworms **Tier 1** (Simple Treat assuming 0% degradation in STP)	0.0827	0.056
Mammals feeding on earthworms **Tier 2** (Refinement assuming 74% degradation, 20% directed to sludge, 6% directed to surface water in STP, $DT50_{soil}$=19.3 d)	0.0121	0.008

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the parent compound DCPP following the tonnage approach are well below 1 and thus acceptable.

Risk characterisation for the metabolite methyl-DCPP

Calculations based on consumption approach

Table 2.2.3.5-30: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for methyl-DCPP based on consumption approach

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.55 mg a.s./kg diet	
Mammals feeding on earthworms **Tier 1** (6% of $C_{influent,DCPP}$ directed to water, 20% of $C_{influent,DCPP}$ directed to the sludge; $C_{effluent,\ DCPP}$ = $C_{effluent,\ methyl\text{-}DCPP}$ and $C_{sludge\ DCPP}$ = $C_{sludge,\ methyl\text{-}DCPP}$)	0.0159	1.03E-02
Mammals feeding on earthworms **Tier 2** (2% of $C_{inf,DCPP}$ =$C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP}$=$C_{sludge,methyl\text{-}DCPP}$)	9.39E-04	6.06E-04

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the metabolite methyl-DCPP following the consumption approach are below 1 and thus acceptable.

Calculations based on tonnage approach

Table 2.2.3.5-31: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for methyl-DCPP based on tonnage approach

Exposure scenario	$PEC_{EARTHWORM}$ (mg a.s./kg wet worm)	PEC/PNEC
	Mammals: $PNEC_{oral}$ = 1.55 mg a.s./kg diet	
Mammals feeding on earthworms **Tier 1** (100% of DCPP is transformed to Methyl-DCPP, $C_{effluent, DCPP} = C_{effluent, methyl\text{-}DCPP}$ and $C_{sludge\ DCPP} = C_{sludge, methyl\text{-}DCPP}$)	0.0155	0.010
Mammals feeding on earthworms **Tier 2** (2% of $C_{inf,DCPP} = C_{effl,methyl\text{-}DCPP}$, 1.2% of $C_{sludge,DCPP} = C_{sludge,methyl\text{-}DCPP}$)	9.28E-04	5.99E-04

Conclusion

The PEC/PNEC ratios for secondary poisoning of earthworm-eating predators concerning the metabolite methyl-DCPP following the tonnage approach are below 1 and thus acceptable.

Aggregated Risk Assessment

An aggregated risk assessment for the active substance DCPP due to the possible overlap of emissions from PT 1, PT 2 and PT 4 in time and space (in this case: waste water is discharging to the same local STP) was calculated. The RMS decided to perform a cumulative risk assessment on the basis of the "Decision tree on the need for estimation of aggregated exposure" mentioned in the research project on cumulative environmental risk assessment of biocides provided by Germany.

The predicted environmental concentrations for all compartments for PT 4 were calculated using the consumption approach and the tonnage approach as well. Due to the higher predicted environmental concentrations executing the consumption approach, the values of this approach were applied for the cumulative risk assessment.

The aggregated risk assessment was calculated using the following formula:

$$RQ_{aggregatedRA} = \sum_{i=1}^{n} \left(\frac{PEC}{PNEC} \right)_i$$

Aggregated Risk Assessment – DCPP

Aquatic Compartment (incl. Sediment)

STP micro-organisms

Table 2.2.3.5-32: PEC/PNEC for micro-organisms in the STP: cumulative risk assessment

PEC for micro-organisms in the STP	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection	0.2975	2.10E-02
PT 2: surface disinfection	0.114	8.06E-03
PT 4: dishwashing liquid	8.50E-02	6.00E-03
PEC_{aggr}/PNEC	**0.497**	**0.035**

The aggregated risk assessment concerning DCPP indicates no unacceptable risk for micro-organisms in the STP.

Aquatic organisms

Table 2.2.3.5-33: PEC/PNEC for surface water: cumulative risk assessment of DCPP

Local PEC in surface water during emission episode (dissolved)	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection	2.56	0.181
PT 2: surface disinfection	0.981	6.92E-02
PT 4: dishwashing liquid	0.730	0.052
PEC_{aggr}/PNEC	**4.271**	**0.302**

The aggregated risk assessment concerning DCPP indicates an unacceptable risk for aquatic organisms in the Tier 1 calculations. Tier 2 calculations indicate no unacceptable risk for aquatic organisms.

Sediment dwelling organisms

Table 2.2.3.5-34: PEC/PNEC ratios for benthic organisms for DCPP

Local PEC in fresh-water sediment during emission episode	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection	0.395	0.029
PT 2: surface disinfection	0.151	1.05E-02
PT 4: dishwashing liquid	0.113	7.93E-03
PEC_{aggr}/PNEC	**0.659**	**0.047**

The aggregated risk assessment concerning DCPP indicates no unacceptable risk for sediment dwelling organisms.

Terrestrial compartment

Terrestrial organisms

Table 2.2.3.5-35: PEC/PNEC ratios for terrestrial organisms for DCPP

	Tier 1	**Tier 2**
Local PEC in agric. soil (total) averaged over 30 days		
PT 1: hygienic hand disinfection	0.255	0.125
PT 2: surface disinfection	9.82E-02	4.81E-02
PT 4: dishwashing liquid	2.68E-02	3.57E-02
PEC_{aggr}/PNEC	**0.380**	**0.209**

The aggregated risk assessment concerning DCPP indicates no unacceptable risk for terrestrial organisms.

Groundwater

Table 2.2.3.5-36: Concentrations of DCPP in groundwater after continuous sludge application

Local PEC in groundwater under agricultural soil	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection [mg/L]	8.68E-04	1.27E-04
PT 2: surface disinfection [mg/L]	0.33	0.049
PT 4: dishwashing liquid [mg/L]	2.73E-03	3.63E-05
Cumulative groundwater concentration [mg/L]	**0.334**	**0.049**

The aggregated risk assessment concerning the concentration of DCPP in groundwater under arable land indicates an unacceptable risk in Tier 1 and Tier 2 calculations. Remark that no biodegradation, transformation and dilution in deeper soil layers are taken into account by EUSES groundwater calculations. According to the ESD for PT 812, substances with a Koc > 500 L.kg-1 and a DT50soil < 21 days may not leach to groundwater. For DCPP both criteria are applicable (Koc = 1427.25 $L.kg^{-1}$, DT50soil = 19.3 d) and therefore no refined groundwater calculations using FOCUS Pearl are required.13

Non compartment specific exposure relevant to food chain (secondary poisoning)

Risk to fish-eating predators

Table 2.2.3.5-337: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for DCPP

Concentration in fish for secondary poisoning (freshwater)	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection	9.12E-02	6.45E-03
PT 2: surface disinfection	3.50E-02	2.47E-03
PT 4: dishwashing liquid	2.61E-02	1.84E-03
PEC_{aggr}/PNEC	**0.152**	**0.011**

The aggregated risk assessment concerning DCPP indicates no unacceptable risk for fish-eating predators.

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13 Please note, that at BPC WGII 2014 a further cut-off-criteria was agreed: the standard cut-off criteria (DT50 <21 d at 20°C and Koc >500 L/kg) could be used for biocide application rates up to 100 kg a.s./ha per year. If biocide uses result in high soil loadings >100 kg a.s./ha per year, it is proposed that a formal FOCUS groundwater assessment may need to be performed. In the case of DCPP, the application rates are far away from this new cut-off-criteria of 100 kg/ha per year.

Risk to worm-eating predators

Table 2.2.3.5-38: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for DCPP

Concentration in earthworms from agricultural soil	**Tier 1**	**Tier 2**
PT 1: hygienic hand disinfection	0.201	2.95E-02
PT 2: surface disinfection	7.73E-02	1.14E-02
PT 4: dishwashing liquid	6.31E-03	8.44E-03
PEC_{aggr}/PNEC	**0.285**	**0.049**

The aggregated risk assessment concerning DCPP indicates no unacceptable risk for worm-eating predators.

Aggregated Risk Assessment – methyl-DCPP

Please note that regarding PT 4 calculations, for methyl-DCPP the Tier 2 calculations are sufficient for an acceptable risk concerning the environmental assessment. Therefore, no Tier 3 calculations regarding methyl-DCPP were performed for PT 4. However, to calculate an aggregated risk assessment for PT 1, PT 2 and PT 4, the value of the RCR of the Tier 2 calculations for PT 4 are applied for the Tier 3 calculations for PT 4.

Aquatic Compartment (incl. Sediment)

STP micro-organisms

Table 2.2.3.5-39: PEC/PNEC for micro-organisms in the STP: aggregated risk assessment for methyl-DCPP

PEC for micro-organisms in the STP	**Tier 1**	**Tier 2**	**Tier 3**
PT 1: hygienic hand disinfection	5.22E-02	1.74E-02	4.35E-03
PT 2: surface disinfection	2.00E-02	6.68E-03	1.67E-03
PT 4: dishwashing liquid	1.49E-02	4.97E-03	4.97E-03
PEC_{aggr}/PNEC	**0.087**	**0.029**	**0.011**

The aggregated risk assessment concerning methyl-DCPP indicates no unacceptable risk for micro-organisms in the STP.

Terrestrial compartment

Terrestrial organisms

Table 2.2.3.5-40: PEC/PNEC ratios for terrestrial organisms for methyl-DCPP

	Tier 1	Tier 2	Tier 3
Local PEC in agric. soil (total) averaged over 30			
PT 1: hygienic hand disinfection	0.211	0.040	0.037
PT 2: surface disinfection	0.081	0.015	0.014
PT 4: dishwashing liquid	0.060	0.011	0.011
PEC_{aggr}/PNEC	**0.352**	**0.066**	**0.062**

The aggregated risk assessment concerning methyl-DCPP indicates no unacceptable risk for terrestrial organisms.

Groundwater

Table 2.2.3.5-41: Concentrations of methyl-DCPP in groundwater after continuous sludge application

Local PEC in groundwater under agricultural	**Tier 1**	**Tier 2**	**Tier 3**
PT 1: hygienic hand disinfection [mg/L]	2.66E-04	1.60E-05	1.33E-05
PT 2: surface disinfection [mg/L]	1.02E-04	6.13E-06	5.12E-06
PT 4: dishwashing liquid [mg/L]	7.60E-05	4.50E-06	4.50E-06
Cumulative groundwater concentration	**4.44E-04**	**2.66E-05**	**2.29E-05**

The aggregated risk assessment concerning methyl-DCPP indicates no unacceptable risk for groundwater.

Non compartment specific exposure relevant to food chain (secondary poisoning)

Risk to fish-eating predators

Table 2.2.3.5-42: PEC/PNEC ratios for the secondary poisoning via the aquatic food chain for methyl-DCPP

Concentration in fish for secondary poisoning (freshwater)	**Tier 1**	**Tier 2**	**Tier 3**
PT 1: hygienic hand disinfection	9.42	3.15	0.79
PT 2: surface disinfection	3.26	1.21	0.303
PT 4: dishwashing liquid	2.697	0.897	0.897
PEC_{aggr}/PNEC	**15.4**	**5.26**	**1.99**

The aggregated risk assessment concerning the concentration of methyl-DCPP in fish for secondary poisoning indicates an unacceptable risk for fish-eating predators.

According to the proposal "Aggregated environmental exposure assessment" provided by the German Federal Environment Agency in May 2014 it must be stated, that so far, neither the PEC_{aggr} nor the ratio between PEC_{aggr}/PNEC that constitutes a risk from an aggregated environmental exposure is defined in the BPR or respective guidelines.

Furthermore it is stated that according to Art. 4 (1) BPR it is sufficient to grant an approval if "at least one biocidal product containing that active substance" complies with the requirements. As all single uses of the active substance DCPP and the metabolite methyl-DCPP result in PEC/PNEC ratios <1, at least one biocidal product meets the criteria laid down in Art.19 BPR. Therefore, it seems to be more successful to encounter the risk resulting from an aggregated environmental exposure on the authorisation-level of biocidal products containing the active substance DCPP.

Risk to worm-eating predators

Table 2.2.3.5-43: PEC/PNEC ratios for the secondary poisoning via the terrestrial food chain for methyl-DCPP

Concentration in earthworms from agricultural soil	**Tier 1**	**Tier 2**	**Tier 3**
PT 1: hygienic hand disinfection	0.036	2.15E-03	1.79E-03
PT 2: surface disinfection	1.37E-02	8.26E-04	6.90E-04
PT 4: dishwashing liquid	1.03E-02	6.06E-04	6.06E-04
PEC_{aggr}/PNEC	**6.00E-02**	**3.58E-03**	**3.09E-03**

The aggregated risk assessment concerning the concentration of methyl-DCPP in earthworms for secondary poisoning indicates no unacceptable risk for worm-eating predators.

2.2.4. List of endpoints

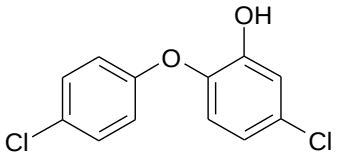
In order to facilitate the work of Member States in granting or reviewing authorisations, , the most important endpoints, as identified during the evaluation process, are listed in Appendix I

APPENDIX I: LIST OF ENDPOINTS

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

Active substance	5-Chloro-2-(4-chlorophenoxy)-phenol (short: DCPP)
Product-type	1, 2, 4

Identity

Chemical name (IUPAC)	5-Chloro-2-(4-chlorophenoxy)-phenol
Chemical name (CA)	Phenol, 5-chloro-2-(4-chlorophenoxy)-
CAS No	3380-30-1
EC No	429-290-0
Other substance No.	n.a.
Minimum purity of the active substance as manufactured (g/kg or g/l)	995 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/F) ≤ 2 pg $TEQ_{WHO-2005}$/g
Molecular formula	$C_{12}H_8Cl_2O_2$
Molecular mass	255.1 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	73.6°C (Purity: > 99%) Methyl-DCPP: The substance is a degradation metabolite which does not manufacture and market therefore the study does not need to be performed.
Boiling point (state purity)	359.3°C (Purity: > 99%) Methyl-DCPP*:* 343.7°C (Calculation based on EPI Suite v4.11) 347.1°C (<t 1013 hPa) (Calculation based on SciFinder)
Temperature of decomposition	>359.3°C
Appearance (state purity)	Crystalline powder; White; Slightly smelling like phenols (Purity: 99.97%) Methyl-DCPP: white powder
Relative density (state purity)	Relative density D^{20}_4=1.47 (Purity: > 99%) Methyl-DCPP: 1.294 kg/m^3at 20°C (Calculation based on SciFinder)

Surface tension	65 mN/m at 19.7 °C DCPP is not surface active
Vapour pressure (in Pa, state temperature)	$1.2*10^{-06}$ Pa at 25 °C Calculated at 20°C = $4.3*10^{-7}$ Pa. Methyl-DCPP: $3.58*10^{-3}$ Pa at 25°C (Calculation based on EPI Suite v4.11) $1.47*10^{-2}$ Pa (Calculation based on SciFinder)
Henry's law constant (Pa m^3 mol^{-1})	25 °C: $6.82*10^{-04}$ Pa*m^3*mol^{-1} (Bond method) 25 °C: $2.53*10^{-03}$ Pa*m^3*mol^{-1} (Group method) Methyl-DCPP: Calculation based on QSAR 0.388 Pa*m^3*mol^{-1}at 25°C (Bond method) 16.8 Pa*m^3*mol^{-1}at 25°C(Group method)
Solubility in water (g/l or mg/l, state temperature)	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 pH 7 not measured Methyl-DCPP: 0.322 mg/L at 20 °C (pH=6.95) (Purity: 99.97%)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility in n-hexane: ~ 8731 mg/L at 10 °C ~ 18638 mg/L at 20 °C ~ 27049 mg/L at 30 °C Solubility in n-octanol: ~ 368228 mg/L at 10 °C ~ 436764 mg/L at 20 °C ~ 513828 mg/L at 30 °C
Stability in organic solvents used in biocidal products including relevant breakdown products	Biocidal products do not contain organic solvents.
Partition coefficient (log P_{OW}) (state temperature)	Log Pow = 4.8 at 10 °C, pH=5 (calculated) Log Pow = 4.6 at 20 °C, pH=5 (calculated) Log Pow = 4.5 at 30 °C, pH=5 (calculated) Log Pow = 3.7 at 20 °C (measured) (Purity>99%) Methyl-DCPP: LogPow=4.58 at 25°C (Calculation based on EPI Suite v4.11) LogP=4.84 at 25°C (Calculation based on SciFinder)
Dissociation constant	pKa=9.49 (20°C). Methyl-DCPP: The substance does not contain any ionisable functional groups therefore the study does not need to be performed
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	There is an absorption maxima at 277 nm
Flammability	DCPP is not highly flammable. DCPP is not auto-flammable. Methyl-DCPP: The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.

Explosive properties	There is no structural alert for explosive properties. Methyl-DCPP: There is no structural alert for explosive properties.

Classification and proposed labelling

with regard to physical/chemical data	--
with regard to toxicological data	Eye Dam. 1 H318: Causes serious eye damage P280: Wear eye protection/face protection. 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
with regard to fate and behaviour data and ecotoxicological data	Aquatic acute 1 (M=10) Aquatic chronic 1 (M=10) H400 – Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	The assay of DCPP in the active substance as manufactured is determined using a capillary gas chromatograph equipped with a flame ionisation detector. The quantification is done by external standard method.
Impurities in technical active substance (principle of method)	The analytical method for the determination of impurities in the active substance as manufactured is preformed using a capillary gas chromatograph equipped with a mass detector.

Residue definitions for monitoring purposes

Soil		DCPP ; Me-DCPP
Air		none
Water	surface	DCPP ; Me-DCPP
	drinking/ground	DCPP ; Me-DCPP
Body fluids and tissues		Not applicable because DCPP is not classified as toxic or highly toxic.

Food of plant origin	Not applicable since it is not expected that food contamination with DCPP will be a significant source of human exposure.
Food of animal origin	Not applicable since it is not expected that food contamination with DCPP will be a significant source of human exposure.

Analytical methods for residues

Soil (principle of method and LOQ)	DCPP: HPLC-MS; LOQ: 1 µg/kg Methyl-DCPP: GC/MSD, LOQ 5ng/ml extract
Air (principle of method and LOQ)	Not applicable
Water (principle of method and LOQ)	Drinking and surface water DCPP: HPLC-MS; LOQ = 0.1 µg/L Methyl-DCPP: GC/MSD, LOQ 5ng/ml extract
Body fluids and tissues (principle of method and LOQ)	Not applicable because DCPP is not classified as toxic or highly toxic.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable since it is not expected that food contamination with DCPP will be a significant source of human exposure. However, an analytical method for the determination of active substance residues in food simulants was developed: HPLC-UV; LOQ = 20 µg/L
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable since it is not expected that food contamination with DCPP will be a significant source of human exposure.

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	79-89% (hamster); about 70% (rats), read across from triclosan assumption for risk assessment: 70%
Rate and extent of dermal absorption:	9.8% (estimation; contact time < 0.5 h, in vitro test) 44.2% (estimation; contact time >0.5 h, in vitro test) The in vitro study was carried out with 30 µg/cm^2 DCPP as a 0.3% solution in an oil/water emulsion on pig skin samples
Rate and extent of inhalative absorption:	100% (default)
Distribution:	Hamster: highest in bile fluid, plasma, kidneys and lungs; lowest in the brain no distinction possible, if parent compound or conjugates were distributed in the body
Potential for accumulation:	Hamster: low potential for accumulation, the terminal half-lives were longer than 24 hours (see below, rate of excretion)
Rate and extent of excretion:	Hamster: terminal half-lives - single dose: 26h for blood and 36h for plasma; 14 day consecutive dosing: 31h to 51h; excretion via urine: with single exposure: 78-88%; with repeated oral exposure ~ 78%; excretion via faeces: with single exposure: 5-13%; with repeated oral exposure:16%
Toxicologically significant metabolite(s)	The major metabolite pathway was the forming of glucuronic acid conjugates of DCPP. Sulfuric acid conjugates of DCPP and/or hydroxylated DCPP were found to a minor extent. With single dosing unchanged parent compound was detected at 2-2.5% in the urine and at 2-3% and 4-8% in the faeces for the high and low dose, respectively. With repeated dosing slightly more radioactivity was excreted as unchanged parent compound (10-16%).

Acute toxicity

Rat LD_{50} oral	> 2000 mg/kg (rat)
Rat LD_{50} dermal	> 2000 mg/kg (rat)
Rat LC_{50} inhalation	-
Skin irritation	Not irritating
Eye irritation	Severe eye damage (CLP Category 1)
Skin sensitization (test method used and result)	Not sensitizing to skin

Repeated dose toxicity

Species/ target / critical effect	Rat / haematology, urine parameters, morphology in oesophagus, (fore)stomach, liver / red blood cell count, polyuria& amorphous urates; hyperplasia, hyper-keratosis, hypertrophy
Lowest relevant oral NOAEL / LOAEL	20 / 100 mg/kg bw day (90 day gavage) Longer studies: read across from triclosan, see respective CAR and LOEP
Lowest relevant dermal NOAEL / LOAEL	-
Lowest relevant inhalation NOAEL / LOAEL	-

Genotoxicity	Overall conclusion negative on basis of: AMES test, AMES test with artificial sun light, in vitro mammalian gene mutation test (TK-assay), in vitro chromosomal aberration test, in vitro chromosomal aberration test with artificial sun light, in vivo mouse micronucleus test, in vivo UDS test

Carcinogenicity

Species/type of tumour	Read across from triclosan: negative in rats and hamsters, positive in mice, but mechanistic data available supporting a MoA not relevant to humans.
lowest dose with tumours	-

Reproductive toxicity

Species/ Reproduction target / critical effect	Read across from triclosan: no classification for reproductive toxicity on the basis of a rat two-generation study
Lowest relevant reproductive NOAEL / LOAEL	P: NOAEL >285 mg/kg bw day F1: 76* / 285 mg/kg bw day F2: NOAEL >311 mg/kg bw day *translated to DCPP by molecular weight: 67 mg/kg bw day
Species/Developmental target / critical effect	Read across from triclosan: no classification for developmental toxicity on the basis of 2 rat and 2 rabbit developmental toxicity studies.
Lowest relevant developmental NOAEL / LOAEL	Maternal: 50[#] / 150 mg/kg bw day Developmental: 50[#] / 150 mg/kg bw day [#]translated to DCPP by molecular weight: 44 mg/kg bw day

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Acute and repeated-dose studies in several species did not indicate the occurrence of preliminary signs of neurotoxic effects in DCPP or triclosan. Contradictive in vitro and in vivo results on potential muscle function

	available.
Lowest relevant developmental NOAEL / LOAEL.	-

Other toxicological studies

.....	Read across from triclosan: The investigation of the potential endocrine disruptive effects of triclosan is on-going under the REACH Regulation

Medical data

.....	No human data on DCPP available.

Summary	Value	Study	Safety factor
systemic AEL, short term	1 mg/kg bw day	Rat sub-acute gavage study, 70% oral absorption assumed	100 (inter-, intra-species)
systemic AEL, medium term	0.140 mg/kg bw day	Rat sub-chronic gavage study, 70% oral absorption assumed	100 (inter-, intra-species)
systemic AEL, long term	0.140 mg/kg bw day	Rat sub-chronic gavage study, 70% oral absorption assumed	100 (inter-, intra-species), no time extrapolation factor, see chapter 2.2.2.2
ADI	0.2 mg/kg bw day	Rat sub-chronic gavage study,	100 (inter-, intra-species); no time extrapolation factor, see chapter 2.2.2.2

Acceptable exposure scenarios (including method of calculation)

Production of active substance (user:)	Not assessed
Formulation of biocidal product (user:)	Not assessed

Application of biocidal product (user:)	PT 1: liquid soap formulations for hand disinfection (professionals, non-professionals)- inhalation and dermal exposure* PT 2: Surface disinfection- wiping with soaked cloth or with mop (professional**, non professionals*)- inhalation and dermal exposure PT 4: liquid dishwashing detergent concentrates (professional*, non-professionals*)- inhalation and dermal exposure *Calculation based on default values taken from Consexpo v.4.1 ** Surface disinfection- model 1 and 3, TNsG on Human Exposure, 2002
Indirect exposure as a result of use	PT 2: Infant crawling over treated floor assessed as representative scenario PT 1,4: Not expected to be relevant
Exposure of pets	PT 1,2,4: Not expected to be relevant
Dietary Exposure	PT 1,2,4: Not expected to be significant

Chapter 4:Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	DCPP: pH 4: stable for 5 days at 50 °C (hydrolysis < 10%) pH 7: stable for 5 days at 50 °C (hydrolysis < 10%) pH 9: stable for 5 days at 50 °C (hydrolysis < 10%) Conclusion of preliminary test (OECD guideline 111): half-life more than one year at temperatures up to 25°C and in the range of tested pH-Levels
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	DCPP Buffer solution pH 7, xenon arc lamp, wavelengths below 290nm were removed with filters: DT_{50} 0.27 days (1^{st} order) Dark control: DCPP was found to be stable Half-life of DCPP at latitudes between 30°N and 50°N: 0.24 day – 4.86 days (depending on latitude and season) (GC SOLAR, version 1.20, U.S. EPA) Metabolites: Formation of six major photodegradates (M1, M4, M7, M8, M16 and M17) accounting more than 10% of the initial amount of DCPP M1: max. concentration (day 2): 26.3% At the end of study (day 19): 2.3% M4: max. concentration (end of study): 14% (not identified) M7: max. concentration (day 1): 19.9% At the end of study: below LOD M8: max. concentration (day 0.25): 20.4% At the end of study: below LOD M16: max. concentration (day 9): 42.9% M17: max. concentration (end of study): 36.3%
Readily biodegradable (yes/no)	**DCPP** Ready biodegradability data: No; 40-50% biodegradation after 28 d (OECD TG 301B) 52 ± 9% after 61 days (OECD TG 301B) 0% biodegradation after 28 d (OECD TG 301F) 0% biodegradation after 28 d (comparable to OECD TG 301C) 100% elimination after 28 d, no data on ultimate degradation (OECD TG 301F) Ready biodegradability data on structural analogue Triclosan: 18-37% biodegradation after 28 d (OECD TG 301B) 0% biodegradation after 28 d (OECD TG 301C) DCPP data on inherent biodegradability:

	DCPP is primary biodegradable: elimination > 99% (due to test design – no DOC measured - the criteria for inherent biodegradability were not fulfilled) CAS-testing with structural analogue triclosan with activated sludge (2 systems) Degradation of parent compound: 1) 98.2 to 99.3% primary degradation, 73.9% to 76.7% mineralization. 2) > 94% primary degradation; > 80% complete degradation (biodegradation or incorporation into biomass) CAS-testing with DCPP: Elimination rate: > 99% **Metabolite methyl-DCPP** Ready biodegradability data: 48% elimination after 28 d, no data on ultimate degradation (OECD TG 301F)
Biodegradation in seawater	Not relevant since DCPP is not used or released in the marine environment at considerable amounts. Therefore, a seawater biodegradation test is not required.
Non-extractable residues	Data from study with structural analogue triclosan: 32.4-33.0% after 104 days
Distribution in water / sediment systems (active substance)	Data from study with structural analogue triclosan: water phase: 0.1% (104 d) sediment extracts: 21.3-21.8% (104 d) DT_{50} = 1.2-1.4 days (water) DT_{50} = 56.4-56.3 days (sediment) DT_{50} = 41.1-58.3 days (whole system) first order kinetics Recalculated to **12°C:** DT_{50} = 2.3 to 2.7 days (water) DT_{50} = 106 days (sediment) DT_{50} = 78 days (whole system, river) DT_{50} = 110 days (whole system, pond)
Distribution in water / sediment systems (metabolites)	Data from study with structural analogue triclosan: water phase: Methyltriclosan (M7): not detected sediment extracts: Methyltriclosan (M7): 3.4-4.8% (104 d) M8 (not identified): max. 6.5% (56 d), 0-5-5.5% (104 d)

Route and rate of degradation in soil

Mineralization (aerobic)	Data from study with structural analogue triclosan: 11.5-16.2% after 124 days (n = 3, 20 ± 2 °C) 5.1% after 124 days (n = 1, 10 ± 2 °C) 11.9-20.1% after 64 days (n = 3, 22 ± 3 °C) [System 1]
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Data from study with structural analogue triclosan: 1) DT50 lab (20 ± 2 °C, aerobic): 2.46-3.28 days (n = 3) DT90 lab (20 ± 2 °C, aerobic): 19.1-25.7 days (n = 3) DT50 lab (10 ± 2 °C, aerobic): 10.7 days (n = 1) DT90 lab (10 ± 2 °C, aerobic): 231 days (n = 1) 2) DT50 lab (20 ± 2 °C, aerobic): 17.4-35.2 days, n = 3, r^2 = 0.89-0.96 Recalculated to 12 °C: DT50 lab (12 °C): 4.7- 95 days (n = 6) Geometric mean. = 19.3 days (for risk assessment used 19.3 days) Data from study with structural analogue triclosan in which methyl-Triclosan (a stuructural analogue to methyl-DCCP) was confirmed: Consecutive first-order kinetics applied DT50 lab (20 ± 2 °C, aerobic): 39.2 - 153 days (n = 3) Recalculated to 12 °C: 74 – 290 days (n = 3), with a geometric mean of 157.8 days.
Field studies (state location, range or median with number of measurements)	No data presented
Anaerobic degradation	No biodegradation of the structurally related compound Triclosan in sewage sludge under anaerobic conditions
Soil photolysis	Not relevant
Non-extractable residues	Data from study with structural analogue triclosan: 60.8-75.8% after 124 days (n = 3, 20 ± 2 °C) 59.6% after 124 days (n = 1, 10 ± 2 °C) 37.7-59.7% after 64 days (n = 3, 22 ± 3 °C) [System 1]
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	Data from study with structural analogue triclosan: Methyl-Triclosan, 24.0% at maximum (day 28) $DT_{50\ lab}$ (20 ± 2 °C, aerobic): 39.2-153 days (n = 3) $DT_{90\ lab}$ (20 ± 2 °C, aerobic): 130-509 days (n = 3)
Soil accumulation and plateau concentration	Not relevant

Adsorption/desorption

DCPP	
Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type ofdependence)	OECD TG 12: Koc = 1427 (acc. GLP-study) Koc =419 (acc non GLP-study) QSAR data: Koc = 1565 based on log Kow Koc= 6470 based on Molecular Connectivity Index (MCI)
Metabolite methyl-DCPP	
Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type ofdependence)	QSAR data: Koc = 3718 based on log Kow Koc= 3228 based on MCI

Fate and behaviour in air

Direct photolysis in air	Guideline not yet available
Photo-oxidative degradation in air	DCPP DT_{50} calculated = 19.7 hours (24 h, $5x10^5$ OH/cm³) Methyl-DCPP DT_{50} calculated = 28.03 hours (24 h, $5x10^5$ OH/cm³)
Volatilization	Not relevant (low vapour pressure = $1.2x10^{-6}$ Pa at 25°C; low Henry's Law Constant: 6.82 x 10^{-4} Pa x m^3/mol (25°C) based on the Bond method resp. 2.53 x 10^{-3} Pa x m^3/mol (25°C) based on the Group method)

Monitoring data, if available

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

Chapter 5:Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
DCPP			
Danio rerio	96h, static	Mortality LC_{50}	0.70 mg a.s./L (m)

Data based on read across study with triclosan: corrected for the molecular weight of DCPP			
Oncorhynchus mykiss	96 days (61d post hatching)	Reproduction, NOEC	0.03 mg/L (m)
Metabolite methyl-DCPP			
Danio rerio	96h, static	Mortality LC_{50}	> 0.091 mg/L
Data based on read across study with triclosan: corrected for the molecular weight of methyl-DCPP			
Oncorhynchus mykiss	96 days (61d post hatching)	Reproduction, NOEC	0.032 mg/L (m)
Invertebrates			
DCPP			
Daphnia magna	48h, static	Immobilisation and Mortality, EC_{50}	0.32 mg/L (n)
Daphnia magna	21 days, semi-static	Mortality & Reproduction	0.094 mg/L (m)
Metabolite methyl-DCPP: d			
Daphnia magna	48h, static	Immobilisation, EC_{50}	> 0.16 mg/L (m)
Daphnia magna	21 days, semi-static	Reproduction	< 0.0049 mg/L (m)
Algae			
DCPP			
Desmodesmus subspicatus	72h, static	Growth Inhibition, E_rC_{50}	0.038 mg/L (n)
Desmodesmus subspicatus	72h, static	Biomass, NOEC & Growth Inhibition, NOEC	0.0093 mg/l (m)
Metabolite methyl-DCPP			
Desmodesmus subspicatus	72h, static	Growth Inhibition, E_rC_{50}	> 0.02 mg/L (<0.18mg/L). (m)
Desmodesmus subspicatus	72h, static	NOEC (Growth Inhibition),	0.013 mg/L (m)
Aquatic plants			
No acceptable study was submitted			
Sediment dwelling organisms			
DCPP			
Data based on read across study with Triclosan: corrected for the molecular weight of DCPP			
Chironomus riparius	28 days	Emergence ratio & development rate, NOEC	> 88.1 mg/kg (n)
Metabolite methyl-DCPP			
Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP			

Chironomus riparius	28 days	Emergence ratio & development rate, NOEC	> 92.9 mg/kg (n)
Microorganisms			
DCPP			
Activated sludge	3 hours	Inhibition of respiratory rate, EC_{50}	8 mg/l (n)
Metabolite methyl-DCPP			
Activated sludge	3 hours	Inhibition of respiratory rate, NOEC	0.322 mg/l based on the water solubility of 0.322 mg methyl-DCPP/L and based on NOEC in a limit test at 56.8 mg methyl-DCPP/L.

Effects on earthworms or other soil non-target organisms

DCPP	
Acute toxicity to *Eisenia fetida*.	LC_{50} = 693 mg/kg dry soil Conversion to standard soil: LC_{50} = 236 mg/kg dry soil
Reproductive toxicity to *Eisenia fetida* (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	NOEC > 89.7 mg/kg dry soil (m) Conversion to standard soil: NOEC > 30.5 mg/kg dry soil (m)
Metabolite methyl-DCPP	
Reproductive toxicity to *Eisenia fetida* (Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP)	NOEC > 28.5 mg/kg dry soil (m) (converted to standard soil)

Effects on other soil non-target organisms

DCPP	
Chronic toxicity to predatory mite *Hypoaspis aculeifer (*Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	NOEC = 1.73 mg/kg dry soil (m) Conversion to standard soil: NOEC = 1.15 mg/kg dry soil (m)
Metabolite methyl-DCPP	
Chronic toxicity to predatory mite *Hypoaspis aculeifer*	NOEC = 5 mg/kg dry soil (n) Conversion to standard soil: NOEC = 3.4 mg/kg dry soil (n)

Effects on terrestrial plant

DCPP	
Chronic toxicity to terrestrial plants (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	NOEC (21 days) = 0.05 mg/kg dry soil (m, TWA) Conversion to standard soil: NOEC = 1.2 mg/kg dry soil
Metabolite methyl-DCPP	
Chronic toxicity to terrestrial plants (Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP)	NOEC (21 days) = 1.29 mg/kg dry soil (m, TWA, converted to standard soil))

Effects on soil micro-organisms

DCPP	
Nitrogen mineralization (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	NOEC >1.7 mg/kg dry soil (n) Conversion to standard soil: NOEC >3.4 mg/kg dry soil
Carbon mineralization (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	NOEC >1.7 mg/kg dry soil (n) Conversion to standard soil: NOEC >3.4 mg/kg dry soil
Metabolite methyl-DCPP	
Nitrogen mineralization (Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP)	NOEC > 3.6 mg/kg dry soil (n, converted to standard soil)
Carbon mineralization (Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP)	NOEC > 3.6 mg/kg dry soil (n, converted to standard soil)

Effects on terrestrial vertebrates

DCPP	
Acute toxicity to mammals	LD_{50} >2000 mg/kg bw (♂+♀)
Acute toxicity to birds (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	LD_{50} = 759 mg/kg bw (n) (*Colinus virgianus*)
Dietary toxicity to birds (Data based on read across study with Triclosan: corrected for the molecular weight of DCPP)	LC_{50} > 4404 mg/kg diet (n) (*Colinus virgianus*)
Reproductive toxicity to birds	No data required
Metabolite methyl-DCPP	
Acute toxicity to mammals	LD_{50} >2000 mg/kg bw (♂+♀) NOECD methyl-DCPP: 211
Dietary toxicity to birds (Data based on read across study with Triclosan: corrected for the molecular weight of methyl-DCPP)	LC_{50} > 4646 mg/kg diet (n) (*Colinus virgianus*)

Effects on honeybees

Acute oral toxicity	No data required
Acute contact toxicity	No data required

Effects on other beneficial arthropods

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

Bioconcentration

DCPP	
Bioconcentration factor (BCF)	Whole fish BCF = 67.4 (at substance concentration 0.02 mg/L) & 76.7 (at substance concentration 0.002 mg/L); corrected for a whole body lipid content of 5% the BCFs are 99.1 and 112.8
Depuration time(DT_{50}) (DT_{90})	More than 95% of the amount of test substance residual DCPP was eliminated in 7 days
Level of metabolites (%) in organisms accounting for > 10 % of residues	No metabolites identified
Metabolite methyl-DCPP	
Bioconcentration factor (BCF)	Whole fish kinetic BCF = 23804 (at substance concentration of 0.0275 mg/L) and 16738 (at substance concentration of 0.263 mg/L); lipid corrected values 17505 and 12129. Whole fish steady state BCF = 20800 (at substance concentration of 0.0275 mg/L) and 14514 (at substance concentration of 0.263 mg/L); lipid corrected values: 15273 and 10517.
Depuration time(DT_{50}) (DT_{90})	No data given on DT50 or DT90
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not applicable

Chapter 6:Other End Points

APPENDIX II: LIST OF INTENDED USES

DCPP is used as disinfectant for human hygiene purposes in the frame of product type (PT) 1 of the Biocidal Product Directive 98/8/EC and to keep surfaces free of potentially harmful germs in private and public health areas (PT 2). Furthermore, dish-washing products – containing DCPP as anti-microbial compound – are intended (i.e. PT 4)

The intended uses for PT 1, 2 and 4 considered in the risk assessment are given in Table II-1 to Table II-3. The efficacy of the representative biocidal products based on DCPP were not satisfactorily proven. They should be tested under practical conditions (phase 2/step 2) at product authorisation stage (see Doc. I, chapter 3.3)

Table II-1: Intended uses of Disinfectant cleaner (PT1) considered in the risk assessment

PT		PT 1 Human hygiene biocidal product
Formu-lation	**Type**	Liquid
	Conc. of a.s. in b.p.	Max. 0.2%w/w DCPP
Field of use envisaged		hand disinfection
User		Professional (hospital or a medicinal practice)
Target Organisms		*Staphylococcus aureus, Pseudomonas aeruginosa , Escherichia coli, Enterococcus hirae*
Likely amount at which the a.s. will be used (all fields of use	**Method of application**	The undiluted biocidal product is dispensed onto hands and forearms. After a contact time of 5 minute the product is rinsed off with tap water.
	Applied amount of product	7 g product per application
	Application rate of a.s.	n.a.
	Number of treatments per year	10 applications per day
	Typical size of application area	hands and forearms

Table II-2: Intended uses of Disinfectant cleaner (PT2) considered in the risk assessment

PT		PT2 Private area and public health area disinfectant and other biocidal products
Formu-lation	**Type**	Liquid
	Conc. of a.s. in b.p.	Max: 0.2%w/w a.s.
Field of use envisaged		Surface disinfection. The product is used as bactericide in hospitals and private homes. It has to be noted that for concentrations below 0.02% w/w a.s. only bacteriostatic efficacy has been proven
User		Professional (hospital or a medicinal practice) and private use (households)
Target Organisms		*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Enterococcus hirae*
Likely amount at which the a.s. will be used (all fields of use envisaged)	**Method of application**	Professional use and private use: The biocidal product is diluted typically 1:50 with water to give the final cleaning solution (0.004% w/w as in final in use concentration, bacteriostatic efficacy). Disinfection of surfaces by mopping (especially large areas) or manual wiping with a soaked cloth (especially small areas) The surface is then air-dried.
	Applied amount of product	Typically 0.8g product per m^2 surface (equivalent to 40ml 1:50 diluted cleaning solution) (default value; reference: Consexpo 4.1; model: cleaning and washing, all-purpose cleaners, liquid cleaner)
	Application rate of a.s.	n.a.
	Number of treatments per year	n.a.
	Typical size of application area	n.a.

Table II-3: Intended uses of Disinfectant cleaner (PT4) considered in the risk assessment

PT		PT4 Food and feed area disinfectant
Formu-lation	**Type**	Liquid
	Conc. of a.s. in b.p.	Max. 0.2%w/w a.s.
Field of use envisaged		Manual and automated dishwashing. It has to be noted that for concentrations below 0.02% w/w a.s. only bacteriostatic efficacy has been proven
User		professional and non-professional users
Target Organisms		*Staphylococcus aureus, Pseudomonas aeruginosa , Escherichia coli, Enterococcus hirae*
Likely amount at which the a.s. will be used (all fields of use	**Method of application**	The in-use concentration (0.0004% technical DCPP) is achieved by pouring or squirting 2 mL concentrate per L into water, i.e., a 1:500 dilution (bacteriostatic efficacy).
	Applied amount of product	n.a.
	Application rate of a.s.	0.0004% a.s. in dishwashing water
	Number of treatments per year	426 times per year
	Typical size of application area	n.a.

APPENDIX III: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE – SORTED BY SECTION NUMBER

Section No / Reference No	**Year**	**Title Source Institution; report nr; GLP-status; Published or unpublished;**	**Data Protec-tion**	**Owner**
A2.1/01	2007a	No title; Date: 2007-07-02; Ciba Specialty Chemicals Inc, Basel, Switzerland; No report no. No GLP unpublished	Yes	BASF SE
A2.6/01	--	Lab-process DCPP Internal Report BASF SE No GLP unpublished	Yes	BASF SE
A2.6/02	2007b	DCPP synthesis pathway. Date: 2007-03-26; Ciba Specialty Chemicals Inc, Basel, Switzerland No GLP unpublished	Yes	BASF SE
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. [redacted] GLP; unpublished	Yes	BASF SE
A2.7/02	2014	DCPP: 5 Batch analysis for Biocide Registration. Date: 2014-04-25; Intertek Expert Services.,	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Basle, Switzerland Test No. [redacted] GLP; unpublished		
A3.1/01	1999	Determination of the melting point / melting range of [redacted] Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report no.: [redacted] GLP:Yes Published: No	Yes	BASF SE
A3.1/02	1999	Determination of the boiling point / boiling range of [redacted] Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report no.: [redacted] GLP:Yes Published: No	Yes	BASF SE
A3.1/03	1999	Determination of the relative densi[redacted] Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report no.: [redacted] GLP:Yes Published: No	Yes	BASF SE
A3.1/04	2007	Bulk density of DCPP [redacted] Date: 2007-07-11 Ciba Spezialitätenchemie Grenzach GmbH, Grenzach, Germany	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Report No.: -- GLP:No unpublished		
A3.2/01	1998	Calculation of the vapour pressure of [redacted] Date: 1998-11-26 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report No. [redacted] 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 Report No: [redacted] GLP: No unpublished	Yes	BASF SE
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 [redacted] GLP: Yes unpublished	Yes	BASF SE
A3.4/01	1999	Report on analytical certification, [redacted] Date: 1999-01-15 CONFIDENTIAL Ciba Specialty Chemicals, Consumer Care, Analytic	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		(GZ5.54), Grenzach-Wyhlen, Germany Report No. [redacted] GLP: No unpublished		
A3.5/01	1999	Determination of the water solubility of [redacted] Date: 1999-02-01 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report No. [redacted] 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 [redacted] GLP: Yes Published:No	Yes	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. [redacted] GLP: Yes Published:No	Yes	BASF SE
A3.9/01	1999	Determination of the partition coefficient (n-octanol/water) of [redacted] Date: 1999-01-21 RCC Ltd, Environmental Chemistry & Pharmanalytics	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Division, Itingen, Switzerland Report No. [redacted] GLP: Yes Published:No		
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. [redacted] GLP: Yes Published:No	Yes	BASF SE
A3.11/01	2007	[redacted](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. [redacted] GLP: Yes Published:No	Yes	BASF SE
A3.11/02	2007	[redacted](DCPP), Determination of the relative self-ignition temperature. Date: 2007-10-30 RCC Ltd., Itingen, Switzerland Report No. [redacted] GLP: Yes Published:No	Yes	BASF SE
A3.13/01	1999	Determination of the surface tension of an aqueous solution of [redacted] Date: 1999-03-19 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland Report No [redacted] GLP: Yes Published:No	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
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 CONFIDENTIAL Ciba Inc. Switzerland, Basel, Switzerland Report No. -- GLP: No Published:No	Yes	BASF SE
A4	2007c	Statement regarding the applicability of analytical methods developed for triclosan to be used for dichloro-phenoxyphenol (DCPP). Date: 2007-07-16 CONFIDENTIAL Ciba Specialty Chemicals Inc, TAOH (Trace Analysis & Occupational Hygiene), Basle, Switzerland Report No. [redacted] GLP: No Published:No	Yes	BASF SE
A4.1/01	2003	Measurement of 2,3,7,8-TCDD/F in [redacted] or 2,3,7,8-substituierte PCDD/F in [redacted] Date: 2003-06-13 CONFIDENTIAL; Ciba Specialty Chemicals Inc, TAOH (Trace Analysis & Occupational Hygiene), Basle, Switzerland; Document / [redacted] No.: [redacted] no GLP unpublished	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
A4.1/02	2008b	Method validation for impurity analysis in DCPP. Date: 2008-03-27; Dep. of Trace Analysis & Occupational Hygiene (TAOH), Expert Services Business Unit of Ciba Inc., Basle, Switzerland Test No. [redacted] no GLP unpublished	Yes	BASF SE
A4.2	2008a	Determination of DCPP in water and soil samples with LC/MS/MS. Date: 2008-03-28 Trace Analysis & Occupational Hygiene (TAOH), Ciba Specialty Chemicals, Basle, Switzerland Report No. Document No. / [redacted] GLP: No Published:No	Yes	BASF SE
A4.2a	2008b	Method check / validation of the method [redacted] for soil samples. Date: 2008-03-28 Trace Analysis & Occupational Hygiene (TAOH), Expert Services, Ciba Specialty Chemicals, Basel, Switzerland Report No. [redacted] GLP: No Published:No	Yes	BASF SE
A4.2b	2001	Ambient monitoring method for triclosan [redacted] in air. Date: 2001-02-28 TAOH (Trace Analysis & Occupational Hygiene), Basle, Switzerland	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Report No. Document No.: [redacted] GLP: No Published:No		
A4.2c	2008c	Method check / validation of the method [redacted] for water samples. Date: 2008-03-26 Trace Analysis & Occupational Hygiene (TAOH), Expert Services, Ciba Specialty Chemicals, Basel, Switzerland Report No [redacted] GLP: No Published:No	Yes	BASF SE
A4.3	2008	Analysis of the DCPP in fatty food stimulant-sunflower oil. Date: 2008-03-13 Ciba Inc., R&T Analytics PA, Basel, Switzerland Report No. Analytical Method [redacted] GLP: No Published:No	Yes	BASF SE
A5.3/01	2010	EN 1040 Chemical disinfectants and antiseptics / Basic bactericidal activity Test method and requirements (phase 1) Technical report L+S-No.: 1[redacted] ([redacted] Stock Solution) and Technical report L+S-No.: [redacted] (Propylene Glycol blank control)	Yes	BASF SE
A5.3/02	2010	EN 1276 Quantitative suspension test for the evaluation of bactericidal activity (membrane filtration) Technical reports L+S-No.: [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		(Formulation [redacted] And L+S – No: [redacted] (Propylene glycol 13% carrier control)		
A5.4.1(01) IIA, V 5.4 also filed A5.7.1(01)	2005	Submission by Colipa to the EU, September 2005. Literature review on bactericidal resistance and Triclosan between 2002 and 2005. - Report No. - GLP:- Published:Yes	No	--
A5.7.1(01) IIA, V 5.7 also filed A5.4.1(01)	2005	Submission by Colipa to the EU, September 2005. Literature review on bactericidal resistance and Triclosan between 2002 and 2005. - Report No. - GLP:- Published:Yes	No	--
A5.7.1(02) IIA, V 5.7	2002	Opinion on DCPP Resistance. Adopted by the Scientific Steering Committee at its meeting of 27-28 June 2002. European Commission, Health and consumer protection directorate-general. Directorate C – Scientific Opinions, C1 – Follow-up and dissemination of scientific opinions. Report No. -- GLP:-- Published:Yes	No	--
A5.7.1(03) IIA, V 5.7	2006	Background paper "Considering the potential of resistance in the efficacy and risk evaluation of biocidal compounds" (based on the TMIII 05 discussion to OECD Thought Starter from October 2005). Date: 2006-03-01 On behalf of the Federal Institute for Risk Assessment, Berlin,	No	--

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Germany (BfR) Report No. Document name: TMI06GEN-item14b-resistence-in-target-organinsms.doc GLP:-- Published:Yes		
A6.1.1	1999a	[redacted] Acute Oral Toxicity Study in Rats. Date: 1999-01-08 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.1.2	1999b	[redacted] Acute Dermal Toxicity Study in Rats. Date: 1999-01-12 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.1.4(01)	1998	[redacted] Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application). Date: 1998-12-22 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.1.4(02)	1999	[redacted] Primary Eye Irritation Study in Rabbits. Date: 1999-01-29 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.1.5	1999	[redacted] Contact Hypersensitivity in Albino Guinea Pigs –	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Maximisation Test. Date: 1999-02-22 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No		
A6.2(01)	1994	14C-Triclosan: Absorption, Distribution, Metabolism and Elimination after Single/Repeated Oral and Intra¬venous Administration to Hamsters. Date: 1994-11-11, amended 1995-02-10 and 1995-08-25 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.2(02)	2006	Pharmacokinetics of Triclosan Following Oral Ingestion in Humans. Institute of Odontology, Karolinska Institutet, Huddinge, Sweden Report No. J. Toxicol. Environ. Health A, 69:1861–1873 GLP:No Published:Yes	No	--
A6.2(03)	2008a	Absorption, Distribution, Excretion and Metabolism of 14C-DCPP in the Hamster After Oral Administration. Date: 2008-10-30 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.2(04)	2008b	Disposition of 14C-DCPP	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		in the Hamster After Multiple Oral Administrations. Date: 2008-10-30 [redacted] Report No. Project No.[redacted] GLP:Yes Published:No		
A6.2(05)	1995	14C-Triclosan: Absorption, Distribution, Metabolism and Elimination after Single/Repeated Oral and Intravenous Administration to Mice. Date: 1995-03-01, amended 1995-05-12	Yes	BASF SE
A6.2(06)	1996	14C-Triclosan: Absorption, Distribution and Excretion after Single Oral and Repeated Oral Administration to Male Rats. Date: 1996-07-17	Yes	BASF SE
A6.2/07		Investigation of the Binding of [redacted] to Human, Hamster and Mouse Plasma Proteins in Vitro.	Yes	BASF SE
A6.2/08	1990	SAFETY (TOLERANCE) AND PHARMACOKINETICS OF TRICLOSAN (TCS) - AN EXPERTISE -	Yes	BASF SE
A6.2/09	2001	[redacted] In Vitro Absorption through Pig Epidermis. Date: 2001-03-28 [redacted] [redacted] REG/REPT GLP:Yes Published:No	Yes	BASF SE
A6.3.1	1999	[redacted] 28-Day Oral Toxicity (Gavage)	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Study in the Wistar Rat Date: 1999-04-13 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No		
A6.3.2	2001	[redacted] 28 Day Dermal Toxicity Study in Rats (OECD EU). Date: 2001-06-13 [redacted] UK Report No. [redacted] GLP:Yes, Published:No	Yes	BASF SE
A6.4.1(01)	2001	[redacted] 13-Week Oral Toxicity (Gavage) Study in Wistar Rats. [redacted] Report No. Project No. [redacted] GLP:Yes; Published:No	Yes	BASF SE
A6.4.1(02)	1994	13-Week Oral Toxicity (Feeding) Study with [redacted] in the Hamster. Date: 1994-10-27; [redacted] Report No. Project No. [redacted] GLP:Yes; Published:No	Yes	BASF SE
A6.4.1(03)	1970	90 Days Oral Toxicity Study in Beagle Dogs with [redacted] Date: 1970-07-10 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.4.1(04)	1993	13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice. Date: 1993-01-28, [redacted] Project No. [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted]		
A6.4.1(05)	1983	90-Day Oral Toxicity Study in Rats with [redacted] Date: 1983-10-11 [redacted] Project No. [redacted]	Yes	BASF SE
A6.4.2	1994	90-Day Subchronic Dermal Toxicity Study in the Rat with Satellite Group with [redacted] Date: 1994-07-14 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.5 A6.7(1)	1986	[redacted] – 2-Year Oral Administration to Rats [redacted] Date: 1986-04-28 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.5 A6.7(2)	1999	[redacted] – Potential tumourigenic and chronic toxicity effects in prolonged dietary administration to hamsters. Date: 1999-03-30 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.6.1	1999	Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		with [redacted] Date: 1999-02-03 [redacted] Germany Report No. Project No. [redacted] GLP:Yes Published:No		
A6.6.2	1999	In Vitro Chromosome Aberration Assay in Chinese Hamster V79 Cells with [redacted] Date: 1999-01-22 [redacted] Report No. Project No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.6.3	2000	Cell Mutation Assay at the Thymidine Kinase Locus (TK+/–) in Mouse Lymphoma Cells with [redacted] Date: 2000-11-30 [redacted] Report No. Project No [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.6.4	1999	Micronucleus Assay in Bone Marrow Cells of the Mouse with [redacted] Date: 1999-06-09 [redacted] Report No. Project No [redacted] GLP:Yes Published:No	Yes	BASF SE
A6.6.5	2002	In Vivo / In Vitro Unscheduled DNA Synthesis in Rat Hepatocytes with [redacted] Date: 2002-01-30 [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] Report No. Project No.[redacted] GLP:Yes Published:No		
A6.8.1(01)	1992a	A Segment II Teratology Study with [redacted] (C-P Sample No.[redacted]). Date: 1992-04-16 [redacted] Report No. Project No.[redacted] GLP:Yes Published:No	Yes	BASF SE
A6.8.1(02)	1992b	A Segment II Teratology Study in Rabbits with [redacted] Date: 1992-04-16 [redacted] Report No. Project No.[redacted] GLP:Yes Published:No	Yes	BASF SE
A6.8.1(03)	1992c	A Range-Finding study to evaluate the toxicity of [redacted] in the pregnant rat Date: 1992-05-06 [redacted] Report No. Project No.[redacted] GLP: Yes; Published:No	Yes	BASF SE
A6.8.1(04)	1992d	A Range-Finding study to evaluate the toxicity of [redacted] in the pregnant rabbit. Date: 1992-04-16 [redacted] Report No. Project No.[redacted] GLP: Yes Published: No	Yes	BASF SE
A6.8.2	1988	Two-Generation Reproduction Study in	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Rats – [redacted] Date: 1988-03-18 [redacted] Report No. Study No. [redacted] GLP:Yes Published:No		
1994-09-16	1992	The Effect of [redacted] on Selected Biochemical and Morphological Liver Parameters Following Subchronic Dietary Administration to Male and Female Mice. Date: 1992-05-22 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.10(02)	1993	The Effects of [redacted] on Selected Biochemical and Morphological Liver Parameters Following Dietary Administration to Male Rats. Date: 1993-08-02 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.10(03)	1994	The Effect of [redacted] and the Model Inducers Phenobarbitone, 3-Methycholanthrene, Pregnenolone-16□-Carbonitrile and Nafenopin on Selected Biochemical and Morphological Liver Parameters in the Syrian Hamster.	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Date: 1994-09-16 [redacted] Report No. [redacted] GLP:Yes Published:No		
A6.10(04)	1993	Cell Proliferation in Rodent Liver. Date: 1993-01-13 [redacted] Report No. Docket No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.10(05)	1993	The Effect of [redacted] on Replicative DNA Synthesis in Hepatocytes Following Dietary Administration to Male Rats. Date: 1993-09-17 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.10(06)	1993	[redacted] – Assessment of Replicative DNA Synthesis in the Course of a 13-Week Oral Toxicity Study in the Hamster ([redacted] Project [redacted]). Date: 1994-09-19 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A6.12.1	2006	Occupational Health Management – [redacted] and formulation at Ciba Specialty Chemicals-site Grenzach Ciba Specialty Chemicals-site Grenzach,	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Germany, GLP:No, Published:No		
A7.1.1.1.1	1999g	Hydrolysis determination of [redacted] at different pH values Date: 1999-03-01 [redacted] Report No. [redacted] 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 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A7.1.1.1.2/02	2009	Aqueous Photolysis of DCPP; Metabolite Identification by LC/MS. Date: 2009-01-09 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A 7.1.1.2.1/02 IIA, VII 7.6.1.1 KEY-STUDY	2012	[redacted] (label: phenole-U-C14) (Radiolabelled [redacted] - 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. [redacted] Date: 2012-11-19 [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] Report [redacted] *GLP:Yes Published:No*		
A 7.1.1.2.1/02 IIA, VII 7.6.1.1 NON-KEY STUDY	1999a	Ready biodegradability of [redacted] in a Manometric Respirometry Test. Date: 1999-01-15 [redacted] Report No. Study Project No.: [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.1.1.2.1/03 IIA, VII 7.6.1.1 NON-KEY STUDY	2000	Biodegradation test of [redacted] by microorganisms Date: 2000-04-13 [redacted] No.: [redacted] CR GLP:Yes Published:No	Yes	BASF SE
A 7.1.1.2.1/04 IIA, VII 7.6.1.1 NON-KEY STUDY	2002	Ready biodegradability of [redacted] (Manometric Respirometry Test). Date: 2002-11-15 Amended: 2002-12-09 [redacted] Report No. [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.1.1.2.1/05 NON-KEY STUDY	1989	Report on the test for ready biodegradability of [redacted] in the modified sturm test. Date: 1989-02-28 [redacted] Project No.: [redacted] GLP:Yes	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Published:No		
A 7.1.1.2.1/06 NON-KEY STUDY	1990	Report on the modified MITI-Test - OECD 301 C - ready biodegradability of [redacted] Date: 1990-08-22 [redacted] Test No.: [redacted] GLP:Yes Published:No	No	BASF SE
A 7.1.1.2.1/07 KEY STUDY	2002	Ciba Specialty Chemicals Inc. (2002). Ready biodegradability of [redacted] (Manometric respirometry test), [redacted] report number: [redacted] report date: 04 Nov 2002 GLP:Yes Published:No	Yes	BASF SE
A 7.1.1.2.2 IIA, VII 7.6.1.2 KEY-STUDY	2001	Inherent biodegradability of [redacted] (Zahn-Wellens/EMPA – Test). Date: 2001-02-02 [redacted] Report No. Test No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.1.2.1.1/01 IIIA, XII.2.1 NON-KEY STUDY	2002	Activated sludge simulation test for the Biodegradability of [redacted] Date: 2002-01-25 [redacted] Report No. Test No. [redacted] GLP:No; Published:No	Yes	BASF SE
A 7.1.2.1.1/02 KEY-STUDY	1992	Assessing the removal of the test substance during secondary wastewater treatment: [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Date: 1992-08-01 [redacted] Report No [redacted] GLP:Yes Published:No		
A 7.1.2.1.1/03 KEY-STUDY	1998	Assessing the removal of the test substance during secondary wastewater treatment: [redacted] Date: 1998-03-16 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.1.2.1.1/04 NON-KEY STUDY	2002	Fate and effects of Triclosan in activated sludge Date for acceptance: 2001-12-05 The Procter & Gamble Company, Cincinnati, USA Environmental Toxicology and Chemistry, Vol. 21, No. 7 (2002), 1330-1337 GLP:No Published:Yes	No	-
A 7.1.2.1.2 IIIA 12.2	1994b	Triclosan - Determination of anaerobic aquatic biodegradation. Date: 14.04.1994 [redacted] Report No. SLI Report #[redacted] SLI Study #: [redacted] GLP:Yes Published:No	No	BASF SE
A 7.1.2.2.2/02 IIIA, XII 2.1	2006	^{14}C-Triclosan: Route and rate of degradation in aerobic aquatic sediment systems.	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Date: 2006-07-25 [redacted] Report No. Study Number: [redacted] GLP:Yes Published:No		
A 7.1.3/01 KEY-STUDY	2007b	Determination of Koc of DCPP according to OECD TG121 Date: 2007-04-24 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.1.3/02 IIA, VII 7.7	2006	Determination of Koc of Methoxytriclosan und DCPP according to OECD TG121 Date: 2006-11-14 [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A 7.1.3/03 KEY-STUDY	2013	BASF SE (2013). EPI Suite (v4.11, Nov. 2012) calculation for methyl-diclosan (CAS 4640-07-7). BASF SE, Department of Product Safety, Ludwigshafen, Germany. Date: 2013-05-29 (unpublished).	Yes	BASF SE
A 7.2.1/02 IIIA XII 1.1	2007	^{14}C-Triclosan: Degradation and metabolism in three soils incubated under aerobic conditions. Date: 2007-07-XX	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] Report No. [redacted] GLP:Yes Published:No		
A 7.2.1/03 IIIA XII 1.1	1994a	Triclosan - Determination of aerobic bio-degradation in soils. Date: 12.04.1994 [redacted] Report No. [redacted] Report [redacted] Study #: [redacted] GLP:Yes Published:No	No	BASF SE
A.7.3.1	2007a	DCPP. Calculation of indirect photodegradation. Date: 2007-02-02. [redacted] Report No. [redacted] GLP:No Published:No	Yes	BASF SE
A 7.4.1.1/01 KEY STUDY	1999b	Acute toxicity of [redacted] to zebra fish (Brachydanio rerio) in a 96-hour static test. Date: 1999-04-06 [redacted] Report No. [redacted] GLP: Yes Published: No	Yes	BASF SE
A 7.4.1.1/02	2000	Acute toxicity of [redacted] to zebra fish (*Brachydanio rerio*) in a 96-hour semi-static test. Date: 2000-07-03 [redacted] Report	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		No. [redacted] GLP: Yes Published: No		
A 7.4.1.1/03	1985	Akute Fischtoxizität (Acute fish toxicity of methyl triclosan) Date: 1985-02-13 [redacted] Report No. [redacted] GLP: No Published: No	Yes	BASF SE
A 7.4.1.1/04 KEY-STUDY	2003	Ciba Spezialitätenchemie AG (2003). Determination of 96h LC50 of [redacted] in an Acute Toxicity Test with the fish Danio rerio – Static Test. [redacted] Report no. [redacted], Date: 2003-03-31 (unpublished)	Yes	BASF SE
A 7.4.1.1/05	2001	Ciba Specialty Chemicals Inc (2001). Acute toxicity of [redacted] to zebra fish (96 hour screening test-OECD 203). [redacted] Report no. [redacted] Date: 2001-11-22 (unpublished)	Yes	BASF SE
A 7.4.1.2/01 KEY-STUDY	1999c	Acute toxicity of [redacted] to Daphnia magna in a 48-hour immobilization test. Date: 1999-01-20 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.4.1.2/02	2006a	Methyl-triclosan: Acute toxicity to *Daphnia*	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		magna in a 48-hours immobilisaiton test. Date: 2006-07-19 [redacted] Study-No. [redacted] GLP:Yes Published:No		
A 7.4.1.2/03 KEY-STUDY	2003	Ciba Spezialitätenchemie AG (2003). Determination of 48hEC50i of [redacted] in an Acute Immobilization Test with Daphnia magna. [redacted] Report no. [redacted]. Date: 2003-03-31 (unpublished)	Yes	BASF SE
A 7.4.1.2/04	2001	Ciba Specialty Chemicals Inc (2001). Acute toxicity of [redacted] to Daphnia magna (48 hour screening test-OECD 202). [redacted] Report no. [redacted]. Date: 2001-11-22 (unpublished)	Yes	BASF SE
A 7.4.1.3/01 KEY-STUDY	1999d	Acute toxicity of [redacted] to Scenedesmus subspicatus in a 72-hour algal growth inhibition test. Date: 1999-04-06 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.4.1.3/02	2006b	Methyl-triclosan: Toxicity to *Scenedesmus subspicatus* in a 72-hour algal growth inhibition test. Date: 2006-07-24	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] Study-No[redacted] GLP:Yes Published:No		
A 7.4.1.3/03	2003	Ciba Spezialitätenchemie (2003). Determination of 72h EC50 of[redacted] using Desmodesmus subspicatus.[redacted] Report no. [redacted] Date: 2003-07-30 (unpublished)	Yes	BASF SE
A 7.4.1.3/04	2001	Ciba Specialty Chemicals Inc (2001). Acute toxicity of[redacted] to green algae (72 hour screening test-OECD 201).[redacted] Report no.[redacted] Date: 2001-12-06 (unpublished)	Yes	BASF SE
A 7.4.1.4/01 KEY-STUDY	1999e	Toxicity of[redacted] to activated sludge in a respiration inhibition test. Date: 1999-03-11 [redacted] Report No.[redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.4.1.4/02 KEY-STUDY	2003	Ciba Spezialitätenchemie AG (2003). Determination of the inhibition of the respiration of activated sludge when exposed to [redacted] Report no.	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] Date: 2003-04-01 (unpublished)		
A 7.4.1.4/03	2001	Ciba Specialty Chemicals Inc (2001). Bacteria toxicity (IC_{50}) of [redacted] (Activated sludge respiration inhibition test – OECD 209) [redacted] Report no. [redacted] Date: 2001-18-28 (unpublished)	Yes	BASF SE
A 7.4.2	2007b	DCPP. Calculation of the Bioconcentration Factor (BCF). Date: 2007-02-12. [redacted] Report No. KC-[redacted] GLP:No Published:No	Yes	BASF SE
A 7.4.3.2/02 KEY-STUDY	1996	Early Life-Stage Toxicity of Triclosan to the rainbow trout (Oncorhynchus mykiss) under flow-through conditions. Date: 1996-11-27 [redacted] Report-No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.4.3.3.1/01 KEY-STUDY	2000	Bioconcentration test of [redacted] in carp (Cyprinus carpio). Date: 2000-05-08 [redacted] Report No. [redacted] CR GLP:Yes Published:No	Yes	BASF SE
A 7.4.3.3.1/02 KEY-STUDY	2003	Ciba Spezialitätenchemie AG (2003). Determination of bioconcentration of [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] in the flow-through fish test, using the species Danio rerio. Date: 2003-06-24 [redacted] Report no. [redacted] GLP:Yes Published:No		
A 7.4.3.4/01 KEY-STUDY	1999	Influence of [redacted] on survival and reproduction of Daphnia magna in a semistatic test over three weeks. Date: 1999-11-02 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A7.4.3.4/02 KEY-STUDY	2001	Ciba Spezialitätenchemie AG (2003). Determination of the effect on reproduction of Daphnia magna after exposition to [redacted] Report no. [redacted] Date: 2001-04-01 (unpublished).	Yes	BASF SE
A 7.4.3.5.1/02 KEY-STUDY	2006	Triclosan: Effects on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system with spiked sediment. Date: 2006-07-17 [redacted]	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		Report-No. [redacted] GLP:Yes Published:No		
A 7.4.3.5.2	1997	Effect of Triclosan on the Growth and Reproduction of Aquatic Plants. Date: 1997-10-13 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.1.1/02 KEY-STUDY	2007a	The Effects of Triclosan on Soil Respiration. Date: 2007-02-21 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A7.5.1.1/03 KEY-STUDY	2007b	The Effects of Triclosan on Soil Nitrification. Date: 2007-02-21 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.1.2 KEY-STUDY	2001	Acute Toxicity of [redacted] to the Earthworm, Eisenia fetida. Date: 2001-07-03 [redacted] Report No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.1.3/02 KEY STUDY	1992	[redacted] – Determination of effects on seedling growth of six plant species. Date: 1992-06-23 [redacted] Report #: [redacted] Study #:	Yes	The Procter & Gamble Company

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		[redacted] GLP:Yes Published:No		
A 7.5.1.3/03 IIIA, XIII 3.4	1997	FDA Seedling Growth Phytotoxicity Test. Date: 1997-04-07 [redacted] Report-No. [redacted](Sponsor Study-No.[redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.1.3/04	2011	Evaluation of seedling emergence and growth using OECD Guideline 208 Test Date: 2011-05-25 [redacted] Report-No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.2.1/01 KEY-STUDY	2010	Effects of[redacted] (Triclosan) on Survival, Growth, and Reproduction of the Earthworm *Eisenia fetida*. [redacted] Study report Nr.[redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.2.1/02 KEY-STUDY	2010	[redacted](Triclosan) Effects on Reproduction of the Soil Predatory Mite *Hypoaspis aculeifer* (Gamasida: Laelapidae), [redacted] Laboratories Study report Nr.[redacted] 24-Mar-2010	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
		GLP:Yes Published:No		
A 7.5.2.1/03 KEY-STUDY	2014	Effects of Benzene, 4-chloro-1—(chlorophenoxy)-2-methoxy- on the reproduction of the predatory mite, *Hypoaspis aculeifer*; [redacted] project No: [redacted] BASF project No.: [redacted] 17-Jun-2014 GLP:Yes Published:No	Yes	BASF SE
A 7.5.3.1.1/01 IIIA, XIII 1.1	1993a	Triclosan [redacted]: 14-Day Acute Oral LD_{50} Study in Bobwhite Quail. Date: 1993-04-19 [redacted] Report-No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.3.1.1/02	1993b	Triclosan ([redacted]14-Day Acute Oral LD_{50} Study in Mallard Ducks. Date: 1993-03-29 [redacted] Report-No. [redacted] GLP:Yes Published:No	Yes	BASF SE
A 7.5.3.1.2/02 KEY-STUDY	1993c	Triclosan ([redacted]): 8-Day Acute Dietary LC_{50} Study in Bobwhite Quail. Date: 1993-04-19 [redacted] Report-No. [redacted] GLP:Yes Published:No	Yes	BASF SE

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
A8	2007	Safety Data Sheet DCPP. Date: 2007-12-14 Ciba AG, Basel, Switzerland Report No. -- GLP:No Published:No	--	BASF SE

Methyl-DCPP

Section No / Reference No	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protec-tion	Owner
A3.1.02.EPISuite, M-DCPP	2013	Calculation of boiling point of MeDCPP using software program EPI Suite v4.11 (online query 29.05.2013)	Yes	BASF SE
A3.1.02.SciFinder, M-DCPP	2013	Calculation of boiling point of MeDCPP using software program ACD/Labs v11.02 cited in SciFinder (online query 05.08.2013), unpublished	Yes	BASF SE
A3.1.03.SciFinder, M-DCPP	2013	Calculation of density of MeDCPP using software program ACD/Labs v11.02 cited in SciFinder (online query 05.08.2013), unpublished	Yes	BASF SE
A3.2/01.EPISuite, M-DCPP	2013	Calculation of vapour pressure of MeDCPP using software program EPI Suite v4.11 (online query 29.05.2013)	Yes	BASF SE
A3.2/02.SciFinder, M-DCPP		Calculation of vapour pressure of MeDCPP using software program ACD/Labs v11.02 cited in SciFinder (online query 05.08.2013), unpublished	Yes	BASF SE
A3.2/01.EPISuite, M-DCPP	2013	Calculation of Henry´s Law constant for MeDCPP using software program EPI Suite v4.11 (online query 29.05.2013), unpublished	Yes	BASF SE
A3.4.M-DCPP	2002	Ciba Specialty Chemicals Inc., TAOH (Trace Analysis & Occupational Hygiene), CH-4002 Basel, Switzerland Chemical Characterisation of	Yes	BASF SE

		Synthesised 4,4'-dichloro-2'-methoxydiphenyl-ether. Report no 02.248, non GLP, [redacted] unpublished		
A3.5. M-DCPP	2003	Ciba Specialty Chemicals Inc. Determination of the water solubility of [redacted] using the column elution method by [redacted] Report no A[redacted], GLP, 10.03.2003, unpublished	Yes	BASF SE
A3.9.EPISuite, M-DCPP	2013	Calculation of partition coefficient n-octanol/water for MeDCPP using software program EPI Suite v4.11 (online query 29.05.2013)	Yes	BASF SE
A3.9.SciFinder, M-DCPP	2013	Calculation of partition coefficient n-octanol/water for MeDCPP using software program ACD/Labs v11.02 cited in SciFinder (online query 05.08.2013), unpublished	Yes	BASF SE

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE –ADDITIONAL LITERATURE

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Allmyr M, Panagiotidis G, Sparve E, Diczfalusy U, Sandborgh-Englund G	2009	Human exposure to triclosan via toothpaste does not change CYP3A4 activity or plasma concentrations of thyroid hormones *Basic Clin Pharmacol Toxicol 2009 November;105(5):339-44*	No	Published
Barret, P et al	2007	Hypothalamic thyroid hormone catabolism acts as a gatekeeper for the seasonal control of body weight and reproduction *Endocrinology 148(8):3608-17*	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Bentley, P. *et al.*	1993	Hepatic Peroxisome Proliferation in Rodents and its Significance for Humans. *Fd. Chem. Toxic.*,**31**, 857-907	No	Published
Boas M, Feldt-Rasmussen U, Skakkebaek NE, Main KM	2006	Environmental chemicals and thyroid function *Eur J Endocrinol; 154(5):599-611*	No	Published
Carmichael NG, Enzmann H, Pate I, Waechter F	1997	The significance of mouse liver tumour formation for carcinogenic risk assessment: results and conclusions from a survey of ten years of testing by the agrochemical industry *Environ. Health Perspect. 105:1196-1203*	No	Published
Cattley, R.C. *et al.*	1998	Do peroxisome proliferating compounds pose a hepatocarcinogenic hazard to humans? *Regul Toxicol Pharmacol.* **27**, 47-60.	No	Published
Cherednichenko G, Zhanga R, Bannisterb RA, Timofeyevc V, Lic N, Fritscha EB, Fenga W, Barrientosa GC, Schebbd NH, Hammockd BD, Beame KG, Chiamvimonvatc N, Pessaha IN	2012	Triclosan impairs excitation-contraction coupling and Ca2+ dynamics in striated muscle *Proc Natl Acad Sci USA. 28;109 (35): 14158-63*	No	Published
Chevrier C, Petit C, Philippat C, Mortamais M, Slama R, Rouget F	2012	Maternal Urinary Phthalates and Phenols and Male Genital Anomalies *Epidemiology 2012 March;23(2):353-6*	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Cooney, C.M.,	2010	Triclosan Comes under Scrutiny *Env. Health Perspect. 118(6), A242.*	No	Published
Crofton, K.M., Paul, K.B., Hedge, J.M., DeVito, M.J.	2007	Short-term in vivo exposure to the water contaminant triclosan: evidence for disruption of thyroxine *Environ. Toxicol. Pharmacol. 24, 194-7.*	No	Published
Crump, K.	1984	A new method for determining allowable daily intakes *Fundam. Appl. Toxicol. 4, 854-71*	No	Published
Dayan, A.D.	2007	Risk assessment of triclosan [redacted] in human breast milk *Food Chem. Toxicol. 45, 125-9*	No	Published
Doull, J. *et al.*	1999	A cancer risk assessment of di(2-ethylhexyl)phthalate: application of the new U.S. EPA Risk Assessment Guidelines *Regul Toxicol Pharmacol.* **29**, 327-57.	No	Published
European Chemicals Agency (Ed.)	2008	Guidance on information requirements and chemical safety assessment. Chapter R.10: Characterisation of dose [concentration]-response for environment. (RIP 3.2) Date: May 2008 European Chemicals Agency (ECHA), Helsinki, Finland	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
European Commission (Editor)	2003	TGD for Risk Assessment (2003): Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Commission Directive 98/8/EEC concerning the Placing of Biocidal Products on the market. EC, JointResearchCenter, Institute for Health and Consumer Protection	No	Published
European Commission (Editor)	2011	Manula of Technical Agrrements, Biocides Technical Meeting, Version 4; http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/new-version-of-mota-manual-of-technical-agreements-published	No	Published
European Commission (Editor)	2004	Guidance Document on Dermal Absorption, European Commission, 2004 http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc20_rev_en.pdf	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Foran CM, Bennett ER, Benson WH	2000	Developmental evaluation of a potential non-steroidal estrogen: triclosan. *Mar Environ Res; 50(1-5):153-6.*	No	Published
Guyton KZ, Weihsueh AC, Bateson TF, Jinot J, Siegel Scott J, Broen RC, Caldwell JC	2009	A Reexamination of the PPAR-α Activation Mode of Action as a Basis for Assessing Human Cancer Risks of Environmental Contaminants *Env Health Perspectives, 117(11); 2009*	No	Published
Haddow, J.E., Palomaki, G.E., Allan, W.C., Williams, J.R., Knight, G.J., Gagnon, J., O`Heir, C.E., Mitchell, M.L., Hermos, R.J., Waisbren, S.E., Faix, J.D., Klein, R.Z.	1999	Maternal thyroid deficiency during pregnancy amd subsequent neurophysiological development of the child *N. Eng. J. Med. 341, 549-55*	No	Published
Ishibashi, H., Matsumura, N., Hirano, M., Matsuoka, M., Shiratsuchi, H., Ishibashi, Y., Takao, Y., Arizono, K.	2004	Effects of triclosan on the early life stages and reproduction of medaka *Oryzias latipes* and induction of hepatic vitellogenin. *Aquat Toxicol 67: 167 – 179*	No	Published
Jacobs MN, Nolan GT, Hood SR	2005	Lignans, bacteriocides and organochlorine compounds activate the human pregnane X receptor (PXR)	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Kluwe, W.M.	1994	The Relevance of Hepatic Peroxisome Proliferation in Rats to Assessment of Human Carcinogenic Risk for Pharma-ceuticals. T*oxicol Appl Pharmacol; 209(2):123-33*	No	Published
Kretschmer XC & Baldwin WS	2005	CAR and PXR: Xenosensors of endocrine disrupters? *Chemico-Biological Interactions 155(2005)111-128*	No	Published
Kumar, V., Chakraborty, A., Kural, M.R., Roy, P.	2009	Alteration of testicular steroidogenesis and histopathology of reproductive system in male rats treated with triclosan *Reprod. Toxicol. 27, 177-85.*	No	Published
Lachapelle, J.M. and Tennstedt, D.	1979	Low Allergenicity of Triclosan. Predictive Testing in Guinea Pigs and in Humans *Dermatologica***158**, 379-383	No	Published
Lake, B.G.	1995	Mechanisms of Hepatocarcino-genicity of Peroxi-someProliferating Drugs and Chemicals. *Annu. Rev. Pharmacol. Toxicol.***35**, 483-507	No	Published
Maurer, T. *et al.*	1979	Predictive evaluation in animals of the contact allergenic potential of medically important substances: II. Comparison of different methods of cutaneous sensitisation with "weak" allergens. *Contact Dermatitis***5**, 1-10	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Miller MD, Crofton KM, Rice DC, Zoeller T	2009	Thyroid-Disrupting Chemicals: Interpreting Upstream Biomarkers of Adverse Outcomes *Environ Health Perspect; 117(7): 1033-1041*	No	Published
Moss, T. *et al.*	2000	Percutaneous Penetration and Dermal Metabolism of Triclosan (2,4,'4'-Trichloro-'2'-hydroxydiphenyl Ether)	No	Published
National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the Australian Government	2009	Triclosan, January 2009.	No	Published
Nielsen, E, Ostergard G, Larsen JC	2008	Toxicological risk assessment of chemicals: a practical guide	No	Published
Philippat C, Mortamais M, Chevrier C, Petit C, Calafat AM, Ye X	2012	Exposure to Phthalates and Phenols during Pregnancy and Offspring Size at Birth *Environ Health Perspect 2011, September 7*	No	Published
Parkinson TJ & Follett BK	1994	Effect of thyroidectomy upon seasonality in rams *J Reprod Fertil, 101:51-58*	No	Published
Parzefall W, Berger W, Kainzbauer E, Teufelhofer O, Schulte-Hermann R, Thurman RG	2001	Peroxisome proliferators do not increase DNA synthesis in purified rat hepatocytes *Carcinogenesis 22(3): 519-523*	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Paul, K.B., Hedge, J.M., DeVito, M.J., Crofton, K.M.	2010	Developmental Triclosan Exposure Decreases Maternal And Neonatal Thyroxine in Rats *Environ. Toxicol. Chem. 29(12), 2840-4.*	No	Published
Philippat C, Mortamais M, Chevrier C, Petit C, Calafat AM, Ye X	2011	Exposure to Phthalates and Phenols during Pregnancy and Offspring Size at Birth *Environ Health Perspect 2011 September 7*	No	Published
Rao, M.S. & Reddy, J.K.	1991	An Overview of Peroxisome Proliferator-Induced Hepatocarcinogenesis *Env. Health Persp.*, **93**, 205-9	No	Published
Richert, L. *et al.*	1996	Comparison of the Induction of Hepatic Peroxisome Proliferation by the Herbicide Oxadiazon *in Vivo* in Rats, Mice, and Dogs and *in Vitro* in Rat and Human Hepatocytes *Toxicol Appl Pharmacol.*,**141,** 35-43	No	Published
Rodricks, J.V., Swenberg, J.A., Bozelleca, J.F., Maronpot, R.R., Shipp, A.m.	2010	Triclosan: A critical review of the experimental data and development margins of safety for consumer products *Critical reviews in toxicology, 2010,; 40(5): 422-484*	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Rodríguez,P.E.A. Sanchez, M.S.	2010	Maternal exposure to triclosan impairs thyroid homeostasis and female pubertal development in Wistar rat offspring *J Toxicol Environ. Health, Part A. 73, 1678-88.*	No	Published
Statistisches Landesamt Freistaat Sachsen	2012	Entsorgung von Klärschlamm aus öffentlichen biologischen Abwasserbehandlungsanlagen im Freistaat Sachsen, Korrekturausgabe 2012.	No	Published
Stoker, T.E., Gibson, E.K., Zorilla, L.M.,	2010	Triclosan Exposure Modulates Estrogen-Dependent Responses in the Female Rat *Tox. Sci. 117(1), 45-53*	No	Published
U.S. Environmental Protection Agency	2010	Triclosan Facts Available: http://www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm (accessed 3 November 2010)	No	Published
U.S. Food and Drug Administration	2010	Triclosan: What Consumers Should Know Available: http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm (accessed 3 November 2010)	No	Published
Versteeg, D.J., Belanger, S.E., Carr, G.J.	1999	Understanding single-species and model ecosystem sensitivity: data-based comparison. *Environmental Toxicology and Chemistry, 18 (6): 1329 - 1346*	No	Published

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Veldhoen, N., Skirrow, R.C., Osachoff, H., Wigmore, H., Clapson, D.J., Gunderson, M.P., Van Aggelen, G., Helbing, C.C.	2006	The bactericidal agent triclosan modulates thyroid hormone-associated gene expression and disrupts postembryonic anuran development *Aquat. Toxicol. 80, 217-27.*	No	Published
Williams GM	1997	Chemicals with carcinogenic activity in the rodent liver; mechanistic evaluation of human risk *Cancer Lett. 117:175-188*	No	Published
Wolff MS, Teitelbaum SL, Windham G, Pinney SM, Britton JA, Chelimo C	2007	Pilot study of urinary biomarkers of phytoestrogens, phthalates, and phenols in girls *Environ Health Perspect 2007 January;115(1):116-21*	No	Published
Wolff MS, Engel SM, Berkowitz GS, Ye X, Silva MJ, Zhu C	2008	Prenatal phenol and phthalate exposures and birth outcomes *Environ Health Perspect 2008 August;116(8):1092-7*	No	Published
Wolff MS, Teitelbaum SL, Pinney SM, Windham G, Liao L, Biro F	2010	Investigation of relationships between urinary biomarkers of phytoestrogens, phthalates, and phenols and pubertal stages in girls *Environ Health Perspect 2010 July;118(7):1039-46*	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
Woodyatt, N.J. *et al.*	1999	The peroxisome proliferator (PP) response element upstream of the human acyl CoA oxidase gene is inactive among a sample human population: significance for species differences in response to PPs. *Carcinogenesis*, **20**, 369-72	No	Published
Yoshimura T, Yasuo S, Watanabe M, Iigo M, Yamamura T, Hirunagi K, Ebihara S	2003	Light-induced hormone conversion of T4 to T3 regulates photoperiodic response of gonads in birds *Nature 426:178-181*	No	Published
Zorilla, L.M., Gibson, E.K., Jeffay, S.C., Crofton, K.M., Setzer, W.R., Cooper, R.L., Stoker, T.E.	2009	The effects of triclosan on puberty and thyroid hormones in male Wistar rats. *Toxicol. Sci. 107, 56-64.*	No	Published

LIST OF STUDIES FOR THE ACTIVE SUBSTANCE –ADDITIONAL LITERATURE ON RESISTANCE

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
European Comission	2009	SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Assessment of the Antibiotic Resistance Effects of Biocides, 19 January 2009	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
European Comission	2010	SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Research strategy to address the knowledge gaps on the antimicrobial resistance effects of biocides, 17 March 2010	No	Published
European Comission	2010	Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on triclosan (antimicrobial resistance), 22 June 2010	No	Published
Bamber A. I., Neal T. J.	1999	An assessment of triclosan susceptibility in methicillin-resistant and methicillin-sensitive *Staphylococcus aureus* Journal of Hospital Infection (1999) 41: 107-109	No	Published
Frank Fan et al.	2002	Defining and Combating the Mechanisms of Triclosan Resistance in Clinical Isolates of *Staphylococcus aureus* ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, Nov. 2002, p. 3343–3347 Vol. 46, No. 11	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
A D Russell	2003	Biocide use and antibiotic resistance: the relevance of laboratory findings to clinical and environmental situations THE LANCET Infectious Diseases Vol 3 December 2003, p 794-803	No	Published
R Chuanchen et al.	2001	Cross-Resistance between Triclosan and Antibiotics in *Pseudomonas aeruginosa* Is Mediated by Multidrug Efflux Pumps: Exposure of a Susceptible Mutant Strain to Triclosan Selects *nfxB* Mutants Overpressing MexCD-OprJ Antimicrobial Agents and Chemotherapy, Feb. 2001, Vol 45, No. 2, p. 428-432	No	Published
R Chuanchen et al.	2003	High-level triclosan resistance in Pseudomonas aeruginosa is solely a result of efflux Am J Infect Control 2003;31:124-7.	No	Published

Authors (s)	Year	Title	Data Protection Claimed (Yes/No)	Data Owner
K. L. Beinlich, R. Chuanchuen, H. P Schweizer	2001	Contribution of multidrug efflux pumps to multiple antibiotic resistance in veterinary clinical isolates of *Pseudomonas aeruginosa* FEMS Microbiology Letters 198 (2001) p. 129-134	No	Published
R. J. Heath, S. W. White, C. O. Rock	2001	Lipid biosynthesis as a target for antibacterial agents Progress in Lipid Research 40 (2001) 467–497	No	Published
Ciusa ML, Furi L, Knight D et al.	2012	A novel resistance mechanism to triclosan that suggests horizontal gene transfer and demonstrates a potential selective pressure for reduced biocide susceptibility in clinical strains of *Staphylococcus aureus*. Int J Antimicrob Agents. 2012 Sep;40(3):210-20.	No	Published

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT– SORTED BY SECTION NUMBER

PT1

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B3.1/01	2007	Physical parameters of a liquid hand soap containing Ciba DCPP (5-chloro-2-(4-chlorphenoxy) phenol). Date: 2007-05-23 CONFIDENTIAL Ciba Specialty Chemicals, Business Line Home & Personal care, Basle, Switzerland Report No. [redacted] GLP: No Published: No	Yes	BASF SE
B3.6/01	2007	Disinfectant cleaner density (25 °C). Date: 2007-07-20 CONFIDENTIAL Ciba Spezialitätenchemie Grenzach GmbH, Segment PA, BL Home & Personal Care Report No. – GLP: No Published: No	Yes	BASF SE
Wieser, E.	2007	Quantification of DCPP in commercial products. Date: 2007-06-18 Ciba Spezialitätenchemie Grenzach GmbH, Grenzach, Germany Report No. – GLP: No Published: No	Yes	BASF SE
B5.10/01	2007	Determination of the anti-microbial activity of a Liquid Hand Soap containing Ciba® DCPP (5-chloro-2-(4-chlorphenoxy)phenol). Ciba Specialty Chemicals, [redacted], Technical Report No. [redacted] date: 2007-04-20 GLP: No Published: No	Yes	BASF SE

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B5.10/02	2004	Determination of the antimicrobial activity of a floor cleaner, a liquid hand soap and a dishwashing liquid containing Ciba TINOSAN® HP 100 antimicrobial. Ciba Specialty Chemicals, [redacted] Technical Report No. [redacted] date: 2004-08-13 GLP: No Published: No	Yes	BASF SE
B8.	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE

PT2

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B3.1/01	2007	Physical parameters of an All Purpose Cleaner containing Ciba DCPP (5-chloro-2-(4-chlorphenoxy) phenol). Date: 2007-05-23 CONFIDENTIAL; Ciba Specialty Chemicals, Business Line Home & Personal care, Basle, Switzerland Report No. [redacted] GLP: No Published: No	Yes	BASF SE
B3.6/01	2007	Disinfectant cleaner density (25 °C). Date: 2007-07-20 CONFIDENTIAL Ciba Spezialitätenchemie Grenzach GmbH, Segment PA, BL Home & Personal Care Report No. – GLP: No Published: No	Yes	BASF SE
B5.10/01	2007	Determination of the bactericidal activity of an All Purpose Cleaner containing [redacted]DCPP (5-chloro-2-(4-chlorphenoxy)phenol). Ciba Specialty Chemicals, [redacted], Technical Report No [redacted], date: 2007-04-23 GLP: No Published: No	Yes	BASF SE
B5.10/02	2004	Determination of the antimicrobial activity of a Surface cleaner containing Ciba® TINOSAN®HP 100 antimicrobial. Ciba Specialty Chemicals, [redacted], Technical Report No. [redacted], date: 2004-05-13 GLP: No Published: No	Yes	BASF SE

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B5.10/03	2005a	Determination of the bactericidal activity of 4 antibacterial floor cleaners containing Ciba® TINOSAN® HP 100 on treated flooring material. [redacted], Technical Report No. [redacted], date: 2005-08-15 GLP: No Published: No	Yes	BASF SE
B5.10/04	2005 b	Determination of the antimicrobial activity of a liquid toilet containing Ciba® TINOSAN® HP 100 antimicrobial. Ciba Specialty Chemicals, [redacted], Technical Report No. [redacted], date: 2005-02-21 GLP: No Published: No	Yes	BASF SE
B5.10(05) IIB, V 5.10	2007	Determination of the bactericidal activity of an All Purpose Cleaner containing [redacted]DCPP (5-chloro-2-(4-chlorphenoxy)phenol). Date: 2007-04-23 Ciba Specialty Chemicals Report No. [redacted]Technical Report No. [redacted] GLP: No Published: No	Yes	BASF SE
B8.1(01) IIB, VIII 8.1 also filed B8.2(01) also filed B8.4(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B8.2(01) IIB, VIII 8.2 also filed B8.1(01) also filed B8.4(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.4(01) IIB, VIII 8.4 also filed B8.1(01) also filed B8.2(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.5(01) IIB, VIII 8.5 also filed B8.1(01) also filed B8.2(01) also filed B8.4(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.6(01) IIB, VIII 8.6 also filed B8.1(01) also filed B8.2(01) also filed B8.4(01) also filed B8.5(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE

PT4

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B3.1/01	2007	Physical parameters of a dishwashing liquid containing Ciba DCPP (5-chloro-2-(4-chlorphenoxy) phenol). Date: 2007-05-23 CONFIDENTIAL Ciba Specialty Chemicals, Business Line Home & Personal care, Basle, Switzerland Report No. [redacted] GLP: No Published: No	Yes	BASF SE
B3.6/01	2007	Disinfectant cleaner density (25 °C). Date: 2007-07-20 CONFIDENTIAL Ciba Spezialitätenchemie Grenzach GmbH, Segment PA, BL Home & Personal Care Report No. – GLP: No Published: No	Yes	BASF SE
B5.10/01	2007	Determination of the anti-microbial activity of a Dishwashing Liquid containing [redacted]® DCPP (5-chloro-2-(4-chlorphenoxy)phenol). Ciba Specialty Chemicals, [redacted] Technical Report No. [redacted], date: 2007-04-20 GLP: No Published: No	Yes	BASF SE

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B5.10/02	2006	Determination of the bactericidal activity of a Dishwashing detergent containing Ciba® TINOSAN®HP 100 anti-microbial. Ciba Specialty Chemicals, [redacted] Technical Report No. [redacted] date: 2006-07-28 GLP: No Published: No	Yes	BASF SE
B8.1(01) IIB, VIII 8.1 also filed B8.2(01) also filed B8.4(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.2(01) IIB, VIII 8.2 also filed B8.1(01) also filed B8.4(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.4(01) IIB, VIII 8.4 also filed B8.1(01) also filed B8.2(01) also filed B8.5(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE

(Sub)Section / Annex point	Year	Title Source Institution; report nr; GLP-status; Published or unpublished;	Data Protection Claimed (Yes/No)	Data Owner
B8.5(01) IIB, VIII 8.5 also filed B8.1(01) also filed B8.2(01) also filed B8.4(01) also filed B8.6(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE
B8.6(01) IIB, VIII 8.6 also filed B8.1(01) also filed B8.2(01) also filed B8.4(01) also filed B8.5(01)	2007	Safety Data Sheet Disinfectant cleaner. Date: 2007-05-29 Ciba Spezialitäten-chemie AG, Basel, Switzerland Report No. – GLP: No Published: No	No	BASF SE

APPENDIX IV-1: STANDARD TERMS AND ABBREVIATIONS

Note: The technical terms “active ingredient” and “active substance” are equivalent

Stand. Term / Abbreviation	Explanation
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein

Stand. Term / Abbreviation	Explanation
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
CAS	Chemical Abstracts Service
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
CSF	Confidential Statement of Formula
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DFR	Dislodgeable Foliar Residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority

Stand. Term / Abbreviation	Explanation
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRES	Dietary Risk Evaluation System
DRP	detailed review paper *(OECD)*
DSC	Differential scanning calorimetry
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWEL	Drinking Water Equivalent Level
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E_bC_{50}	median effective concentration, biomass
E_rC_{50}	median effective concentration, growth rate
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EEC	Estimated Environmental Concentration
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EPMA	electron probe micro-analysis
ERL	extraneous residue limit

Stand. Term / Abbreviation	Explanation
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FDA	Food and Drug Administration
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal

Stand. Term / Abbreviation	Explanation
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMM	genetically modified micro-organism
GMO	genetically modified organism
GPC	gel-permeation chromatography
GPS	global positioning system
GRAS	Generally Recognized As Safe as designated by FDA
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
HA	Health Advisory
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography

Stand. Term / Abbreviation	Explanation
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient

Stand. Term / Abbreviation	Explanation
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD	Lethal Dose-low
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LEL	Lowest Effect Level
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOC	Level of Concern
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre

Stand. Term / Abbreviation	Explanation
M	molar
µm	micrometer (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MATC	Maximum Acceptable Toxicant Concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCLG	Maximum Contaminant Level Goal
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLD	median lethal dose
MLT	minimum lethal time
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
Mp	melting point
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRE	maximum residue expected
MRID	Master Record Identification (number).
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid

Stand. Term / Abbreviation	Explanation
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a., N/A	not applicable
n-	normal (defining isomeric configuration)
N	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPDES	National Pollutant Discharge Elimination System
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances

Stand. Term / Abbreviation	Explanation
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants

Stand. Term / Abbreviation	Explanation
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion ($10^{-24)}$
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PRN	Pesticide Registration Notice
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
Q*1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
RED	Reregistration Eligibility Decision
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid

Stand. Term / Abbreviation	Explanation
RRT	relative retention time
RS	Registration Standard
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
ssp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)

Stand. Term / Abbreviation	Explanation
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TC	Toxic Concentration
TCD	thermal conductivity detector
TD	Toxic Dose
TDR	time domain reflectrometry
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TEP	Typical End-Use Product
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGAI	Technical Grade Active Ingredient
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon

Stand. Term / Abbreviation	Explanation
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TTC	Toxicological-Threshold-of-Concern
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
Wk	week
WP	Wettable Powder
WPS	Worker Protection Standard
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
Yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

APPENDIX IV-2: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances

Abbreviation	Explanation
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation

Abbreviation	Explanation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund