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 13
(Metalworking-fluid preservatives)

April 2016 ; Revised November 2017

France

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance chlorocresol (also referred to as p-chloro-m-cresol or CMK) as product-type 13 (Metalworking-fluid preservatives), 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 13.

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

On 27th 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 5th of February 2008.

On 24th of July 2013, the Rapporteur Member State submitted to the European Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the 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 13, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

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

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

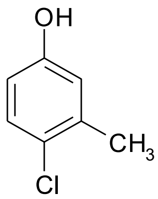
[1] COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014,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

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity

Table 2.2-1: 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 Synonyms	Common name: chlorocresol EINECS name: Chlorocresol Trade name: Preventol CMK CMK, PCMC
Molecular formula	C_7H_7ClO
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^3.

It has a vapor pressure of 1.4×10^{-03} Pa and the Henry's Law Constant is 5.87×10^{-05} $Pa\times m^3\times mol^{-1}$ at pH 7 and 20°C.

CMK has a dissociation constant of 9.4 ± 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. Data were provided in July 2017 by the applicant. The new study performed is acceptable and enables to set a log Pow value of 2.73 at 25°C.

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.

No method is required for analysis of residues in food or feedstuffs as no exposure is expected for CMK use of a product type 13.

2.2. Presentation of the Representative product

2.2.1. Identification of the biocidal product

Table 2.2-1: Identification of the biocidal product

Trade name:	Preventol CMK	
Manufacturer's development code number:	Product number: 430587	
Ingredient of preparation	Function	Content [% (w/w)]
p-chloro-m-cresol	Active substance	100%
Physical state and nature of the preparation:	Nearly white solid pellets with characteristic smell	
Nature of the preparation:	XX (Other)	

Preventol CMK is the active substance as manufactured and contains the active ingredient p-chloro-m-cresol (CMK) with a specified minimal purity of 99.8%.

2.2.2. Physico-chemical properties

Preventol CMK is stable at ambient and elevated temperatures (54 °C) over a 14-day period. Its pH is 5.6 at 22.9 °C.

Preventol CMK is not flammable or auto-flammable and has neither oxidizing nor explosive properties.

Technical properties of Preventol CMK are the following:

- Foam stability (Concentration: 0.3% in CIPAC water):

10 s: < 1 mL foam

1, 3 and 12 min: no volume of foam

- Wettability without swirling: < 1 second.
- Optical dust factor: 0.77 (nearly dust free)
- Flowability results:

After 14 days at 35 °C.

- Amount remaining on a sieve of mesh size 5 mm:

- 19.4% drop spontaneously through the sieve.
- 60.0% remain on the sieve after 5 liftings
- 3.2% remain on the sieve after 20 liftings

- Amount remaining on a sieve of mesh size 10 mm:

- 100% drop spontaneously through the sieve.

- Particle size distribution:

Pellets are usually in the shape of 4-6 mm diameter 1 mm high disk. Some pellets can be misshaped or broken in pieces in the sample.

- Particle size distribution data:

< 1 µm: <0.006%

> 2000 µm: 91.7 %

For the representative product PREVENTOL, complete phys-chem properties studies will have to be submitted at product authorization stage.

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 13 is:

Main Group 02: Preservative.

Product-Type 13: Metalworking fluid preservatives.

2.3.2. Function

p-chloro-m-cresol is an antimicrobial preservative for aqueous metal working fluids (MWF).

2.3.3. Mode of action

p-chloro-m-cresol has a multi-site mode of action, with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane.

2.3.4. Effects on target organisms

p-chloro-m-cresol is a biocide with antimicrobial activity versus Gram-negative, Gram-positive bacteria and, yeasts and molds. It exhibits inhibition of growth at low levels and cidal effects at higher levels.

The representative product Preventol CMK functions are bactericide, bacteristat, fungicide, and fungistat depending on the dose applied.

Organisms and rates for which efficacy of the active substance CMK has been proved sufficiently are presented in the table below:

Application mode	Effect	Target organism	a.s rate
Emulsification Tank-side addition	Bactericide Fungicide	*Bacillus subtilis* *Pseudomonas aeruginosa* *Alcaligenes faecalis* *Penicillum brevicaule* *Chaetomium globosum* *Aspergillus niger* *Trichoderma viridae* *Aureobasidium pullulans* *Alternaria alternate* *Cladosporium cladosporioides* *Rhodotorula rubra* (yeast) *Fusarium solani* *Geotrichum candidum*	0.25 to 0.3 % w/v i.e. 2.5 to 3 g/L

2.3.5. Resistance

The literature analysis showed that especially if the concentration of CMK is in the recommended range, no acquired resistance occur. In addition, 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 sporocidal 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:

Classification according to Regulation (EC) No 1272/2008 (CLP)		
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 36th 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 36th 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.
Specific Concentration limits, M-Factors	M factor = 1 (acute)

Labelling based on the RAC opinion adopted at the 36th 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
Labelling	
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.
Specific Concentration limits, M-Factors	M factor = 1 (acute)

2.4.3. Proposed classification for the product

The biocidal product Preventol CMK contains the active substance CMK with a specified minimal purity of 99.8%. Therefore its classification / labelling are the same as given for the active substance.

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)[2] 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)[3] 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 LD_{50} in the rat is 1830 mg/kg bw (males). CMK is thus classified for its acute oral toxicity as follows: Acute Tox Cat 4 H302: Harmful if swallowed.

No acute toxicity occurred to both male and female rats and rabbits exposed via the *dermal route*. The acute dermal LD_{50} in rat is higher than 2000 mg/kg. In the harmonised classification Acute Tox Cat 4 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,

[2] http://echa.europa.eu/documents/10162/19680902/mota_v6_en.doc
[3] EFSA Journal 2012;10(4):2665

after a review of the literature, this classification Acute Tox Cat 4 H312 is not proposed anymore. Rac agreed to remove the classification for acute dermal toxicity.

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

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^3.

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 statistical 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.

As the concentrated product Preventol CMK is classified for respiratory irritation, for uses under some product types where exposure via inhalation is relevant, an inhalation AEC is set at least for the scenario where the concentrated product is handled.

The NOAEC of 50 mg/m^3 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^3 is proposed.

A medium-term respiratory AEC of 0.7 mg/m^3 is proposed.

A long-term respiratory AEC of 0.3 mg/m^3 is proposed.

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

Summary of the reference values is reported below:

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

2.5.1.2. Exposures assessment and risks characterisation

Exposure during industrial/professional application of CMK based products is possible during mixing and loading (metalworking fluid dilution, sump maintenance), tool setting and other tasks in the workshop (tool setting, dismantling of tool setting, handling work pieces) and metalworking.

Table 2.5-1: Exposure paths to Preventol CMK

Exposure path	Industrial/professional use	General public (secondary exposure)	Via the environment
Inhalation	Yes	No	Negligible
Dermal	Yes	Negligible	Negligible
Oral	No	No	Negligible

CMK induces systemic effects at higher doses that the ones at which local effects are observed, according to the available toxicological studies. Both local exposure and systemic exposure will be assessed.

2.5.1.2.1. *Professional exposure estimations*

- **Primary exposure**

Exposure estimations are performed to obtain realistic upper limit exposure levels to CMK when used in metalworking fluids.

There are three primary exposure task scenarios identified for the use of PT13 products:

1. Mixing and Loading:
   - Preparation of 6%-CMK solution : the 100% CMK biocidal product is added directly to the metal working fluid or the pre-mix tank to obtain a 6%-CMK concentrate,

     and

   - Addition of 6%-CMK solution to the MWF circuit : the 6%-CMK solution is pumped into the MWF circuit

2. Application: the metalworking process itself involves operating the machines, handling objects wetted with MWF, and other daily tasks, such as cleaning the wetted tools and surfaces,

3. Post application (includes disposal): tasks involved include sump maintenance, fluid monitoring, disposal and recycling.

For each exposure scenario, Tier 1 exposure estimates are provided. Tier 2 assessment has been developed only when Tier 1 assessment leads to unacceptable risks. Tier 1 estimates assume there is no Personal Protective Equipment (PPE) used. Tier 2 estimates assume there are appropriate PPE and/or risk mitigation measures.

As the effects of CMK are local such as irritation and could induce sensitization, external exposure for different routes is calculated:

- Concentration of CMK deposited on skin (as mg a.s./cm^2) for dermal exposure,
- Concentration of CMK in the inhaled air (as mg a.s./m^3), during the tasks and as 8-hours time weighted average (8-hr-TWA).

Mixing and loading

Preparation of 6%-CMK solution: CMK is soluble in concentrated metalworking fluids and can be mixed with them (before the emulsion is produced), on the manufacturing site itself. Depending on the recommended dilution factor, CMK is added to the concentrated metalworking fluid at a concentration of 4-6%. A large enterprise produces around 10,000 tonnes of MWF concentrate per year. This means that around 40 tonnes of concentrated MWF are produced per work day. This requires 2400 kg of Preventol CMK per day (assuming a 6% dosage into the concentrate).

Addition of 6%-CMK to MWF: Metalworking fluid is preserved by adding the 6%-CMK solution to the metalworking fluid system. The mixing and loading tasks involve the removal of the product from its container and introduction to the metalworking fluid sump and may be conducted by automation or manually. If the process is automated, the biocide is metered directly into the sump from a holding tank or other type of bulk container. If the process is manual, a worker dispenses (via a tap or by pouring) a measured quantity of product into a jug and manually pours the product into the sump.

Application

The exposure of professional users during metalworking tasks (metalworking fluid with 0.3% of CMK, worst case) was estimated according to the Technical Notes for Guidance (TNsG)[4] on human exposure to biocidal products.

Metalworking machines and operations are of varying degrees of sophistication, but all require human intervention. Dermal exposure may occur through direct contact with fluid, articles and surfaces contaminated with fluid, and deposition from aerosols. Exposure by inhalation occurs through aerosols generated at the cutting head of metalworking machinery. The oral route is considered insignificant.

Metalworking professionals who set tools, dismantle equipment, manipulate metal and manufactured pieces utilize coveralls and face/eyes protection for these operations. Depending on the tasks, protective gloves may or may not be used as wearing gloves could be dangerous if worn near rotating machinery.

Post-Application

The primary tasks in post-application activities include sump maintenance and fluid monitoring. Sump maintenance involves cleaning filters, removing tramp oil, removing swarf (shaving) and emptying sump. Fluid monitoring consists in taking refractive index measurements and using dip slides to monitor bacterial contamination. Other tasks that would fall into this category include cleaning surfaces and equipments, collecting swarfs (shavings), used MWFs and empty drums for recycling or disposal and transferring worked pieces to storage.

These tasks can be done by operators involved in the application or by ancillary workers not involved in the application phase, so the exposure may be considered as secondary. Nevertheless, all professional exposures are assessed in this section.

[4] 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

Table 2.5-2: Summary of professional exposure estimates at metalworking facilities (in-use dose of 0.3% CMK)

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
Task – time frame :	**Preparation of 6%-CMK solution (mixing/loading-pellets)**		
Tier 1: Without PPE, big bag automated loading (low level of containment 90% reduction)[5]	6.94 x 10^{-3}	-*	6.94 x 10^{-3}
Task – time frame :	**Professional addition of 6%-CMK solution onto the MWF (mixing/loading-liquid)**		
Manual Tier 1: Without PPE	1.02 x 10^{-4}	5.64 x 10^{-1}	5.64 x 10^{-1}
Manual Tier 2: With gloves and impermeable coveralls	1.02 x 10^{-4}	4.20 x 10^{-2}	4.21 x 10^{-2}
Semi-automated Tier 1: Without PPE	4.74 x 10^{-3}	2.58 x 10^{00}	2.62 x 10^{00}
Semi-automated Tier 2: With gloves and impermeable coveralls	4.74 x 10^{-3}	2.65 x 10^{-2}	3.13 x 10^{-2}
Automated Tier 1: Without PPE	4.74 x 10^{-3}	1.96 x 10^{-7}	4.74 x 10^{-3}
Task – time frame :	**Professional metalworking (application)**		
Tier 1: Without PPE	1.65 x 10^{-4}	5.25 x 10^{00}	5.25 x 10^{00}
Tier 2: With gloves and cotton coveralls	1.65 x 10-4	1.18 x 10^{00}	1.18 x 10^{00}
Tier 2.5: With gloves and impermeable coveralls	1.65 x 10^{-4}	2.20 x 10^{-1}	2.20 x 10^{-1}
Task – time frame :	**Sump maintenance (post-application)**		
Tier 1: Without PPE	8.25 x 10^{-5}	4.95 x 10^{-1}	4.95 x 10^{-1}
Tier 2: With gloves and impermeable coveralls	8.25 x 10^{-5}	4.09 x 10^{-2}	4.09 x 10^{-2}
Task – time frame :	**Fluid monitoring (post application)**		

5 Low containment level is defined in Advance Reach Tool as: Physical containment or enclosure of the source of emission. The air within the enclosure is not actively ventilated or extracted. The enclosure is not opened during the activity. The process is contained with a loose lid or cover, which is not air tight. This includes tapping molten metal through covered launders and placing a loose lid on a ladle. This class also includes bags or liners fitted around transfer points from source to receiving vessel. These include Muller seals, Stott head and single bag, and associated clamps and closures.

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
Tier 1: Without PPE	3.44×10^{-6}	2.06×10^{-2}	2.06×10^{-2}

Combined exposure

It should be noted that the exposure during preparation of 6%-CMK was considered to be negligible due to the wear of PPE and proposed risk mitigation measures (RMMs). The risks for dermal local and systemic effects were assessed qualitatively.

The combined exposure scenario considers one worker conducting several tasks in the same work shift. The sump maintenance is excluded as it occurs only once a month and, due to its duration (4 hours), it is improbable that the same operator does sump maintenance and application phase on the same day. The resulting exposure estimates are based on a worker loading the biocidal product into the sump, metalworking and conducting post application (including cleaning and monitoring) activities all on the same day.

The systemic doses values for each scenario and route were added to derive a combined exposure estimate for the scenario described above.

Table 2.5-3: Combined exposure estimates to metalworking operator

Tier 1 manual tasks: without PPE					
		Addition of 6%-CMK solution to the circuit	Metal working	Monitoring*	TOTAL
Dermal exposure					
Systemic dose via skin	mg a.s./kg bw	5.64×10^{-1}	5.25×10^{00}	2.06×10^{-2}	5.83×10^{00}
Exposure by inhalation Systemic inhaled dose	mg a.s./kg bw	1.02×10^{-4}	1.65×10^{-4}	3.44×10^{-6}	2.70×10^{-4}
Total systemic dose	mg a.s./kg bw	5.64×10^{-1}	5.25×10^{00}	2.06×10^{-2}	5.83×10^{00}

*: The sump maintenance is excluded as it occurs only once a month and due to its duration (4 hours)

Tier 1 Monitoring, Manual task: without PPE Tier 2,5 Application: metal working (1h) automated and maintenances and others tasks (7h) manual with gloves and impermeable coveralls Tier 2 Addition of 6%-CMK solution to the circuit, manual task: PPE with gloves and impermeable coveralls					
		Addition of 6%-CMK solution to the circuit	Metal working	Monitoring*	TOTAL
Dermal exposure					
Systemic dose via skin	mg a.s./kg bw	4.20×10^{-2}	2.20×10^{-1}	2.06×10^{-2}	2.82×10^{-1}
Inhalation exposure Systemic inhaled dose	mg a.s./kg bw	1.02×10^{-4}	1.65×10^{-4}	3.44×10^{-6}	2.70×10^{-4}
Total systemic dose	mg a.s./kg bw	4.21×10^{-2}	2.20×10^{-1}	2.06×10^{-2}	2.83×10^{-1}

*: The sump maintenance is excluded as it occurs only once a month and due to its duration (4 hours)

- **Secondary exposure**

Other potential secondary exposure scenarios include cleaning surfaces and equipment, collecting shavings (swarf), used fluid and empty drums for recycling or disposal and transferring worked pieces to storage. Potential exposure to CMK from these tasks is anticipated to be covered by the exposure during the fluid monitoring, as explained hereafter.

The daily cleaning and collecting tasks are included in the exposure assessment for the application phase. The exposure to residues on surfaces and objects is anticipated to be lower than the exposure by handling worked pieces and operating the machines.

The exposure during transfer of worked pieces to storage is negligible compared to application phase, as the residues of CMK are intended to be removed by the degreasing of the pieces.

The empty containers containing residues of the concentrated product must be considered as dangerous wastes and handled very carefully according to the related appropriate regulations. Before cleaning or dismantling, the pumps and lines must be rinsed to insure a sufficient dilution. In these conditions, the exposure potential while handling or cleaning empty containers, product wastes and pumps is anticipated to be far less than those for the sump loading phase.

2.5.1.2.2. *Non-professional exposure estimations*

- **Primary exposure**

As Preventol CMK is for professional use only, exposure of general population is not expected during use of treated metalworking fluids.

- **Secondary exposure**

Secondary exposure to CMK used as TP13 could be possible if work clothes soiled with MWF were washed at home with other clothes. But, in the context of industrial and professional uses, when protective clothes are required, they should be directly thrown away (one-use impermeable coveralls) or washed by specialised services. Moreover, exposure of workers in specialised washing services can be considered negligible as procedures (e.g. use of hydrosoluble laundry bags) would be in place to prevent any exposure.

2.5.1.2.3. *Risk characterisation for professional users*

2.5.1.2.3.1. *Application PT 13 – Biocidal product with 6 % CMK and metalworking-fluid*

➔ **Critical endpoints**

AELs, AECs used for the risk characterisation are presented in the section 2.5.1.1.

➔ **Relevant exposure paths**

The most relevant exposure routes to CMK are the dermal and inhalation routes. The oral route is considered negligible.

➔ Risk characterisation for CMK in metalworking fluids (MWF)

- 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.

Table 2.5-4: Results of risk characterisation for systemic effects

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE_{ref} (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	%AEL
Task: Preparation of 6%-CMK solution (mixing/loading-pellets)						
Tier 1: Without PPE, big bag automated loading (low level of containment 90% reduction)	6.94×10^{-3}	30.00	100	4320	3×10^{-1}	**2%**
Qualitative assessment and RMM	Negligible with gloves and coverall					
Task: Professional addition of 6%-CMK solution onto the MWF (mixing/loading-liquid)						
Manual: Tier 1 : Without PPE	5.64×10^{-1}	30	100	53	0.30	**188**
Manual: Tier 2: with gloves and impermeable coveralls	4.21×10^{-2}	30	100	179	0.30	**14**
Semi automated: Tier 1 : Without PPE	2.62×10^{00}	30	100	11	0.30	**87**
Semi automated: Tier 2: with gloves and impermeable coveralls	3.13×10^{-2}	30	100	958	0.30	**10**
Automated: Tier 1 : Without PPE	4.74×10^{-3}	30	100	6329	0.30	**2**
Task: Professional metalworking (application) Direct Operating 60 min/day; others tasks 420 min/day						
Manual: Tier 1: Without PPE	5.25×10^{00}	30	100	6	0.30	**1750**
Manual: Tier 2: with gloves and cotton coveralls	1.18×10^{00}	30	100	25	0.30	**392**
Tier 2.5: metal working (1h) automated and maintenances and others tasks (7h) manual with gloves and impermeable coveralls	2.20×10^{-1}	30	100	136	0.30	**73**

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE_{ref} (sum of AFs)	MOE	AEL (mg a.s./kg bw/d)	%AEL
Fully automated: Tier 1 : Without PPE	Negligible					
Task: Sump maintenance (post-application) 240 min/day; once a month						
Manual: Tier 1 : Without PPE	4.95×10^{-1}	30	100	61	0.30	**165**
Manual: Tier 2: with gloves and cotton coveralls	7.55×10^{-2}	30	100	397	0.30	**25**
Manual: Tier 2.5: with gloves and impermeable coveralls	4.09×10^{-2}	30	100	733	0.30	**14**
Task: Fluid monitoring (post-application) 10 min/day; once a week						
Manual: Tier 1: Without PPE	2.06×10^{-2}	30	100	1456	0.30	**7**

The risk for systemic exposure during the preparation of 6%-CMK solution is acceptable without of PPE but with RMMs protecting against local effects preventing dermal exposure such as the low containment level[6] reducing aerosols.

The risk characterisation for systemic exposure during the manual addition of 6%-CMK solution to the MWF circuit is not acceptable without PPE and acceptable wear the wear of coverall (impermeable) and gloves. The risk is considered to be acceptable when the addition is semi-automated without PPE with a %AEL below 100. The risks are considered to be acceptable when this task is completely automated.

The risk for the manual application (professional metalworking) is unacceptable without PPE or with gloves and cotton coverall. The risk is acceptable when the metal working is automated and when professionals wear impermeable coverall and gloves for maintenance and other tasks since the %AEL is above 100. This step can be completely automated. In this case, the exposure is considered to be negligible and the risk for automated application is considered to be acceptable.

The risk characterisation for systemic exposure during the sump maintenance is not acceptable in Tier 1. The risk is acceptable when cotton or impermeable coverall is worn with a %AEL below 100.

The risk for the fluid monitoring is acceptable in Tier 1 since the %AEL is below 100.

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[6] Low containment level is defined in Advance Reach Tool as: Physical containment or enclosure of the source of emission. The air within the enclosure is not actively ventilated or extracted. The enclosure is not opened during the activity. The process is contained with a loose lid or cover, which is not air tight. This includes tapping molten metal through covered launders and placing a loose lid on a ladle. This class also includes bags or liners fitted around transfer points from source to receiving vessel. These include Muller seals, Stott head and single bag, and associated clamps and closures.

- <u>Risk characterisation for respiratory local effects</u>

The estimated exposure is compared to the AEC long-term, to derive a fraction of the AEC (expressed as % AEC), for risk characterization for respiratory local effects.

Table 2.55-5: Summary of risk assessment for professionals – local effects via inhalation

	Inhalation exposure (mg/m^3)	AEC long term (mg/m^3)	% AEC	Conclusion of local risk assessment by inhalation
Task:		Primary exposure (preparation of 6%-CMK solution)		
Tier 1 (without mask)	4	3.0×10^{-1}	1300%	Unacceptable
Tier 2 (with mask FFP3)	2×10^{-1}		67%	Acceptable

[1]FFP3Mask: protection factor 20

An acceptable risk has been identified for professionals with the wear of respiratory protection equipment (FFP3 mask) during the dilution of the product.

- <u>Qualitative risk assessment for dermal local effects</u>

The product is an eye, skin irritant and has skin sensitization potential. However, this risk of skin and eye irritation/sensitization and/or respiratory irritation when handling concentrated formulations of CMK can be controlled through the use of proper risk mitigation measures. Therefore, packaging, equipments and procedures, e.g. automated dosing systems, should be designed to prevent exposure as much as possible. Moreover, effective skin protections such as gloves, goggles and protective overalls are required for the use of CMK based products. Additionally, the use of concentrated formulations is restrained to professional operators. MSDS and product use instructions shall inform the users of the potential risks and prevention measures.

By using adapted processes, protective equipments and respecting good professional practices, the local exposure potential to CMK based products can be avoided and the risk of adverse local effects can be reduced to an acceptable level[7].

During the metalworking process the end-use concentration of CMK would not be classified for local effects and so a local risk assessment is not necessary.

➔ Risk assessment for combined exposure

The combined exposure scenario involves one worker conducting several tasks in the same work shift. The resulting exposure estimates are based on a worker loading the biocidal product into the sump, metalworking and conducting post-application (including cleaning and monitoring) activities all on the same day.

[7] The guidance on local effects is currently on discussion; only a qualitative risk would be assessed for dermal local effect. This part will be revised when the guidance will be updated.

- Risk characterisation for systemic effects for combined exposure (mixing loading, application and post-application)

Table 2.5-6: Results of risk characterisation for systemic effects

	Total exposure (mg a.s./kg bw/d)	Relevant NOAEL (mg a.s./kg bw/d)	MOE_{ref}	MOE	AEL (mg a.s./kg bw/d)	%AEL
Manual (all phases): Tier 1 : Without PPE	5.83×10^{0}	30	100	5	0.30	1943
Manual: Tier 1 post-application* **Tier 2.5 Application** Tier 2 : Addition of 6%-CMK,	2.83×10^{-1}	30	100	106	0.30	**94**

*: The sump maintenance is excluded as it occurs only once a month and, due to its duration (4 hours)

Tier 2.5: metal working (1h) automated and maintenances and others tasks (7h) manual with gloves and impermeable coveralls.

The risk characterisation for combined systemic exposure identified an unacceptable risk in Tier 1. The risk is considered as acceptable when PPE are worn during metal working (application) and when the addition of 6-CMK solution into the circuit was completely automated and the preparation of 6% solution was performed by big bag method. In this case, the MOE (106) is higher than the MOE_{ref} (100) and the %AEL (94) below 100.

2.5.1.2.4. *Non-professional users*

The use of CMK as a preservative for MWFs does not involve non-professional users.

2.5.2. Overall conclusion for occupational Human Health

The risk of professional has been assessed task by task and considering a combined exposure. In the latter case, exposures during each task have been summed up.

Considering each task separately, the risk is acceptable during:

- preparation of 6%-CMK solution, with the wear of gloves, coverall, mask and low containment level[8] during big bag unloading.
- addition of 6%-CMK solution in the MWF circuit, when this task is manual with impermeable coverall and gloves, semi-automated (without PPE) or when this task is completely automated,

[8] Low containment level is defined in Advance Reach Tool as: Physical containment or enclosure of the source of emission. The air within the enclosure is not actively ventilated or extracted. The enclosure is not opened during the activity. The process is contained with a loose lid or cover, which is not air tight. This includes tapping molten metal through covered launders and placing a loose lid on a ladle. This class also includes bags or liners fitted around transfer points from source to receiving vessel. These include Muller seals, Stott head and single bag, and associated clamps and closures.

- application, when the metal working is automated and the professional wears gloves and impermeable coverall during maintenance and other tasks or when this task is completely automated in order to reduce exposure,
- sump maintenance, with gloves and coveralls,
- fluid monitoring, without PPE.

For combined exposure, the risk is considered to be acceptable for operators during:

- preparation of 6%-CMK solution, with the wear of gloves, coverall, mask and low containment level during big bag unloading
- addition of 6%-CMK solution in the MWF circuit, when this task is manual with impermeable coverall and gloves, semi-automated (without PPE) or when this task is completely automated,
- application, when the professional wears gloves and impermeable coverall or when this task is completely automated in order to reduce exposure,
- fluid monitoring, without PPE.

The sump maintenance is excluded of this calculation as it occurs only once a month and as its duration is short (4 hours).

This risk of skin and eye irritation/sensitization and/or respiratory irritation from CMK, can be readily controlled through the use of proper risk mitigation measures when handling concentrated formulations. Therefore, packaging, equipment and procedures, e.g. automated dosing systems, should be designed to prevent exposure as much as possible. Moreover, effective skin protection such as gloves, goggles, protective coveralls and boots is required under all the identified scenarios for use of CMK based products. Additionally, the use of concentrated formulations is restrained to professional operators. MSDS and product use instructions shall inform the users of the potential risks and prevention measures.

By using adapted processes, protective equipment and respecting good professional practices, the local exposure potential to CMK based products can be avoided and the risk of adverse health effects can be reduced to an acceptable level.

During the metalworking process the end-use concentration of CMK would not be classified for local effects and so a local risk assessment is not necessary.

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[9] resulted in a half-life of 0.625 days, corresponding to 14.995 hours, considering an OH-radicals concentration of 0.5 x10^6 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 ($DT_{50,\ 12°C}$ ≤ 3.6 d) as in the water phase ($DT_{50,\ 12°C}$ ≤ 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 TGD[10] for a readily biodegradable substance has been therefore applied to calculate concentrations of CMK in soil (DT_{50}: 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^{-1} (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^{-1}).

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_{fish} of 73.6 was assessed. This value is in good accordance with the supportive experimental data (5.5-121 L.kg^{-1}). These results indicate a low potential of CMK to bioaccumulate in the aquatic food chain. For the terrestrial compartment, a $BCF_{earthworm}$ 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.

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[9] v. 1.91, 2000, US-EPA

[10] 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^{-1} 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 PNECmicroorganisms of 0.57 mg.L^{-1}.

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_{50} = 0.92 mg CMK. L^{-1}).

A fish (*Oncorhynchus mykiss*) juvenile growth test has also been conducted. The NOEC was determined to be 0.15 mg CMK.L^{-1}.

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^{-1}.

2.5.3.2.3. *Sediment*

The $PNEC_{sed}$ was calculated using the equilibrium partitioning method according to the Guidance document on Risk Assessment. The $PNEC_{sed}$ was determined to be 75.5 µg CMK.kg^{-1} 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 $PNEC_{soil}$, applying an assessement factor of 100 according to the Guidance document. However, the EC_{50} (531 mg kg^{-1}dw) from the soil microorganism study is far higher than the EC_{50} from the acute study performed on plant (54.3 mg kg^{-1}dw). Therefore, an assessment factor of 1000 has been applied to this EC_{50} from the plant study, dealing to a $PNEC_{soil}$ value of 5.43 x 10^{-2} mg CMK $kg^{-1}{}_{dry\ soil}$. The $PNEC_{soil}$ value for CMK of 4.81 x 10^{-2} mg $kg^{-1}{}_{wet\ soil}$ 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_{50} > 2995 mg CMK.kg^{-1} food. Applying an assessment factor of 3000, the $PNEC_{oral,\ birds}$ is calculated to be 0.998 mg.kg^{-1} 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^{-1} food. The $PNEC_{oral,\ mammals}$ of 66.7 mg CMK.kg^{-1} food is derived by applying an assessment factor of 30 to the calculated NOEC of 2000 mg CMK.kg^{-1} food.

2.5.3.2.6. *Summary of PNEC values*

Summary of the selected PNEC values used for the risk characterisation:

ENVIRONMENTAL COMPARTMENT	PNEC	Unit
$PNEC_{water}$	15	µg CMK.L^{-1}
$PNEC_{stp}$	0.57	mg CMK.L^{-1}
$PNEC_{sed}$	75.5	µg CMK.kg$^{-1}_{wwt}$
$PNEC_{soil,\ in\ tial}$	48.1	µg CMK.kg$^{-1}_{wwt}$
$PNEC_{oral,\ birds}$	0.998	mgCMK.kg^{-1} food
$PNEC_{oral,\ mammals}$	66.7	mgCMK.kg^{-1} 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 risk assessment for CMK used as preservative in metalworking fluids (PT13) is based on the scenario of its use in a water-based emulsifiable lubricant, which runs in a circulation system during metalworking processes. The CMK concentrate is diluted before use to give a final concentration in the working solution of 0.25-0.3% w/v active substance. In a worst case approach, calculations have been carried out with 0.3% of CMK in the emulsifiable working fluid (corresponding to 3 $kg_{CMK}.m^{-3}_{MWF}$).

According to the applicant, the functional fluid must be exchanged 2 to 3 times a year and it is either recycled first or the fluid can be in such condition that it is collected for disposal. The direct release of MWFs is not allowed in accordance with European legislation. The exhausted MWF is separated into the oil and the water phases. The oil phase is either recycled by distillation and the remaining sump, containing CMK residues, is incinerated or the whole oil phase is treated as hazardous waste. According to the applicant's line of argument, the MWF water phase is treated physically or chemically, resulting in a complete elimination of CMK therein.

Consequently, the applicant considers that direct and indirect CMK emissions to the environment are extremely limited. Nonetheless, in the lack of numerical data dealing with the efficiency of CMK removal through the physical and chemical treatments, as described by the applicant, an environmental exposure according to the Emission Scenario Document for PT13[11] has been carried out.

An external STP is considered as a potential compartment for direct emissions. Emissions to the environment have been calculated according to the refinement[12] of the PT13 ESD[13]. In the refinement of the scenario, two cases are considered, which are close to the description provided by the applicant, e.g. end-users of metal working fluid who treat their waste on–site, and waste management companies who receive waste from smaller companies who do not treat their fluids directly on site.

[11] Harmonization of Environmental Emission Scenarios for biocides used as metalworking fluid preservatives (Product type 13) European Commission DG ENV/RIVM, May 2003.
[12] Refinement of the Emission Scenario Document for Product Type 13, working or cutting fluid preservatives, Hesse and Hahn from Fraunhofer and ECHA 2015. Endorsed by the Environment Working Group (March 2015).
[13] European Commission DG ENV/RIVM (2003): Harmonisation of Environmental Emission Scenarios for biocides used as metalworking fluid preservatives (Product type 13).

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 water via atmospheric deposition has been deemed negligible considering the low vapour pressure (1.98 x 10^{-3} Pa) and Henry's law constant (5.87 x 10^{-5} $Pa.m^3.mol^{-1}$) 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. The proposed uses of CMK in the EU as preservative in emulsifiable metal working fluids are predicted to result in negligible concentrations in air and are therefore not reported.

2.5.3.4. Risk characterisation for the Environment

To carry out a quantitative risk assessment for the environment when CMK is used as a preservative to control microbial contamination in metal working fluids (PT13), the PEC values were compared to the respective PNEC values for the different compartments, resulting in the following $PEC_{CMK}/PNEC_{CMK}$ ratios. The table below summarized the PEC/PNEC ratios considering the two kinds of treatment plant receiving used metal working fluids which have been treated with CMK.

Table 2.5-7: PEC/PNEC values for Preventol CMK use – Emulsifiable MWF- Use of concentration of 0.3% (3 $kg.m^{-3}$)

	PEC_{CMK} / $PNEC_{CMK}$ ratio	
	End-user + on-site treatment	External waste treatment company
Sewage treatment plant	0.11	0.04
Surface water	0.40	0.15
Sediment	0.40	0.15
Agricultural Soil	0.81	0.20
Groundwater	≤0.001 µg/L	≤0.001 µg/L
Air	n.r	n.r
Aquatic food chain, birds	0.22	0.08
Aquatic food chain, mammals	3.34E-03	1.25E-03
Terrestrial food chain, birds	2.19E-02	5.48E-03
Terrestrial food chain, mammals	3.28E-04	8.22E-05

n.r. not relevant

2.5.3.4.1. *Sewage treatment plants*

The estimated risk from the proposed use of CMK as preservative in emulsifiable metalworking fluids is acceptable for the STP whatever the kind of treatment plant where the used metal working fluid is directed. Risk assessment has been carried out considering an emission of CMK in the effluents of STP of 12.5%. However, data on industrial STP receiving waste water from metal working fluid plants showed a higher removal of CMK in the effluent, which supports the conclusions of the risk assessment for the aquatic compartment.

2.5.3.4.2. *Aquatic compartment*

When MWF sent to the recovery plant are assumed to be treated with CMK, estimated risk from the proposed use of CMK as preservative in emulsifiable metalworking fluids is acceptable for surface water and sediment, whatever the kind of treatment plant where the used metal working fluid is directed.

2.5.3.4.3. *Terrestrial compartment (agricultural soil)*

When MWF sent to the recovery plant are assumed to be treated with CMK, the PEC/PNEC values calculated for the agricultural soil are below 1 whatever the kind of treatment plant where the used metal working fluid is directed , indicating acceptable risk for this compartment from the proposed use of CMK as preservative in emulsifiable metalworking fluids.

2.5.3.4.4. *Groundwater*

In a first approach, based on TGD equations, the concentration in porewater (surrogate for groundwater) is above the 0.1 µg/L threshold concentration for a use of CMK as preservative in emulsifiable soluble working fluids, whatever the kind of treatment plant where the used metal working fluid is directed. These values indicate unacceptable risk to groundwater due to the use of CMK as preservative in emulsifiable soluble working fluids.

However, refined assessment using FOCUS groundwater model PEARL[14] leads to concentrations predicted ≤ 0.001 µg.L^{-1}, indicating acceptable risk for groundwater due to the use of CMK as preservative in emulsifiable soluble working fluids.

2.5.3.4.5. *Atmosphere*

No risks are expected due to extremely low volatility of CMK.

2.5.3.4.6. *Non compartment specific effects relevant to the food chain (secondary poisoning)*

For MWF treated with CMK and sent to the recovery , estimated risk from the proposed use of CMK as preservative in emulsifiable metalworking fluids is acceptable for the birds and mammals of the aquatic and terrestrial food chain whatever the kind of treatment plant where the used metal working fluid is directed.

2.5.4. Overall conclusion for the environment

The environmental risk assessed with the assumption of used MWF volume treated with CMK sent either to on-site plant or to waste management companies which receive waste from smaller companies, has demonstrated that the use of CMK in emulsifiable metalworking fluids at 3 $kg_{a.s.}.m^{-3}{}_{MWF}$ leads to acceptable risks for the environment.

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.

[14] version 4.4.4

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^{-1}. A substance is considered very bioaccumulative (vB) when the BCF exceeds a value of 5000 L kg^{-1}.

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_{fish} = 73.6 L kg^{-1} and $BCF_{earthworm}$ = 13.4 L kg^{-1}). For the aquatic compartment, the calculated value is in good accordance with supportive data where a maximum BCF value of 121 L kg^{-1} 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^{-1} 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^{-1}) and is over 0.01 mg L^{-1}. 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-mcresol in product-type 13 is specified in the BPC opinion following discussions at the 15th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website

SCENARIO	Human primary exposure		Human secondary exposure		Environment (2)					
	Professional	Non professional	Worker	General public	STP	Aquatic compartment	Terrestrial compartment	Groundwater	Air	Secondary poisoning
Preservation of metalworking fluid										
Bactericide, fungicide 0.25 to 0.3 % w/v i.e. 2.5 to 3 g/L	Acceptable (1)	NR	Acceptable	NR	Acceptable	Acceptable	Acceptable	Acceptable (3)	NR	Acceptable

NR: not relevant.

Conditions:

(1) Acceptable for preparation of 6%-CMK solution (unloading of big bag), with the wear of gloves, coverall, goggles and mask; manual addition of 6%-CMK solution in the MWF circuit with the wear of gloves, impermeable coverall; manual application, when the professional wears gloves and impermeable coverall and metalworking tasks automated or when this task is completely automated in order to reduce exposure; monitoring, without PPE. Risk for local dermal effects can be considered acceptable if PPE (gloves and coverall) are worn and if packaging, equipments and procedures, e.g. automated dosing systems are designed to prevent exposure as much as possible.

(2) The release of biocides used as metalworking fluids has to be considered by the relevant national authorities when issuing permits for recovery plants (according to agreement at Technical Meeting IV09 - required when an environmental risk for metalworking fluids has been identified).

(3) Acceptable according to FOCUS groundwater model PEARL.

2.7. Requirement for further information related to the reference biocidal product

For the representative product PREVENTOL, complete phys-chem properties studies will have to be submitted at product authorization stage.

2.8. List of endpoints

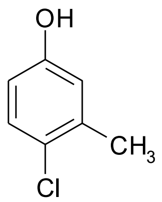
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

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

Active substance (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_7H_7ClO
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)	Technical substance: Nearly white solid pellets with characteristic smell. Purified substance: Nearly white solid with slight phenolic odour. Nearly dust free.
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)	1.4×10^{-03} Pa at 20 °C 6.0×10^{-03} Pa at 25 °C 3.8 Pa at 50 °C
Henry's law constant (Pa m^3 mol^{-1})	Ratio between vapour pressure and water solubility: 6.05×10^{-05} $Pa\times m^3\times mol^{-1}$ at 20 °C and pH 5 5.87×10^{-05} $Pa\times m^3\times mol^{-1}$ at 20 °C and pH 7 4.87×10^{-05} $Pa\times m^3\times mol^{-1}$ at 20 °C and pH 9
	EPIWIN calculation: 4.64×10^{-02} $Pa\times m^3\times mol^{-1}$ at 25 °C (Bond method) 6.08×10^{-02} $Pa\times m^3\times mol^{-1}$ at 25 °C (Group method)
Solubility in water (g/l or mg/l, state temperature)	Results at pH 5: 2.5 g/L at 10°C 3.3 g/L at 20°C 4.5 g/L at 30°C
	Results at pH 7: 2.6 g/L at 10°C 3.4 g/L at 20°C 4.6 g/L at 30°C
	Results at pH 9: 3.1 g/L at 10°C 4.1 g/L at 20°C 5.5 g/L at 30°C
Solubility in organic solvents (in g/l or mg/l, state temperature)	n-Heptane: 4.9 g/L at 10 °C 8.5 g/L at 20 °C 15.4 g/L at 30 °C p-Xylene: 147.9 g/L at 10 °C 233.2 g/L at 20 °C > 250 g/L at 30 °C 1,2-Dichloroethane: 205.7 g/L at 10 °C > 250 g/L at 20 °C > 250 g/L at 30 °C The solubilities of CMK in 1-octanol, 2-propanol, acetone and ethyl acetate are > 250 g/L at each temperature.

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_{OW}) (state temperature)	To be confirmed before approval of the active substance Data were provided in July 2017 the applicant. The new study performed is acceptable and enables to set a log Pow value of 2.73 at 25°C.
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^{-1} cm^{-1}) Maxima at 281 nm (ε = 2241 l mol^{-1} cm^{-1}) (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	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: 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. Signal Word: Danger
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 unvolatisable 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^3 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_{50} oral	1830 mg/kg bw (♂), H302
Rat LD_{50} dermal	> 2000 mg/kg bw (♀), > 5000 mg/kg bw (♂)
Rat LC_{50} inhalation	> 2871 mg/m³ (♂+♀)

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^3 based on thymus effects local : 50 mg/m^3 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	Negative (*in vitro* + *in vivo*)

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	Rat: reduced foetal weight, increased resorption rate, reduced foetus number. No malformations
Relevant maternal NOAEL	30 mg/kg bw/day
Relevant developmental NOAEL	100 mg/kg bw/day

Fertility

Species/critical effect	Rat: no reproductive effects
Relevant parental NOAEL	parental NOAEL = 750 ppm (90 mg/kg bw/day) based on effects on liver and kidneys and a statistical significant decrease in body weight gain (equivalent to 365 mg/kg/day)

Relevant offspring NOAEL	NOAEL for offspring toxicity = 750 ppm (corresponding to 47 mg/kg bw/day – F1) based on pup weight ↓ (♀) at 3000 ppm (F2b).
Relevant fertility NOAEL	No effects on fertility parameters; NOAEL for toxicity on fertility = 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.

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

No indications for special concern.

Medical data

Some reports of poisoning with CMK-containing disinfectants with homicidal intent. Corrosive damage to oesophagus/stomach was evident.

Several reports of contact hypersensitivity to CMK-containing products.

Summary

	Value	Study	Safety factor
$AEL_{long\text{-}term}$			
$AEL_{medium\text{-}term}$			
$AEL_{short\text{-}term}$			

ADI[15]	0.3 mg/kg bw/d	Rat developmental study	100
ARfD[8]	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	Not relevant
Intended uses	Protection of metalworking fluid
Industrial users	Acceptable with PPE and RMMs
Professional users	See industrial users
Non-professional users	Not relevant
General public	Not relevant
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_{50}) (state pH and temperature)	No hydrolysis at 50°C at pH 4, 7 and 9.
pH 5	-
pH 9	-
Other pH: *[indicate the value]*	

[15] 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	Water sediment system 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)	$DT_{50\ whole\ system}$ = 1.22-1.90 days at 20°C (dissipation) $DT_{50\ whole\ system}$ = 2.31-3.60 days at 12°C (dissipation) Endpoint for the risk assessment (worst case of two values): $DT_{50\ whole\ system}$ = 3.60 days at 12°C
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%) $DT_{50\ whole\ system}$ = 6.97-36.4 days at 20°C $DT_{50\ whole\ system}$ = 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_{50} = 30 days.
DT_{50lab} (20°C, aerobic):	
DT_{90lab} (20°C, aerobic):	
DT_{50lab} (10°C, aerobic):	
DT_{50lab} (20°C, anaerobic):	
degradation in the saturated zone:	

Field studies (state location, range or median with number of measurements)	No key study available
DT_{50f}:	
DT_{90f}:	
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_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	<u>HPLC screening test:</u> Koc = 158.5 (log Koc = 2.21) <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 $K_F a$ = 3, 11 $\mu g^{1-1n}(cm^3)^{1/n}g^{-1}$ $K_{oc}a$= 270, 322 $\mu g^{1-1n}(cm^3)^{1/n}g^{-1}$ $K_F d$ = 0.5, 1.8 $\mu g^{1-1n}(cm^3)^{1/n}g^{-1}$ Arithmetic mean of Koc = 195.6 mgL/g. Endpoint selected for the risk assessment.

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_{50} = 14.995 hours (AOPWIN calculation, considering an OH-radicals concentration of 0.5 x10^6 molec.cm^{-3} 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	

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
Fish			
Oncorhynchus mykiss	96 hours U.S.-EPA FIFRA § 72-1 Static renewal	Mortality	$LC_{50,\ 48h}$ = 0.92 mg/L mean measured concentration
Oncorhynchus mykiss	28 days OECD 204 (1984) + 215 (2000) semi static	Mortality, symptoms of intoxication, growth parameters	NOEC = 0.15 mg/L mean measured concentration
Brachydanio rerio	14 days Comparable with OECD 204 (1984) Flow-through	Mortality, sublethal and behaviour response	NOEC = 1.0 mg/L Nominal concentration
Invertebrates			
Daphnia magna	48 hours U.S.-EPA FIFRA § 72-2 static	Mortality; behavioural, sub-lethal effects	$EC_{50,\ 48h}$: 2.29 mg/L mean measured concentration

Daphnia magna	21 d OECD 211 (1998) Semi static	Survival of parent animals and number of offsprings	NOEC = 0.32 mg/L Nominal concentration
Algae			
Desmodesmus subspicatus	72 hours OECD 201 (2006) static	Growth inhibition	$NOEC_{, 72h}$ = 3.1 mg/L (biomass) $NOEC_{, 72h}$ = 9.8 mg/L (growth rate) $E_bC_{50, 72h}$ = 17.18 mg/L $E_rC_{50, 72h}$ = 30.62 mg/L Nominal concentration
Microorganisms			
Activated sludge	3 hours OECD 209	Respiration inhibition	EC_{10} = 5.7 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	OECD 207 (1984); *Eisenia fetida*; Mortality LC_{50} (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_{50} (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_{50} (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_{50} (14 days) > 1449 mg/kg bw
Dietary toxicity to birds	US-EPA FIFRA 71-2 (1982); *Colinus virginianus*, sub-acute toxicity (5 days), LC_{50} > 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_{50})	Not relevant
Depration time (DT_{90})	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	**Productname**	**Organisms controlled**	**Formulation**		**Application**			**Applied amount per treatment**			**Remarks**
			Type	Conc. of as	Method kind	Number min / max	Interval between applications (min)	g as/L min / max	water L/m^2 min / max	g as/m^2 min / max	
Metalworking fluid preservatives	Preventol CMK	Bacteria Fungi (including yeasts)	Solid b.p. (SG Pellets)	998 g/kg	Either mixed with the fluid before its emulsification (concentrate containing 4 to 6% CMK) or added as a 6% CMK solution to the emulsion during its use (tank-side addition)	1 to 7 per weeks	-	0.25 to 0.3% w/v i.e. 2.5 to 3 g/L	-	-	-

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

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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)	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

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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
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

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(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
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

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(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
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

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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 CONFIDENTIAL	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

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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
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

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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
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

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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
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 Deutschland GmbH

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A6.1.4 Non-key study	[redacted]	2006a	Preventol CMK – Acute Skin Irritation/ Corrosion on Rabbits. Date: 2006-07-24	[redacted]	AT03215	No	No	Yes	LANXESS Deutschland GmbH
A6.1.4 Non-key study	[redacted]	2006b	Preventol CMK – T 7053199 – Acute Eye Irritation on Rabbits. Date: 2006-07-24	[redacted]	AT03216	No	No	Yes	LANXESS Deutschland 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 Deutschland GmbH
A6.1.5(01)	[redacted]	2000	Preventol CMK, Pastillen LOCAL LYMPH NODE ASSAY IN MICE (LLNA/IMDS). Date: 2000-11-13	[redacted]	PH 30408	Yes	No	Yes	LANXESS Deutschland GmbH
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

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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	[redacted]	1980	Excretion kinetics of Preventol CMK after a single oral administration to rats. Date: 1980-12-02	[redacted]	9605	No	No	Yes	LANXESS Deutschland GmbH
A6.2(02) Non-key study	[redacted]	1981	Investigation into the detection of Preventol CMK in fatty tissue and liver tissue in rats. Date: 1981-02-17	[redacted]	9807	No	No	Yes	LANXESS Deutschland GmbH
A6.2(03) Published	Roberts, M.S. *et al.*	1977	Permeability of human epidermis to phenolic compounds.	Pharmacy Dept., Univ. of Sydney, Australia	*J. Pharm. Pharmac.* 29, 677-683	No	Yes	No	–
A6.2(04)	[redacted]	2009	Mass Balance and Metabolism of [14C]-4-Chloro-3-methylphenol in Male and Female Rats After Single Oral Administration. Date: 2009-02-19	[redacted]	C07812	Yes	No	Yes	LANXESS Deutschland GmbH

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A6.2 Non-key Published	[redacted]	1998	Comparative metabolism of *ortho*-phenylphenol in mouse, rat and man.	[redacted]	*Xenobiotica* 28(6), 579-594	No	Yes	No	–
A6.2 Non-key study Published	[redacted]	1986	Permeation of Water Contaminative Phenols Through Hairless Mouse Skin.	[redacted]	*Arch. Environ. Contam. Toxicol*. 15, 557-566	No	Yes	No	--
A6.2 Non-key study Published	[redacted]	1986	Disposition of *o*-Benzyl-*p*-Chlorophenol in Male Rats	[redacted]	*Journal of Toxicology and Environmental Health*, 18, 441 - 458, 1986	No	Yes	No	–
A6.3.1(01)	[redacted]	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	[redacted]	17739	No	No	Yes	LANXESS Deutschland GmbH

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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

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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

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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)	[redacted]	1990	Preventol CMK MICRONUCLEUS TEST ON THE MOUSE. Date: 1990-01-17 Amended: 1991-08-08	[redacted]	18686 Amendment: 18686A	Yes	No	Yes	LANXESS Deutschland GmbH
A6.6.4 Non-key study	[redacted]	1981	Preventol CMK. Micronucleus Test on the Mouse to test for a Mutagenic Effect. Date: 1981-10-16	[redacted]	10255	No	No	Yes	LANXESS Deutschland GmbH
A6.7(01) A6.5(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

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A6.8.1(01)	[redacted]	1991	Preventol CMK - Study for embryotoxic effects in rats after oral administration. Date: 1991-11-29	[redacted]	20869	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2(01)	[redacted]	2006b	4-Chloro-3-methylphenol – Two-Generation Reproduction Study in Rats by Administration in the Diet. Date: 2006-12-19	[redacted]	AT03531	Yes	No	Yes	LANXESS Deutschland GmbH
A6.8.2 Non-key	[redacted]	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	[redacted]	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

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A6.10 Non-key study Published	Meiss, R. *et al.*	1981	New aspects of the origin of hepatocellular vacuoles.	Univ. of Münster, Germany	*Exp. Path.* 19, 239-246	No	Yes	No	–
A6.10 Non-key study Published	[redacted]	1980	Alterations in the Rat Liver Induced by p-Chlor-m-Cresol with Emphasis on the Intercellular Junctions.	[redacted]	*J. Submicrosc. Cytol.* 12(4), 635-646	No	Yes	No	–
A6.11 Non-key study Published	Wien, R.	1939	The Toxicity of *Para*chloro*meta*cresol and of Phenylmercuric Nitrate.	–	*Q.J. Pharm. Pharmacol.* 12, 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	*Lancet* 1: 705	No	Yes	No	–
A6.12.2(02) A6.12.6	Hancock, B.W. and Naysmith, A.	1975	Hypersensitivity to Chlorocresol-preserved Heparin. *British Medical Journal:* 746-747, 1975	Royal Hospital, Sheffield, UK	*British Medical Journal*, 746 – 747,	No	Yes	No	--
A6.12.2(03)	Joppich, G.	1960	Tödliche Vergiftung durch Sagrotan bei Säuglingen.	University Children's Hospital Göttingen, Germany	*Deut. Med. J.* 11; 20 -21	No	Yes	No	--

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A6.12.2(04) Published	Wiseman, H.M. *et al.*	1980	Acute poisoning to Wright´s Vaporizing Fluid.	National Poisons Information Service, London, UK	*Postgraduate Medical Journal:* 56, 166 - 168 (1980)	No	Yes	No	--
A6.12.2 Non-key Published	Jonsson, J. and Voigt, G.E.	1984	Homicidal intoxications by lye- and parachlorcresol-containing disinfectants.	State Dept. of Forensic Chemistry, Linköping, Sweden	*Am. J. Forensic Med. Pathol.* 5(1), 57-63	No	Yes	No	--
A6.12.6(01)	Angelini, G. *et al.*	1975	Contact dermatitis in patients with leg ulcers.	Dept. of Dermatology, Univ. of Bari, Italy	*Contact Dermatitis* 1, 81-87	No	Yes	No	–
A6.12.6(02) published	Oleffe J.A. *et al.*	1979	Allergy to chlorocresol and propylene glycol in a steroid cream to chlorocresol-preserved heparin	–	*Contact Dermatitis* 5: 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	*Contact Dermatitis* 7: 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	*Contact Dermatitis* 12, 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	*Contact Dermatitis* 11, 144-145	No	Yes	No	–

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A6.12.6 Non-key study Published	Brasch, J. *et al.*	1993	Patch Test Reactions to a Preliminary Preservative Series.	Information Network of Dermatological Clinics (IVDK)	*Dermatosen* 41,2; 71-76	No	Yes	No	--
A6.12.6 Non-key study Published	Burry, J.N. *et al.*	1975	Chlorocresol sensitivity	St. Peters, South Australia	*Contact Dermatitis* 1, 41-42	No	Yes	No	--
A6.12.6 Non-key study Published	de Boer, E.M. *et al.*	1989	Dermatoses in metal workers (II). Allergic contact dermatitis.	Free University Academic Hospital, Amsterdam, The Netherlands	*Contact Dermatitis* 20, 280-286	No	Yes	No	–
A6.12.6 Non-key study Published	Dooms-Goossen, A. *Et al.*	1981	Chlorocresol and chloracetamide: Allergens in medications, glues, and cosmetics	Dept. Of Dermatology, Academisch Ziekenhuis St.Peter, Leuven, Belgium	*Contact Dermatitis* 7, 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	*Contact Dermatitis* 15, 252	No	Yes	No	–
A6.12.6 Non-key study Published	Geier, J. *et al.*	1996	Contact Allergy due to Industrial Biocides.	Information Network of Dermatological Clinics (IVDK)	*Dermatosen* 44 (4), 154-159	No	Yes	No	--
A6.12.6 Non-key study Published	Goncalo, M. *et al.*	1987	Immediate and delayed sensitivity to chlorocresol.	Clinica de Dermatologica e Venereologica, Coimbra, Portugal	*Contact Dermatitis* 17, 46-47	No	Yes	No	--

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A6.12.6 A6.12.2(02)	Hancock, B.W. and Naysmith, A.	1975	Hypersensitivity to Chlorocresol-preserved Heparin. *British Medical Journal:* 746-747, 1975	Royal Hospital, Sheffield, UK	*British Medical Journal*, 746 – 747,	No	Yes	No	--
A6.12.6 Non-key study published	Rudner, E.J.	1977	North American Group Results	–	*Contact Dermatitis* 3: 208-209	No	Yes	No	–
A6.12.6 Non-key study Published	Uter, W. *et al.*	1993	Contact Allergy in Metal Workers.	Information Network of Dermatological Clinics (IVDK) in Germany	*Dermatosen* 41(6), 220-227	No	Yes	No	–
A6.12.6 Non-key study Published	Wilkinson, J.D. *et al.*	1980	Comparison of Patch Test Results in Two Adjacent Areas of England. II. Medicaments.	Slade Hospital, Oxford & Wycombe General Hospital, England	*Acta Dermatovener (Stockholm)* 60, 245-249	No	Yes	No	
A6.12.7 A6.12.8	Joppich, G.	1962	Klinik und Behandlung der Sagrotanvergiftung. *Deut. Med. J.*:11; 20 -21, 1960	University Children's Hospital Göttingen, Germany	*Deut. Med. J.* 13; 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

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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, G.	1992	Investigations of the ecological behaviour of Preventol CMK Date: 1992-02-25	Bayer AG, Institut für Umweltananlyse und Bewertungen, Leverkusen, Gemany	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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A7.1.1.2.1(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-methyl-phenol), OECD 301 D. Date: 1981-05-26	Bayer AG, OC-P/Ökologie, Leverkusen, Germany	NHH-Go/2694	No	No	Yes	LANXESS Deutschland GmbH

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A7.1.1.2.1(05) Non-key study	N.N.	1985	Biodegradability of Preventol CMK (4-chloro-3-methyl-phenol), 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-methyl-phenol), 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	--

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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

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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. *Organohalogen Compounds, Vol. 40, 65-68.*	-	-	No	Yes	No	-
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. *Environmental Pollution, 115, 291-301*	-	-	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. *Organohalogen Compounds, Vol. 37, 269-272.*	-	-	No	Yes	No	-

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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. *Chemosphere, Vol. 40, 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. *Chemosphere, Vol. 35, 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. *Vom Wasser, 90, 295-309.*	-	-	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

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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. *J. appl. Bact., 40, 67 - 72, 1976*	Laboratory of General and Industrial Microbiology, State University of Gent, Gent, Belgium.	--	No	Yes	No	--
A7.1.2.1.2(03)	O'Conner, O.A. & Young, L.Y.	1989	Toxicity and anaerobic biodegradability of substituted phenols under methanogenic conditions. *Environ. Toxicol. Chem.* 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. *Environm. Technol. Lett. 10, 405 – 414, 1989*	Public Health Engineering Laboratory, Department of Civil Engineering, Imperial College of Science, Technology and Medicine, London, UK	--	No	Yes	No	--

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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, Gemany	AS 142	Yes	No	Yes	LANXESS Deutschland GmbH
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: 20111-05-26	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

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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	^{14}C-Preventol CMK: Aerobic degradation of ^{14}C-Preventol CMK in two different aquatic sediment systems. Date: 2009-03-26	RLP AgroScience GmbH, Neustadt a.d. Weinstraße, Gemany	AS 85	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(02)	Möndel, M.	2010b	^{14}C-Preventol CMK: Characterisation of non-identified radioactivity of ^{14}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-methyl-phenol in water. Draft final report to the Department of the Environment, UK. 72p	-	No	Yes	No	-	-

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A7.1.2.2.2(03)	Bolz, U. *et al.*	1999	Determination of phenolic xenoestrogens in sediments and sewage sludges by HRGC/LRMS. *Organohalogen Compounds, Vol. 40, 65-68.*	-	-	No	Yes	No	-
A7.1.2.2.2(03) / B7.5(04)	Bolz, U. *et al.*	2001	Phenolic xenoestrogens in surface water, sediments, and sewage sludge from Baden-Württemberg, south-west Germany. *Environmental Pollution, 115, 291-301*	-	-	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. *Journal of Aquatic Ecosystem Stress and Recovery, 8, 215-229.*	-	-	No	Yes	No	-

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A7.1.2.2.2(03) / B7.5(06)	Lacorte, S. *et al.*	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). Journal of Environmental Monitoring, 3, 475-482	-	-	No	Yes	No	-
A7.1.2.2.2(03) / B7.5(03)	Schmidt-Bäumler, K., *et al.*	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

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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(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. *The Science of the Total Environment 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

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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	--
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: 20111-05-26	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

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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. *Journal of Soil Contamination 1(4), 339-360, 1992*	Environmental and Water Resources Engineering Laboratories, Texas, Austin, USA	--	No	Yes	No	--
A7.2.1/ A7.2.2 Non-key study/ published	Sattar, M.A.	1989	Fate of chlorinated cresols from environmental samples. *Chemosphere 19 (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

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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.	--	*Hazardous Waste and Hazardous Materials 7 (2), 151 – 168*	No	Yes	No	--
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)	[redacted]	1993a	Acute Toxicity of Preventol CMK Technical to the Rainbow Trout (*Oncorhynchus mykiss*) Under Static Renewal Conditions. Date: 1993-02-19	[redacted]	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 (*Daphnia magna*) under static conditions. Date: 1993-02-19	Miles Incorporated, Agriculture Division, South Metcalf, Stilwell, Kansas, US	105021	Yes	No	Yes	LANXESS Deutschland GmbH

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A7.4.1.3(01)	Caspers, N.	1983/1991	Preventol CMK (4-chloro-3-methyl-phenol) – Growth Inhibition Test Algae. Date: 1991-01-28	Bayer AG, WV-Umweltschutz, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
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 *Desmodesmus subspicatus* 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

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(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
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	--

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
A7.4.2(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. *Mar. Freshwater Res. 47, 951 – 959, 1996*	--	--	No	Yes	No	--
A7.4.3.1(01)	Caspers, N. and Müller, G.	1991	Preventol CMK: Prolonged Toxicity Test with Zebrafish (Brachydanio rerio). 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)	[redacted]	2007	Toxicity of 4-Chloro-3-methylphenol (Preventol CMK) to Rainbow Trout (*Oncorhynchus mykiss*) in a Prolonged Semi Static Test over 28 Days. Date: 2007-03-28	[redacted]	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 *Daphnia* reproduction test as a basis for assessing their environmental hazard in aquatic systems. Date: 1988-03-31	Instiute 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 *Daphnia* 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 - Daphnia magna 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 *Eisenia fetida* 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)	[redacted]	1993a	Preventol CMK: An acute oral LD_{50} with Bobwhite Quail. Date: 1993-02-19	[redacted]	105005	Yes	No	Yes	LANXESS Deutschland GmbH
A7.5.3.1.2(01)	[redacted]	1993b	Preventol CMK: A subacute dietary LD_{50} with Bobwhite Quail. Date: 1993-02-19	[redacted]	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 IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B2.2(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

Section No. in Doc III-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B2.3(01) B3.1(01)	Kraus, H.	2006a	4-Chloro-3-methylphenol / Appearance. Date: 2006-05-23	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B3.2(01)	Kraus, H.	2006a	4-Chloro-3-methylphenol / Explosive properties. Date: 2006-03-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B3.3(01)	Kraus, H.	2006b	4-Chloro-3-methylphenol / Oxidising properties. Date: 2006-03-03	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B3.4(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
B3.5(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-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.6(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
B3.6(02)	Haßmann, V.	1992	Preventol CMK – Bulk density. Date: 1992-03-06	Bayer AG, Krefeld-Uerdingen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B3.7(01)	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
B3.7(02)	European Commission (Ed.)	2006	Content of the product dossier accompanying the active substance for Annex I inclusion. Date: 2006-09-14	European Commission, Directorate-General-JRC, Institute for Health and Consumer Protection, Unit: Toxicology and Chemical Substances, European Chemicals Bureau	--	No	Yes	No	European Commission, European Chemicals Bureau
B3.8(01)	Jungheim, R.	2007	Physicochemical properties (foam stability and wettability) of Preventol CMK (pellets). Date: 2007-06-25	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	2006/0025/11	Yes	No	Yes	LANXESS Deutschland GmbH

Section No. in Doc III-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.8(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
B3.8(03)	Eğilmez, D.	2011	Flowability of Preventol® CMK after accelerated storage under pressure. Date: 2011-05-24	LANXESS Deutschland GmbH, Leverkusen, Germany	None	No	No	Yes	LANXESS Deutschland GmbH
B3.10(01)	Olf, G.	2006	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
B3.11(01)	Erstling, K.	2008	Physicochemical properties of Preventol CMK. Date: 2008-11-03	CURRENTA GmbH & Co. OHG, Services Analytik, Leverkusen, Germany	2006/0025/14	Yes	No	Yes	LANXESS Deutschland GmbH
B4.1(01)	Jungheim, R.	2006	Validation of a GC-Method for Preventol CMK (Pellets). Date: 2006-04-21 CONFIDENTIAL	Bayer Industry Services GmbH & Co. OHG, BIS-SUA-Analytics, Leverkusen, Germany	Study No.: 2006/0014/01	Yes	No	Yes	LANXESS Deutschland GmbH
B8	Anonymous	2005	Safety Data Sheet Preventol CMK pellets. Date: 2005-10-06	LANXESS Deutschland GmbH, Leverkusen, Germany	690981/13	No	No	--	LANXESS Deutschland GmbH

Section No. in Doc III-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B8.1(02)	Kraus, H.	2006c	4-Chloro-3-methylphenol (CMK) / Reactivity towards container material. Date: 2006-06-01	LANXESS Deutschland GmbH, Leverkusen, Germany	--	No	No	Yes	LANXESS Deutschland GmbH
B5.10(01)/ 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
B5.10(02)	Wachtler, P.	2008	Efficacy Study submitted for registration of Preventol® CMK (PCMC) for Product Type 13 according to the Biocidal Products Directive 98/8/EC. Date: 2008-07-07	LANXESS Deutschland GmbH, Leverkusen, Germany	2008-07-07	No	No	Yes	LANXESS Deutschland GmbH
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-B or IIIA	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	1992	Investigations of the ecological behaviour of Preventol CMK Date: 1992-02-25	Bayer AG, Institut für Umweltananlyse und Bewertungen, Leverkusen, Gemany	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
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

Section No. in Doc III-B or IIIA	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(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
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

Section No. in Doc III-B or IIIA	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(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. *Organohalogen Compounds, Vol. 40, 65-68.*	-	-	No	Yes	No	-
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 *Environmental Pollution* 115, 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. *Chemosphere, Vol. 40, 1131-1142*	-	-	No	Yes	No	-

Section No. in Doc III-B or IIIA	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. *Chemosphere, Vol. 35, 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. *Vom Wasser, 90, 295-309.*	-	-	No	Yes	No	-
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, Gemany	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, Gemany	AS 85	Yes	No	Yes	LANXESS Deutschland GmbH
A7.1.2.2.2(02)	Möndel, M.	2010b	^{14}C-Preventol CMK: Characterisation of non-identified radioactivity of ^{14}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

Section No. in Doc III-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
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
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 contaminats in the aquatic system in Berlin. Part II: Substituted phenols in Berlin surface water. *Acta hydrochim. Hydrobiol*. 27, 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 *Environmental Pollution* 115, 291 – 301, 2001	Institute of Organic Chemistry, University of Tübingen, Tübingen, Germany	--	No	Yes	No	--

Section No. in Doc III-B or IIIA	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
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. *WRC-Final Report to the Department of the Environment,* Report No. DoE 4259(P)	--	DoE 4259(P)	No	Yes	No	--
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. *Organohalogen Compounds, Vol. 40, 65-68.*	-	-	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. *Journal of Aquatic Ecosystem Stress and Recovery, 8, 215-229.*	-	-	No	Yes	No	-

Section No. in Doc III-B or IIIA	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)	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 *The Science of the Total Environment 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. *Chemosphere* 19 (8/9), 1421 – 1426, 1989	Department of Soil Science, Agricultural University, Mymensingh, Bangladesh	--	No	Yes	No	--

Section No. in Doc III-B or IIIA	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(02) Non-key/ published	Loehr, R.C. and Matthews, J.E.	1992	Loss of organic chemicals in soil. Pure compound treatability studies. *Journal of Soil Contamination 1(4), 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. *Mar. Freshwater Res. 47, 951 – 959, 1996*	--	--	No	Yes	No	--