

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

*Evaluation of active substances*

Assessment Report



## **Chlorocresol (CMK)**

Product-type PT 2  
(Private area and public health area  
disinfectants and other biocidal products)

April 2016

France

**CONTENTS**

<b>1. STATEMENT OF SUBJECT MATTER AND PURPOSE</b> .....	<b>4</b>
<b>1.1. Procedure followed</b> .....	<b>4</b>
<b>1.2. Purpose of the assessment report</b> .....	<b>4</b>
<b>2. OVERALL SUMMARY AND CONCLUSIONS</b> .....	<b>5</b>
<b>2.1. Presentation of the Active Substance</b> .....	<b>5</b>
2.1.1. Identity .....	5
2.1.2. Physico-chemical properties .....	5
2.1.3. Methods of analysis.....	6
<b>2.2. Presentation of the Representative product</b> .....	<b>6</b>
2.2.1. Identification of the biocidal product.....	6
2.2.2. Physico-chemical properties .....	6
2.2.3. Methods of analysis.....	7
<b>2.3. Intended Uses and Efficacy</b> .....	<b>7</b>
2.3.1. Field of use.....	7
2.3.2. Function.....	7
2.3.3. Mode of action.....	7
2.3.4. Effects on target organisms.....	7
2.3.5. Resistance.....	8
<b>2.4. Classification and Labelling</b> .....	<b>8</b>
2.4.1. Current classification of the active substance .....	8
2.4.2. Proposed classification for the active substance .....	9
2.4.3. Proposed classification for the product.....	10
<b>2.5. Summary of the Risk Assessment</b> .....	<b>10</b>
2.5.1. Human Health Risk Assessment.....	10
2.5.1.1. Hazard identification and effects assessment.....	10
2.5.1.2. Exposures assessment and risks characterisation .....	13
2.5.2. Overall conclusion for human health.....	20
2.5.3. Environmental Risk Assessment .....	20
2.5.3.1. Fate and distribution in the environment.....	20
2.5.3.2. Hazard identification and effects assessment.....	22
2.5.3.3. Environmental Exposure assessment .....	23
2.5.3.4. Risk characterisation for the Environment.....	24
2.5.4. Overall conclusion for the environment .....	24
2.5.5. PBT and POP assessment .....	25
2.5.5.1. PBT assessment.....	25
2.5.5.2. POP assessment .....	25
2.5.6. Assessment of endocrine disruptor properties .....	26
<b>2.6. Overall conclusions</b> .....	<b>27</b>
<b>2.7. List of endpoints</b> .....	<b>28</b>
<b>APPENDIX I: LIST OF ENDPOINTS</b> .....	<b>29</b>

<b>Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling ....</b>	<b>29</b>
<b>Chapter 2: Methods of Analysis.....</b>	<b>32</b>
<b>Chapter 3: Impact on Human Health .....</b>	<b>32</b>
<b>Chapter 4: Fate and Behaviour in the Environment.....</b>	<b>36</b>
<b>Chapter 5: Effects on Non-target Species .....</b>	<b>39</b>
<b>Chapter 6: Other End Points .....</b>	<b>41</b>
<b>APPENDIX II: LIST OF INTENDED USES .....</b>	<b>42</b>
<b>APPENDIX III: LIST OF STUDIES .....</b>	<b>43</b>

## 1. STATEMENT OF SUBJECT MATTER AND PURPOSE

### 1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance chlorocresol (also referred to as p-chloro-m-cresol or CMK) as product-type 2 (Private area and public health area disinfectants and other biocidal products), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Chlorocresol (CAS no. 59-50-7) was notified as an existing active substance, by LANXESS Deutschland GmbH hereafter referred to as the applicant, in product-type 2.

Commission Regulation (EC) No 1062/2014 of 4 August 2014<sup>1</sup> lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

On 27<sup>th</sup> of July 2007, French competent authorities received a dossier from LANXESS Deutschland GmbH. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 5<sup>th</sup> of February 2008.

On 8<sup>th</sup> of October 2013, the Rapporteur Member State submitted to the Agency (ECHA) and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the the "Agency" (ECHA). Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

### 1.2. Purpose of the assessment report

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

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

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

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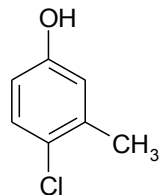
<sup>1</sup> COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014,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

## 2. OVERALL SUMMARY AND CONCLUSIONS

### 2.1. Presentation of the Active Substance

#### 2.1.1. Identity

Table 2.1-1: Identification of the active substance

CAS-No.	59-50-7
EINECS-No.	200-431-6
Other No. (CIPAC, ELINCS)	Not allocated
IUPAC Name	4-Chloro-3-methylphenol
CAS Name	Phenol, 4-Chloro-3-methyl-
Common name	Common name: chlorocresol EINECS name: Chlorocresol Trade name: Preventol CMK
Synonyms	CMK, PCMC
Molecular formula	C <sub>7</sub> H <sub>7</sub> ClO
SMILES	Oc(ccc(c1C)Cl)c1
Structural formula	
Molecular weight (g/mol)	142.6 g/mol

p-chloro-m-cresol (CMK) is an active substance with a specified minimal purity of 99.8%. The analysis of representative production batches of the active substance were provided. The relevant impurity m-cresol specification is 0.1%.

Considering the classification of m-cresol and its content in the active substance (0.1%), m-cresol is not considered as a substance of concern for (eco)toxicological point of view.

The value of dissociation constant of 9.4 indicates that CMK can be found in salt form at higher pH levels. The active substance is the acid form of CMK.

All studies used to set physico-chemical, toxicological and ecotoxicological values were performed on the acid form and are consistent with a purity of production of 99.9% (nominal value found in the 5-batch analysis).

The toxicological and ecotoxicological tests cover the technical specifications. Specifications for the reference source are established.

In the text of this report, when p-chloro-m-cresol is mentioned, it refers to the active substance chlorocresol.

#### 2.1.2. Physico-chemical properties

CMK is a nearly white solid with a slightly phenolic odor which melts at 64.2°C and decomposes around 240°C. It has a relative density of 1.335 and a bulk density of 570-670 kg/m<sup>3</sup>.

It has a vapor pressure of  $1.4 \times 10^{-3}$  Pa and the Henry's Law Constant is  $5.87 \times 10^{-5}$  Pa·m<sup>3</sup>·mol<sup>-1</sup> at pH 7 and 20°C.

CMK has a dissociation constant of  $9.4 \pm 0.1$  at 20 °C and its solubility in water at 20 °C varies from 3.3 g/L at pH 5 to 4.1 g/L at pH 9. CMK is also soluble in n heptane (8.5 g/L) and in p-Xylene, 1,2-Dichloroethane, 1-octanol, 2-propanol, acetone and ethyl acetate (> 200g/L).

Log Pow is to be confirmed before product authorization stage.

CMK is not highly flammable, does not have oxidizing and explosive properties and does not undergo spontaneous combustion. CMK is not surface active.

CMK is stable in container materials such as paper, glass, PE, steel (zinc coated) and high-grade steel.

### 2.1.3. Methods of analysis

Adequate methodology exists for the determination of the active substance and the known impurities in the technical active substance.

Adequate methodology exists for the determination of the active substance in soil, water, air.

No analytical method is submitted for the determination of CMK residues in animal and human body fluids and tissues because the active substance is not classified as toxic or highly toxic.

Considering data (concentration, application rate, ADI) and first exposure and risk calculations, no analytical method for residues in food and feedstuffs are required as no exposure expected for CMK use of a product type 2.

## 2.2. Presentation of the Representative product

### 2.2.1. Identification of the biocidal product

Table 2.2-1: Identification of the biocidal product

<b>Trade name:</b>	DETTOL New Wave	
<b>Manufacturer's development code number:</b>	Manufacturer's development code name: Project Jonas	
<b>Ingredient of preparation</b>	<b>Function</b>	<b>Content [% (w/w)]</b>
p-chloro-m-cresol	Active substance	4%
The other ingredients of the biocidal product are confidential.	Please refer to the confidential part of the Competent Authority Report	
<b>Physical state and nature of the preparation:</b>	Clear yellow transparent liquid with washing-medium odour.	
<b>Nature of the preparation:</b>	Formulation type: EC (emulsion concentrate)	

### 2.2.2. Physico-chemical properties

The preparation Dettol New Wave is a clear yellow, typically washing-medium odour water-based liquid formulation (emulsion concentrate), containing 4 % of CMK. This formulation does not present explosive nor oxidising properties. It has a self-ignition temperature higher than 100, with a flash point of 36.5°C. The product is therefore classified Flam. Liq. 3, H226 according to CLP regulation.

Its density is 0.992 g/l. The pH of the undiluted formulation is 9.4 while the pH of a 5%

dilution is 8.7 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and/or 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The surface tension of pure biocidal product is 30 mN/m. The product is surface active. After 1 minute, no persistent foam remained, indicating that the preparation is not a foaming product. Emulsifiability, emulsion stability re-emulsification and Pourability were not measured and must be submitted at product authorization stage.

The content of active substance is unchanged by 3 years storage at ambient temperature but the lack of studies for assessment of technical properties before and after storage prevents RMS to set a shelf life for biocidal product.

### **2.2.3. Methods of analysis**

Adequate methodology exists for the determination of the active substance in the biocidal product.

## **2.3. 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 organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious. In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in [Appendix II](#).

### **2.3.1. Field of use**

The intended use of p-chloro-m-cresol (CMK) as PT 2 is:

*Main Group 01:* Disinfectants, general biocidal products

*Product Type 02:* Private area and public health area disinfectants and other biocidal products.

### **2.3.2. Function**

The representative product DETTOL New Wave is a product for private and public area disinfection (biocidal product type 2), which is intended to be used in industrial premises and in institutional and private areas, including lavatories. The disinfection in hospital and the use as laundry disinfectant have not been intended for the approval of the active substance. It is efficacious against various bacteria and fungi.

### **2.3.3. Mode of action**

p-chloro-m-cresol as active substance of biocidal products is a multi-site bactericide and fungicidal, with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane. At high concentrations, CMK also has an effect on cytoplasm by general coagulation.

### **2.3.4. Effects on target organisms**

Active substance:

The basic activity of the substance CMK has been demonstrated for the bactericidal and fungicidal activities, according to phase 1 tests in the efficacy assays.

Product:

The efficacy of the product Dettol New Wave has been demonstrated for:

- bactericidal and yeasticidal activities for dipping application in hospitals, in dirty conditions. But this mode of application has not been claimed by the applicant.
- bactericidal and fungicidal activities for surface application, in clean conditions, in private areas. It has to be noted that the testing performed may also be used to demonstrate disinfecting activity for surfaces in hospitals under clean conditions following discussions in Efficacy WG but this use has not been taken into account for the approval of the active substance..

At product authorisation stage, additional studies should be provided in accordance with efficacy guidance for disinfectants.

Table 2.3-1: Organisms and rates for which efficacy of the active substance CMK has been proved

	<b>Application method</b>	<b>Product</b>	<b>In use concentration (product density: 0.998) / Contact time</b>	<b>Activity (in use conditions)</b>
Private areas PT 2	Dipping (not claimed by the applicant)	Dettol New Wave 4 % w/w	0.1 % w/w a.s. for 5 minutes 0.1 % w/w a.s. for 15 minutes	Bactericide Yeasticide
	Surface	Dettol New Wave 4 % w/w	0.1 % w/w a.s. for 5 minutes 0.4 % w/w a.s. for 15 minutes	Bactericide, yeasticide Fungicide

### **2.3.5. Resistance**

The literature analysis showed that especially if the concentration of CMK is in the efficient range, no acquired resistance occurs. In addition, using bactericidal concentrations, the risk of development of cross-resistance or co-resistance is in general low, considering the multi-site activity of CMK. Since it interacts with many different targets of the bacterial cell wall, the risk of developing resistance mechanisms is minimal.

Few authors described insufficient sporicidal effects of CMK and explained this by development of resistance. However, CMK is not efficacious against microbial spores and such well-known lack of sporicidal efficacy cannot be interpreted as result of resistance development.

## **2.4. Classification and Labelling**

### **2.4.1. Current classification of the active substance**

The current harmonised classification and labelling of CMK in accordance with Regulation (EC) No 1272/2008 is given in table below:

<b>Classification according to Regulation (EC) No 1272/2008 (CLP)</b>	
Class of danger	Acute Tox. 4
	Eye Dam. 1
	Skin Sens 1
	Aquatic acute 1



Hazard Statement	H302	Harmful if swallowed.
	H312	Harmful in contact with skin.
	H318	Causes serious eye damage.
	H317	May cause an allergic skin reaction.
	H400	Very toxic to aquatic organisms.

#### 2.4.2. Proposed classification for the active substance

According to the conclusion of the 36<sup>th</sup> RAC meeting (March 2016), amendment to the harmonised classification according to Regulation (EC) No 1272/2008 was adopted for CMK:

Classification according to the RAC opinion adopted at the 36 <sup>th</sup> RAC meeting	
Hazard Class and Category Codes	Acute Tox. 4 STOT SE 3 Skin Corr. 1C Eye Dam. 1 Skin Sens 1B Aquatic acute 1 Aquatic chronic 3
Signal Word	Danger
Hazard Statement	H302 Harmful if swallowed. H335 May cause respiratory irritation. H314 Causes severe skin burns and eye damage H318 Causes serious eye damage H317 May cause an allergic skin reaction. H400 Very toxic to aquatic organisms. H412 Harmful to aquatic life with long lasting effects.
<b>Specific Concentration limits, M-Factors</b>	M factor = 1 (acute)

Labelling based on the RAC opinion adopted at the 36 <sup>th</sup> RAC meeting	
Hazard Class and Category Codes	Acute Tox. 4 STOT SE 3 Skin Corr. 1C Skin Sens 1B Aquatic acute 1 Aquatic chronic 3
<b>Labelling</b>	
Pictogram codes	GHS05 GHS07 GHS09
Signal Word	Danger
Hazard Statement	H302 Harmful if swallowed. H335 May cause respiratory irritation. H314 Causes severe skin burns and eye damage H317 May cause an allergic skin reaction. H400 Very toxic to aquatic organisms. H412 Harmful to aquatic life with long lasting effects.
<b>Specific Concentration limits, M-Factors</b>	M factor = 1 (acute)

### 2.4.3. Proposed classification for the product

The proposed classification / labelling of DETTOL New Wave by RMS, is summarised in **Erreur ! Source du renvoi introuvable.**

Classification according to Regulation (EC) No 1272/2008 (CLP)	
Class of danger	Flam. Liq. 3
	Eye Dam. 1
Hazard Statement	H226 Flammable liquid and vapour
	H318 Causes serious eye damage.

No classification is required when considering the dilution form of the product.

## 2.5. Summary of the Risk Assessment

### 2.5.1. Human Health Risk Assessment

#### 2.5.1.1. Hazard identification and effects assessment

- **Toxicokinetic**

CMK is rapidly and extensively absorbed in rats following oral administration and is excreted mainly in urine. CMK is also extensively metabolised. The urinary metabolite pattern consists of at least 5 metabolite fractions, among which two fractions are predominant.

CMK induces no accumulation.

From the key study, 85% of the administered dose was recovered in urines 24h after administration. Since it is mentioned in the Manual of Technical Agreements (MOTA) (Version 6, 2013)<sup>2</sup> that an oral absorption of 100% should be considered when experimental data is above 80%, an oral absorption percentage of 100% has been chosen to set the systemic NOAEL.

No key study is identified for dermal absorption percentage. The available studies do not allow a reliable quantification of the permeability coefficient of the tested substance. Therefore, default values from EFSA guidance (2012)<sup>3</sup> will be applied for risk assessment. A value of 25% will be used for concentrated products (> 5% a.s.) and 75% will be used for diluted products (< 5% a.s.).

Absorption by inhalation has not been investigated. Thus a 100% absorption percentage is retained.

- **Acute effects**

The acute oral LD50 in the rat is 1830 mg/kg bw (males). CMK is thus classified for its acute oral toxicity as follows: H302: Harmful if swallowed.

No acute toxicity occurred to both male and female rats and rabbits exposed via the *dermal route*. The acute dermal LD50 in rat is higher than 2000 mg/kg. In the harmonised classification H312: harmful in contact with skin is set but no data available in this dossier support this classification. Consequently, in the CLH report submitted to ECHA, after a review of the literature, this classification Acute Tox Cat 4 H312 is not proposed anymore.

No mortalities occurred in acute studies by *inhalation* performed in rats at doses up to and including 2871 mg/m<sup>3</sup>. Further tests on rats exposed to fumes contaminated with CMK support the results. The no-effect level is < 2871 mg/m<sup>3</sup> after 4 hours static spray exposure in rats.

<sup>2</sup> [http://echa.europa.eu/documents/10162/19680902/mota\\_v6\\_en.doc](http://echa.europa.eu/documents/10162/19680902/mota_v6_en.doc)

<sup>3</sup> EFSA Journal 2012;10(4):2665

Local effects are observed during the acute toxicity studies, whatever the exposure route. From these observations, a classification Stot SE Cat 3 H335: may cause respiratory irritation is proposed. Moreover, a skin irritation study leads to propose the classification: Skin Corr Cat 1C H314: Cause severe skin burns and eye damage.

From eye irritation and sensitisation studies, the classification of CMK Eye Dam. Cat 1 H318: causes serious eye damage and Skin Sens Cat 1B H317: May cause an allergic skin reaction is confirmed.

- **Repeated toxicity studies**

*Oral* application of CMK for 4 weeks to rats caused no adverse effects. Therefore the oral sub-acute NOAEL is 790 and 920 mg/kg/day for males and females, respectively.

4-week dermal application of CMK to rats caused moribundity, reduced body weight gain, due to reduced food consumption, increased water intake and urinary tract effects (ureterectasia, blood clots in the bladder), and local skin effects at the application site (erythema, oedema, wounds and crustification, and increase in skin thickness) at 1000 mg/kg bw/day. No effect was observed at the lower dose of 200 mg/kg bw/day which is considered as the sub-acute NOAEL for systemic and local effects to rats.

In another *dermal* study with rabbits, dermal treatment with CMK for 21 days causes no systemic effects but only local skin reactions at the lower tested dose 10 mg/kg bw/day. Therefore, no NOAEC can be determined for local effects, only a LOAEC of 10 mg/kg/day is retained.

In an *inhalation* study in Wistar rats, focused on respiratory effects, some local effects were observed. The NOAEL and the NOAEC determined from this study are 50 mg/m<sup>3</sup>.

Sub-chronic *oral* administration of CMK to rats for 3 months produced no adverse effects at doses up to and including 120 mg/kg bw/day (males) and 170 mg/kg bw/day (females). No NOAEL has been determined in this study.

*Dermal* application of CMK to rats for 13 weeks causes no effects. The sub-chronic dermal NOEL is considered to be 500 mg/kg bw/day.

- **Combined chronic/carcinogenicity toxicity study**

In the combined chronic/carcinogenicity study in rats exposed via diet, the long-term NOAEL is considered to be 103.1 mg/kg bw/day for males based on delayed body weight development, increased water intakes, effects on kidneys, statistically significant reduced spermatozoa in the epididymides and 134.3 mg/kg bw/day for females based on delayed body weight development, poor general condition, increased water intakes as well as increased relative and absolute kidney weight.

No treatment-related malign tumors were observed. CMK is not considered as carcinogenic and no classification for carcinogenicity is deemed justified.

- **Genotoxicity**

There is no evidence for genotoxicity in a standard battery of *in vitro* tests (Ames test, UDS assay and mutation assay in mammalian cells) and *in vivo* test (micronucleus test in mouse). Moreover, the carcinogenicity study concluded that CMK is not a mutagenic carcinogen.

- **Reprotoxicity**

No teratogenic effect of CMK was observed in the rat teratogenicity study. The maternal NOAEL is 30 mg/kg bw/day and the developmental NOAEL is 100 mg/kg bw/day.

The waiving for developmental toxicity study in rabbits was discussed at WG V 2015. The WG considered that because there is only information on one species (rat) in the whole data package, an additional assessment factor would normally be required, but not in this specific case because of:

- 1- Very low NOAEL (30 mg/kg/d) compared to NOAELs of other studies
- 2- Sensitivity of rabbits to antimicrobials
- 3- Information on other species with related substances

In the two-generation reproduction study with Wistar rats, a NOAEL for offspring toxicity is 750 ppm (47 mg/kg bw/day) based on effects on pup weights. The parental NOAEL is 750 ppm (90 mg/kg bw/day). This NOAEL is based on a statistically significant decrease in body weight gain noted in lactating (equivalent to 365 mg/kg/day) and on liver and kidney effects. The NOAEL for toxicity on fertility is at 3000 ppm (corresponding to 288 mg/kg bw/day) based on the increased weights of the seminal vesicles effects at 12 000 ppm. In addition, at 12 000 ppm, ovarian atrophy, increased metoestrus, decreased dioestrus and atrophy of the vaginal epithelium appear in F0 and F1 females.

Several published reports and articles mention a potential endocrine disruption activity of CMK especially in vitro. These results permit to conclude that CMK possess a slight endocrine disruption potential in vitro.

Based on the sub-chronic studies (oral and dermal), teratogenicity and combined chronic/carcinogenicity studies, no changes in endocrine function are observed. In addition, the two-generations study carried out in rat, showing no indication for an endocrine disrupting activity of CMK, confirmed the result of non-endocrine disrupter activity of CMK. Therefore these results do not lead to consider that the active substance fulfills the exclusion criteria as defined in article 5 d) of regulation ((EU) n°528/2012).

- **Determination of AEL/AEC/ADI/ARfD**

The lowest NOAEL is 30 mg/kg bw/day, obtained in the rat developmental toxicity study. The NOAEL from this study is therefore considered conservative for setting of AELs.

An oral absorption percentage of 100 % will be used to set the systemic NOAEL.

The safety factors (SF) are 10 for the inter-species variations and 10 for intra-species variation. The SF is therefore 100 for acute-term, medium-term and long-term exposure.

An acute-term, medium-term and long-term AEL of 0.30 mg/kg bw/day is proposed.

The NOAEC of 50 mg/m<sup>3</sup> from the 14-day inhalation rat study will be used to set the inhalation AEC.

Concerning the local effects (inhalation route) the default factor of 10 to assess the intra-species variation, is not subjected to modification. However, a reduced factor of 2.5 for inter-species variations will be applied. In addition, SF to consider longer exposure will be added.

The assessment factor proposed is thus 25 for acute exposure, 75 for medium-term and 150 for long-term respiratory exposure.

An acute respiratory AEC of 2 mg/m<sup>3</sup> is proposed.

A medium-term respiratory AEC of 0.7 mg/m<sup>3</sup> is proposed.

A long-term respiratory AEC of 0.3 mg/m<sup>3</sup> is proposed.

An ARfD and an ADI of 0.30 mg/kg is proposed.

The summary of the reference values is reported below:

	<b>AEL/AEC/ARfD/ADI</b>	<b>SF</b>
<b>Local effects by inhalation</b>	<b>AEC [mg/m<sup>3</sup>]</b>	<b>[-]</b>
acute	<b>2</b>	25
medium-term	<b>0.7</b>	75
long-term	<b>0.3</b>	150
<b>Systemic effects</b>	<b>AEL [mg/kg bw/d]</b>	<b>[-]</b>
acute- medium- long- term	0.30	100
	<b>ARfD – ADI [mg/kg bw/d]</b>	<b>[-]</b>
	0.30	100

### 2.5.1.2. Exposures assessment and risks characterisation

The biocidal product DETTOL New Wave is a surface disinfectant which is intended to be used in industrial premises and in institutional and private areas, including lavatories. The exposure of the users (professional cleaning personnel in private areas and non-professionals in private areas) to CMK during and after application of the biocidal product is assessed.

Secondary exposure to the general public could result from direct contact with the treated surfaces as well as from inhalation; for infants, oral uptake from hand-to-mouth contact may occur.

The most relevant exposure paths are dermal and inhalation, exposure paths are presented in the table below:

Table 2.55-1: Exposure of main paths of human exposure

<b>Exposure path</b>	<b>Industrial use</b>	<b>Professional use</b>	<b>General public</b>	<b>Via the environment</b>
<b>Inhalation</b>	Yes	Yes	Yes	Negligible
<b>Dermal</b>	Yes	Yes	Yes	Negligible
<b>Oral</b>	No	No	Yes	Negligible

Quantitative risk assessment was performed for both systemic effects, comparing the estimated exposure with relevant reference value (AEL).

Based on the Guidance for human health risk assessment, volume III, part B, version 2,



October 2015; no local risk assessment has been conducted because the product is not classified for local effects leading to any assessment.

### 2.5.1.2.1. Primary Exposure (professional users)

#### 2.5.1.2.1.1. Risk characterisation for professional users - Household (HH), and industrial and institutional (I&I) uses

CMK is used at a maximal concentration of 0.4 % w/w/ a.s. for surfaces disinfection in private areas (e.g. households, industrial and institutional uses).

In private areas, cleaning and disinfection can be performed by professional cleaning personnel. Dermal and inhalation exposure takes place during mixing (diluting the 4% concentrate 1:10 in a bowl or bucket with water) and application of the product. The oral route is excluded since it is assumed that exposure via this route can occur only by accident.

The respective exposure can be assessed using the surface disinfection models from the TNsG<sup>4</sup> (models 1 and 3, TNsG (2002) pages 175 and 177, User guidance page 27). These models include exposure during diluting and mixing the surfactant in water and wiping surfaces using a rung cloth or a mop.

These models give indicative values expressed as mg/min of the diluted solution, i.e. actually applied by wiping or mopping<sup>5</sup>.

Table 2.5-2: Households and Industrial and Institutional uses professional primary exposure summary (Chronic exposure) - Weight fraction of active substance in diluted solution of 0.4%

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.s. / kg bw /day	mg a.s. / kg bw /day	mg a.s. / kg bw /day
<b>Task - time frame:</b>	<b>Professionals mixing/loading and wiping surfaces with disinfection product</b>		
Tier 1: Without PPE no RPE*	$1.05 \times 10^{-2}$	2.60	2.61
Tier 2: With gloves and coated coverall, no RPE*	$1.05 \times 10^{-2}$	$4.60 \times 10^{-1}$	$4.70 \times 10^{-1}$

\*Respiratory protective equipment

<sup>4</sup> Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market 28 March 2002

<sup>5</sup> As confirmed by the HEEG opinion, agreed at TM of December 2007.

Table 2.5-3: Households and Industrial and Institutional uses professional primary exposure summary (Chronic exposure)- Weight fraction of active substance in diluted solution of 0.1%

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.s. / kg bw /day	mg a.s. / kg bw /day	mg a.s. / kg bw /day
<b>Task - time frame:</b>	<b>Professionals mixing/loading and wiping surfaces with disinfection product</b>		
Tier 1: Without PPE no RPE	$6.51 \times 10^{-1}$	$2.62 \times 10^{-3}$	$6.54 \times 10^{-1}$
Tier 2: With gloves and coated coverall, no RPE	$1.15 \times 10^{-1}$	$2.62 \times 10^{-3}$	$1.17 \times 10^{-1}$

→ **Risk characterisation for systemic effects**

Each estimated exposure is compared to the NOAEL and to the AEL, to derive a MOE and a fraction of the AEL (expressed as % AEL), respectively, for risk characterisation. The results are presented in the following tables:

Table 2.5-41: Summary of risk assessment for professionals wiping surfaces with disinfection product- Weight fraction of active substance in diluted solution of 0.4%

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE <sub>ref</sub> (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	%AEL
<b>Task:</b>	<b>Professionals mixing/loading and wiping surfaces with disinfection product</b>					
Tier 1 : Without PPE	2.61	30.00	100	11	$3.00 \times 10^{-1}$	<b>870</b>
Tier 2: With gloves, coated coveralls	$4.70 \times 10^{-1}$	30.00	100	64	$3.00 \times 10^{-1}$	<b>156</b>

An **unacceptable** risk has been identified for professionals wiping surfaces with the wear of gloves and coated coverall, since MOE is lower than MOE<sub>ref</sub> (100) and associated %AEL is above 100%, for the systemic effects.



Table 2.5-5: Summary of risk assessment for professionals wiping surfaces with disinfection product- Weight fraction of active substance in diluted solution of 0.1%

	<b>Total exposure</b> (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE <sub>ref</sub> (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	%AEL
<b>Task:</b>	<b>Professionals mixing/loading and wiping surfaces with disinfection product</b>					
Tier 1 : Without PPE	$6.54 \times 10^{-1}$	30.00	100	46	$3.00 \times 10^{-1}$	<b>218</b>
Tier 2: With gloves, coated coveralls	$1.17 \times 10^{-1}$	30.00	100	256	$3.00 \times 10^{-1}$	39

An acceptable risk has been identified for professionals wiping surfaces with the wear of gloves and coated coverall, since MOE is higher than MOE<sub>ref</sub> (100) and associated %AEL is below 100%, for the systemic effects.

#### → **Risk characterisation for local effects- eye irritation**

The DETTOL New Wave is classified Eye dam. Cat 1. H318 Causes serious eye damage. Due to this classification, the professionals should wear goggles during the dilution of DETTOL NEW WAVE to obtain the biocidal diluted at 0.4% or 0,1 %-CMK.

#### **2.5.1.2.2. Primary Exposure (non-professional users)**

##### **2.5.1.2.2.1. Household, industrial and institutional uses – non-professional exposure**

CMK is used at a maximal concentration of 0.4% w/w a.s. for surfaces disinfection in private areas (e.g. households, industrial and institutional uses).

The representative use for this kind of products is wiping or mopping hard surfaces such as floors, where repeated direct contacts with the cleaning product are expected.

ConsExpo 4.1<sup>6</sup> was used to estimate the exposure while cleaning surfaces with liquid detergents. The default assumptions reported in the Cleaning products fact sheet (RIVM, 2007) for the application of "Floor, carpet and furniture products – Floor cleaning liquid" were used. The assumptions do not differ significantly from those used with the TNsG models.

Exposure estimates are summarised in the table hereafter.

The scenario is divided in 2 tasks:

- Mixing & Loading of the biocidal product
- Application on surfaces.

<sup>6</sup> Delmaar JE, Park MVDZ, Van Engelen JGM (2005). ConsExpo 4.0 Consumer Exposure and Uptake Models Program Manual. Report 320104004/2005., RIVM Bilthoven, The Netherlands.



Table 2.5-62: Households and Industrial and Institutional uses non-professional primary exposure summary (Chronic exposure) Weight fraction of active substance in diluted solution of 0.4%

Tier	Inhalation exposure	Dermal exposure		Total exposure
	Systemic dose	Deposit on skin (hands)	Systemic dose	Systemic dose
	mg a.s. / kg bw /day	mg a.s. /cm <sup>2</sup>	mg a.s. / kg bw /day	mg a.s. / kg bw /day
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – mixing and loading phase</b>			
Tier 1: Without PPE	9.59 x 10 <sup>-8</sup>	1.86 x 10 <sup>-3</sup>	5.00 x 10 <sup>-3</sup>	5.00 x 10 <sup>-3</sup>
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – application phase</b>			
Tier 1: Without PPE	1.86 x 10 <sup>-6</sup>	4.00 x 10 <sup>-2</sup>	0.95	0.95
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – combined exposure (mixing and loading + application phase)</b>			
Tier 1: Without PPE	1.96 x 10 <sup>-6</sup>	Not relevant*	0.96	0.96

\*As for local dermal effect it is the concentration of the CMK during the event of contact that is relevant, combined exposure has only been assessed for systemic exposure.

Table 2.5-7: Households and Industrial and Institutional uses non-professional primary exposure summary (Chronic exposure) Weight fraction of active substance in diluted solution of 0.1%

Tier	Inhalation exposure	Dermal exposure		Total exposure
PPE	Systemic dose	Deposit on skin (hands)	Systemic dose	Systemic dose
	mg a.s. / kg bw /day	mg a.s. /cm <sup>2</sup>	mg a.s. / kg bw /day	mg a.s. / kg bw /day
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – mixing and loading phase</b>			
Tier 1: Without PPE	2.40 x 10 <sup>-8</sup>	4.65 x 10 <sup>-4</sup>	1.25 x 10 <sup>-3</sup>	1.25 x 10 <sup>-3</sup>
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – application phase</b>			
Tier 1: Without PPE	4.65 x 10 <sup>-7</sup>	1.00 x 10 <sup>-2</sup>	2.40 x 10 <sup>-1</sup>	2.40 x 10 <sup>-1</sup>
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – combined exposure (mixing and loading + application phase)</b>			
Tier 1: Without PPE	4.89 x 10 <sup>-7</sup>	-	2.41 x 10 <sup>-1</sup>	2.41 x 10 <sup>-1</sup>

### 2.5.1.2.2.2. Risk characterisation for Household (HH) uses

#### → Risk characterisation for systemic effects

Each estimated exposure is compared to the NOAEL and to the AEL, to derive a MOE and a fraction of the AEL (expressed as % AEL), respectively, for risk characterisation. The results are presented in the following tables:

Table 2.5-83: Summary of risk assessment for non-professional wiping surfaces with disinfection product -Weight fraction of active substance in diluted solution of 0.4%

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE <sub>ref</sub> (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	%AEL
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – mixing and loading phase</b>					
Tier 1 : Without PPE	$5.00 \times 10^{-3}$	30.00	100	6000	$3.00 \times 10^{-1}$	2
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – application phase</b>					
Tier 1 : Without PPE	0.95	30.00	100	32	$3.00 \times 10^{-1}$	<b>317</b>
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – combined exposure (mixing and loading + application phase)</b>					
Tier 1 : Without PPE	0.96	30.00	100	31	$3.00 \times 10^{-1}$	<b>320</b>

**Unacceptable** risk has been identified for the non-professionals wiping surfaces with disinfection product, since MOE is lower than MOE<sub>ref</sub> (100) and associated %AEL is above 100%, for the systemic effects during application.

Table 2.55-94: Summary of risk assessment for non-professional wiping surfaces with disinfection product-Weight fraction of active substance in diluted solution of 0.1%

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE <sub>ref</sub>	MOE	AEL (mg a.s./kg bw/d)	%AEL
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – mixing and loading phase</b>					
Tier 1 : Without PPE	$1.25 \times 10^{-3}$	30.00	100	24000	$3.00 \times 10^{-1}$	< 1
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – application phase</b>					
Tier 1 : Without PPE	$2.40 \times 10^{-1}$	30.00	100	125	$3.00 \times 10^{-1}$	80
<b>Task:</b>	<b>Non-professionals wiping surfaces with disinfection product – combined exposure (mixing and loading + application phase)</b>					
Tier 1 : Without PPE	$2.41 \times 10^{-1}$	30.00	100	125	$3.00 \times 10^{-1}$	80



Acceptable risk has been identified for the non-professionals wiping surfaces with disinfection product, since MOE is higher than  $MOE_{ref}$  (100) and associated %AEL is below 100%, for the systemic effects during mixing loading and application.

→ **Risk characterisation for local effects- eye irritation**

The DETTOL New Wave is classified Eye dam. Cat 1. H318 Causes serious eye damage. Due to this classification, the non-professionals should wear goggles during the dilution of DETTOL NEW WAVE to obtain the biocidal diluted at 0.1 or 0.4%.

To conclude, the risk of primary exposure is considered to be unacceptable for professionals and non-professionals during use of a diluted solution at 0.4 % w/w of CMK and acceptable for professionals during use of a diluted solution at 0.1 % w/w of CMK with goggles during dilution phase.

Given the classification of the representative product and the likelihood that eye protection may be needed in the dilution phase, use by non-professionals is unlikely to show acceptable risks.

**2.5.1.2.3. Secondary Exposure: Indirect exposure as a result of use**

**2.5.1.2.3.1. Indirect exposure for Household (HH) uses**

Indirect exposure following the use of surface cleaner occurs when an infant is crawling on a surface cleaned with the product containing CMK (inhalation, dermal and oral exposure).

Table 2.5-10: Household (HH) uses indirect exposure summary (medium term exposure)

Tier	Inhalation exposure	Dermal exposure		Oral exposure	Total exposure
	Systemic dose	Deposit on skin (hands)	Systemic dose	Systemic dose	Systemic dose
	mg a.s. / kg bw /day	mg/cm <sup>2</sup>	mg a.s. / kg bw /day	mg a.s. / kg bw / day	mg a.s. / kg bw /day
<b>Task</b>	<b>Infant crawling on surface cleaned with treated detergent- diluted at 0.4%</b>				
Tier 1	$8.75 \times 10^{-2}$	$1.20 \times 10^{-3}$	4.86	0.72	5.67
<b>Task</b>	<b>Infant crawling on surface cleaned with treated detergents diluted at 0.1%</b>				
Tier 1	$8.75 \times 10^{-2}$	$3.00 \times 10^{-3}$	1.22	0.18	1.42

**2.5.1.2.3.2. Risk characterisation for indirect exposure for Household (HH) uses**

→ **Risk characterisation for systemic effects**

Each estimated exposure is compared to the NOAEL and to the AEL, to derive a MOE and a fraction of the AEL (expressed as % AEL), respectively, for risk characterisation. The results are presented in the following tables.



Table 2.55-51: Summary of risk assessment for indirect exposure for an infant crawling on a surface cleaned with treated product

	<b>Total exposure</b> (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE <sub>ref</sub> (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	<b>%AEL</b>
<b>Task</b>	<b>Infant crawling on surface cleaned with treated detergent diluted at 0.4%</b>					
Tier 1 :	5.67	30.00	100	5	$3.00 \times 10^{-1}$	<b>1890</b>
<b>Task:</b>	<b>Infant crawling on surface cleaned with treated detergents diluted at 0.1%</b>					
	1.42	30.00	100	21	$3.00 \times 10^{-1}$	<b>473</b>

**Unacceptable** risk has been identified for the indirect exposure of an infant crawling on a surface cleaned with disinfection product, since MOE lower than MOE<sub>ref</sub> (100) and associated %AEL is above 100%, for the systemic effects, when considering both concentrations of CMK in the biocidal product.

### **2.5.2. Overall conclusion for human health**

An **unacceptable risk** associated with the primary exposure has been identified for professionals and non-professionals wiping or mopping surfaces with a detergent diluted at 0.4%.

An acceptable risk associated with the primary exposure has been identified for professionals wiping or mopping surfaces with a detergent diluted at 0.1% with the wear of goggles during the dilution phase of the biocidal product. A local risk assessment has been conducted for local eye effects. Given the classification of the representative product, goggles should be worn during the dilution phase for professionals. The likelihood that eye protection may be needed in the dilution phase, use by non-professionals is unlikely to show acceptable risks.

For secondary exposure, the risk for infant crawling on a surface cleaned with treated product is considered to be **unacceptable**. In consequence, application of CMK based products should be restricted to areas where children are not present.

### **2.5.3. Environmental Risk Assessment**

#### **2.5.3.1. Fate and distribution in the environment**

##### **2.5.3.1.1. Abiotic degradation**

###### **2.5.3.1.1.1. Hydrolysis as a function of pH**

CMK is stable to hydrolysis at pH values of 4, 7 and 9 (50° C). Therefore, it is not to be expected that hydrolytic processes will contribute to the degradation of CMK in the aquatic environment.

###### **2.5.3.1.1.2. Photolysis in water**

A photodegradation study has been provided but it has not been considered acceptable by RMS due to numerous deficiencies such as the absence of irradiation apparatus description. Nevertheless, according to absorbance properties (maximum absorbance at 228 and 281 nm), p-chloro-m-cresol is expected to be stable to the photolysis in water.

### 2.5.3.1.1.3. *Photolysis in air*

Calculations of the chemical lifetime in the troposphere by the AOPWIN program<sup>7</sup> resulted in a half-life of 0.625 days, corresponding to 14.995 hours, considering an OH-radicals concentration of  $0.5 \times 10^6 \text{ molec.cm}^{-3}$  and 24 hour). Therefore, CMK should be rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is expected.

### 2.5.3.1.2. *Biodegradation*

No key study dealing with the degradation of CMK in STP has been provided. However supportive simulation studies, monitoring reports and publications indicate that an efficient elimination of CMK occurs in industrial as in domestic STPs. Considering that CMK is readily biodegradable (10-day window fulfilled), a half-life of 0.03 days has been applied for STP compartment for the exposure calculation.

Two studies concerning the biodegradation in water sediment systems have been provided. The first one shows that the dissipation of CMK is rapid in the whole system (DT50, 12°C ≤ 3.6 d) as in the water phase (DT50, 12°C ≤ 3.3 d). The mineralization rate was over 20% and the bound residues remained below 55%. This first study clearly indicates that no extractable metabolite occurred over 10% in the sediment. As the picture was less clear for the metabolite in the water phase, a further study has been provided in order to better separate and quantify the metabolites. This second study allows confirming that no metabolite of concern occurred in the water phase, the only metabolite near the threshold of 10% being phenol (9.9 % of applied radioactivity). A non-key laboratory study and analysis of sediment and water in German rivers support the high aerobic biodegradation rate in aquatic compartment. Additionally, several insights dealing with the metabolic pathway of CMK in water have been provided.

Only supportive data have been provided for the assessment of the degradation of CMK in soil and default degradation value from the TGD8 for a readily biodegradable substance has been therefore applied to calculate concentrations of CMK in soil (DT50: 30 days).

### 2.5.3.1.3. *Mobility*

A batch equilibrium study allows to derive an organic carbon-water partition coefficient (Koc) value of 195.6 L.kg<sup>-1</sup> (arithmetic mean Koc value for the tested soils where the recovery was sufficient, which was supported by an HPLC test (Koc = 158.5 L.kg<sup>-1</sup>).

Besides, a publication indicates a low leaching ability of CMK in soil, (CMK found in only one of 41 soil pore samples from three sites in USA).

### 2.5.3.1.4. *Bioaccumulation*

For CMK, a log Kow value of 3.02 at 22 ± 1°C has been determined. Calculating the BCF for CMK on the basis of this partition coefficient n-octanol/water according to the Guidance document on Risk Assessment, a BCF<sub>fish</sub> of 73.6 was assessed. This value is in good accordance with the supportive experimental data (5.5-121 L.kg<sup>-1</sup>). These results indicate a low potential of CMK to bioaccumulate in the aquatic food chain. For the terrestrial compartment, a BCF<sub>earthworm</sub> of 13.41 has been calculated according to the Guidance document on Risk Assessment.

Taking into consideration these low bioconcentration factors, no food chain concern is expected.

<sup>7</sup> v. 1.91, 2000, US-EPA

<sup>8</sup> European Commission (2003): Technical Guidance Document on Risk Assessment. European Commission Joint Research Centre, EUR 20418

### 2.5.3.2. Hazard identification and effects assessment

#### 2.5.3.2.1. Sewage treatment plant

In an activated sludge respiration inhibition test, an EC10 of 5.7 mg CMK .L<sup>-1</sup> was obtained for micro-organisms. According to the Guidance document for Risk Assessment for such tests an assessment factor of 10 should be applied to the available EC10, resulting in a PNEC<sub>microorganisms</sub> of 0.57 mg.L<sup>-1</sup>.

#### 2.5.3.2.2. Aquatic compartment

Acute toxicity of CMK has been investigated in fish (*Oncorhynchus mykiss*), invertebrates (*Daphnia magna*) and algae (*Desmodesmus subspicatus*). Fish were found to be the most sensitive species (LC<sub>50</sub> = 0.92 mg CMK. L<sup>-1</sup>).

A fish (*Oncorhynchus mykiss*) juvenile growth test has also been conducted. The NOEC was determined to be 0.15 mg CMK.L<sup>-1</sup>.

As NOECs for species representing three trophic levels, fish and algae, are available, an assessment factor of 10 was applied on the most sensitive NOEC resulting in a PNEC of 15 µg.L<sup>-1</sup>.

#### 2.5.3.2.3. Sediment

The PNEC<sub>sed</sub> was calculated using the equilibrium partitioning method according to the Guidance document on Risk Assessment. The PNEC<sub>sed</sub> was determined to be 75.5 µg CMK.kg<sup>-1</sup> susp. sed (wet weight).

#### 2.5.3.2.4. Terrestrial compartment

The effects of CMK to terrestrial non-target organisms have been tested in earthworms, soil micro-organisms and plants.

Soil micro-organisms study can be considered as a long term study and could be retained to derive the PNEC<sub>soil</sub>, applying an assessment factor of 100 according to the Guidance document. However, the EC50 (531 mg kg<sup>-1</sup>dw) from the soil microorganism study is far higher than the EC50 from the acute study performed on plant (54.3 mg kg<sup>-1</sup>dw). Therefore, an assessment factor of 1000 has been applied to this EC50 from the plant study, dealing to a PNEC<sub>soil</sub> value of 5.43 x 10<sup>-2</sup> mg CMK kg<sup>-1</sup>dry soil. **The PNEC<sub>soil</sub> value for CMK of 4.81 x 10<sup>-2</sup> mg kg<sup>-1</sup> wet soil** is calculated taking into account a conversion factor for soil concentration wet-dry weight soil of 1.13, according to the Guidance document. (equation 82b).

#### 2.5.3.2.5. Non-compartment specific effects relevant to the food chain (secondary poisoning)

A short-term dietary study with the bobwhite quail (*Colinus virginianus*) resulted in a LC<sub>50</sub> > 2995 mg CMK.kg<sup>-1</sup> food. Applying an assessment factor of 3000, the PNEC<sub>oral, birds</sub> is calculated to be 0.998 mg.kg<sup>-1</sup> food.

For mammals, a NOAEL of 103 mg a.s./kg bw/day was obtained from a chronic, 105 week dietary study with rats, which corresponds to a NOEC of 2000 mg CMK.kg<sup>-1</sup> food. The PNEC<sub>oral, mammals</sub> of 66.7 mg CMK.kg<sup>-1</sup> food is derived by applying an assessment factor of 30 to the calculated NOEC of 2000 mg CMK.kg<sup>-1</sup> food.

### 2.5.3.2.6. Summary of PNEC values

The summary of the selected PNEC values used for the risk characterisation is reported below:

ENVIRONMENTAL COMPARTMENT	PNEC	Unit
PNEC <sub>water</sub>	15	µg CMK.L <sup>-1</sup>
PNEC <sub>stp</sub>	0.57	mg CMK.L <sup>-1</sup>
PNEC <sub>sed</sub>	75.5	µg CMK.kg <sup>-1</sup> <sub>wwt</sub>
PNEC <sub>soil, in tial</sub>	48.1	µg CMK.kg <sup>-1</sup> <sub>wwt</sub>
PNEC <sub>oral, birds</sub>	0.998	mgCMK.kg <sup>-1</sup> food
PNEC <sub>oral, mammals</sub>	66.7	mgCMK.kg <sup>-1</sup> food

### 2.5.3.2.7. Environmental effect assessment of the biocidal product

No additional data on the environmental effects of the biocidal products were submitted. The risk assessment is based on the effect of the active substance CMK.

### 2.5.3.3. Environmental Exposure assessment

The environmental exposure assessment was carried out for CMK as active substance in DETTOL New Wave, a surface disinfectant biocidal product (PT 2) which is intended to be used in industrial premises and in institutional and private areas, including lavatories. The disinfection in hospital and the use as laundry disinfectant have not been intended for the approval of the active substance. The surface disinfection of areas occurs at the highest dose of CMK of 0.4% w/v a.s.

After surface disinfection, the product is rinsed off with water and released to wastewater which will be discharged to a sewage treatment plant (STP), being the primary residues receiving environmental compartment. Soils and surface water bodies are only understood as indirect targets for emissions. Due to the physical and chemical properties of CMK, air is not a compartment of concern.

Emissions to the STP have been calculated according to the EU Environmental Emission Scenario Document for biocides used as private and public area disinfectants (ESD for PT02; EC, 2011)<sup>9</sup>. In this document, exposure assessments for industrial premises and institutional areas are proposed. The scenario for institutional areas is assumed to cover both public domain and private uses. Two approaches can be used to conduct the risk assessment: a consumption approach considering the specific parameters of the product in link with its intended uses (scenario applied for the industrial premises and the institutional areas) and a tonnage approach based on the volume of the active substance used as PT02 put on the European market (scenario applicable to the institutional areas only according to the ESD).

For the consumption approach, a market share of DETTOL New Wave amongst all the disinfection products potentially applied for this use of 0.5 has been used for institutional and private areas scenario. The risk characterisation for each compartment are first carried out for the surface disinfection of industrial premises and institutional/privates areas separately. Then, as both sub-uses could result in emission to the same STP, PEC/PNEC ratios in the environment are also cumulated.

Secondary emissions to surface freshwater, sediment, air, soil, groundwater and biota have been calculated according to the equations from the TGD. Indirect contamination of surface

<sup>9</sup> Emission Scenario document for Product Type 2 – Private and public health area disinfectants and other biocidal products. JRC Scientific and Technical Reports (2011).

water via atmospheric deposition has been deemed negligible considering the low vapour pressure ( $1.98 \times 10^{-3}$  Pa) and Henry's law constant ( $5.87 \times 10^{-5}$  Pa.m<sup>3</sup>.mol<sup>-1</sup>) of CMK. The emission fractions from the STP to the surface water and to the STP sludge have been determined through the SimpleTreat model integrated in EUSES. Considering the ready biodegradation of CMK (10 days time window fulfilled), its physico-chemical characteristics and adsorption properties, emission fractions to surface water of 0.125 and to sludge of 0.018 are predicted. The soil risk assessment is based on time-weighted average concentrations over 30 days (PEC30 d TWA) after 10 years of sludge applications on agricultural soil.

#### 2.5.3.4. Risk characterisation for the Environment

To carry out a quantitative risk assessment for the environment when CMK is used as surface disinfectant, the PEC values were compared to the respective PNEC values for the different compartments, resulting in PEC<sub>CMK</sub>/PNEC<sub>CMK</sub> ratios. These ratios are presented below for the consumption approach, proposed for the disinfection of both industrial premises and institutional/private areas. Cumulated values are further presented. Acceptability of the PEC/PNEC ratios from the tonnage approach carried out for the scenario 'institutional/privates areas' is also summarized.

Table 2.55-62: Risk assessment (PEC/PNEC ratios) for the use of CMK surface disinfectant

Compartment / PEC/PNEC*	STP	Surface water	Sediment	Soil	Ground water, µg.L <sup>-1</sup> *	Food chain (birds)**	
						aquatic	terrestrial
<b>Tonnage approach</b>							
Institutional and private areas	< 1 < 0.1 µg.L <sup>-1</sup> for groundwater						
<b>Consumption approach</b>							
Industrial premises	4.39E-02	0.17	0.17	0.22	<0.1	9.22E-02	6.05E-03
Institutional and private areas	1.54E-02	0.06	0.06	0.08	<0.1	3.23E-02	2.12E-03
Total	5.92E-02	0.22	0.22	0.30	<0.1	1.24E-01	8.16E-03

\*For groundwater, PEC values are compared to the threshold value of 0.1 µg.L<sup>-1</sup>.

\*\* As the PNEC<sub>oral</sub> for birds is more conservative than PNEC<sub>oral</sub> for mammals, only results for birds are presented, as a worst case.

As shown in Table 2.55-62, the risk assessment for the environment of the CMK use as surface disinfectant indicates acceptable risks for all compartments whatever the approach applied (tonnage / consumption; separate / cumulated sub-uses).

#### 2.5.4. Overall conclusion for the environment

The environmental risk assessment of CMK used for PT 2 purposes is based on its use for disinfection of private and public health areas (hospital excluded). The assessment has been carried out through a consumption approach for surface disinfection in industrial premises and through consumption and tonnage approaches for disinfection of institutional/privates areas. For the consumption approach, the highest concentration validated in the efficacy section (0.4% w/v) has been taken into account. Considering both end-uses, sewage treatment plants are the only compartment for direct CMK emissions, whereas surface water bodies (water and



sediment) and soils are indirect targets via STP effluents or the application of sewage sludge to agricultural fields. Due to the physical and chemical properties of CMK, the air is not a compartment of concern. Risk assessment for the environment based on the consumption approach has been performed considering both sub-uses separately and cumulated exposure, as emissions from professional and private uses could occur in the same STP. Whatever the approach considered, acceptable risks for the environment are predicted for the use of CMK as surface disinfectant at a concentration of 0.4% w/v a.s.

### **2.5.5. PBT and POP assessment**

#### **2.5.5.1. PBT assessment**

According to the annex XIII of the REACH regulation EC/1907/2006, substances are classified when they fulfil the criteria for all three inherent properties Persistent, Bioaccumulable, Toxic.

##### ***Persistence criterion***

According to the annex XIII of the REACH regulation EC/1907/2006, a readily biodegradable substance is considered as not persistent in the PBT assessment. CMK is readily biodegradable and the P criterion is therefore considered as not fulfilled.

##### ***Bioaccumulation criterion***

A substance is considered to fulfil the B criterion when the bioconcentration factor (BCF) exceeds a value of 2000 L kg<sup>-1</sup>. A substance is considered very bioaccumulative (vB) when the BCF exceeds a value of 5000 L kg<sup>-1</sup>.

For CMK, according to the BCF values calculated from the log Kow, B criterion is not fulfilled for the aquatic and the terrestrial compartment (BCF<sub>fish</sub> = 73.6 L kg<sup>-1</sup> and BCF<sub>earthworm</sub> = 13.4 L kg<sup>-1</sup>). For the aquatic compartment, the calculated value is in good accordance with supportive data where a maximum BCF value of 121 L kg<sup>-1</sup> has been reported. Considering these results, CMK is considered as not bioaccumulable (B).

##### ***Toxicity criterion***

According to the annex XIII of the REACH regulation EC/1907/2006, the toxicity criterion is fulfilled when the chronic NOEC for aquatic organisms is less than 0.01 mg L<sup>-1</sup> or when the substance is toxic to mammals and classified as Very Toxic or Toxic after oral dosing.

Based on ecotoxicity data on aquatic organisms, the lowest NOEC is obtained in the chronic study performed on *Oncorhynchus mykiss* (Growth rate, semi static 28 d, NOEC = 0.15 mg L<sup>-1</sup>) and is over 0.01 mg L<sup>-1</sup>. Therefore, T criterion is not fulfilled based on ecotoxicity data. Besides, CMK does not meet criteria for classification as carcinogenic, mutagenic or substance toxic for reproduction. At last, CMK does not meet criteria for STOT RE1 or STOT RE2. Therefore, T criterion is not fulfilled based on the human health data.

### **Conclusion**

On the basis of the characteristics of the substance, CMK should not be considered as a PBT nor vPvB substance.

#### **2.5.5.2. POP assessment**

CMK is readily biodegradable, not bioaccumulable and degrades fast in air. Therefore, according to the screening criteria described in the Annex D of the Stockholm convention, CMK is not considered as a POP.

### ***2.5.6. Assessment of endocrine disruptor properties***

According to the human health data, there is slight evidence of endocrine disruption potential of p-chloro-m-cresol *in vitro*. Nevertheless, there were no indications for an endocrine disrupting activity of CMK in a 2 generation study on rats. These results do not lead to consider that the active substance fulfills the exclusion criteria as defined in article 5 d) of regulation (EU)n°528/2012.

## 2.6. Overall conclusions

The outcome of the assessment for p-chloro-m-cresol in product-type 2 is specified in the BPC opinion following discussions at the 15<sup>th</sup> meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

SCENARIO	Human primary exposure		Human secondary exposure		Environment					
	Professional	Non professional	Worker	General public	STP	Aquatic compartment	Terrestrial compartment	Groundwater	Air	Secondary poisoning
<b>Surfaces disinfection in private areas (e.g. households, industrial and institutional uses)</b>										
Bactericidal Fungicidal  0.4 % w/w a.s. for 15 minutes	Not acceptable	Not acceptable	NR	Not acceptable	Acceptable	Acceptable	Acceptable	Acceptable	NR	Acceptable
0.1 % w/w a.s. for 5 minutes	Acceptable	Not acceptable	NR	Not acceptable	Acceptable	Acceptable	Acceptable	Acceptable	NR	Acceptable

NR: not relevant.

**Conditions:** none.

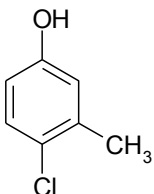
## **2.7. List of endpoints**

The most important endpoints, as identified during the evaluation process, are listed in [Appendix](#).

**Appendix I: List of endpoints****Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling**

Active substance (ISO Name)	p-chloro-m-cresol
Product-type	Fungicide

**Identity**

Chemical name (IUPAC)	4-Chloro-3-methylphenol
Chemical name (CA)	Phenol, 4-Chloro-3-methyl-
CAS No	59-50-7
EC No	200-431-6
Other substance No.	Not allocated
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥ 99.8%
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	m-cresol < 0.1 %
Molecular formula	C <sub>7</sub> H <sub>7</sub> ClO
Molecular mass	142.6 g/mol
Structural formula	

**Physical and chemical properties**

Melting point (state purity)	64.2 °C (purity: 99.9%).
Boiling point (state purity)	242 °C (purity: 100%). After boiling the liquid substance change the colour from colourless to yellowish. This is an indication for a beginning decomposition.
Thermal stability / Temperature of decomposition	The active substance decomposes in a minor degree starting at 95 °C. A significant decomposition is observed at a temperature of approx. 240 °C. CMK is stable at normal and elevated temperatures (54 °C).

Appearance (state purity)	<p>Technical substance: Nearly white solid pellets with characteristic smell.</p> <p>Purified substance: Nearly white solid with slight phenolic odour. Nearly dust free.</p>
Relative density (state purity)	1.335 at 20 °C (purity: 99.9%)
Surface tension (state temperature and concentration of the test solution)	61.49 mN/m at 20 °C CMK is not surface active.
Vapour pressure (in Pa, state temperature)	<p><math>1.4 \times 10^{-03}</math> Pa at 20 °C</p> <p><math>6.0 \times 10^{-03}</math> Pa at 25 °C</p> <p>3.8 Pa at 50 °C</p>
Henry's law constant ( $\text{Pa m}^3 \text{ mol}^{-1}$ )	<p>Ratio between vapour pressure and water solubility:</p> <p><math>6.05 \times 10^{-05} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}</math> at 20 °C and pH 5</p> <p><math>5.87 \times 10^{-05} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}</math> at 20 °C and pH 7</p> <p><math>4.87 \times 10^{-05} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}</math> at 20 °C and pH 9</p> <p>EPIWIN calculation:</p> <p><math>4.64 \times 10^{-02} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}</math> at 25 °C (Bond method)</p> <p><math>6.08 \times 10^{-02} \text{ Pa} \times \text{m}^3 \times \text{mol}^{-1}</math> at 25 °C (Group method)</p>
Solubility in water (g/l or mg/l, state temperature)	<p><u>Results at pH 5:</u> 2.5 g/L at 10°C 3.3 g/L at 20°C 4.5 g/L at 30°C</p> <p><u>Results at pH 7:</u> 2.6 g/L at 10°C 3.4 g/L at 20°C 4.6 g/L at 30°C</p> <p><u>Results at pH 9:</u> 3.1 g/L at 10°C 4.1 g/L at 20°C 5.5 g/L at 30°C</p>
Solubility in organic solvents (in g/l or mg/l, state temperature)	<p>n-Heptane: 4.9 g/L at 10 °C 8.5 g/L at 20 °C 15.4 g/L at 30 °C</p> <p>p-Xylene: 147.9 g/L at 10 °C 233.2 g/L at 20 °C &gt; 250 g/L at 30 °C</p> <p>1,2-Dichloroethane: 205.7 g/L at 10 °C &gt; 250 g/L at 20 °C &gt; 250 g/L at 30 °C</p> <p>The solubilities of CMK in 1-octanol, 2-propanol, acetone and ethyl acetate are &gt; 250 g/L at each temperature.</p>
Stability in organic solvents used in biocidal products including relevant breakdown products	No study is submitted because the active substance CMK as manufactured does not include an organic solvent.

Partition coefficient (log P <sub>ow</sub> ) (state temperature)	To be confirmed before approval of the active substance
Dissociation constant	pK = 9.4 ± 0.1 at 20 °C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Maxima at 228 nm (ε = 9625 l mol <sup>-1</sup> cm <sup>-1</sup> ) Maxima at 281 nm (ε = 2241 l mol <sup>-1</sup> cm <sup>-1</sup> ) (Acetonitrile was used as solvent)
Flammability or flash point	CMK is not highly flammable, does not liberate gases in hazardous amounts when contact with water, does not deliver indications of pyrophoric properties and does not undergo spontaneous combustion.
Explosive properties	Based on scientific judgement it is certified that due to the structural formula CMK contains no oxidising groups or other chemically instable functional groups. Thus the active substance is incapable of rapid decomposition with evolution of gases or release of heat, i.e. the solid material does not present any risk for explosion.
Oxidising properties	Based on scientific judgement it is certified that due to the structural formula CMK does not contain oxidising groups in its molecular backbone and thus may not react exothermically with a combustible material. Therefore the active substance does not have oxidising properties.
Auto-ignition or relative self-ignition temperature	CMK does not undergo spontaneous combustion.

### Classification and proposed labelling

with regard to physical hazards	No classification / labelling results from the physico-chemical properties.
with regard to human health hazards	<p>According to the conclusion of the 36th RAC meeting (March 2016), amendment to the harmonised classification according to Regulation (EC) No 1272/2008 was adopted for CMK:</p> <p>Acute Tox. 4 STOT SE 3 Skin Corr. 1C Eye Dam. 1 Skin Sens 1B H302 Harmful if swallowed. H335 May cause respiratory irritation. H314 Causes severe skin burns and eye damage H318 Causes serious eye damage H317 May cause an allergic skin reaction.</p> <p>Signal Word: Danger</p>

with regard to environmental hazards

No classification / labelling results from the fate and behaviour data.

According to the conclusion of the 36th RAC meeting (March 2016), amendment to the harmonised classification according to Regulation (EC) No 1272/2008 was adopted for CMK:

Aquatic acute 1

Aquatic chronic 3

H400 Very toxic to aquatic organisms.

H412 Harmful to aquatic life with long lasting effects.

M factor = 1 (acute)

## Chapter 2: Methods of Analysis

### Analytical methods for the active substance

Technical active substance (principle of method)

CMK is separated by means of gas chromatography using flame ionisation detection. The quantitative evaluation is carried out by area normalisation with consideration of water content and unvolatilisable components.

Impurities in technical active substance (principle of method)

The analytical method for the determination of impurities in the active substance as manufactured is confidential. This information is provided separately in the confidential part of the dossier.

### Analytical methods for residues

Soil (principle of method and LOQ)

HPLC-MS/MS; LOQ = 5 µg/kg

Air (principle of method and LOQ)

GC-MS; LOQ = 0.3 µg/m<sup>3</sup> air

Water (principle of method and LOQ)

HPLC-MS/MS; LOQ = 0.05 µg/L

Body fluids and tissues (principle of method and LOQ)

Not applicable since CMK is not classified as toxic or highly toxic.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)

No methods required as no exposure is expected.

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)

No methods required as no exposure is expected.

## Chapter 3: Impact on Human Health

### Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:

Assumed to be complete: 100% (from study: 85%)



Rate and extent of dermal absorption\*:

Default values from EFSA guidance (2012):  
25% will be used for concentrated products (> 5% a.s.) and 75% will be used for diluted products (< 5% a.s.).

Distribution:

Potential for accumulation:

None

Rate and extent of excretion:

Within 24 hours after administration, 85.21% and 84.30% of the administered dose was excreted in urine of male and female rats, respectively

Toxicologically significant metabolite(s)

None

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

**Acute toxicity**Rat LD<sub>50</sub> oral

1830 mg/kg bw (♂), H302

Rat LD<sub>50</sub> dermal

&gt; 2000 mg/kg bw (♀), &gt; 5000 mg/kg bw (♂)

Rat LC<sub>50</sub> inhalation> 2871 mg/m<sup>3</sup> (♂ + ♀)**Skin corrosion/irritation**

Skin corr. 1C H314 Causes severe skin burns and eye damage

**Eye irritation**

Eye Dam 1 H318 Causes serious eye damage

**Respiratory tract irritation**

Stot SE 3 H335 May cause respiratory irritation.

**Skin sensitisation (test method used and result)**

Sensitising (GPMT, LLNA),  
Skin Sens; 1B H317 May cause an allergic skin reaction.

**Respiratory sensitisation (test method used and result)****Repeated dose toxicity****Short term**

Species / target / critical effect

Relevant oral NOAEL / LOAEL

3-month rat feeding study: NOEL = 1500 ppm  
 ≅ 120/170 mg/kg/day (♂/♀) based on no effect

combined chronic/carcinogenicity study :  
 105-week rat feeding study: NOAEL = 2000 ppm  
 ≅ 103.1/134.3 mg/kg/day (♂/♀) based on delayed bw gain, poor general condition (♀), water intake↑, kidney weight↑, nephrotoxicity (♂), at terminal sacrifice: reduced spermatozoa in the epididymides and increased degeneration of seminiferous tubules (♂).

No carcinogenic effects.

Relevant dermal NOAEL / LOAEL

21 days study in rabbit:  
 LOAEC = 10 mg/kg/d

13-week rat dermal study:  
 NOEL = 500 mg/kg/day (♂/♀) No adverse effect

Relevant inhalation NOAEL / LOAEL

14days rat (7 days/week):  
 systemic:  
 50 mg/m<sup>3</sup> based on thymus effects  
 local : 50 mg/m<sup>3</sup> based on respiratory effects

**Subchronic**

Species/ target / critical effect  
 Relevant oral NOAEL / LOAEL  
 Relevant dermal NOAEL / LOAEL  
 Relevant inhalation NOAEL / LOAEL


**Long term**

Species/ target / critical effect  
 Relevant oral NOAEL / LOAEL  
 Relevant dermal NOAEL / LOAEL  
 Relevant inhalation NOAEL / LOAEL


**Genotoxicity**

--

**Carcinogenicity**

Species/type of tumour

Rat: Slightly increased incidence of benign Leydig cell tumours of the testes in males as well as adenomas of the pars distalis of the pituitary glands in both sexes, were within the historical control range.

Conclusion: CMK is not considered as having carcinogenic effects and none classification for carcinogenicity is deemed justified.

Relevant NOAEL/LOAEL

**Reproductive toxicity**Developmental toxicity

Species/ Developmental target / critical effect

Relevant maternal NOAEL

Relevant developmental NOAEL

Fertility

Species/critical effect

Relevant parental NOAEL

Relevant offspring NOAEL

Relevant fertility NOAEL

**Neurotoxicity**

Species/ target/critical effect

Rat: no neurotoxicity observed in subchronic or acute neurotoxicity testing

**Developmental Neurotoxicity**

Species/ target/critical effect

**Immunotoxicity**

Species/ target/critical effect

**Developmental Immunotoxicity**

Species/ target/critical effect

**Other toxicological studies****Medical data****Summary**

Value	Study	Safety
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			factor
AEL <sub>long-term</sub>			
AEL <sub>medium-term</sub>			
AEL <sub>short-term</sub>			
ADI <sup>10</sup>	0.3 mg/kg bw/d	Rat developmental study	100
ARfD <sup>8</sup>	0.3 mg/kg bw	Rat developmental study	100

**MRLs**

Relevant commodities

Not relevant.

**Reference value for groundwater**

According to BPR Annex VI, point 68

**Dermal absorption**Study (*in vitro/vivo*), species tested

Formulation (formulation type and including concentration(s) tested, vehicle)

Dermal absorption values used in risk assessment

**Acceptable exposure scenarios (including method of calculation)**

Formulation of biocidal product

Intended uses

Industrial users

Professional users

Non-professional users

General public

Exposure via residue in food

Not relevant.

**Chapter 4: Fate and Behaviour in the Environment****Route and rate of degradation in water**Hydrolysis of active substance and relevant metabolites (DT<sub>50</sub>) (state pH and temperature)

pH 5

pH 9

Other pH: *[indicate the value]*

No hydrolysis at 50°C at pH 4, 7 and 9.

-

-

-

<sup>10</sup> If residues in food or feed.

Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not relevant (absorbance < 290 nm)
Readily biodegradable (yes/no)	Yes (4% of degradation at 5 days, 79% at 15 days, 10-day window fulfilled)
Inherent biodegradable (yes/no)	Yes (after 35 days of acclimatation, 78% of degradation reported at 28 days).
Biodegradation in freshwater	No data
Biodegradation in seawater	Not relevant (no use in the marine environment).
Non-extractable residues	maximum 54.2-54.3 % at 28-14 days, 46.4-52.4% at the end of the study (35d)
Distribution in water / sediment systems (active substance)	<u>Water sediment system</u> DT <sub>50 whole system</sub> = 1.22-1.90 days at 20°C (dissipation) DT <sub>50 whole system</sub> = 2.31-3.60 days at 12°C (dissipation) <u>Endpoint for the risk assessment (worst case of two values): DT<sub>50 whole system</sub> = 3.60 days at 12°C</u>
Distribution in water / sediment systems (metabolites)	Not identified radioactivity Water: maximum 27-32.7% at 3-4 days, 2.4-17.8% at the end of the study (35d). A complementary study allowed to state that 7 different metabolites contribute to this not identified radioactivity. Only one metabolite, identified as phenol amounted to 9.9% of the initial applied radioactivity and has been considered as metabolite of concern. Sediment: not relevant (<10%) DT <sub>50 whole system</sub> = 6.97-36.4 days at 20°C DT <sub>50 whole system</sub> = 13.22-71.95 days at 12°C

### Route and rate of degradation in soil

Mineralization (aerobic)	No key study available
Laboratory studies (range or median, with number of measurements, with regression coefficient)	No key study available. A default value based on the ready biodegradation test is assumed: DT <sub>50</sub> = 30 days.
DT <sub>50lab</sub> (20°C, aerobic):	
DT <sub>90lab</sub> (20°C, aerobic):	
DT <sub>50lab</sub> (10°C, aerobic):	
DT <sub>50lab</sub> (20°C, anaerobic):	
degradation in the saturated zone:	
Field studies (state location, range or median with number of measurements)	No key study available
DT <sub>50f</sub> :	

DT <sub>90f</sub> :	
Anaerobic degradation	No key study available. An anaerobic biodegradation test with digested sludge revealed the compound not to be susceptible to this degradation mechanism.
Soil photolysis	Photolysis is not a major way of degradation for CMK (see above).
Non-extractable residues	Not determined
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not determined
Soil accumulation and plateau concentration	Not determined

### Adsorption/desorption

Ka , Kd Ka <sub>oc</sub> , Kd <sub>oc</sub> pH dependence (yes / no) (if yes type of dependence)	<p><u>HPLC screening test:</u> Koc = 158.5 (log Koc = 2.21)</p> <p><u>Batch equilibrium test (four tested soil but only two soil with recovery ≥77%)</u> K'a = 1.9, 7.6 mgL/g K'oc = 160.9, 230.3 mL/g K<sub>Fa</sub> = 3, 11 μg<sup>1-1n</sup>(cm<sup>3</sup>)<sup>1/n</sup>g<sup>-1</sup> K<sub>oc</sub>a = 270, 322 μg<sup>1-1n</sup>(cm<sup>3</sup>)<sup>1/n</sup>g<sup>-1</sup> K<sub>Fd</sub> = 0.5, 1.8 μg<sup>1-1n</sup>(cm<sup>3</sup>)<sup>1/n</sup>g<sup>-1</sup> Arithmetic mean of Koc = 195.6 mgL/g. Endpoint selected for the risk assessment.</p>
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### Fate and behaviour in air

Direct photolysis in air	Not relevant because there is no relevant release of the compound to the air compartment.
Quantum yield of direct photolysis	Not relevant because there is no relevant release of the compound to the air compartment.
Photo-oxidative degradation in air	DT <sub>50</sub> = 14.995 hours (AOPWIN calculation, considering an OH-radicals concentration of 0.5 x10 <sup>6</sup> molec.cm <sup>-3</sup> and 24 hours)
Volatilization	According to the vapour pressure and the Henry's law constant there are no indications for a significant volatilisation of CMK.

### Reference value for groundwater

According to BPR Annex VI, point 68	
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**Monitoring data, if available**

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

**Chapter 5: Effects on Non-target Species****Toxicity data for aquatic species (most sensitive species of each group)**

Species	Time-scale	Endpoint	Toxicity
<b>Fish</b>			
<i>Oncorhynchus mykiss</i>	96 hours U.S.-EPA FIFRA § 72-1 Static renewal	Mortality	LC <sub>50, 48h</sub> = 0.92 mg/L mean measured concentration
<i>Oncorhynchus mykiss</i>	28 days OECD 204 (1984) + 215 (2000) semi static	Mortality, symptoms of intoxication, growth parameters	NOEC = 0.15 mg/L mean measured concentration
<i>Brachydanio rerio</i>	14 days Comparable with OECD 204 (1984) Flow-through	Mortality, sublethal and behaviour response	NOEC = 1.0 mg/L Nominal concentration
<b>Invertebrates</b>			
<i>Daphnia magna</i>	48 hours U.S.-EPA FIFRA § 72-2 static	Mortality; behavioural, sub-lethal effects	EC <sub>50, 48h</sub> : 2.29 mg/L mean measured concentration
<i>Daphnia magna</i>	21 d OECD 211 (1998) Semi static	Survival of parent animals and number of offsprings	NOEC = 0.32 mg/L Nominal concentration
<b>Algae</b>			
<i>Desmodesmus subspicatus</i>	72 hours OECD 201 (2006) static	Growth inhibition	NOEC <sub>, 72h</sub> = 3.1 mg/L (biomass) NOEC <sub>, 72h</sub> = 9.8 mg/L (growth rate) E <sub>b</sub> C <sub>50, 72h</sub> = 17.18 mg/L E <sub>r</sub> C <sub>50, 72h</sub> = 30.62 mg/L Nominal concentration
<b>Microorganisms</b>			

Activated sludge	3 hours OECD 209	Respiration inhibition	EC <sub>10</sub> = 5.7 mg/L
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### Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms

OECD 207 (1984); *Eisenia fetida*; Mortality  
LC<sub>50</sub> (14 days) = 139.4 mg/kg d.wt. soil  
(94.8 mg/kg d.wt. soil for an organic matter  
content of 3.4%)

Reproductive toxicity to earthworms

No study available

### Effects on terrestrial plants

Acute toxicity to terrestrial plants  
(Annex IIIA, point XIII 3.4)

OECD 208 (Draft 2005); *Brassica napus*;  
Growth reduction  
EC<sub>50</sub> (14 days) = 27.7 mg/kg d.wt. soil (54.3  
mg/kg d.wt. soil for an organic matter  
content of 3.4%)

### Effects on soil micro-organisms

Nitrogen mineralization

OECD 216 (2000); Nitrate transformation  
NOEC (28 days) = 30 mg/kg d.wt. soil (40.3  
mg/kg d.wt. soil for an organic matter  
content of 3.4%)

Carbon mineralization

OECD 217 (2000); Respiration  
EC<sub>50</sub> (28 days) > 19 mg/kg d.wt. soil (>34.5  
mg/kg d.wt. soil for an organic matter  
content of 3.4%)

### Effects on terrestrial vertebrates

Acute toxicity to mammals

1830 mg/kg bw (♂)

Acute toxicity to birds

U.S.-EPA FIFRA 71-1;  
*Colinus virginianus*, single dose  
LD<sub>50</sub> (14 days) > 1449 mg/kg bw

Dietary toxicity to birds

US-EPA FIFRA 71-2 (1982);  
*Colinus virginianus*, sub-acute toxicity (5  
days),  
LC<sub>50</sub> > 2995 mg/kg feed  
mean measured concentration

Reproductive toxicity to birds

No study available

### Effects on honeybees

Acute oral toxicity

No study available

Acute contact toxicity

No study available



**Effects on other beneficial arthropods**

Acute oral toxicity	No study available
Acute contact toxicity	No study available
Acute toxicity to .....	No study available

**Bioconcentration**

Bioconcentration factor (BCF)	OECD 305C BCF = 5.5 - 11
Depration time (DT <sub>50</sub> )	Not relevant
Depration time (DT <sub>90</sub> )	Not relevant
Level of metabolites (%) in organisms accounting for > 10 % of residues	No metabolites identified

**Chapter 6: Other End Points**

None

### Appendix II: List of Intended Uses

Object and/or situation	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment, as proved with efficacy data submitted	Remarks
			Type	Conc. of as	method kind	number min max	interval between applications (min)	g as/L min max	
private area disinfectant PT 2	Dettol New Wave	Bacteria Fungi	SC suspension concentrate	40 g/L (4 % w/w)	Surface	-	-	Bacteria, Yeasts : 0,1 % w/v CMK; 5 minutes Fungi: 0.4 % w/v CMK; 15 minutes	-

**Appendix III: List of studies**List of Submitted Studies - Part A

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A2.7(01)	Anonymous	2002	Product specification Preventol CMK pellets. Date: 2002-08-16	LANXESS Deutschland GmbH, Leverkusen, Germany	Art.-No.: 04189671	No	No	Yes	LANXESS Deutschland GmbH
A3.1(01) A3.10(01)	Erstling, K.	2001a	Physicochemical properties: Preventol CMK (pellets). Date: 2001-11-15 Amended: 2006-03-29	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/01 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.1(02)	Haßmann, V.	1992	Preventol CMK – Bulk density. Date: 1992-03-06	Bayer AG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.1(03)	Erstling, K.	2007	Melting point of Preventol CMK. Date: 2007-10-17	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	2006/0014/04	Yes	No	Yes	LANXESS Deutschland GmbH
A3.1(04)	Erstling, K.	2008	Boiling point of Preventol CMK. Date: 2008-05-15	CURRENTA GmbH & Co. OHG, Services Analytik, Leverkusen, Germany	2006/0025/13	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.10(01) A3.1(01)	Erstling, K.	2001a	Physicochemical properties: Preventol CMK (pellets). Date: 2001-11-15 Amended: 2006-03-29	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/01 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.10(02)	Ambroz, J.	2000	Determination of the stability of Preventol CMK to normal and elevated temperature. Date: 2000-09-12	ABC Laboratories, Inc., Columbia, Missouri, USA	Study No.: 46189	Yes	No	Yes	LANXESS Deutschland GmbH
A3.10(03)	Königer, A.	2010	Amendment to Physicochemical properties: Preventol CMK (pellets). Date: 2010-02-24	CURRENTA GmbH & Co. OHG, Services Analytik, Leverkusen, Germany	A 01/0108/01 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.11(01)	Heitkamp, D.	2006	Determination of safety-relevant data of Preventol CMK Pastillen. Date: 2006-03-29	Bayer Industry Services GmbH & Co. OHG, Leverkusen, Germany	2006/00416	Yes	No	Yes	LANXESS Deutschland GmbH
A3.13(01)	Olf, G.	2006b	Surface tension, Physical-chemical properties. Date: 2006-03-17 Amended: 2006-05-10	Bayer AG, BTS-PT-RPT-KPM, Leverkusen, Germany	06/002/03	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.15(01)	Kraus, H.	2006b	4-Chloro-3-methylphenol / Explosive properties. Date: 2006-03-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.16(01)	Kraus, H.	2006c	4-Chloro-3-methylphenol / Oxidising properties. Date: 2006-03-03	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.17(01)	Kraus, H.	2006d	4-Chloro-3-methylphenol (CMK) / Reactivity towards container material. Date: 2006-06-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.2(01)	Olf, G.	2006a	Vapour pressure, Physical-chemical properties. Date: 2006-04-25 Amended: 2006-05-10	Bayer AG, BTS-PT-RPT-KPM, Leverkusen, Germany	06/002/01	Yes	No	Yes	LANXESS Deutschland GmbH
A3.2(02)	Beißel, U.	2006	Calculation of Henry's Law Constant of p-chloro-m-cresol (CMK). Date: 2006-05-17	Dr. Knoell Consult GmbH, Leverkusen, Germany	2006/05/17/UB	No	No	Yes	LANXESS Deutschland GmbH
A3.2(03)	Wielpütz, T.	2008	4-Chloro-3-methylphenol (Preventol CMK), Batch No.: CHA0152, Vapour pressure A.4 (OECD 104). Date: 2008-08-19	Siemens AG, Prozess-Sicherheit, Industriepark Hoechst, Frankfurt am Main, Germany	20080599.01	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.3(01)	Kraus, H.	2006a	4-Chloro-3-methylphenol / Appearance. Date: 2006-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.3(02)	Güldner, W.	2009	Determination of dustiness (optical dust factor) of Preventol CMK pastilles. Date: 2009-09-30	Bayer CropScience AG, Development, Formulation Technology, Monheim, Germany	FM0045(RP00)G01	Yes	No	Yes	Bayer CropScience AG
A3.4(01)	Wesener, J.	2006	Spectra. Date: 2006-03-14 Amended: 2006-04-03	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	2006/0025/03	No	No	Yes	LANXESS Deutschland GmbH
A3.5(01)	Erstling, K.	2001b	Water solubility. Date: 2001-09-11	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/02 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.6(01) A3.9(01)	Reusche, W.	1991	Partition coefficient, dissociation constant and pH value, Preventol CMK. Date: 1991-01-07 Amended: 2007-03-06	Bayer AG, ZF-D/Zentrale Analytik, Leverkusen, Germany	A90/0107/03 LEV	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.6(02) A3.9(02)	Erstling, K.	2001c	Partition coefficient (n-octanol/water) / dissociation constant, Preventol CMK (pellets). Date: 2001-10-23 Amended: 2001-11-14 Amended: 2006-03-29	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/03 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.6(03)	Feldhues, E.	2006a	Statement, Dissociation constant of 4-chloro-3-methylphenol Preventol CMK. Date: 2006-08-31	Bayer Industry Services, BIS-SUA-PUA I, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.7(01)	Jungheim, R.	2006a	Solubility of Preventol CMK (pellets) in different organic solvents at 10 °C, 20 °C and 30 °C. Date: 2006-11-30	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	2006/0025/09	Yes	No	Yes	LANXESS Deutschland GmbH
A3.9(01) A3.6(01)	Reusche, W.	1991	Partition coefficient, dissociation constant and pH value, Preventol CMK. Date: 1991-01-07 Amended: 2007-03-06	Bayer AG, ZF-D/Zentrale Analytik, Leverkusen, Germany	A90/0107/03 LEV	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.9(02) A3.6(02)	Erstling, K.	2001c	Partition coefficient (n-octanol/water) / dissociation constant, Preventol CMK (pellets). Date: 2001-10-23 Amended: 2001-11-14 Amended: 2006-03-29	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/03 LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A3.9(03)	Jungheim, R.	2006b	Calculation of the partition coefficient (1-octanol/water) at 10 °C, 20 °C and 30 °C based on water solubility and 1-octanol solubility of Preventol CMK (pellets) determined under study number A 01/0108/02 LEV and 2006/0025/09. Date: 2006-12-01	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	2006/0025/08	Yes	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.9(04)	Feldhues, E.	2007	Appraisal of the results obtained in Bayer Report A 90/0107/03 LEV, Bayer Report A 01/0108/03 LEV and in Bayer Industry Services Report 2006/0025/08 for the partition coefficient of Preventol CMK. Date: 2007-01-29	Bayer Industry Services, BIS-SUA-PUA I, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A4.1(01)	Jungheim, R.	2006c	Validation of a GC-Method for Preventol CMK (Pellets). Date: 2006-04-21 <b>CONFIDENTIAL</b>	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	Study No.: 2006/0014/01	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2(01)	Brumhard, B.	2006	Analytical method 00998 for the determination of residues of Preventol CMK (4-chloro-3-methylphenol) in soil by HPLC-MS/MS. Date: 2006-08-24	Bayer Crop Science AG, Development, Residues, Operator and Consumer Safety, Monheim am Rhein, Germany	MR-06/102	Yes	No	Yes	LANXESS Deutschland GmbH
A4.2(02)	Feldhues, E.	2006b	Validation of an analytical method for the determination of Preventol CMK in air samples. Date: 2006-08-30	Bayer Industry Services, BIS-SUA-Analytics, Leverkusen, Germany	2006/0014/03	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A4.2(03)	Krebber, R.	2006	Analytical method 01004 for the determination of Preventol CMK (4-chloro-3-methylphenol) in drinking and surface water by HPLC-MS/MS. Date: 2006-09-05	Bayer Crop Science AG, Development, Residues, Operator and Consumer Safety, Monheim am Rhein, Germany	MR-06/112	Yes	No	Yes	LANXESS Deutschland GmbH
A5.3.1(01)	Kugler, M.	2003	Determination of the antimicrobial effects of Preventol CMK against bacteria and fungi. Date: 2003-05-22	Bayer Chemicals AG, Leverkusen, Germany	Report No. 2003-05-21	No	No	Yes	LANXESS Deutschland GmbH
A5.3.1(02)	Schlicht, A. and Kőszegi, D.	2008	<i>Quantitative suspension test according to EN 1040 and EN 1275 (Dilution neutralisation). SF-CMK without Preventol CMK/SF-CMK with 10% Preventol CMK.</i>	<i>Technical Report Labor L&amp;S AG, Bad Bocklet-Großenbrach, Germany, 2008-09-24 (unpublished).</i>	-	No	No	Yes	LANXESS Deutschland GmbH
A5.3.1(03)	Schlicht, A. and Schlösser, A.	2008	<i>Quantitative surface test according to EN 13697 (pour plate). Preventol CD 260 with 4.8 % PCMC with pine oil.</i>	<i>Technical Report Labor L&amp;S AG, Bad Bocklet-Großenbrach, Germany, 2008-09-03 (unpublished).</i>	-	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.1.1(01)	[REDACTED]	1988a	Preventol CMK Untersuchung zur akuten oralen Toxizität an männlichen und weiblichen Wistar-Ratten. Date: 1988-08-18	[REDACTED]	17062	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.1(02)	[REDACTED]	1978 and 1992	Preventol CMK Untersuchung zur akuten oralen Toxizität an männlichen und weiblichen Wistar-Ratten. Date: 1992-11-24 (revised report)	[REDACTED]	21862	No	No	Yes	LANXESS Deutschland GmbH
A6.1.1 Non-key study	[REDACTED]	1981	Acute Oral Toxicity of PCMC (p-Chloro-m-cresol) to rats. Date: 1981-01-06	[REDACTED]	80-011-14	No	No	Yes	LANXESS Deutschland GmbH
A6.1.2(01)	[REDACTED]	1999	Acute Dermal Toxicity Study with Preventol CMK Pastillen in Rats. Date: 1999-10-29	[REDACTED]	99-A22-FN	Yes	No	Yes	Bayer Corporation

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.1.2 Non key study	[REDACTED]	1988b	Preventol CMK – Investigation of acute cutaneous toxicity in male and female Wistar rats. Date: 1988-08-18	[REDACTED]	17063	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.2 Non-key study	[REDACTED]	1979	Acute Dermal Administration Study in Male and Female Rabbits. Preventol CMK. Date: 1979-10-12	[REDACTED]	Project No. 339-108	No	No	Yes	LANXESS Deutschland GmbH
A6.1.3(01)	[REDACTED]	2003	PREVENTOL CMK Study on Acute Inhalation Toxicity Study in Rats according to OECD No. 403. Date: 2003-01-28	[REDACTED]	AT00251	Yes	No	Yes	LANXESS Deutschland GmbH
A6.1.3 Non-key study	Thyssen, J.	1981	Preventol CMK, Study for Acute Toxicity of Fumes and Dusts after Inhalation. Date: 1981-10-21	Bayer AG, Institute of Toxicology, Wuppertal, Germany	10282	No	No	Yes	LANXESS Deutschland GmbH
A6.1.4(01)	Lamb, D.W.	1976	Preventol CMK – The eye and dermal irritancy of Mobay sample p-Chloro-m-cresol. Date: 1976-11-30	Chemagro Agricultural Division, Mobay Chemical Corp. R&D	50874	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.1.4 Non-key study	Krötlinger, F.	1991	Preventol CMK. Date: 1991-02-14	Bayer AG, Fachbereich Toxikologie, Wuppertal, Germany	--	No	No	Yes	LANXESS Deutschlan d GmbH
A6.1.4 Non-key study	██████████	2006a	Preventol CMK – Acute Skin Irritation/ Corrosion on Rabbits. Date: 2006-07-24	██████████ ██████████ ██████████	AT03215	No	No	Yes	LANXESS Deutschlan d GmbH
A6.1.4 Non-key study	██████████	2006b	Preventol CMK – T 7053199 – Acute Eye Irritation on Rabbits. Date: 2006-07-24	██████████ ██████████ ██████████	AT03216	No	No	Yes	LANXESS Deutschlan d GmbH
A6.1.4 Non-key study	Thyssen, J.	1978	Preventol CMK, Investigation of Skin and Mucous Membrane Tolerance. Date: 1978-09-20 Addendum: 1983-01- 11	Bayer AG, Institute of Toxicology, Wuppertal, Germany	--	No	No	Yes	LANXESS Deutschlan d GmbH
A6.1.5(01)	██████████	2000	Preventol CMK, Pastillen LOCAL LYMPH NODE ASSAY IN MICE (LLNA/IMDS). Date: 2000-11-13	██████████ ██████████ ██████████ ██████████	PH 30408	Yes	No	Yes	LANXESS Deutschlan d GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.1.5(02)	Bomhard, E. and Löser, E.	1980	Preventol CMK– Investigation of sensitizing effect (Maximisation test after Magnusson and Kligman). Date: 1980-01-23	Bayer AG, Institute of Toxicology, Wuppertal, Germany	8897	No	No	Yes	LANXESS Deutschland GmbH
A6.1.5 Non-key study	Bomhard, E. and Löser, E.	1981	Preventol CMK, Evaluation to determine the sensitisation effect by means of the open epicutaneous test. Date: 1981-09-25	Bayer AG, Institute of Toxicology, Wuppertal, Germany	9447	No	No	Yes	LANXESS Deutschland GmbH
A6.2(01) Non-key study	██████████	1980	Excretion kinetics of Preventol CMK after a single oral administration to rats. Date: 1980-12-02	██████████ ██████████ ██████████	9605	No	No	Yes	LANXESS Deutschland GmbH
A6.2(02) Non-key study	██████████ ██████████ ██████████	1981	Investigation into the detection of Preventol CMK in fatty tissue and liver tissue in rats. Date: 1981-02-17	██████████ ██████████ ██████████	9807	No	No	Yes	LANXESS Deutschland GmbH
A6.2(03) Published	Roberts, M.S. <i>et al.</i>	1977	Permeability of human epidermis to phenolic compounds.	Pharmacy Dept., Univ. of Sydney, Australia	<i>J. Pharm. Pharmac.</i> <b>29</b> , 677-683	No	Yes	No	–

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.2(04)	██████████	2009	Mass Balance and Metabolism of [14C]-4-Chloro-3-methylphenol in Male and Female Rats After Single Oral Administration. Date: 2009-02-19	██████████ ██████████ ██████████	C07812	Yes	No	Yes	LANXESS Deutschland GmbH
A6.2 Non-key Published	Bartels, M.J. <i>et al.</i>	1998	Comparative metabolism of <i>ortho</i> -phenylphenol in mouse, rat and man.	Dow Chemical Company, Midland, MI, USA	<i>Xenobiotica</i> <b>28</b> (6), 579-594	No	Yes	No	-
A6.2 Non-key study Published	Huq, A.S. <i>et al.</i>	1986	Permeation of Water Contaminative Phenols Through Hairless Mouse Skin.	College of Pharmacy, University of Michigan, Ann Arbor, MI, USA	<i>Arch. Environ. Contam. Toxicol.</i> <b>15</b> , 557-566	No	Yes	No	--
A6.2 Non-key study Published	Kao, L.R. and Birnbaum, L.S.	1986	Disposition of <i>o</i> -Benzyl- <i>p</i> -Chlorophenol in Male Rats	Systemic Toxicology Branch, NIEHS, Research Triangle Park, NC, USA	<i>Journal of Toxicology and Environmental Health</i> , <b>18</b> , 441 - 458, 1986	No	Yes	No	-
A6.3.1(01)	██████████	1989	Preventol CMK – Range-finding subacute toxicological investigations in Wistar rats for the determination of a maximum tolerable dosage (Administration with food over 4 weeks). Date: 1989-02-20	██████████ ██████████ ██████████	17739	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.3.2(01)	[REDACTED]	1993a	PREVENTOL CMK – Preliminary trial for determining the dose for a sub-chronic study on male Wistar rats (dermal treatment for 4 weeks). Date: 1993-10-19	[REDACTED]	22606	No	No	Yes	LANXESS Deutschland GmbH
A6.3.2(02)	[REDACTED]	1980	Subchronic Dermal Study in Rabbits. Preventol CMK. Date: 1980-07-31	[REDACTED]	Project No. 339-109	Yes	No	Yes	LANXESS Deutschland GmbH
A6.3.3	Rajsekhar, P.V.	2011	14-Day Repeated Dose Inhalation Toxicity Study with Preventol CMK	International Institute of Biotechnology and Toxicology (IIBAT), Padappai, Tamil Nadu, India	Report No. 11011	Yes	No	Yes	LANXESS Deutschland GmbH
A6.4.1(01)	[REDACTED]	1988	Preventol CMK: Subchronic toxicological study in rats (feeding study lasting 3 month). Date: 1988-11-24	[REDACTED]	17414 (revision of Report No. 10283)	No	No	Yes	LANXESS Deutschland GmbH
A6.4.2(01)	[REDACTED]	1991	Preventol CMK: Subchronic Toxicity Study in Wistar Rats (Dermal Treatment for 13 Weeks). Date: 1991-08-30	[REDACTED]	20585	Yes	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.4.1 Non-key study	[REDACTED]	1981	Preventol CMK: Subchronic toxicological test in rats. 3-Month feeding test. Date: 1981-10-21	[REDACTED]	10283	No	No	Yes	LANXESS Deutschland GmbH
A6.5(01) A6.7(01)	[REDACTED]	1993b	Preventol CMK: Chronic Toxicity and Carcinogenicity Study in Wistar Rats (Administration in Feed for 105 Weeks). Date: 1993-04-02 Addendum: 1994-12-06	[REDACTED]	22168	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.1(01)	Herbold, B.A.	1991	Preventol CMK – Salmonella/Microsome Plate Test. Date: 1991-08-08	Bayer AG, Wuppertal, Germany	20516	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.2(01)	[REDACTED]	1988	Mutagenicity Test on Preventol CMK in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay. Date: 1988-10-04	[REDACTED]	R 4545	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.6.3(01)	Lehn, H.	1989	Preventol CMK – Mutagenicity Study For The Detection Of Induced Forward Mutations in the CHO-HGPRT Assay in vitro. Date: 1989-02-22	Bayer AG, Wuppertal, Germany	17755	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.4(01)	██████████	1990	Preventol CMK MICRONUCLEUS TEST ON THE MOUSE. Date: 1990-01-17 Amended: 1991-08-08	██████████ ██████████ ██████████	18686 Amendment: 18686A	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.4 Non-key study	██████████	1981	Preventol CMK. Micronucleus Test on the Mouse to test for a Mutagenic Effect. Date: 1981-10-16	██████████ ██████████ ██████████ ██████████	10255	No	No	Yes	LANXESS Deutschland GmbH
A6.7(01) A6.5(01)	██████████	1993b	Preventol CMK: Chronic Toxicity and Carcinogenicity Study in Wistar Rats (Administration in Feed for 105 Weeks). Date: 1993-04-02 Addendum: 1994-12-06	██████████████████ ██████████████ ██████████████ ██████████████ ██████████	22168	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.8.1(01)	██████████	1991	Preventol CMK - Study for embryotoxic effects in rats after oral administration. Date: 1991-11-29	██████████ ██████████ ██████████	20869	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2(01)	██████████	2006b	4-Chloro-3-methylphenol – Two-Generation Reproduction Study in Rats by Administration in the Diet. Date: 2006-12-19	██████████████████ ██████████████ ██████████████ ██████████	AT03531	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2 Non-key	██████████	2006a	4-Chloro-3-methylphenol (Preventol CMK), One-Generation Reproduction Study in Wistar Rats (Pilot Study for a Two-Generation Reproduction Study with Administration in the Diet). Date: 2006-02-06	██████████████████ ██████████████ ██████████████ ██████████	AT02804	Yes	No	Yes	LANXESS Deutschland GmbH
A6.9 Non-key study	Leser, K.H.	1992	Preventol CMK (PCMC) / Adverse neurological effects. Date: 1992-09-07	Bayer AG, GB PH/F+E, Institut für Toxikologische Industriechemikalien, Wuppertal, Germany	--	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.10 Non-key study Published	Meiss, R. <i>et al.</i>	1981	New aspects of the origin of hepatocellular vacuoles.	Univ. of Münster, Germany	<i>Exp. Path.</i> <b>19</b> , 239-246	No	Yes	No	-
A6.10 Non-key study Published	Robenek, H. <i>et al.</i>	1980	Alterations in the Rat Liver Induced by p-Chlor-m-Cresol with Emphasis on the Intercellular Junctions.	Univ. of Münster, Germany	<i>J. Submicrosc. Cytol.</i> <b>12</b> (4), 635-646	No	Yes	No	-
A6.11 Non-key study Published	Wien, R.	1939	The Toxicity of <i>Parachlorometacresol</i> and of Phenylmercuric Nitrate.	-	<i>Q.J. Pharm. Pharmacol.</i> <b>12</b> , 212-229	No	Yes	No	-
A6.12.2(01)	Ainley, E.J., Mackie, I.G. and Macarthur, D.	1977	Adverse reaction to chlorocresol-preserved heparin.	University Hospital of Wales, Cardiff, UK	<i>Lancet</i> <b>1</b> : 705	No	Yes	No	-
A6.12.2(02) A6.12.6	Hancock, B.W. and Naysmith, A.	1975	Hypersensitivity to Chlorocresol-preserved Heparin. <i>British Medical Journal</i> : 746-747, 1975	Royal Hospital, Sheffield, UK	<i>British Medical Journal</i> , 746 - 747,	No	Yes	No	--
A6.12.2(03)	Joppich, G.	1960	Tödliche Vergiftung durch Sagrotan bei Säuglingen.	University Children's Hospital Göttingen, Germany	<i>Deut. Med. J.</i> <b>11</b> ; 20 -21	No	Yes	No	--
A6.12.2(04) Published	Wiseman, H.M. <i>et al.</i>	1980	Acute poisoning to Wright's Vaporizing Fluid.	National Poisons Information Service, London, UK	<i>Postgraduate Medical Journal</i> : 56, 166 - 168 (1980)	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.12.2 Non-key Published	Jonsson, J. and Voigt, G.E.	1984	Homicidal intoxications by lye- and parachlorocresol-containing disinfectants.	State Dept. of Forensic Chemistry, Linköping, Sweden	<i>Am. J. Forensic Med. Pathol.</i> <b>5</b> (1), 57-63	No	Yes	No	--
A6.12.6(01)	Angelini, G. <i>et al.</i>	1975	Contact dermatitis in patients with leg ulcers.	Dept. of Dermatology, Univ. of Bari, Italy	<i>Contact Dermatitis</i> <b>1</b> , 81-87	No	Yes	No	-
A6.12.6(02) published	Oleffe J.A. <i>et al.</i>	1979	Allergy to chlorocresol and propylene glycol in a steroid cream to chlorocresol-preserved heparin	-	<i>Contact Dermatitis</i> <b>5</b> : 53-54	No	Yes	No	--
A6.12.6(03) published	Lewis, P.G. and Emmett, E.A.	1987	Irritant dermatitis from tri-butyl tin oxide and contact allergy from chlorocresol.	Johns Hopkins Medical Institutions, Baltimore, MD, USA	<i>Contact Dermatitis</i> <b>7</b> : 129-132, 1987	No	Yes	No	--
A6.12.6 Non-key study Published	Andersen, K.E. and Veien, N.K.	1985	Biocide patch tests	Gentofte Hospital, Hellerup, Denmark	<i>Contact Dermatitis</i> <b>12</b> , 99-103	No	Yes	No	-
A6.12.6 Non-key Published	Archer, C.B. and MacDonald, D.M.	1984	Chlorocresol sensitivity induced by treatment of allergic contact dermatitis with steroid creams.	Dept. of Dermatology, Guy's Hospital, London, UK	<i>Contact Dermatitis</i> <b>11</b> , 144-145	No	Yes	No	-
A6.12.6 Non-key study Published	Brasch, J. <i>et al.</i>	1993	Patch Test Reactions to a Preliminary Preservative Series.	Information Network of Dermatological Clinics (IVDK)	<i>Dermatosen</i> <b>41,2</b> ; 71-76	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.12.6 Non-key study Published	Burry, J.N. <i>et al.</i>	1975	Chlorocresol sensitivity	St. Peters, South Australia	<i>Contact Dermatitis</i> <b>1</b> , 41-42	No	Yes	No	--
A6.12.6 Non-key study Published	de Boer, E.M. <i>et al.</i>	1989	Dermatoses in metal workers (II). Allergic contact dermatitis.	Free University Academic Hospital, Amsterdam, The Netherlands	<i>Contact Dermatitis</i> <b>20</b> , 280-286	No	Yes	No	-
A6.12.6 Non-key study Published	Dooms-Goossen, A. <i>Et al.</i>	1981	Chlorocresol and chloracetamide: Allergens in medications, glues, and cosmetics	Dept. Of Dermatology, Academisch Ziekenhuis St.Peter, Leuven, Belgium	<i>Contact Dermatitis</i> <b>7</b> , 51-52	No	Yes	No	-
A6.12.6 Non-key study Published	Freitas, J.P. and Brandao, F.M.	1986	Contact urticaria to chlorocresol.	Dept. Of Dermatology, Santa Maria Hospital, Lisbon, Portugal	<i>Contact Dermatitis</i> <b>15</b> , 252	No	Yes	No	-
A6.12.6 Non-key study Published	Geier, J. <i>et al.</i>	1996	Contact Allergy due to Industrial Biocides.	Information Network of Dermatological Clinics (IVDK)	<i>Dermatosen</i> <b>44</b> (4), 154-159	No	Yes	No	--
A6.12.6 Non-key study Published	Goncalo, M. <i>et al.</i>	1987	Immediate and delayed sensitivity to chlorocresol.	Clinica de Dermatologica e Venereologica, Coimbra, Portugal	<i>Contact Dermatitis</i> <b>17</b> , 46-47	No	Yes	No	--
A6.12.6 A6.12.2(02)	Hancock, B.W. and Naysmith, A.	1975	Hypersensitivity to Chlorocresol-preserved Heparin. <i>British Medical Journal</i> : 746-747, 1975	Royal Hospital, Sheffield, UK	<i>British Medical Journal</i> , 746 - 747,	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.12.6 Non-key study published	Rudner, E.J.	1977	North American Group Results	-	<i>Contact Dermatitis</i> <b>3</b> : 208-209	No	Yes	No	-
A6.12.6 Non-key study Published	Uter, W. <i>et al.</i>	1993	Contact Allergy in Metal Workers.	Information Network of Dermatological Clinics (IVDK) in Germany	<i>Dermatosen</i> <b>41</b> (6), 220-227	No	Yes	No	-
A6.12.6 Non-key study Published	Wilkinson, J.D. <i>et al.</i>	1980	Comparison of Patch Test Results in Two Adjacent Areas of England. II. Medicaments.	Slade Hospital, Oxford & Wycombe General Hospital, England	<i>Acta Dermatovener (Stockholm)</i> <b>60</b> , 245-249	No	Yes	No	
A6.12.7 A6.12.8	Joppich, G.	1962	Klinik und Behandlung der Sagrotanvergiftung. <i>Deut. Med. J.</i> :11; 20-21, 1960	University Children's Hospital Göttingen, Germany	<i>Deut. Med. J.</i> <b>13</b> ; 691-693	No	Yes	No	--
A7.1.1.1.1(01)	Erstling, K. and Feldhues, E.	2001a	Abiotic degradation. Date: 2001-08-31 Amended: 2007-02-22	Bayer AG, Zentrale Analytik, Leverkusen, Germany	A 01/0108/04 LEV	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.1.1.2(01)	Wilmes, R.	1988	Tests to determine the photodegradation of 4-chloro-3-methylphenol (Preventol CMK) in water. Determination of the quantum yield of direct photodegradation in water in polychromatic light (ECETOC method). Date: 1988-05-30	Bayer AG, Sector 5. Agrochemicals Business Group, PF-F/CE-ME, Monheim, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(01)	Müller, G.	1992	Investigations of the ecological behaviour of Preventol CMK Date: 1992-02-25	Bayer AG, Institut für Umweltanalyse und Bewertungen, Leverkusen, Germany	A 330 A/91	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(02)	Weyers, A.	2007	Preventol CMK – Biodegradation. Re-Evaluation based on Study Report 330 A/91, corresponding raw data and additional information provided by the sponsor. Date: 2007-03-09 Amended: 2007-03-16	Bayer Industry Services, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.1.2.1(01, 02, 04)	Neuhahn, A.	2012	2. Amendment to GLP-Final Report Study Title: Biodegradation. Re-evaluation based on study report 330 A/91. Date: 2012-05-14	Currenta GmbH & Co. OHG, Leverkusen, Germany	-	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(03)	Hanstveit, A.O. and Pullens, M.A.H.L.	1993	The biodegradability of the product Preventol CMK in a closed bottle test according to a draft OECD guideline: ready biodegradability; the influence of inoculum activity. Date: 1993-01-15 Amended: 2007-03-30	TNO Institute of Environmental Sciences, Delft, The Netherlands	R 92/198	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(04) A7.1.1.2.2(02) Non-key study	Neuhahn	1981	Biodegradability of Preventol CMK (4-chloro-3-methylphenol), OECD 301 D. Date: 1981-05-26	Bayer AG, OC-P/Ökologie, Leverkusen, Germany	NHH-Go/2694	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.1.2.1(05) Non-key study	N.N.	1985	Biodegradability of Preventol CMK (4-chloro-3-methylphenol), OECD 301 C. Date: July 1985	Bayer AG, WV-UWS/LE, Microbiology, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(06) A7.1.2.1.1(01) Non-key study	Cernick, S.L.	1999	A study of the biodegradability of 4-chloro-3-methylphenol by aerobic biological treatment. Date: 1999-05-13	Duquesne University	--	No	Yes	No	--
A7.1.1.2.2(01)	Thompson, R.S.	1993	Parachlorometacresol : Further study of inherent biodegradability. Date: 1993-06-29	Brixham Environmental Laboratory, Zeneca limited, Brixham Devon, UK	BL4783/B	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.2(02) A7.1.1.2.1(04) Non-key study	Neuhahn	1981	Biodegradability of Preventol CMK (4-chloro-3-methylphenol), OECD 301 D. Date: 1981-05-26	Bayer AG, OC-P/Ökologie, Leverkusen, Germany	NHH-Go/2694	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(01) A7.1.1.2.1(06) Non-key study	Cernick, S.L.	1999	A study of the biodegradability of 4-chloro-3-methylphenol by aerobic biological treatment. Date: 1999-05-13	Duquesne University	--	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.1.1(02) Non-key study	Dohm	1981	Biodegradability of Preventol CMK. Date: 1981-08-20	Bayer Uerdingen Site, Organic Chemicals Division, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(03) Non-key study	Dohm	1984	CMK content in ppb in wastewater, Uerdingen wastewater treatment plant. Date: 1984-07-03	Bayer Uerdingen Site, Organics BG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(04) Non-key study	Dohm	1985	CMK in the wastewater treatment plant outlet. Date: 1985-03-01	Bayer Uerdingen Site, Organics BG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(05) Non-key study	N.N.	1981	Degradability of p-chloro-m-cresol in the central biological wastewater treatment plant Uerdingen. Date: 1981-08-25	Bayer Uerdingen Site, UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(06) Non-key study	N.N.	1983	Elimination of p-chloro-m-cresol (CMK) in the biological wastewater treatment plant Uerdingen. Date: 1983-01-07	Bayer Uerdingen Site, UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.1.1(07) Non-key study	N.N.	1986	Elimination of chlorometacresol (CMK) in the 2-stage biological wastewater treatment plant UE. Date: 1986-05-16	Bayer Uerdingen Works, WV-UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(08) Non-key study	N.N.	1988	CMK concentration in the discharge of the Uerdingen biological wastewater treatment plant. Date: 1988-12-02	Bayer Uerdingen Site, WV-UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(09) Non-key study	Rother	1996	Preventol CMK, CMK-Na: Analysis of Wastewater from the Leather Industry Date: 1996-01-25	Bayer, Material Protection Unit, Organic Chemicals Business Group, Uerdingen	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(10) Non-key study	Morris, R.	2002	Bench Scale Biological Treatment of Preventol CMK for General Motor's Lansing Plant #5 Date: 2002-08-30	Bayer's Corporate Environmental Testing Services Laboratory, New Martinsville, West Virginia	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1 (11) Non-key Published	Bolz, U. et al.	1999	Determination of phenolic xenoestrogens in sediments and sewage sludges by HRGC/LRMS. <i>Organohalogen Compounds, Vol. 40, 65-68.</i>	-	-	No	Yes	No	-

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.1.1 (11) Non-key Published	Bolz, U. et al.	2001	Phenolic xenoestrogens in surface water, sediments, and sewage sludge from Baden-Württemberg, south-west Germany. <i>Environmental Pollution, 115, 291-301</i>	-	-	No	Yes	No	-
A7.1.2.1.1 Non-key Published	Körner, W. et al.	1998	Input/output balance of estrogenic active compounds in a major municipal sewage plant in Germany. <i>Organohalogen Compounds, Vol. 37, 269-272.</i>	-	-	No	Yes	No	-
A7.1.2.1.1(11) Non-key Published	Körner, W. et al.	2000	Input/output balance of estrogenic active compounds in a major municipal sewage plant in Germany. <i>Chemosphere, Vol. 40, 1131-1142</i>	-	-	No	Yes	No	-

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.1.1(11) Non-key published	Schnaak, W. et al.	1997	Organic contaminants in sewage sludge and their ecotoxicological significance in the agricultural utilization of sewage sludge. <i>Chemosphere, Vol. 35, 5-11.</i>	-	-	No	Yes	No	-
A7.1.2.1.1(11) Non-key published	Ternes, Th. A.	1998	Simultaneous determination of antiseptics and acidic drugs in sewage and river water. <i>Vom Wasser, 90, 295-309.</i>	-	-	No	Yes	No	-
A7.1.2.1.2(01)	Reis, K.-H.	2007	Anaerobic biodegradability of 4-chloro-3-methylphenol (Preventol CMK) in digested sludge: Measurement of gas production	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	32321168	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.2(02)	Voets, J.P., Pipyn, P., van Lancker, P. and Verstrate, W.	1976	Degradation of Microbiocides under Different Environmental Conditions. <i>J. appl. Bact., 40, 67 - 72, 1976</i>	Laboratory of General and Industrial Microbiology, State University of Gent, Gent, Belgium.	--	No	Yes	No	--

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A7.1.2.1.2(03)	O'Conner, O.A. & Young, L.Y.	1989	Toxicity and anaerobic biodegradability of substituted phenols under methanogenic conditions. <i>Environ. Toxicol. Chem.</i> 8, 853 – 862, 1989	Institute of Environmental Medicine and Department of Microbiology, New York University Medical Center, New York, USA	--	No	Yes	No	--
A7.1.2.1.2(04)	Kirk, P.W.W. & Lester, J.N.	1989	Degradation of phenol, selected chlorophenols and chlorophenoxy herbicides during anaerobic sludge digestion. <i>Environm. Technol. Lett.</i> 10, 405 – 414, 1989	Public Health Engineering Laboratory, Department of Civil Engineering, Imperial College of Science, Technology and Medicine, London, UK	--	No	Yes	No	--
A7.1.2.1.2(05)	Feil, N.	2009	Anaerobic biodegradability of 4-Chloro-3-methylphenol (Preventol CMK) in digested sludge: Measurement of gas production.	Institut für biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	45822168	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.2(06)	Möndel, M.	2010a	Anaerobic biodegradability of Preventol CMK in digested sludge Date: 2010-05-26	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Germany	AS 142	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.1.2(07) A7.2.1/A7.2.2	Gerharz, T.	2011a	Degradation of 4-chloro-3-cresol in pork liquid manure under anaerobic conditions. Date: 2011-05-26	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-10	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.1(01)	Rast, H.-G. and Kölbl, H.	1987	Microbial degradation of Preventol CMK in Rhine water. Date: 1987-10-20 Amended:	Bayer AG, FBT Leverkusen, Germany	LEV 14/76 and LEV 11/76	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.1(02) A7.2.1/A7.2.2	Gerharz, T.	2011b	Degradation of 4-chloro-3-cresol in a liquid environment (washing water after stable cleaning – stable with laying hens). Date: 2011-05-26	LANXESS Deutschland GmbH, Leverkusen, Germany	None	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(01)	Möndel, M.	2009	<sup>14</sup> C-Preventol CMK: Aerobic degradation of <sup>14</sup> C-Preventol CMK in two different aquatic sediment systems. Date: 2009-03-26	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Germany	AS 85	Yes	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.2.2(02)	Möndel, M.	2010b	<sup>14</sup> C-Preventol CMK: Characterisation of non-identified radioactivity of <sup>14</sup> C-Preventol CMK in aquatic sediment systems. Date: 2010-05-21	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Gemany	AS 139	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(03) / B7.5(05)	Dixon, E.M.	1997	Proposed environmental quality standards for 4-chloro-3-methylphenol in water. Draft final report to the Department of the Environment, UK. 72p	-	No	Yes	No	-	-
A7.1.2.2.2(03)	Bolz, U. <i>et al.</i>	1999	Determination of phenolic xenoestrogens in sediments and sewage sludges by HRGC/LRMS. <i>Organohalogen Compounds, Vol. 40, 65-68.</i>	-	-	No	Yes	No	-

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A7.1.2.2.2(03) / B7.5(04)	Bolz, U. <i>et al.</i>	2001	Phenolic xenoestrogens in surface water, sediments, and sewage sludge from Baden-Württemberg, south-west Germany. <i>Environmental Pollution</i> , 115, 291-301	-	-	No	Yes	No	-
A7.1.2.2.2(03)	Körner, W. <i>et al.</i>	2001	Steroid analysis and xenosteroid potentials in two small streams in southwest Germany. <i>Journal of Aquatic Ecosystem Stress and Recovery</i> , 8, 215-229.	-	-	No	Yes	No	-
A7.1.2.2.2(03) / B7.5(06)	Lacorte, S. <i>et al.</i>	2001	Main findings and conclusions of the implementation of Directive 76/464/CEE concerning the monitoring of organic pollutants in surface waters (Portugal, April 1999 – May 2000). <i>Journal of Environmental Monitoring</i> , 3, 475-482	-	-	No	Yes	No	-

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.2.2.2(03) / B7.5(03)	Schmidt-Bäumler, K., <i>et al.</i>	1999	Occurrence and distribution of organic contaminants in the aquatic system in Berlin. Part II: substituted phenols in Berlin surface water.	-	-	No	Yes	No	-
B7.5(01) Non-key study	Grote	1987	No title. Date: 1987-07-14	LE Environmental Protection/ AWALU, Analytics, Air Laboratory, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B7.5(02) Non-key study	Oblak	1989	Determination of 4-chloro-3-methylphenol (CMK) in Rhine water (Ultra Trace range). Date: 1989-12-06	Bayer AG, Uerdingen, Central Analytics, Uerdingen, Germany	LM Ue 50/89	No	No	Yes	LANXESS Deutschland GmbH
A7.1.3(01)	Erstling, K. and Feldhues, E.	2001b	Adsorption/Desorption. Date: 2001-09-13 Amended: 2001-11-13 and 2007-02-22	Bayer AG, ZF – Zentrale Analytik, Leverkusen, Germany	A 01/0108/05/ LEV	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.1.3(01) Non-key study/ published	Ohlenbusch, G., Kumke, M.U. and Frimmel, F.H.	2000	Sorption of phenols to dissolved organic matter investigated by solid phase microextraction. <i>The Science of the Total Environment</i> 253, 63 – 74, 2000	Bereich Wasserchemie, Universität Karlsruhe, Germany	--	No	Yes	No	--
A7.1.3(02) and A7.2.3.1(01)	Meinerling, M.	2007	Determination of the Adsorption / Desorption behaviour of 4-Chloro-3-methylphenol (Preventol CMK) Date: 2007-06-20	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany,	32323195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.3(02) and A7.2.3.1(01)	Meinerling, M.	2008	Determination of the Stability of 4-Chloro-3-methylphenol (Preventol CMK) in Soils of an Adsorption/Desorption Study	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	45821195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.2.1/ A7.2.2 Non-key study/ published	Federle, T.W.	1988	Mineralization of monosubstituted aromatic compounds in unsaturated and saturated subsurface soils. Can. J. Microbiol. 34: 1037-1042	-	-	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.2.1/A7.2.2/ A7.1.2.1.2(07)	Gerharz, T.	2011a	Degradation of 4-chloro-3-cresol in pork liquid manure under anaerobic conditions. Date: 2011-05-26	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-10	No	No	Yes	LANXESS Deutschland GmbH
A7.2.1/A7.2.2 A7.1.2.2.1(02)	Gerharz, T.	2011b	Degradation of 4-chloro-3-cresol in a liquid environment (washing water after stable cleaning – stable with laying hens). Date: 2011-05-26	LANXESS Deutschland GmbH, Leverkusen, Germany	None	No	No	Yes	LANXESS Deutschland GmbH
A7.2.1/ A7.2.2 Non-key study/ published	Gerharz, T.	2011c	Vaporisation behaviour of 4-chloro-3-methylphenol from an inert surface (glass petri dish)	LANXESS Deutschland GmbH, Leverkusen, Germany	Lab Report ID: D 2011-22.1.5	No	No	Yes	LANXESS Deutschland GmbH
A7.2.1/ A7.2.2 Non-key study/ published	Loehr, R.C. and Matthews, J.E.	1992	Loss of organic chemicals in soil. Pure compound treatability studies. <i>Journal of Soil Contamination</i> <b>1(4)</b> , 339-360, 1992	Environmental and Water Resources Engineering Laboratories, Texas, Austin, USA	--	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.2.1/ A7.2.2 Non-key study/ published	Sattar, M.A.	1989	Fate of chlorinated cresols from environmental samples. <i>Chemosphere</i> <b>19</b> (8/9), 1421 - 1426, 1989	Department of Soil Science, Agricultural University, Mymensingh, Bangladesh	--	No	Yes	No	--
A7.2.2.1	Nitsche, M.	2011	Biodegradation of Preventol® CMK (4-Chloro-3-methylphenol) in soil under aerobic conditions.	LANXESS Deutschland GmbH	2011-07-25	No	No	Yes	LANXESS Deutschland GmbH
A7.2.3.1(01) and A7.1.3(02)	Meinerling, M.	2007	Determination of the Adsorption / Desorption behaviour of 4-Chloro-3-methylphenol (Preventol CMK) Date: 2007-06-20	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany,	32323195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.2.3.1(02) and A7.1.3(02)	Meinerling, M.	2008	Determination of the Stability of 4-Chloro-3-methylphenol (Preventol CMK) in Soils of an Adsorption/Desorption Study	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	45821195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.2.3.2 Non-key study	Brown, K.W., Barbee, G.C. and Thomas, J.C.	1990	Detecting organic contaminants in the unsaturated zone using soil and soil-pore water samples.	--	<i>Hazardous Waste and Hazardous Materials</i> <b>7 (2)</b> , 151 - 168	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.3.1(01)	Anthe, M.	2006	p-Chloro-m-cresol. Calculation of indirect photodegradation. Date: 2006-07-05	Dr. Knoell Consult GmbH, Leverkusen, Germany	KC-PD-04/06	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.1(01)	██████████ ██████████ ██████████	1993a	Acute Toxicity of Preventol CMK Technical to the Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) Under Static Renewal Conditions. Date: 1993-02-19	████████████████████ ████████████████████ ████████████████████ ████████████████████	105020	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.2(01)	Gagliano, G.G. and Bowers, L.M.	1993b	Acute Toxicity of Preventol CMK technical to the Waterflea ( <i>Daphnia magna</i> ) under static conditions. Date: 1993-02-19	Miles Incorporated, Agriculture Division, South Metcalf, Stilwell, Kansas, US	105021	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3(01)	Caspers, N.	1983/1991	Preventol CMK (4-chloro-3-methylphenol) – Growth Inhibition Test Algae. Date: 1991-01-28	Bayer AG, WV-Umweltschutz, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.4.1.3(02)	Weyers, A.	2006a	Preventol CMK – Algae, Growth Inhibition Test. Re-Evaluation based on Study Report Growth Inhibition Test Algae (1983) and the corresponding raw data. Date: 2006-07-07	Bayer Industry Services, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.3(03)	Vinken, R. and Wydra, V.	2007	Toxicity of 4-Chloro-3-methylphenol (Preventol CMK) to <i>Desmodesmus subspicatus</i> in an Algal Growth Inhibition Test. Date: 2007-01-04	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	Project No. 32324210	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.1.4(01)	Kanne, R.	1988	Preventol CMK – Toxicity towards Bacteria. Date: 1988-02-10	Bayer AG, WV-LE Umweltschutz, Leverkusen, Germany	88105507	No	No	Yes	LANXESS Deutschland GmbH
A7.4.1.4(02)	Weyers, A.	2006b	Preventol CMK – Toxicity towards Bacteria. Re-Evaluation based on Study Report No. 88105507, corresponding raw data and additional information provided by the sponsor. Date: 2006-06-29	Bayer Industry Services, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.4.1.4(03)	Neuhahn, A.	2008	Activated Sludge, Respiration Inhibition Test with Preventol CMK Pastillen. Date: 2008-08-19	Currenta GmbH & Co. OHG, Services Analytik, Leverkusen, Germany	2006/0025/16	Yes	No	Yes	Lanxess Deutschland GmbH
A7.4.2(01)	Paul, A.	2007	p-Chloro-m-cresol (CMK) – Calculation of the bioconcentration factor (BCF) Date: 2007-05-31	DR. KNOELL CONSULT GmbH, Mannheim, Germany	KC-BCF-07/07	No	No	Yes	LANXESS Deutschland GmbH
A7.4.2(02) Non-key study/ published	MITI (Ministry of International Trade & Industry)	1992	Biodegradation and bioaccumulation: Data of existing chemicals based on the CSCL Japan. Published by Japan Chemical Industry Ecology-Toxicology & Information Center, 1992	--	--	No	Yes	No	--
A7.4.2(03) Non-key study/ published	Jennings, J.G., de Nys, R., Charlton, T.S., Duncan, M.W. and Steinberg, P.D.	1996	Phenolic compounds in the nearshore waters of Sidney, Australia. <i>Mar. Freshwater Res.</i> <b>47</b> , 951 – 959, 1996	--	--	No	Yes	No	--

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.4.3.1(01)	Caspers, N. and Müller, G.	1991	Preventol CMK: Prolonged Toxicity Test with Zebrafish ( <i>Brachydanio rerio</i> ). Date: 1991-11-13	Bayer AG, Institut für Umweltanalyse und Bewertungen, Leverkusen, Germany	212 A/90FL	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.1(02)	Weyers, A.	2006c	Preventol CMK – Fish, prolonged toxicity test. Re-Evaluation based on Study Report 212 A/90FL, corresponding raw data and additional information provided by the sponsor. Date: 2006-07-05	Bayer Industry Services, Leverkusen, Germany	--	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.2(01)	██████████ ██████████ ████	2007	Toxicity of 4-Chloro-3-methylphenol (Preventol CMK) to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) in a Prolonged Semi Static Test over 28 Days. Date: 2007-03-28	██████████ ██████████████████ ██████████████████ ██████████████████	32325231	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.4.3.4(01) Non-key study/ published	Kühn, R., Pattard, M., Pernak, K.-D. Winter, A.	1988	Research Report 10603052: Harmful effects of chemicals in the <i>Daphnia</i> reproduction test as a basis for assessing their environmental hazard in aquatic systems. Date: 1988-03-31	Institute for Water, Land and Air Hygiene of the Federal German Health Office	--	No	Yes	No	--
A7.4.3.4(01) Non-key study/ published	Jungheim R	2006	Addendum to Research Report 10603052: Harmful effects of chemicals in the <i>Daphnia</i> reproduction test as a basis for assessing their environmental hazard in aquatic systems.	Bayer Industry Services, Leverkusen, Germany	--	Yes	No	Yes	LANXESS Deutschland GmbH
A7.4.3.4(02)	Weyers, A.	2007	Preventol CMK Pastillen - <i>Daphnia</i> <i>magna</i> Reproduction Test. Date: 2007-03-08	Bayer Industry Services GmbH & Co. OHG, Leverkusen, Germany	2006/0025/10	Yes	No	Yes	Lanxess Deutschland GmbH
A7.5.1.1(01)	Reis, K.-H.	2007	Effects of 4-Chloro-3- methylphenol (Preventol CMK) on the activity of the soil microflora in the laboratory.	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	32322080	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.5.1.1(02)	Schulz, L.	2012	Preventol CMK – Effects on the activity of soil microflora (Nitrogen transformation test). Date: 2012-04-13.	BioChem agrar, Labor für biologische und chemische Analytik GmbH 04827 Gerichshain, Germany	Project-No. 12 10 48 011 N,	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.2	Lührs, U.	2007	Acute Toxicity (14 Days) of 4-Chloro-3-methylphenol (Preventol CMK) to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5% Peat. Date: 2007-01-17	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	Project No. 32326021	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.1.3(01)	Buetzler, R. and Meinerling, M.	2007	Effects of Preventol CMK on terrestrial (non-target) plants: Seedling emergence and seedling growth test	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	32327086	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.3.1.1(01)	██████████ ██████	1993a	Preventol CMK: An acute oral LD <sub>50</sub> with Bobwhite Quail. Date: 1993-02-19	██████████ ██████████ ██████████ ██████████	105005	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.3.1.2(01)	██████████ ██████	1993b	Preventol CMK: A subacute dietary LD <sub>50</sub> with Bobwhite Quail. Date: 1993-02-19	██████████ ██████████ ██████████ ██████████	105006	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A7.5.5(01)	Fàbregas, E.	2007	p-Chloro-m-cresol (CMK) – Calculation of the bioconcentration factor in earthworms (BCFearthworm). Date: 2007-05-30	DR. KNOELL CONSULT GmbH, Mannheim, Germany	KC-BCF-06/07	No	No	Yes	LANXESS Deutschland GmbH
Published	European Commission	2000	IUCLID Dataset – CAS No. 108-95-2 - Phenol	-	-	No	Yes	No	-
Published	United States Environmental Protection Agency (EPA) (Ed.)	2009	Reregistration Eligibility Decision for Phenol & Salts	-	EPA 739-R-08-010	No	Yes	No	-

## List of Submitted Studies - Part B

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.1(01) B3.5(02) B3.7(03) B3.8(01)	Gerharz, T.	2011 a	Storage stability of the formulation Dettol New Wave at 0 °C. Date: 2011-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-25	No	No	Yes	LANXESS Deutschland GmbH
A3.2(02)	Beiell, U.	2006	Calculation of Henry's Law Constant of p-chloro-m-cresol (CMK). Date: 2006-05-17	Dr. Knoell Consult GmbH, Leverkusen, Germany	2006/05/17/UB	No	No	Yes	LANXESS Deutschland GmbH
B3.4(01) B3.6(01) B3.10(01)	Gaudio, C.	2007	Chemical properties testing of Dettol New Wave 1256-144. Date: 05-08-2007	Reckitt Benckiser Center of Innovation, Montale NJ	Report UND #M1126-003-v1.0	No	No	Yes	Reckitt Benckiser
B3.4(01)	Gaudio, C.	2007	Chemical properties testing of Dettol New Wave 1256-144. Date: 05-08-2007	Reckitt Benckiser Center of Innovation, Montale NJ	Report UND #M1126-003-v1.0	No	No	Yes	Reckitt Benckiser
B3.5(01) B3.7(01)	Kilvington, K.	1991 a	Project Jonas-Fifty-two week storage stability data (Z459). Date: August 1991	Reckitt & Colman Products Ltd	Report No. SORS 33042/019	No	No	Yes	Reckitt Benckiser

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.5(02) B3.1(01) B3.7(03) B3.8(01)	Gerharz, T.	2011 a	Storage stability of the formulation Dettol New Wave at 0 °C. Date: 2011-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-25	No	No	Yes	LANXESS Deutschland GmbH
B3.5(03) B3.7(02) B3.8(03)	Kilvington, K.	1993	Project Jonas-Three year stability data (Z459). Date: October 1993	Reckitt & Colman Products Ltd	Report No. SORS 33042/023	No	No	Yes	Reckitt Benckiser
B3.6(01) B3.4(01) B3.10(01)	Gaudio, C.	2007	Chemical properties testing of Dettol New Wave 1256-144. Date: 05-08-2007	Reckitt Benckiser Center of Innovation, Montale NJ	Report UND #M1126-003-v1.0	No	No	Yes	Reckitt Benckiser
B3.7(01)	Kilvington, K.	1991	Project Jonas-Fifty-two week storage stability data (Z459). Date: August 1991	Reckitt & Colman Products Ltd	Report No. SORS 33042/019	No	No	Yes	Reckitt Benckiser
B3.7(02)	Kilvington, K.	1993	Project Jonas-Three year stability data (Z459). Date: October 1993	Reckitt & Colman Products Ltd	Report No. SORS 33042/023	No	No	Yes	Reckitt Benckiser
B3.7(01) B3.5(01)	Kilvington, K.	1991 a	Project Jonas-Fifty-two week storage stability data (Z459). Date: August 1991	Reckitt & Colman Products Ltd	Report No. SORS 33042/019	No	No	Yes	Reckitt Benckiser
B3.7(02) B3.5(03) B3.8(03)	Kilvington, K.	1993	Project Jonas-Three year stability data (Z459). Date: October 1993	Reckitt & Colman Products Ltd	Report No. SORS 33042/023	No	No	Yes	Reckitt Benckiser

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.7(03) B3.5(02) B3.1(01) B3.8(01)	Gerharz, T.	2011 a	Storage stability of the formulation Dettol New Wave at 0 °C. Date: 2011-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-25	No	No	Yes	LANXESS Deutschland GmbH
B3.8(01) B3.1(01) B3.5(02) B3.7(03)	Gerharz, T.	2011 a	Storage stability of the formulation Dettol New Wave at 0 °C. Date: 2011-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-25	No	No	Yes	LANXESS Deutschland GmbH
B3.8(02)	Gerharz, T.	2011 b	Persistent foaming of the formulation Dettol new Wave. Date: 2011-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	D 2011-25	No	No	Yes	LANXESS Deutschland GmbH
B3.8(03) B3.7(02) B3.5(03)	Kilvington, K.	1993	Project Jonas-Three year stability data (Z459). Date: October 1993	Reckitt & Colman Products Ltd	Report No. SORS 33042/023	No	No	Yes	Reckitt Benckiser
A3.10(01)	Erstling, K.	2001	Physicochemical properties: Preventol CMK (pellets). Date: 2001-11-15 Amended: 2006-03-29	Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany	A 01/0108/01 LEV	Yes	No	Yes	LANXESS Deutschland GmbH



Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A3.10(02)	Ambroz, J.	2000	Determination of the stability of Preventol CMK to normal and elevated temperature. Date: 2000-09-12	ABC Laboratories, Inc., Columbia, Missouri, USA	Study No.: 46189	Yes	No	Yes	LANXESS Deutschland GmbH
A3.11(01)	Heitkamp, D.	2006	Determination of safety-relevant data of Preventol CMK Pastillen. Date: 2006-03-29	Bayer Industry Services GmbH & Co. OHG, Leverkusen, Germany	2006/00416	Yes	No	Yes	LANXESS Deutschland GmbH
A3.15(01)	Kraus, H.	2006 a	4-Chloro-3-methylphenol / Explosive properties. Date: 2006-03-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.16(01)	Kraus, H.	2006 b	4-Chloro-3-methylphenol / Oxidising properties. Date: 2006-03-03	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A3.17(01) A8.1(02)	Kraus, H.	2006 c	4-Chloro-3-methylphenol (CMK) / Reactivity towards container material. Date: 2006-06-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B3.10(01) B3.4(01) B3.6(01)	Gaudio, C.	2007	Chemical properties testing of Dettol New Wave 1256-144. Date: 05-08-2007	Reckitt Benckiser Center of Innovation, Montale NJ	Report UND #M1126-003-v1.0	No	No	Yes	Reckitt Benckiser

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B4.1(01)	Kilvington, K.	1991 b	Project Jonas – Parachlorometacresol Assay Validation. Date: February 1991 <b>CONFIDENTIAL</b>	Reckitt & Colman Products Ltd	Report No. SORL 33042/012	No	No	Yes	Reckitt Benckiser
A8	Anonymous	2005	Safety Data Sheet Preventol CMK pellets. Date: 2005-10-06	LANXESS Deutschland GmbH, Leverkusen, Germany	690981/13	No	No	--	LANXESS Deutschland GmbH
A8.1(02) A3.17(01)	Kraus, H.	2006 c	4-Chloro-3-methylphenol (CMK) / Reactivity towards container material. Date: 2006-06-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B8	Anonymous	2007	Safety Data Sheet Dettol® New Wave Disinfectant. Date: 2007-03-19	Reckitt Benckiser (U.K.), HULL, United Kingdom	Product code: 0011891 (1147-131A)	No	No	No	Reckitt Benckiser
B5.10(01)	Richardson, J. L. et al.	1991	In vitro antimicrobial activity of Project Jonas in comparison with Dettol and Savlon using a modified European Suspension Test. Date: August 1991	Reckitt & Colman Products	Report No. SORL 33042/011	No	No	Yes	Reckitt Benckiser

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B5.10(02)	Gibson, S.A.W.	1991 b	Assessment of the in vitro antimicrobial activity of Project Jonas using the Australian Therapeutic Goods Act (TGA) Test. Date: March 1991	Reckitt&Colman Products, Australia	Test Report No. SORL 33042/008	No	No	Yes	Reckitt Benckiser
B5.10(03)	Richardson, J. L.	1991	Assessment of the in vitro antimicrobial activity of Project Jonas using the Kelsey Sykes Capacity Test. Date: March 1991	Reckitt&Colman Products, U.K.	Test Report No. SORL 33042/005	Yes	No	Yes	Reckitt Benckiser
B5.10(04)	Gibson, S.A.W.	1991 a	Assessment of the in vitro antimicrobial activity of Project Jonas using the AOAC – Use Dilution Method Date: March 1991	Reckitt&Colman Products, U.K.	Test Report No. SORL 33042/007	No	No	Yes	Reckitt Benckiser
B5.10(05)	Gibson, S.A.W.	1991 c	Assessment of the in vitro antimicrobial activity of Project Jonas using the French AFNOR Standard Test. Date: March 1991	Reckitt&Colman Products, U.K.	Test Report No. SORL 33042/014	No	No	Yes	Reckitt Benckiser

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B5.10(06)	Gerharz, T.	2011c	Preventol® CMK - Determination of disinfection properties of Preventol® CMK in accordance with EN 13697. Date: 2011-12-08	LANXESS Deutschland GmbH, Leverkusen, Germany	None	No	No	Yes	LANXESS Deutschland GmbH
A6.1.1(02)	[REDACTED]	1978 and 1992	Preventol CMK Untersuchung zur akuten oralen Toxizität an männlichen und weiblichen Wistar-Ratten. Date: 1992-11-24 (revised report)	[REDACTED]	21862	No	No	Yes	LANXESS Deutschland GmbH
A6.1.2(01)	[REDACTED]	1999	Acute Dermal Toxicity Study with Preventol CMK Pastillen in Rats. Date: 1999-10-29	[REDACTED]	99-A22-FN	Yes	No	Yes	Bayer Corporation
A6.1.3(01)	[REDACTED]	2003	PREVENTOL CMK Study on Acute Inhalation Toxicity Study in Rats according to OECD No. 403. Date: 2003-01-28	[REDACTED]	AT00251	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
A6.1.4(01)	Lamb, D.W.	1976	Preventol CMK – The eye and dermal irritancy of Mobay sample p-Chloro-m-cresol. Date: 1976-11-30	Chemagro Agricultural Division, Mobay Chemical Corp. R&D	50874	No	No	Yes	LANXESS Deutschland GmbH
B6.2	Roberts, M.E.	1991	Human 5-Day Open Application Study of Project Jonas, Dettol and Savlon. Date: 1991-03-11	Toxicol Laboratories Ltd., Ledbury, UK	Study No. R/3/90	Yes	No	Yes	Reckitt Benckiser
B6.3(01)	██████████	1998	Examination of Preventol CD 260 in a Skin Sensitisation Test in Guinea Pigs. Date: 1998-12-04	██████████ ██████████ ██████████	R7319	Yes	No	Yes	LANXESS Deutschland GmbH
B6.3(02)	Dickson, J.E.A.	2007	Dose Range Finding Study followed by a Human Repeat Insult Patch Test (based on the Shelanski and Shelanski Method). Date: 2007-03-20	Charles River Laboratories, Tranent, UK	27635	Yes	No	Yes	Reckitt Benckiser plc
B6.3(03) Non-key	Cuthbert, J.A. and Neilson, L.	1991	Dettol Liquid; Project Jonas: A Human Repeat Insult Patch Test. Date: 1991-03-29	Inveresk Research International, Tranent, UK	6970	No	No	Yes	Reckitt Benckiser plc

Section No. in Doc III-B or III-A	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B6.5	Exner, O., Matysiak, R. and Stroeck, K.	2001	Preventol CD 590 - Measurement of the concentrations of orthophenylphenol and p-chloro-metacresol in the air during and after floor disinfection	Bayer AG, Krefeld, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B6.5 Published	IPCS	1990	Environmental Health Criteria 103, Section 8.1.3	International Programme on Chemical Safety	-	-	Yes	No	-
B6.5 Published	IUCLID	2000	IUCLID Dataset Propan-2-ol, EINECS No. 200-661-7, 19-Feb-2000	-	-	-	Yes	No	-
Published	Van Veen, M.P.	2001	CONSEXPO 3.0, Consumer exposure and uptake models.	RIVM, Bilthoven, The Netherlands	612810 011	No	Yes	No	-
A7.1.1.1.1(01)	Erstling, K. and Feldhues, E.	2001a	Abiotic degradation. Date: 2001-08-31 Amended: 2007-02-22	Bayer AG, Zentrale Analytik, Leverkusen, Germany	A 01/0108/04 LEV	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.1.2(01)	Wilmes, R.	1988	Tests to determine the photodegradation of 4-chloro-3-methylphenol (Preventol CMK) in water. Determination of the quantum yield of direct photodegradation in water in polychromatic light (ECETOC method). Date: 1988-05-30	Bayer AG, Sector 5. Agrochemicals Business Group, PF-F/CE-ME, Monheim, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(01)	Müller	1992	Investigations of the ecological behaviour of Preventol CMK Date: 1992-02-25	Bayer AG, Institut für Umweltanalyse und Bewertungen, Leverkusen, Germany	A 330 A/91	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.1.2.1(02)	Weyers, A.	2007	Preventol CMK – Biodegradation. Re-Evaluation based on Study Report 330 A/91, corresponding raw data and additional information provided by the sponsor. Date: 2007-03-09 Amended: 2007-03-16	Bayer Industry Services, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.2.1.1(02) Non-key study	Dohm	1981	Biodegradability of Preventol CMK. Date: 1981-08-20	Bayer Uerdingen Site, Organic Chemicals Division, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(03) Non-key study	Dohm	1984	CMK content in ppb in wastewater, Uerdingen wastewater treatment plant. Date: 1984-07-03	Bayer Uerdingen Site, Organics BG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(04) Non-key study	Dohm	1985	CMK in the wastewater treatment plant outlet. Date: 1985-03-01	Bayer Uerdingen Site, Organics BG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(05) Non-key study	N.N.	1981	Degradability of p-chloro-m-cresol in the central biological wastewater treatment plant Uerdingen. Date: 1981-08-25	Bayer Uerdingen Site, UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(06) Non-key study	N.N.	1983	Elimination of p-chloro-m-cresol (CMK) in the biological wastewater treatment plant Uerdingen. Date: 1983-01-07	Bayer Uerdingen Site, UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH



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A7.1.2.1.1(07) Non-key study	N.N.	1986	Elimination of chlorometacresol (CMK) in the 2-stage biological wastewater treatment plant UE. Date: 1986-05-16	Bayer Uerdingen Works, WV-UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(08) Non-key study	N.N.	1988	CMK concentration in the discharge of the Uerdingen biological wastewater treatment plant. Date: 1988-12-02	Bayer Uerdingen Site, WV-UE Environmental Protection/AWALU, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(09) Non-key study	Rother	1996	Preventol CMK, CMK-Na: Analysis of Wastewater from the Leather Industry Date: 1996-01-25	Bayer, Material Protection Unit, Organic Chemicals Business Group, Uerdingen	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1(10) Non-key study	Morris, R.	2002	Bench Scale Biological Treatment of Preventol CMK for General Motor's Lansing Plant #5 Date: 2002-08-30	Bayer's Corporate Environmental Testing Services Laboratory, New Martinsville, West Virginia	--	No	No	Yes	LANXESS Deutschland GmbH
A7.1.2.1.1 (11) Non-key Published	Bolz, U. et al.	1999	Determination of phenolic xenoestrogens in sediments and sewage sludges by HRGC/LRMS. <i>Organohalogen Compounds, Vol. 40, 65-68.</i>	-	-	No	Yes	No	-

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B7.5(04) Non-key/ published A7.1.2.1.1(11)	Bolz, U., Hagenmaier, H. and Körner, W.	2001	Phenolic xenoestrogens in surface water, sediments, and sewage sludge from Baden-Württemberg, south-west Germany <i>Environmental Pollution</i> <b>115</b> , 291 – 301, 2001	Institute of Organic Chemistry, University of Tübingen, Tübingen, Germany	--	No	Yes	No	--
A7.1.2.1.1(11) Non-key Published	Körner, W. et al.	2000	Input/output balance of estrogenic active compounds in a major municipal sewage plant in Germany. <i>Chemosphere, Vol. 40</i> , 1131-1142	-	-	No	Yes	No	-
A7.1.2.1.1(11) Non-key published	Schnaak, W. et al.	1997	Organic contaminants in sewage sludge and their ecotoxicological significance in the agricultural utilization of sewage sludge. <i>Chemosphere, Vol. 35</i> , 5-11.	-	-	No	Yes	No	-
A7.1.2.1.1(11) Non-key published	Ternes, Th. A.	1998	Simultaneous determination of antiseptics and acidic drugs in sewage and river water. <i>Vom Wasser, 90</i> , 295-309.	-	-	No	Yes	No	-

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A7.1.2.1.2(06)	Möndel, M.	2010a	Anaerobic biodegradability of Preventol CMK in digested sludge Date: 2010-05-26	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Germany	AS 142	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(01)	Möndel, M.	2009	14C-Preventol CMK: Aerobic degradation of 14C-Preventol CMK in two different aquatic sediment systems. Date: 2009-03-26	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Germany	AS 85	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(02)	Möndel, M.	2010b	<sup>14</sup> C-Preventol CMK: Characterisation of non-identified radioactivity of <sup>14</sup> C-Preventol CMK in aquatic sediment systems. Date: 2010-05-21	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Germany	AS 139	Yes	No	Yes	LANXESS Deutschland GmbH
B7.5(01) Non-key study	Grote	1987	No title. Date: 1987-07-14	LE Environmental Protection/AWALU, Analytics, Air Laboratory, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B7.5(02) Non-key study	Oblak	1989	Determination of 4-chloro-3-methylphenol (CMK) in Rhine water (Ultra Trace range). Date: 1989-12-06	Bayer AG, Uerdingen, Central Analytics, Uerdingen, Germany	LM Ue 50/89	No	No	Yes	LANXESS Deutschland GmbH

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B7.5(03) Non-key study/ published A7.1.2.2.2(03)	Schmidt-Bäumler, K., Heberer, Th. and Stan, H.-J.	1999	Occurrence and distribution of organic contaminants in the aquatic system in Berlin. Part II: Substituted phenols in Berlin surface water. <i>Acta hydrochim. Hydrobiol.</i> <b>27</b> , 143 – 149, 1999	--	--	No	Yes	No	--
B7.5(04) Non-key/ published A7.1.2.2.2(03)	Bolz, U., Hagenmaier, H. and Körner, W.	2001	Phenolic xenoestrogens in surface water, sediments, and sewage sludge from Baden-Württemberg, south-west Germany <i>Environmental Pollution</i> <b>115</b> , 291 – 301, 2001	Institute of Organic Chemistry, University of Tübingen, Tübingen, Germany	--	No	Yes	No	--
B7.5(05) Non-key/published A7.1.2.2.2(03)	Dixon, E.M., Gowers, A. and Sutton, A.	1997	Proposed environmental quality standards for 4-chloro-3-methylphenol in water. <i>WRC-Final Report to the Department of the Environment</i> , Report No. DoE 4259(P)	--	DoE 4259(P)	No	Yes	No	--

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B7.5(06) Non-key study/ published A7.1.2.2.2(03)	Lacorte, S., Viana, P., Guillamon, M, Tauler, R., Vinhas, T. and Barceló, D.	2001	Main findings and conclusions of the implementation of Directive 76/464/CEE concerning the monitoring of organic pollutants in surface waters (Portugal, April 1999 – May 2000). J. Environ. Monit. 3, 475 – 482, 2001	--	--	No	Yes	No	--
A7.1.2.1.1 (11) Non-key Published A7.1.2.2.2(03)	Bolz, U. et al.	1999	Determination of phenolic xenoestrogens in sediments and sewage sludges by HRGC/LRMS. <i>Organohalogen Compounds, Vol. 40, 65-68.</i>	-	-	No	Yes	No	-
A7.1.2.2.2(03)	Körner, W. et al.	2001	Steroid analysis and xenosteroid potentials in two small streams in southwest Germany. <i>Journal of Aquatic Ecosystem Stress and Recovery, 8, 215-229.</i>	-	-	No	Yes	No	-

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A7.1.3(01)	Erstling, K. and Feldhues, E.	2001b	Adsorption/Desorption. Date: 2001-09-13 Amended: 2001-11-13 and 2007-02-22	Bayer AG, ZF – Zentrale Analytik, Leverkusen, Germany	A 01/0108/05/ LEV	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.3(02) and A7.2.3.1(01)	Meinerling, M.	2007	Determination of the Adsorption / Desorption behaviour of 4-Chloro-3-methylphenol (Preventol CMK) Date: 2007-06-20	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany,	32323195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.3(02) and A7.2.3.1(01)	Meinerling, M.	2008	Determination of the Stability of 4-Chloro-3-methylphenol (Preventol CMK) in Soils of an Adsorption/Desorption Study	Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	45821195	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.3(02) Non-key/ published	Ohlenbusch, G., Kumke, M.U. and Frimmel, F.H.	2000	Sorption of phenols to dissolved organic matter investigated by solid phase microextraction <i>The Science of the Total Environment</i> 253, 63 – 74, 2000	Bereich Wasserchemie, Universität Karlsruhe, Germany	--	No	Yes	No	--
A7.2.1(01) Non-key/ published	Sattar, M.A.	1989	Fate of chlorinated cresols from environmental samples. <i>Chemosphere</i> <b>19</b> (8/9), 1421 – 1426, 1989	Department of Soil Science, Agricultural University, Mymensingh, Bangladesh	--	No	Yes	No	--

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A7.2.1(02) Non-key/ published	Loehr, R.C. and Matthews, J.E.	1992	Loss of organic chemicals in soil. Pure compound treatability studies. <i>Journal of Soil Contamination</i> <b>1(4)</b> , 339-360, 1992	Environmental and Water Resources Engineering Laboratories, Texas, Austin, USA	--	No	Yes	No	--
A7.2.2.1	Nitsche, M.	2011	Biodegradation of Preventol® CMK (4-Chloro-3-methylphenol) in soil under aerobic conditions.	LANXESS Deutschland GmbH	2011-07-25	No	No	Yes	LANXESS Deutschland GmbH
A7.3.1(01)	Anthe, M.	2006	p-Chloro-m-cresol. Calculation of indirect photodegradation. Date: 2006-07-05	Dr. Knoell Consult GmbH, Leverkusen, Germany	KC-PD-04/06	No	No	Yes	LANXESS Deutschland GmbH
A7.4.2(01)	Paul, A.	2007	p-Chloro-m-cresol (CMK) – Calculation of the bioconcentration factor (BCF) Date: 2007-05-31	DR. KNOELL CONSULT GmbH, Mannheim, Germany	KC-BCF-07/07	No	No	Yes	LANXESS Deutschland GmbH
A7.4.2(02) Non-key/ published	Jennings, J.G. et al.	1996	Phenolic compounds in the nearshore waters of Sidney, Australia. <i>Mar. Freshwater Res.</i> <b>47</b> , 951 – 959, 1996	--	--	No	Yes	No	--