MCCP REACH Consortium

Response to Call for Evidence on Medium-Chain Chlorinated Paraffins (MCCP) Alkanes, C14-17, chloro - EC 287-477-0 - CAS 85535-85-9

Introduction

These comments are from the MCCP REACH Consortium[1] (the "Consortium") in response to the European Chemicals Agency's (ECHA) Call for Comments and Evidence (CfE) on medium-chain chlorinated paraffins (MCCP), Alkanes, C_{14-17}, chloro (EC 287-477-0). MCCP is one of several historically defined[2] ranges of chlorinated paraffins (CPs) in the European Union (EU) that also included short-chain CPs (SCCP) and long-chain CPs (LCCP).

The Consortium is aware of ECHA's efforts to prepare an Annex XV dossier for the nomination of MCCP to the list of substances of very high concern (SVHC) and the potential for risk management via a REACH restriction. MCCP is a commercially important substance for many industries and businesses in the EU and the Consortium strongly urges ECHA to carefully review these comments and the other submissions from downstream users and potentially impacted businesses prior to taking any proposed action on MCCP. The Consortium believes that the ongoing manufacture and use of MCCP in the EU is being managed in an environmental appropriate manner and that a Weight of Evidence (WoE) approach to the evaluation of MCCP under REACH Annex XIII does not support its addition to the SVHC list.

ECHA should not go into this process with a predetermined timeline, such as noting plans for completion of the Annex XV SVHC dossier by 8 February 2021, but take the necessary and appropriate time to review, reflect, and request follow-up information as needed on the submissions from this CfE. The outcome of this process will have significant impacts and it should be conducted in a methodical manner and not rushed. This action will likely impact job opportunities in the EU, affect billions of euros of commercial activity in the EU, and may have a wide range of unintended consequences from limiting ongoing research of MCCP use in new green chemistries, causing substitutions to alternatives that have not been fully evaluated, or simply to the replacement of EU goods by imported articles that are manufactured under less-regulated conditions and that contain poorly defined chloro-alkanes that may not be considered MCCP.

In these comments, the Consortium is providing information and evidence on:

1. Substance evaluation of MCCP and ongoing research on MCCP
2. Production and use of MCCP based on a new survey of the registrants
3. Release and environmental assessment of MCCP
4. Approaches to risk management
5. Evaluation of substitutes

[1] MCCP REACH Consortium represent the co-registrants of EC 24-477-0 under the REACH regulation. Current participants in the Consortium are Altair Chimica, Caffaro Industrie S.p.A., INOVYN, QUIMICA DEL CINCA S.L.U. and Vantage Leuna GmbH.

[2] The carbon-range definitions for SCCP, C_{10-13}, MCCP, C_{14-17}, and LCCP, C_{18+}, were developed at the advent of EU chemical inventory and were based on the predominant carbon-ranges of the feedstocks used in their manufacture. All are UVCB substances (see footnote #4).

1. Substance Evaluation of MCCP

Whilst MCCP's starting materials, C_{14-17} alkanes and chlorine, are relatively simple, the random nature of the chlorination process means that MCCP contains hundreds of thousands[3] of individual isomers and is a UVCB[4] substance. Further, as the original (EINECS) substance definition of MCCP is based just on the carbon-chain length of the starting n-paraffin (i.e. Alkanes, C_{14-17}) and not on specific levels of chlorination there are a range of commercial products[5] with differing chlorination levels by weight under this substance. This complex composition creates complexities in the substance evaluation of MCCP that have been addressed through a variety of methods such as evaluating MCCP products at different levels of chlorination, evaluating individual carbon chain lengths, testing uniquely synthesised test materials with specific isomeric structures, modelling individual structures thought to be representative of MCCP, and more recently considering "congener groups" - groups of isomers with the same molecular formula - within chloroalkanes. Further, it has even been suggested, by the ECHA Board of Appeal[6], that MCCP could be broken up into separate registrations covering different subsets of the range of MCCP commercial products.

All of these approaches to the evaluation of MCCP have merits, but also limitations. In the case of separately registering different substances under the MCCP range, the registrants decided against this since it was not an option given the existing substance definition for MCCP[7]. As ECHA now undertakes further evaluation and regulation of MCCP under REACH, the Consortium believes it is important to understand how the approaches to evaluating MCCP impact not only the conclusions reached but also the subsequent risk management and regulation of MCCP.

The following is a review of the recent approaches to evaluating MCCP, focusing on the key endpoints related to the Persistence, Bioaccumulation and Toxicity (PBT) assessment and then a summary of the ongoing research on by the Consortium on MCCP.

Matrices Comparing Carbon-Chain Length to Chlorination Level

For the recently completed substance evaluation (SEv) of MCCP under REACH, the method used to evaluate persistence (P) and bioaccumulation (B) was a matrix that compared carbon-chain length on one axis against average chlorination level by weight on the other axis (see figure 1.1 below from ECHA's decision on MCCP). This matrix approach for the P and B endpoints builds upon earlier assessments of MCCP, which focused on the testing of individual chain-length chloroalkanes for the P and B endpoints. One impact of this particular approach to MCCP SEv is that much of the resulting data in the MCCP dossier on the P and B endpoints is for single-chain length test materials and not commercial forms of MCCP. Another consideration for this matrix is

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[3] MCCP is estimated to contain >10^5 individual isomers. Yang (2020) estimated 410 000 isomers for just C14 and C15.

[4] UVCB stands for unknown or variable composition, complex reaction products or of biological materials.

[5] Under REACH, MCCP "products" generally only vary by level of chlorination by weight as the starting hydrocarbon feedstock (Alkanes, C14-17) is expected to be the same for all products. The term "mixtures" or "commercial mixtures" is never appropriate for MCCP products as these are not intentionally mixed, but a reaction product of chlorine and alkanes C14-17.

[6] ECHA Board of Appeal decision, 9 September 2015, Paragraph 49, page 9 of 33.

[7] MCCP existed as a single substance under EINECS, which only allowed for the pre-registration during the phase-in period of a single substance. The joint registration of MCCP followed the REACH principle of "one substance, one registration" in developing the MCCP dossier.

that the chlorination ranges do not represent unique constituents in MCCP but rather different common chlorination levels used in commercial forms of MCCP. Indeed, all such single chain chloroalkane substances produced as unique test materials for the evaluation of MCCP are themselves UVCB substances with tens of thousands of isomers.

Figure 1.1: P and B Matrix from ECHA's 25 February 2014 SEv Decision on MCCP

Estimated P & B properties of potential constituents of MCCPs

Carbon no.	Chlorine content (w/w)			
	~40-50%	~50-55%	~55%-65%	>65%
	Constituents that may be present at >1% w/w			
14	Not P vB	P? B	P? Borderline B?	P Not B?
15	P? Not B	P? Borderline B	P Not B	P Not B
16	P? Not B	P? Not B	P Not B	P Not B
17	P? Not B	P? Not B	P Not B	P Not B

Note: This is a partial version of the original matrix, which also included C10-C13 carbon numbers.

For the current SEv under REACH, the testing program on MCCP focused specifically on the C_{14}, 50-55% Cl, C_{14}, 55-65% Cl and C_{15}, 50-55% Cl boxes in the above matrix. Upon completion of the additional P and B testing on these test materials, a final SEv report was developed. The draft version of this report (September 2019) included an updated version of this matrix (Figure 1.2), though the final SEv report did not include this matrix or a similar version.

Figure 1.2: P and B Matrix from September 2019 DRAFT SEv on MCCP

ESTIMATED PERSISTENCE (P) AND BIOACCUMULATION (B) PROPERTIES OF POTENTIAL CONSTITUENTS OF MCCPS

Carbon no.	Chlorine content (w/w)			
	~ 40-≤50 %	~ 50-≤55 %	~ 55 %-≤65 %	>65 %
	Constituents that may be present at >1 % w/w			
14	Not P vB	P (vP?) vB	P (vP?) vB	P (vP?) B?
15	P? Not B	P? B?	P Not B	P Not B
16	P? Not B	P? Not B	P Not B	P Not B
17	P? Not B	P? Not B	P Not B	P Not B

The removal of this matrix in the final SEv created a loss of continuity from the initial SEv and the SEv testing decision (including the appeal and defence of this decision). For example, the SEv testing decision focused exclusively on MCCP grades of 50% Cl and higher due to the determination that MCCP products <50% Cl did not meet the criteria for Annex XIII base on their biodegradability (i.e. not P/vP), a conclusion backed by testing of lower chlorinated materials in multiple OECD 301D studies. This conclusion is no longer present in the SEv, though there have been no new data developed on <50% Cl MCCP products/test materials to change this prior conclusion that these are not P. The Consortium is actually in the process of conducting new biodegradation testing, discussed later in this section, but the data that have been generated from this testing so far only supports the biodegradability of MCCP products in this lower chlorinated range. Curiously, the final SEv states "it is possible that lower chlorine content MCCP products (≤45% Cl wt.) might not be persistent within the meaning of the Annex XIII criteria, but definitive data to confirm this are not available" even though there are multiple acceptable biodegradation studies on MCCP-range test materials in the 30-51% Cl (by wt.) range that show either ready or inherently biodegradable results. These are data in the REACH dossier that meet the Annex XIII criteria for a not P conclusion and thus there was no reason to equivocate on that conclusion in the final SEv.

The change in PBT conclusions and abandonment of the original SEv matrix appears to be related in large part to new data on CP congeners. The ability to analyse for CP congener groups has created a new wave of testing results for CPs, but as with all evaluation approaches there are important considerations and limitations to the use of these data. Evaluation of test data that includes congener group analysis is still very much an evolving science and there may be important limitations in the use of these data for CP assessment that are not fully understood. The use of these congener data should not go beyond the fundamentals of using test materials that are representative of the registered substance. Individual isomers within congener groups are generally not identified or identifiable, so each congener group is itself a UVCB subset of a larger UVCB substance. In the case of the congener data on daphnid bioaccumulation from Castro et al. (2019), only one of the test materials was an MCCP product and it was MCCP at 45% Cl, a chlorination level that was previously considered to be bioaccumulative, but not persistent. There have also been concerns raised regarding some of the other test materials used in this research program[8]. As noted in the SEv report, there are "major uncertainties in the numerical values" from this study. New results such as these need to be considered as part of an overall weight of evidence approach on the B endpoint, as presented below.

Bioaccumulation Assessment

Bioaccumulation is a particularly challenging endpoint in the assessment of MCCP. There are a variety of different types of studies, conducted both in the laboratory and in the field. Further, this endpoint has itself been evolving since the creation of REACH as the science of bioaccumulation continues to expand. ECHA[9] and SETAC[10] have held recent conferences that have considered different approaches to the evaluation of this endpoint beyond just the bioconcentration factor

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[8] See INOVYN comments concerning test material correspondence [redacted]

[9] CEFIC-LRI and ECHA Workshop on Recent Scientific Developments in Bioaccumulation Research;.Helsinki, Finland, 24 September 2014

[10] SETAC ''Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs,'' January 2008, Florida, USA. See Gobas et al. "Revisiting Bioaccumulation Criteria for POPs and PBT Assessments."

(BCF) metric. To address the inherent complexities of this endpoint, the Consortium has commissioned a series of expert reviews on the bioaccumulation endpoint for MCCP. The first of these expert reviews was written by Dr. Roy Thompson and included in the original 2010 REACH registration dossier; this review was later expanded and published (Thompson and Vaughan 2014).

Several subsequent bioaccumulation assessments have been conducted by Dr. Jon Arnot (2014, 2020) using weight of evidence (WoE) approaches consistent with the frameworks proposed in Burkhard et al. (2012), Gobas et al. (2009), and discussed at the ECHA/Cefic 2014 bioaccumulation conference. In the Arnot (2014) assessment, measured bioaccumulation data for MCCP/constituents from various aquatic species (plankton, invertebrates, fish) from laboratory testing (BCF, BMF) and environmental monitoring (BMF, BAF, TMF) were assessed against a common criterion. A total of 97 measured data points were compared against the bioaccumulation assessment criterion of 1 (red horizontal line in Figure 1.3) proposed by Burkhard et al. (2012). Data derived from field studies, and in particular TMF values, are considered to be the ultimate indicator of a compound's potential to bioaccumulate in the natural environment (Gobas 2009). A total of 93% of the data in Figure 1 are from environmental (field) studies and are thus considered highly relevant ("real world") B assessment data. Of these 97 measured data points, 7 (7.2%) met or exceeded the threshold criterion and 90 (92.8%) were lower than the threshold criterion. The median value (central tendency) is 0.27 (black dashed line). The SETAC POP/PBT expert workshop experts considered that a TMF >1 represented the most conclusive evidence of the bioaccumulative nature of a chemical (Gobas 2009). Figure 1 shows that all the TMFs for the MCCP constituents are < 1. This WoE assessment concluded that MCCP constituents are not likely to biomagnify in fish and in aquatic food webs.

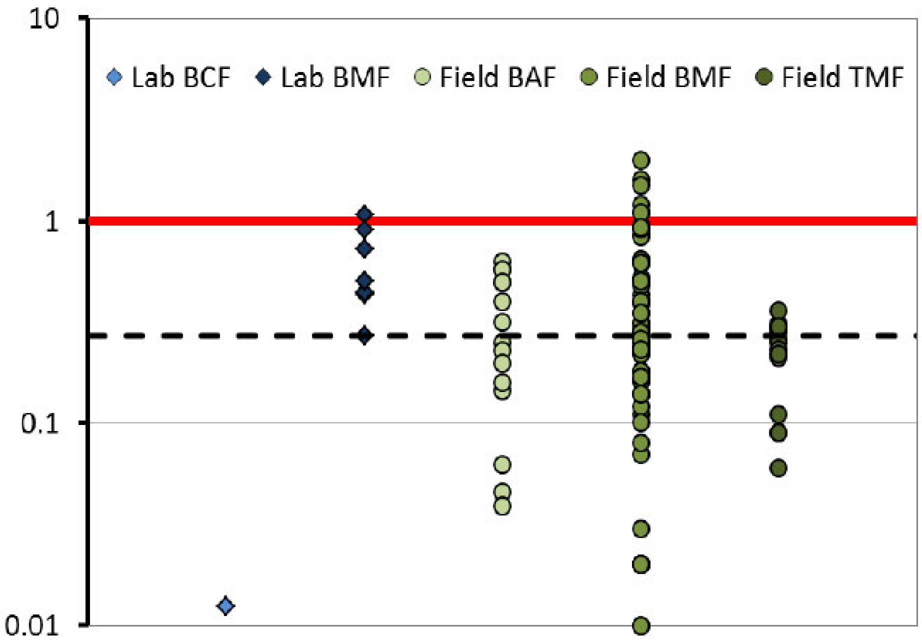


Figure 1.3. Fugacity ratios calculated using the recommended methods (Burkhard et al., 2012) for available relevant and reliable bioaccumulation data for MCCP constituents (Arnot 2014). Values > 1 (red line) indicate biomagnification (bioaccumulation) hazard. 93% of the data points are < 1 and the median value = 0.27

In a new WoE bioaccumulation assessment (Arnot 2020), the Bioaccumulation Assessment Tool (BAT) version 2.0[11] was used to systematically review the available bioaccumulation data on MCCP. The BAT WoE approach was used to individually critically evaluate 113 measured and reported B data points for MCCP for reliability. These individual results, called “lines of evidence” (LOE) in the BAT, were then compared against B thresholds and summarised. The full report is attached and the supporting modelling, which is massive file, will be uploaded separately on ECHA CfE webform. Here are some of the key finding of this assessment:

- Each of the 113 measured LOE for MCCPs are included in the BAT were subject to reliability scores using the BAT Data Evaluation Templates (DETs). The data reliability assessment methods and criteria are derived from OECD testing guidelines and published guidance for evaluating measured lab and field bioaccumulation data.

- 77 of 113 measured LOE were deemed reliable for B assessment.

- In addition to the measured LOE, the bioaccumulation models in BAT provide an additional 7 LOE (e.g., model calculated lab BCF, field BAF, field BMF) to compare against measured data.

- 82% of the measured reliable quality LOE classify MCCPs as “nB” compared to 18% of reliable quality measured LOE that classify MCCPs as “vB”.

- An additional WoE using fugacity ratios is included in this report. The fugacity ratio approach sought to address whether a chemical biomagnifies in the environment or not.

- 77 reliable quality LOEs for MCCPs were converted to fugacity ratios and 92% of these data were below the biomagnification threshold of 1 indicating it is unlikely that MCCPs biomagnify in fish and the aquatic environment.

The Consortium believes that these various WoE approaches to the assessment of bioaccumulation are entirely consistent with REACH Annex XIII and represent a significant effort to fully understand the science of bioaccumulation. MCCP’s complex database on MCCP should not be viewed based on only those results that achieve the B/vB criteria using BCF but on a broader assessment of the database. This is especially important considering that data on higher tier metrics (BMF, TMF) are available for MCCP and consistently show that it does not biomagnify. These results are also fully supported by measured exposure monitoring data from the environment (see Section 3) that show wide margins of exposure/safety for MCCP in Europe after decades of continuous production and use.

[11] Available on the CEFIC-LRI website http://cefic-lri.org/toolbox/bioaccumulation-assessment-tool-bat-a-quantitative-weight-of-evidence-qwoe-framework-to-aid-bioaccumulation-assessment/.

New Biodegradation Testing

The evaluation of the biodegradability or persistence (P) of MCCP has largely been based on a series of OECD Guideline 301D Closed Bottle Tests (CBT) and an OECD Guideline 308 sediment biotransformation study. These data are well described in the registration dossier and SEv report. The Consortium believes that the OECD 301D studies present a compelling and relevant data set for MCCP since they have evaluated the effect of chlorination level on biodegradability of MCCP and MCCP constituents. This test system was modified to make MCCP bioavailable, which is allowed by the guideline when testing such a poorly soluble chemical. It has repeatedly shown high levels of mineralisation and significant removal of many of the MCCP test materials. In contrast, the Consortium believes that as currently conducted, the OECD 308 test system greatly overestimates persistence in sediments, particularly for sparingly soluble substances that tenaciously sorb to inert solids and hence are rendered non-bioavailable. This raises an environmental relevance question for substances that are not directly applied to surface waters but primarily enter the environment pre-associated with biosolids in treated wastewater effluents. Other substances (e.g. phenanthrene) for which a balanced weight of evidence assessment would indicate are biodegradable have also performed poorly in this test and have been classified as persistent (Hughes 2020). Moreover, while multiple studies[12] have documented the shortcomings and interpretation issues with the OECD 308 test, there exist no meta-analyses or other systematic studies combining OECD 308 study results and field monitoring. Such as analysis is needed to demonstrate that this test has an ability to reliably discriminate real-world persistence and accumulation in sediments of unequivocally nonbiodegradable substances from that of otherwise biodegradable materials that perform poorly in the OECD 308.

To better understand the real-world biodegradability of MCCP at a critical potential release point into the environment, the Consortium has begun a testing program based on the OECD 314B test guidelines. To the extent that there appears to be a fundamental contradiction between the OECD 301D and 308 results, the Consortium believes that an additional biodegradation simulation assay, one that is highly relevant for MCCP's use and possible entry into the environment, will be very informative relative to actual exposure in aquatic compartments, including sediments.

One aspect to this new testing program is the use of tritium (^{3}H) as a radiolabel for chloroalkane test materials. Tritium is a commonly used radiolabel in environmental fate testing, but it had not been previously used for CPs which historically used ^{14}C carbon as a radiolabel or no radiolabel (i.e. cold test materials). The advantages of using tritium with CPs is that the tritiation process is random so radiolabelling occurs at multiple sites along the carbon chain in all constituents of MCCP, whereas with ^{14}C the radiolabel is typically on the central carbon in the chain. Any commercial CP product can be tritiated so this method allows for direct testing of the types of MCCP products on the market as opposed to surrogate test materials. The testing program is still in the early stage, but the results so far have demonstrated that the tritiation process does not significantly alter the chloroalkane in terms of chlorination levels/pattern and that the test material has a high specific activity allowing for testing at a wide range of environmentally relevant test concentrations.

In September 2020, the Consortium initiated a pilot study, conducted by Eurofins EAG, based on the OECD 314B test guideline using a ^{3}H-C14, 30% Cl (wt.) test material. This test material was selected because it was readily available having been synthesised for a separate testing program for

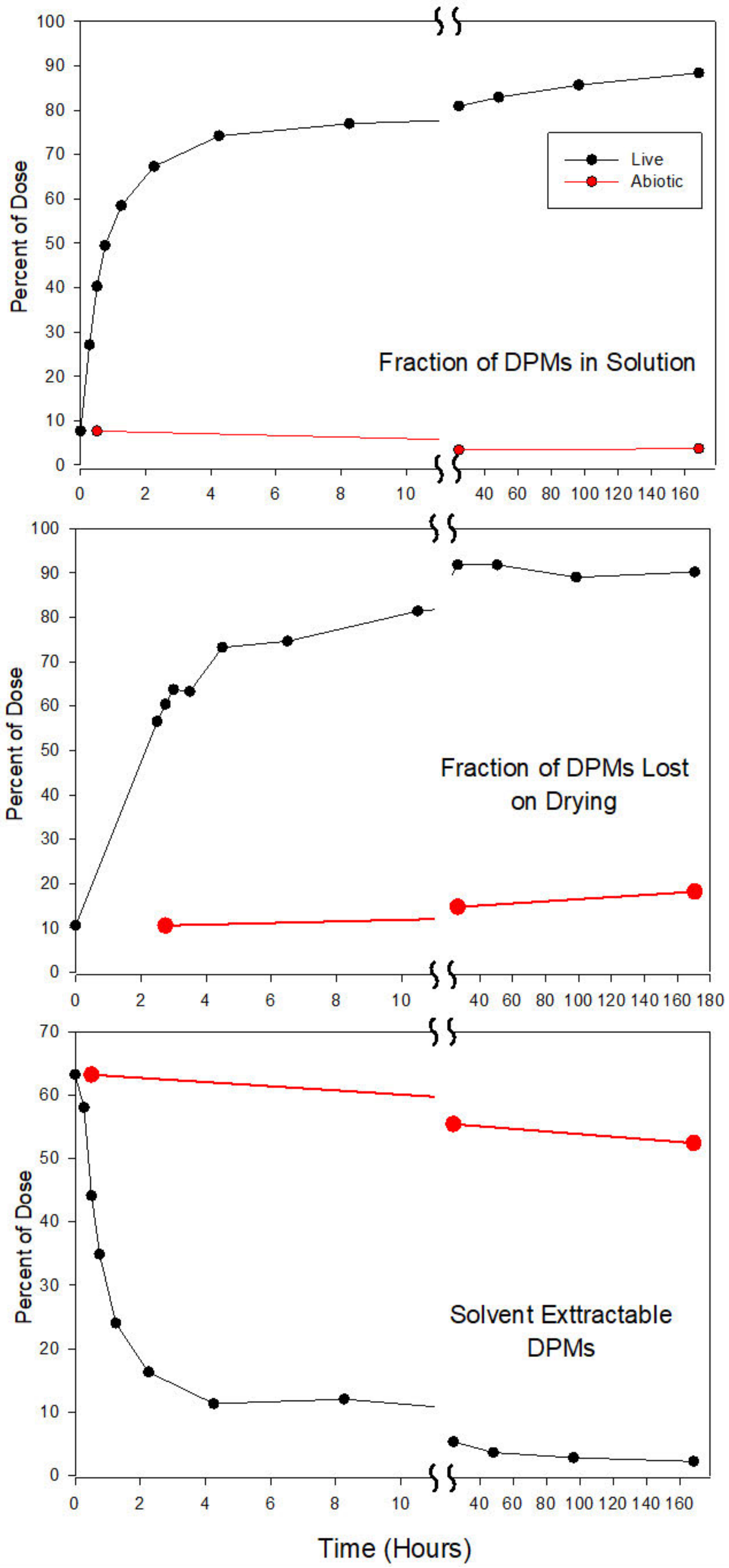
[12] See Ericson (2007), Ericson (2013), Mechteld (2016), Honti and Fenner (2015), Shrestha (2016), and Southwell (2020).

U.S. EPA[13]. In this pilot study, the test apparatus consisted of two 500-mL Wheaton bottles (test vessels) containing biologically active (biotic) or abiotic activated sludge. The abiotic control was identical to the biologically active treatment with the exception that it was amended at a nominal concentration of 1µg/L with mercuric chloride buffer solution and autoclaved prior to test initiation. The test substance was dosed to both 250mL biotic and 50 mL abiotic test volumes at a nominal concentration of 1 µg/L. Samples were removed from the test vessels over 7 days. Disappearance of the parent test substance and the formation of metabolites were determined by RAD-TLC analysis. This study was just completed in early December 2020 and a final report should be available in January 2021 and will be provided to ECHA as soon as it is ready.

Based on results recently provided by the test lab, the primary objective of the study to assess the feasibility of using a tritiated chloroalkane to determine the loss of parent, formation of metabolites and mineralization of a multi-constituent chloroalkane substance, was achieved. The test substance exhibited rapid and significant mineralisation based on an evaluation of dried samples - drying removes the ultimate mineralisation product tritiated water ($^3H_20$ or T_20). While samples were collected over a 7-day period, the vast majority of the mineralisation (91.8%) occurred during the first 24 hours. Figure 1.4 below summarises the main results from the study, including migration of radioactivity (DPM) from the sludge solids to the aqueous phase over time (due to the formation of highly polar metabolites and full mineralisation to ^3H_2O) and the organic solvent extractable parent and metabolites.

[13] This same test material was used in an OECD 225 sediment toxicity study for U.S. EPA in 2020. In the in-life portion of this study has concluded and a report is expected in early 2021.

Figure 1.4: OECD 314B Pilot Biodegradation Study Results (^{3}H-C14, 30% Cl (wt.))



Preliminary RAD-TLC analyses were also successful with the chromatograms showing a decrease of the parent (chloroalkane) test material and the formation and disappearance of low levels of transient metabolites[14] at early sampling periods. After 24 hours, 91.8% of the dosed radioactivity had been mineralized to $^{3}H_2O$ and only 5.5% was extractable in organic solvents. The overall results of this study indicate that this test material (tetradecane with 30% Cl by wt.) will rapidly and extensively biodegrade in a wastewater treatment facility, consistent with the ready biodegradability of tetradecane with similar levels of chlorination.

Based on the success of this pilot study, the Consortium is now undertaking a definitive OECD 314B guideline study on commercial MCCP at 52% Cl wt. This test material was chosen because it is the most prevalent form of MCCP manufactured and used in Europe.

MCCP Not a SVHC-Containing or PBT-Containing Substance

The SEv also notes that MCCP may include minor constituents above 0.1% that are $<C_{14}$ and equates those to SCCP, concluding that "MCCPs with a chlorine content equal to or greater than 50% wt." is a "PBT-containing substance". This conclusion is based on the notion that these $<C_{14}$ constituents have the same PBT properties as SCCP, though caveated by the fact that there is a biodegradation study of SCCP at 50% Cl (wt.) that shows it is readily biodegradable.

As note previously, the carbon-range numbers used to originally define SCCP, MCCP and LCCP were never intended to be precise down to the level of 0.1% but were based on the predominant carbon-chain lengths. The fact that there is some minor overlap in these carbon-chain lengths is not an appropriate basis to apply the 0.1% SVHC/PBT "mixtures" policy to MCCP. One UVCB substance cannot be a constituent in another UVCB substance and, moreover, testing of MCCP products has included these minor $<C_{14}$ constituents. Further, SCCP has a completely different profile than the C_{14} constituents in MCCP.

The Consortium encourages ECHA to focus this assessment on MCCP itself and not as a "PBT-containing" or "SVHC-containing" substance.

2. <u>Production and Use of MCCP</u>

In addition to the information that individual registrants have provided on production and importation of MCCP, the Consortium has undertaken several efforts to summarise the tonnages of total MCCP production, importation and use in the EU. These summary data on MCCP tonnages were collected by confidential surveys of the REACH registrants and the used in the environmental assessment in the Consortium-developed Chemical Safety Report (CSR) – see Annex A. Additional specific data have also been provided by the lead registrant and other registrants in recent dossier updates.

For this current CfE, the Consortium has untaken a new survey to collect tonnages for MCCP used in various applications in 2019 in the EU (excluding the UK). This survey was sent to all registrants and responses, to date, have been received from the following companies: Altair Chimica, Caffaro

[14] The metabolites were not identified, but appear to align with the region of the plate where chlorinated fatty acids have been shown to go.

Industrie S.p.A., INOVYN, QUIMICA DEL CINCA S.L.U. and Vantage Leuna GmbH. Based on historical data and prior surveys of the registrants, we believe that these companies account for the vast majority of the total production/import of MCCP in the EU.

The results of this survey are in Table 2.1, which shows the tonnages by use applications for MCCP in the EU-27, not including the UK, by chlorination level of MCCP product. This survey excluded MCCP use tonnages in the UK since these are now subject to UK chemical regulation[15].

Table 2.1: Summary of MCCP Use in EU (not including UK) in 2019

Polymer Applications (EU-27 in 2019)	Tonnage <50% Cl (wt.)	Tonnage/Yr 50-52% Cl (wt.)	Tonnage/Yr >52% Cl (wt.)	Totals	% of Total
Polymer Applications					
PVC/Plastisol	977.5	10551.6	39.6	11568.7	25.9%
Rubber	511.0	2195.9	13.8	2720.7	6.1%
Foam and other polymers	964.2	1642.7	1290.9	3897.8	8.7%
			Subtotal	18187.1	**40.7%**
Sealants & adhesives	9958.5	10697.9	3221.0	23877.3	**53.4%**
Lubricants and Metal Working Fluids	275.2	460.4	426.5	1162.2	**2.6%**
Textile	152.9	25.8	10.0	188.8	**0.4%**
Paints	85.6	296.9	41.2	423.7	**0.9%**
Additional Uses	107.0	695.0	76.0	878.0	**2.0%**
Sub-total	**13031.9**	**26566.3**	**5119.0**	**44717.2**	100.0%
Relative amounts by Cl (wt)	**29.1%**	**59.4%**	**11.4%**		

From this survey we found that the total use of MCCP in the EU is 44 717 metric tonnes, which is approximately 9 thousand tonnes less than the total tonnage of 53 726 that used in the environmental assessment of MCCP in the Consortium generated Chemical Safety Report (CSR). This difference is likely due to the exclusion of the UK from this current survey, though it may also reflect changes over time and some tonnages from registrants who did not participate in the current survey. The other major changes based on this survey are the relative total amounts used in certain applications as compared to 2019 CSR (Appendix A) and the 2019 SEv (Table 17 from the SEv). These relative amounts used by application in the CSR and SEv report are based on an earlier survey conducted by the Consortium for calendar year 2012. Whilst the overall size of the MCCP market has not changed dramatically between 2012 and 2019, and neither have the use applications, there may have been some shifts in overall use rates between the various applications. The current survey also has a better break-down in usages by chlorination level, which was not available in the prior survey.

[15] The Consortium is in communication with the UK chemical regulatory agencies, which are separately developing regulations on MCCP.

Here are some of the key results of this survey of calendar year 2019 uses:

- The majority (59.4%) of MCCP used in the EU is 50-52% Cl by weight
- The second largest class (29.1%) of MCCP used in the EU is <50% Cl by weight
- Only a small minority (11.4%) of MCCP products used in the EU are >52% Cl by weight
- Use of MCCP in polymers/rubber (all uses) and adhesive and sealants represents the vast majority (94.1%) of all use in the EU
- Sealants and adhesives is now the largest use category with 53.4% of the total, followed by polymer/rubber applications at 40.7%
- Metalworking and lubricant applications with MCCP have decreased to 2.6%.
- Other minor use categories remain relatively small.
- Overall, the use patterns of MCCP in the EU in 2019 are relatively similar to prior evaluations indicating a stable market situation and use pattern.

Information on manufacturing and import levels were also collected in this survey, though competition law prevents a summation of those results in this survey in these comments. The Consortium will separately provide these results to ECHA.

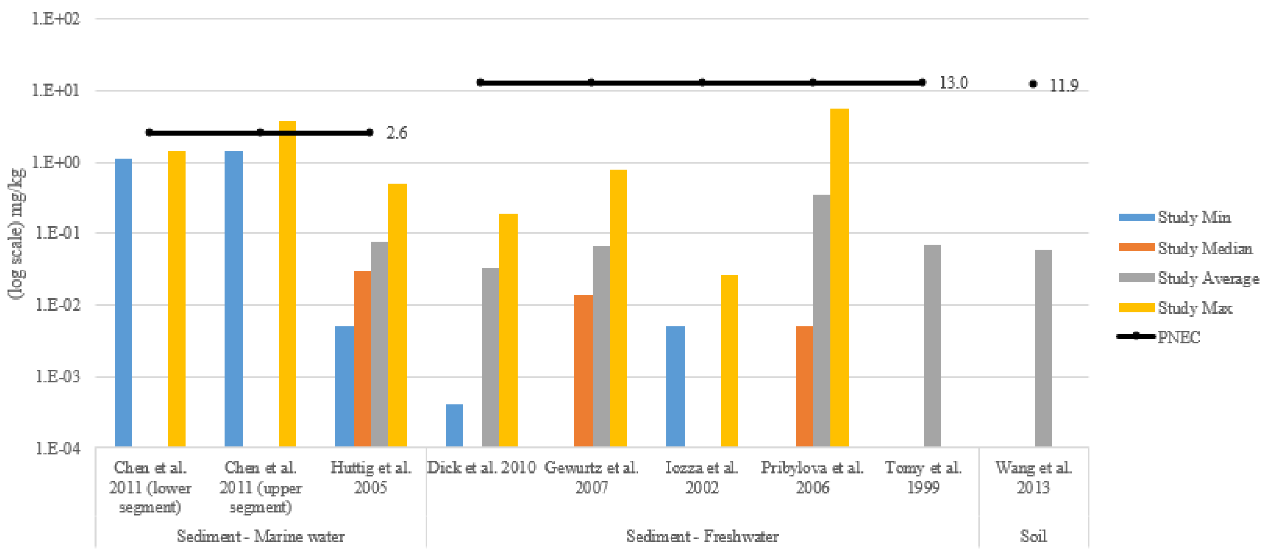
3. **MCCP Release and Exposure**

As previously discussed, the Consortium prepared a jointly-developed environmental exposure assessment in the June 2019 Chemical Safety Report (CSR) – provided in Appendix A. The environmental exposure assessment determined that all current uses of MCCP in the EU do not result in unacceptable risks to human health or the environment. The December 2019 SEv report made a similar conclusion noting that "the environmental exposure scenarios are well described" and "no PEC/PNEC ratios are above one."

The Consortium believes that the parameters used in the environmental exposure assessment presented in Annex A were the best available at the time this assessment was conducted, but we are aware that ECHA is expected to receive additional information from downstream users/organisations that may help further refine these estimates. Based on the information the Consortium has received from various downstream users/organisations, we believe our release estimates in the June 2019 CSR are accurate or perhaps even overstated. Thus, the actual exposures are lower than what is presented in Appendix A. The Consortium is certainly willing to update this environmental exposure assessment with any new data provided by the downstream users of MCCP in the EU as a part of this CfE.

Whilst this environmental exposure assessment was based on modelled results using established emissions estimates, it also included an assessment of recent measured levels of MCCP in the environment from the published literature. This review found 29 studies that measured for MCCPs in sediment, water, and biota from global sampling locations and used a subset of 22 studies in the summarized in data tables by media. Studies were eliminated if unreliable analytical techniques were used or if the study was a review paper or repeated data previously considered. This subset was further refined to include only those that were deemed relevant as a basis of comparison to the PNECs and modelled concentrations. A complete description of this decision process is provided in the Excel spreadsheet attached in Section 13.2 of the June 2019 lead registration dossier update. The table below provides a summary of measured concentrations included in the comparison to the PNECs.

Table 9.43 from the June 2019 MCCP CSR



It is notable that the only measured value above a PNEC was from a sediment sample taken in the Pearl River Delta in China. These measured results further support the reliability of the exposure assessment and its conclusions.

Another recent exposure assessment of MCCP using measured data was conducted by the European Food Safety Agency (EFSA 2020), which conducted a chronic exposure assessment for SCCPs and MCCPs for the consumption of fish meat and human milk.

ESFA fish meat assessment of MCCP was based on a data set consisting of 422 analytical results from 184 samples of fish meat collected in Germany between 2014 and 2017, which were collected specifically for use in this study. The mean and P95 occurrence levels for MCCP in fish were 13 µg/kg wet weight (ww) lower bound (LB) and 44 µg/kg ww upper bound (UB). The mean LB and UB exposure estimates ranged from 3.2 to 59 ng/kg bw per day. At the 95th percentile exposure, the LB and UB estimates ranged from 8.5 to 148 ng/kg bw per day. The lowest exposures were found in the Adult groups whilst the highest were for Toddlers. Comparison of the MCCP dietary exposures from fish consumption to the $BMDL_{10}$ of 36 mg/kg bw per day resulted in margins of exposure (MOEs) of 6.9 x 10^5 and 3.9 x 10^5 or higher for the mean and 95th percentile exposures, respectively. The EFSA CONTAM Panel concluded that these MOEs do not suggest a health concern, for the consumption of fish in the EU.

For the exposure assessment of breastfed infants, data from pooled human milk samples from 11 European countries between 2014 and 2016 were analysed within the WHO/UNEP Coordinated Survey of Human Milk for POPs. For MCCPs, the exposure ranged from < 25 to 514 ng/kg bw per day, and from < 38 to 771 ng/kg bw per day, respectively, for average and high consumption of human milk. Similar to the fish exposure assessment, these exposures were compared to the $BMDL_{10}$ of 36 mg/kg bw per day and resulted in MOEs of 7.9 x 10^4 and 5.9 x 10^4 or higher for average and high human milk consumption, respectively. The EFSA CONTAM Panel also concluded that these MOEs do not suggest a health concern.

These fish and human milk measured data for MCCP are relevant not only to the evaluation of exposure but also speak to whether the long-term use of MCCP in Europe has caused bioaccumulation of MCCP. Meat fish are relatively high in the environmental food web and certainly humans are the generally considered the apex of the food web. MCCP had been manufactured and used in Europe for at least 50 years prior to the collection of these samples (between 2014-2017). To the extent that meaningful bioaccumulation is occurring within the environment and food-web in Europe, direct samples such as these provide a real-world evaluation of this. With MOEs 10^4 to 10^5 and higher, it appears that decades of continuous use of MCCP is not resulting in the primary concern evaluated by the bioaccumulation endpoint – that long-term production and use of MCCP is leading to higher levels of environmental exposure. These EFSA results are not unusual and are very much consistent with other environmental studies of MCCP in regions with good management practices (Canada, Norway, UK, U.S., etc.).

4. <u>Possible approaches to risk management</u>

The fact that the CSR and SEv both find that the risks of ongoing production and use of MCCP in the EU are well controlled is an encouraging consideration in the development of risk management regulation for MCCP. Nonetheless, the Consortium fully supports the development of thoughtful risk management approaches to ensure the releases of MCCP are minimised. We believe that there are established successful management practices from which to develop these risk management approaches. Based on information that has been provided from downstream users and their organisations, the Consortium believes that industrial use of MCCP in formulation and in the manufacture of articles and preparations have minimal to zero emissions. Further, the types of articles that incorporate MCCP (e.g. wire cable coatings) have very long service lives with little, if any, release to the environment.

One risk management approach that Consortium members have been discussing is the development of a general uses advised against scenario that would advise against any use of MCCP with discharge to the environment. Given that MCCP is not volatile (it decomposes at relatively low temperatures, approximately 200-220^{o} C) and is not applied directly to soil, this use advised against would be directed primarily towards preventing uses that have discharges to water. We are still collecting information as to the feasibility of implementing this risk management approach, but if feasible it could potentially be implemented on an expedited basis. The Consortium would welcome the opportunity to discuss this approach with ECHA in 2021.

Options such as separating MCCP into different substances or limiting the chlorination level of commercial products have also been raised by various parties. The Consortium has not formally considered any of these options yet. Fundamentally, controlling the release of MCCP is the best approach to risk management and the Consortium believes that ongoing use of any current form MCCP should be permitted if this can be demonstrated.

5. Benefits of MCCP and Evaluation of Substitutes

MCCPs are chosen for their current applications because of effectiveness and efficiency. In many cases MCCP helps finished products meet specific national safety performance requirements, such as in the case of flame retardancy and electrical insulation for PVC coatings on wire cables or in the case of flame retardancy for intumescent paints. In one study of on the use of MCCP in PVC, research by Manchester University determined that MCCP has a 44% lower carbon footprint throughout its lifecycle when compared to other PVC additives[16].

If ECHA decides to compile a list of substitutes for MCCP, the Consortium encourages ECHA to thoroughly evaluate the cost, effectiveness, practicality, and environmental assessment of any listed substitute. If a substitute is not as well test or thoroughly evaluated as MCCP, the Consortium questions the appropriateness of such substitutes being promoted in official documents. Prior efforts to list possible substitutes rarely conduct a comprehensive evaluation of the full impact of the substitutes nor how robustly they have been tested and evaluated for similar concerns under REACH Article 57.

A major concern of the Consortium is that elimination of MCCP from ongoing production and use in the EU will likely have the effect of eliminating EU based manufacturing and encourage the importation of foreign articles and preparations that contain chlorinated paraffins (CPs). The EU represents a small minority[17] of the global production and use of chlorinated paraffins and much of the chlorinated paraffins produced in Asia do not meet the specific definitions of SCCP, MCCP or LCCP in Europe. Even if MCCP is added to the SVHC list, it is unclear if imported articles/preparations that contain CPs would consider that they meet the definition of MCCP. This is not unlike the ongoing situation with SCCP where the POPs "listed" definition of SCCP is different than the EU definition of SCCP and articles contain broad-range CPs are routinely shipped into the EU and flagged for having SCCP content. This situation is likely to continue and potentially grow with the elimination of the EU MCCP industry.

6. Conclusions

The Consortium would like to thank ECHA for conducting this current Call for Comments and Evidence (CfE) on MCCP. The Consortium believes that ECHA will receive significant new information during this CfE that will impact the assessment of MCCP, the potential listing of MCCP on the SVHC candidate list, and ultimately the regulation of MCCP under REACH. The Consortium encourages ECHA to carefully review the information submitted, seek clarifications as needed, and not be bound by an arbitrary deadline for producing the Annex XV dossier as mentioned in the CfE notice.

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[16] See INOVYN submission to ECHA 15 December 2020.

[17] Based on production and use of 50-100 Ktonnes/yr (including MCCP and LCCP), the EU is less than 10% of the total global market for CPs. Total CP production in China and India has been reported to be over 1000 Ktonnes/year. Direct comparison on MCCP is difficult since much of the CPs produced in China and India do not meet the specific standards for MCCP or LCCP.

The Consortium recognises that the SEv of MCCP under REACH is a complex and significant undertaking. As such, we believe it is important to take an objective and balanced view of the data relevant for a possible SVHC listing of MCCP. The Consortium has attempted to do this with multiple weight of evidence (WoE) evaluations of the bioaccumulation (B) endpoint, including the new BAT tool assessment that was just prepared. The Consortium believes that these WoE assessments all support the conclusion that MCCP is not a B/vB substance in the environment. Likewise, while the Consortium recognises that the current data set indicates that not all forms of MCCP are readily or inherently biodegradable, we believe that those data that do show ready or inherent biodegradation should be fully considered prior to an SVHC listing. The Consortium is continuing to research the biodegradability of MCCP in appropriate test systems using new forms of tritiated test materials. Given that the ongoing use of MCCP is well controlled and monitoring data in the EU from the environment, fish and human milk do not indicate a significant risk, the Consortium believes that it would be appropriate for ECHA to allow this research to continue prior to making a formal decision on the SVHC listing of MCCP.

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Annex A: Environmental exposure assessment of MCCP (from June 2019 Joint CSR)

This exposure assessment considers release of MCCP based on relevant use scenarios. A summary of the uses and relevant exposure scenario is presented in Table 9.3 This section provides general information relevant for all of the environmental exposure scenarios. The exposure scenarios are presented in Sections 9.16 through 9.32. A discussion of measured data is provided in Section 9.33 and a generic scaling equation for extension of the exposure scenarios is provided in Section 9.34. In general, the result of the exposure assessment indicates that for industrial and professional uses of MCCP, local wastewater releases to the standard municipal sewage treatment plant must be less than 50 kg/year based on the sediment compartment, the most sensitive environmental compartment for this substance. The scaling equation presented in Section 9.34 may be used to extend the default exposure scenarios to the conditions of local use.

Table 9.3. Overview on exposure scenarios and coverage of substance life cycle

Use/Category	Exposure Scenarios	Approximate Tonnage[a] (tonnes/annum)
Continental tonnage	--	53726
Manufacturing	ES1: Manufacture	50000
PVC Plasticisers	ES2: Formulation	34,189
Flame Retardants Rubber	ES3: Conversion	
Other plasticizer	ES4: Service Life	
Sealants & adhesives	ES5: Formulation and use ES6: Outdoor service life ES7: Indoor service life	14,447
Metal working lubricants[b]	ES9: Formulation E10: Use (emulsion)[b] E11: Use (neat oil)[b]	3766
Textile – flame retardant	ES11: Formulation and use	482
Textile – waterproofing	ES12: Outdoor service life ES13: Indoor service life	
Paints	ES14: Formulation and use ES15: Outdoor service life ES16: Indoor service life	692
Paper products	ES17: Paper manufacture and recycling	150

[a]Use tonnes based on 2012 survey of MCCP registrants. Manufacturing based on estimate of registered EU manufacturers.
[b]Use in metal working lubricants was allocated 67% to neat oils and 33% to emulsion fluids based on information provided in the RAR (EU, 2005).

An overview of the use scenarios and life cycle stages is presented in Table 9.4. The environmental exposure assessment has been conducted based on an assumed continental use of 53726 tonnes/annum. Substance-specific parameters have been derived from the RAR (EU, 2005, 2007) cited in the MCCP Annex XV restriction report (UK, 2008). Environmental exposure was assessed using EUSES version 2.1.1. As shown in Table 9.2, Environmental Release Categories (ERCs) have been used to classify each exposure scenario. However, in most cases, refined emission factors have been developed, as documented in the exposure tables provided with each scenario. When a default ERC emission factor has been used, this is noted in the individual exposure scenarios.

MCCPs are characterized by a range of chlorine contents and therefore this chemical category is represented by a range of physical and chemical properties. Therefore, representative physical and chemical properties must be selected. It is assumed that MCCP chlorine contents of 45 to 52% are typical and that the final MCCP content in products is typically 5 to 10%. MCCPs are characterized by high log Kow, low water solubility, low volatility and low rates of biodegradation. The MCCP substance-specific EUSES model input values are shown in Table 9.5.

Measured data presented in the RAR (EU, 2005) show that environmental levels of MCCPs in surface water are negligible (< 0.1 µg/L), but that detections in sediment are possible (subject to complications relating to interferences from other chlorinated paraffins and chlorinated compounds). Soil data generally indicates that the half-life in biologically active soil may be on the order of 2 years, however (consistent with the EU RAR) as a worst-case assumption MCCPs have been considered non-biodegradable in this part of the assessment. In the RAR (EU, 2005), measured data was used to replace model predicted surface water concentration. However, the predicted regional surface water concentration for the covered scenarios resulted in a predicted regional surface water concentration of 0.04 µg/L, which is consistent with the recent data as well the physical properties of MCCPs. Accordingly, no adjustment was made to the model predicted regional surface water concentration.

In this environmental assessment, waste life was not quantitaively assessed separately because the tonnages from each use already include potential for lose to the environment via use and service life. Further, waste operations are assumed to be in compliance with legal requirements including the Landfill Directive, Waste Incineration Directive and Waste Oils Directive. When appropriate practices are followed, including the Waste Treatment Industries BREF (EU, 2006b), environmental releases of MCCPs are expected to be negligible in line with the legal requirements for the operation of these waste treatment facilities.

Table 9.4 Overview on exposure scenarios and coverage of substance life cycle

ES number	Volume (tonnes)	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Identified uses: Service life (for Resulting life cycle	Product and use	Note	Base ERC(s)	Trade Association for ERC
Continental Use	53726									
ES1	50000	X					MCCPs	Manufacture	ERC 1	N/A
ES2	34189		X				PVC and Rubber (plasticiser)	Formulation	ERC 3	PEST
ES3	34189			X				Conversion	ERC 5	PEST
ES4	34189					X		Indoor service life	ERC 11a	PEST
ES5	14447		X	X	X		Sealant & Adhesives (plasticizer / flame retardant)	Formulation and use	ERC 2, ERC 5, ERC 8f and ERC 8c	FEICA
ES6	7223.5					X		Outdoor service life	ERC 10a	--
ES7	7223.5					X		Indoor service life	ERC 11a	--
ES8	3766		X				Metal Working Lubricants (Extreme pressure additive)	Formulation	ERC 2	ATIEL
ES9	1243			X				Emulsion use	ERC 4 and ERC 8a	ATIEL / CONCAWE
ES10	2523			X				Neat oil use	ERC 4 and ERC 8a	ATIEL / CONCAWE

ES number	Volume (tonnes)	Manufacture	Identified uses: Formulation	Identified uses: End use	Identified uses: Consumer use	Identified uses: Service life (for Resulting life cycle	Product and use	Note	Base ERC(s)	Trade Association for ERC
ES11	482		X	X			Textile (Flame retardant / water proofing)	Formulation and use	ERC 2 and ERC 5	TEGEWA
ES12	241					X		Outdoor use	ERC 10a	TEGEWA
ES13	241					X		Indoor use	ERC 11a	TEGEWA
ES14	692		X	X	X		Paint (plasticiser)	Formulation and use	ERC 2, ERC 5, ERC 8f, and ERC 8c	CEPE
ES15	346					X		Outdoor service life	ERC 10a	--
ES16	346					X		Indoor service life	ERC 11a	--
ES17	150			X		X	Paper (solvent)	Manufacture of paper and recycled paper	ERC 5	Euro Chlor (cited in RAR)

Table 9.5. Substance specific input parameters for ECETOC/EUSES model

Parameter	MCCP Value	MCCP Notes
CAS Number	85535-85-9	RAR (EU, 2005)
Physical State	Liquid	RAR (EU, 2005)
Chlorine Content	52%	RAR (EU, 2005) considered 45% and 52% in model. A content of 52% has been selected as most representative of the expected range of 40% to 63%.
Molecular Weight	488 g/mol	RAR (EU, 2005)
Vapour Pressure at 20 °C	0.00027 Pa	RAR (EU, 2005)
Melting Point (pour point)	0 °C	RAR (EU, 2005); Liquid at ambient temperatures. Maximum pour point of 25°C corresponds to very high chlorine content of > 60%.
Boiling Point	200 °C	RAR (EU, 2005); Decomposition at 200 °C
Water Solubility at 20 °C	0.027 mg/L	RAR (EU, 2005)
Partition coefficient – log K_{ow}	7	RAR (EU, 2005)
Half-life for degradation in air	HL = 48 hours k_{OH} = 8E-12 cm^3 $molecule^{-1}$ s^{-1}	RAR (EU, 2005)
Bioconcentration factor for fish (BCF_{fish})	1087 L/kg ww 1.087 m^3/kg ww	RAR (EU, 2005)
Bioconcentration factor for earthworm ($BCF_{earthworm}$)[a]	5.6 unitless [$K_{earthworm,porewater}$ = 58.194 m^3/kg ww = 58,194 L/kg ww]	RAR (EU, 2005; Draft RAR Environmental Addendum (EU, 2007)
Bioconcentration factor for plant (BCF_{plant})[b]	0.034	RAR (EU, 2005)
Bioaccumulation/biomagnification factor for fish/predator (BMF)	3[c]	RAR (EU, 2005); Plausible range is 1 to 3
Partition coefficient between plant and water, $K_{plant-water}$	330 m^3/m^3	Draft RAR Environmental Addendum (EU, 2007)
Chemical class for Koc-QSAR	Predominantly hydrophobics	RAR (EU, 2005)

Biodegradability	Although biodegradation does occurr, considered not biodegradable	RAR (EU, 2005)
Sewage treatment plant removal rate (sludge)-	97.1%	Simple Treat 4.0 based on Coelhan 2010 (modelling below)

[a]$K_{earthworm,porewater}$ = 0.17 / 1700 kg/m^3 * 17666 m^3/m^3 = 1.8 m^3/kg. See RAR (EU, 2005). The RAR presents potential BCFs of 0.17 and 5.6 with a value of 5.6 selected. The BCF of 0.17 has been selected for this assessment. It is noted that in the original assessment, it appears that the authors may have input a value of 5.6 into EUSES without correction to porewater concentration (56 m^3/kg), or alternatively, used the BCF directly to calculate earthworm concentration.
[b]EUSES indicates a transpiration-stream concentration factor (TSCF) of 0.038 by default. No adjustment was made to the default value. The TSCF is on a water basis, whereas the BCF in the EU RAR is on a soil basis.
[c]There is uncertainty regarding the expression of BMF (EU, 2007). It has been suggested that “data provide some evidence that uptake from food may increase the actual accumulation of medium-chain chlorinated paraffins over that expected purely from bioconcentration processes alone.“ The BMF at the upper end of the suggest range of 1 to 3 was used to take this uncertainty into account, but no additional adjustment was made.

Prediction of Effluent Concentrations of MCCPs based upon Effluent Data in Coelhan 2010
Influent wastewater concentrations of C_{14}-C_{16} chlorinated paraffins (CPs) from 15 wastewater treatment plants (WWTPs) in a central European country (Coelhan 2010) were used to predict their expected effluent concentrations and levels on effluent solids using Simple Treat 4.0 assuming no biodegradation. The influent values used for these predictions were based on ECNI-MS detection. The same physical properties used by the EUSES assessment were used for this analysis. Using normal default conditions, Simple Treat predicted 97.1% removal of MCCCPs in WWTPs. Below are the results of this exercise.

Table 9.6: Removal Efficiency of Wastewater Treatment Plants for MCCP

Parameter	**MCCP Concentrations (ng/L) from Coelhan (2010)**		**Predicted MCCP Concentration on Effluent Solids (mg/kg)**
	Reported in Influent	**Predicted in Effluent**	
Minimum	< 100	< 2.9	< 0.24
Maximum	4600	134	11.0
Median	700	20	1.68
Mean	1250	36	3.01

9.16. MCCP Manufacturing – environmental exposure

9.16.1. Exposure Scenario

Chlorinated paraffins are manufactured in a stirred reactor by addition of chlorine gas at a temperature of 80 to 100 °C. The degree of chlorination is determined by the contact time with the chlorine gas. Air or nitrogen is used to purge the reactor. The product is filtered and piped to batch storage tanks for filling drums, tankers or bulk storage tanks. The primary by-product is chlorine gas (EU, 2005). MCCPs are characterized by a low vapour pressure, and therefore releases to air during air manufacturing and transportation are expected to be negligible (EU, 2005). The exposure scenario is summarized in Table 9.7. Based on information from the production facilities, sewage sludge from STP's receiving waste from MCCP production sites is not applied to agricultural soil (EU, 2005). MCCP's are manufactured in a closed system with no direct release to air or water. Releases of MCCP to water should be prevented by appropriate spill containment measures.

Table 9.7. Environmental exposure scenario for MCCP manufacturing

Information type	Data field	Explanation or citation
Short Title	ES1: MCCP Manufacturing	--
Description of activities and processes	Manufacture of MCCPs within closed or contained systems consisting of a stirred reactor with the addition of chlorine gas at a temperature of 80 to 100 °C. The degree of chlorination is determined by the contact time with the chlorine gas and air or nitrogen is used to purge the reactor. The product is filtered and piped to batch storage tanks for filling drums, tankers or bulk storage tanks.	RAR (EU, 2005).
Contributing scenarios controlling environmental exposure	• Manufacture of substance (ERC 1)	Default ERC for substance manufacture.
Product characteristics	• Liquid at room temperature • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C)	RAR (EU, 2005).
Amount produced (local site)	40000 ton/year	Approximate maxmum local annual production a single site in the EU based on known manufacturers.
...Fraction of tonnage to region	0.8	Approximate total prduction based on known manufacturers. The RAR indicated one production facility per region (EU, 2005).
...Fraction of main source	1	Based on ERC 1 default. One facility per region is assumed in line with the RAR (EU, 2005).
Frequency and duration of use	300 d/y	Based on information available in EU RAR (EU, 2000).

Information type	Data field	Explanation or citation
Environment factors not influenced by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Manufacture of MCCPs within closed or contained systems consisting of a stirred reactor with the addition of chlorine gas at a temperature of 80 to 100°C.	RAR (EU, 2005).
..Fraction of applied amount lost from process/use to waste gas	0 kg/kg	Releases to air during air manufacturing and transportation are expected to be negligible (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	3×10^{-8} kg/kg	Annual mandatory regualtory reporting from main integrated facility in the UK documents an emission rate to water of < 1kg/year. Therefore, the worst case emission rate to water is (1 kg/year) / (40 000 000 kg/year) = 3×10^{-8}. The worst case emission rate from facilities with lower production capacity is presented separately below.
...Absolute amount of waste released per year	1 kg/year (wastewater)	Annual mandatory regualtory reporting from main integrated facility in the UK documents an emission rate to water of < 1kg/year. The worst case emission rate from facilities with lower production capacity is presented separately below.
Technical conditions and measures at process level to prevent release	Manufacture of MCCPs in accordance with the Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals (August, 2006).	Organic Fine Chemical BREF (EU, 2006a).
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.

Information type	Data field	Explanation or citation
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1 (directed to sludge). Sewage sludge from STP's receiving waste from MCCP production sites shall not be applied to soil. Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010

9.16.2. Exposure Estimate

Substance-specific parameters have been derived from the Risk Assessment Reports (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.7. The PECs are presented in Table 9.8.

Table 9.8. Environmental PECs for MCCP manufacturing

Compartment	PEC_{local}[a]
Sediment (fresh water) (mg/kg wet wt)	0.528
Sediment (marine water) (mg/kg wet wt)	0.0696
Surface water (fresh) (mg/L)	0.0000412
Surface water (marine) (mg/L)	0.00000543
Agricultural soil (mg/kg wet wt)	0.156
Concentration in fish for secondary poisoning (mg/kg ww)	0.129
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.61
STP micro-organisms (mg/L)	0.000058

[a]PEC_{local} includes the contribution from all regional sources.

An alternate manufacturing scenario was considered to account for the emissions from facilities with less production capacity than the main (highest production) facility. The RAR (EU, 2005) summarizes emission information for four of the five sites considered in the report. The highest emission rate was 65 kg/year and the minimum contemporaneous production rate was 10000 tonnes/annum. The basis for this emission rate is not clear and it likely overstates the emission rates from modern manufacturing facilities operating in the EU. However, a worst case emission rate to water of (65 kg/year) / (10 000 000 kg/year) = 7E-6 has been used for this scenario. The main facility considered in the previous calculation accounted for 40000 of the 50000 tons/year of manufacturing capacity. It was assumed that the production rate at the facility with the second highest production rate was one-half of the remaining tonnage not accounted for by the main facility, or 5000 tons/year. Thus, the emission rate to water for an emission factor to water of 7E-6 is 35 kg/year. This value is somewhat less than the value presented in the 2005 RAR because production rates have decreased. Nevertheless, it is conservative because it does not account for any reduction in emissions required as part of regulatory reporting and compliance. The environmnetal PECs for a manufacturing facility with a production rate of 5000 tons/year and emission factor to water of 7E-6 is shown in Table 9.9 below.

Table 9.9. Environmental PECs for MCCP manufacturing

Compartment	PEC_{local}[a]
Sediment (fresh water) (mg/kg wet wt)	1.64
Sediment (marine water) (mg/kg wet wt)	0.181
Surface water (fresh) (mg/L)	0.000128
Surface water (marine) (mg/L)	0.0000141

Agricultural soil (mg/kg wet wt)	2.17
Concentration in fish for secondary poisoning (mg/kg ww)	0.245
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	7.77
STP micro-organisms (mg/L)	0.00169

[a]PEC_{local} includes the contribution from all regional sources.

9.17. PVC and Rubber Formulation – environmental exposure

9.17.1. Exposure Scenario

MCCP's are used as secondary plasticizers (with flame retardant properties) in PVC typically at a content of 10-15 parts per hundred resin (phr). The nominal MCCP Cl content is approximately 52% wt. Cl. For this Cl content, MCCPs are estimated to be a factor of 1.4 times more volatile than DEHP (EU, 2005). However, the EU RAR indicated that the default ESD rates likely "overestimate the actual emission rates from plastic processing in general, particularly at well controlled sites" (EU, 2005). Therefore, the DEHP (medium volatility) emission factors were used with no adjustment. The emission factors are derived from the OECD Emission Scenario Document (ESD) for Plastic Additives.

The ESD and RAR (EU, 2005) indicate that there are two PVC compounding methods: dry blending and plastisol blending. Emissions from plastisol blending at ambient temperature are negligible and plastisol blending accounts for about 30 to 35% of the total. Emissions from dry blending were considered as a worst case. The DEHP ESD emission factor for dry blending is 0.01%. When allocated evenly between air and water, the emission factor is 0.005% to each of air and wastewater. Best practice with respect to treatment of air to remove fumes, exhaust recovery and incineration is assumed.

The ESD and EU RAR propose an emission factor of 0.01% for spills. This pathway is eliminated by appropriate risk management measures consisting of closed sinks and basins to prevent discharge to waste- and surface water (RMM Library E11.01). In principle, rubber and plastic formulation are similar processes and both uses are covered by this scenario (EU, 2005). The exposure scenario is summarized in Table 9.10.

Table 9.10. Environmental exposure scenario for PVC formulation

Information type	Data field	Explanation or citation
Short Title	ES2: PVC Formulation	--
Description of activities and processes	Use of MCCP's as secondary plasticizers (with flame retardant properties) in PVC typically at a content of 10-15 parts per hundred resin with a typical MCCP Cl content of 52% wt. Cl. Compounding of MCCPs by Banbury or dry blending at 100 to 140 °C or plastisol blending at ambient temperature.	RAR (EU, 2005); OECD ESD (2004a).
Contributing scenarios controlling environmental exposure	• Manufacture of substance (ERC 3)	Default ERC for formulation in materials.

Information type	Data field	Explanation or citation
Product characteristics	• Formulated into a matrix; dry process • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • MCCP similar in volatility to DEHP at process temperature	RAR (EU, 2005).
Amount used (local site)	110 ton/year	The RAR indicated a RCR for PVC compounding+conversion greater than 4 for with partially open systems and use of 599 tonnes/annum (EU, 2005). Therefore a reduced maximum usage for safe use is required. The TGD A/B-Table fraction of main source of 0.05 based on assumed MCCP content in PVC of 10% is assumed. This equates to approximately 2160 tonnes/annum x 0.05 = 110 tonnes/annum at the local site. Local uses greater than 110 tonnes/annum are to be addressed by scaling.
...Fraction of tonnage to region	0.10	PVC formulation facilities are widely distributed. A default fraction to the region of 10% is assumed (OECD, 2004a).
...Fraction of main source	0.0322	A usage of 110 ton/year corresponds to a fraction of the main source of (110 tonnes/annum) / (34189 tonnes/annum x 0.1) = 0.0322.
Frequency and duration of use	300 d/y	Based on information available in RAR (EU, 2005).
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Compounding of MCCPs by Banbury or dry blending at 100 to 140 °C or plastisol blending at ambient temperature.	RAR (EU, 2005).

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	5×10^{-5}	The typical MCCP Cl content is assumed to be 52% wt. Cl. For this weight content, MCCPs are estimated to be a factor of 1.4 times more volatile than DEHP (EU, 2005). However, the EU RAR indicated that the default ESD rates "may overestimate the actual emission rates from plastic processing in general, particularly at well controlled sites". Monitoring data also shows that emissions are lower than those assumed in the EU RAR (EU, 2008). Therefore, the DEHP (medium volatility) emission factors were used with no adjustment. The emission factors are derived from the OECD ESD for Plastic Additives. Emission factors are defined for raw handling, compounding and conversion. These factors assume that air is treated to remove fume. For compounding and conversion, the release is initially to air with 50% assumed to condense and ultimately released to wastewater. The ESD and RAR (EU, 2005) indicate that there are two PVC compounding methods: dry blending and plastisol blending. Emissions from plastisol blending at ambient temperature are negligible and plastisol blending accounts for about 30 to 35% of the total. Emissions from dry blending will be considered as a worst case. The DEHP ESD emission factor for dry blending is 0.01%. When split 50:50 between air and water, the emission factor is 0.005% to air and wastewater.
...Fraction of applied amount lost from process/use to wastewater	5×10^{-5}	
...Absolute amount of waste released per year	5.5 kg/year (wastewater) 5.5 kg/year (air)	Release estimate based on well-controlled emissions and best practice with respect to treatment of air to remove fumes, exhaust recovery and incineration.
Technical conditions and measures at process level to prevent release	Exhaust recovery and treatment by thermal or catalytic oxidation.	CEFIC RMM Library W17.01. CEFIC RMM Library E12.12 or E12.13.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).

Information type	Data field	Explanation or citation
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010.
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.17.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.10. The PECs are presented in Table 9.11.

Table 9.11. Environmental PECs for PVC formulation

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.76
Sediment (marine water) (mg/kg wet wt)	0.0927
Surface water (fresh) (mg/L)	0.0000593
Surface water (marine) (mg/L)	0.00000724
Agricultural soil (mg/kg wet wt)	0.595
Concentration in fish for secondary poisoning (mg/kg ww)	0.153
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	3.73
STP micro-organisms (mg/L)	0.000399

[a]PEC_{local} includes the contribution from all regional sources.

9.18. PVC and Rubber Processing – environmental exposure

9.18.1. Exposure Scenario

MCCP's are used as secondary plasticizers (with flame retardant properties) in PVC typically at a content of 10-15 parts per hundred resin (phr). The nominal MCCP Cl content is approximately 52% wt. Cl. For this weight content, MCCPs are estimated to be a factor of 1.4 times more volatile than DEHP (EU, 2005). However, the EU RAR indicated that the default ESD rates likely "overestimate the actual emission rates from plastic processing in general, particularly at well controlled sites". Therefore, the DEHP (medium volatility) emission factors were used with no adjustment. The emission factors are derived from the OECD ESD for Plastic Additives. Best practice with respect to treatment of air to remove fumes, exhaust recovery and incineration is assumed.

For conversion, the release is initially to air with 50% assumed to condense and ultimately released to wastewater. When information on the specific process is not available emission factors to air and water of 0.005% (closed), 0.015% (partially open) and 0.025% (open) are proposed in the ESD for DEHP. The ESD indicates a distribution of approximately 72% closed, 7% partially open and 21% closed. Data from industry representing a variety of air treatment methods showed low or non-measurable emissions. The rate of emission for a site using 820 tonnes/annum was 6.4 kg/year equating to an emission factor of 8E-6. Therefore, the emission factor for closed systems (5E-5) is assumed representative and reasonably conservative of all uses. The ESD and EU RAR propose an emission factor of 0.01% for spills. This pathway is eliminated by appropriate risk management measures consisting of closed sinks and basins to prevent discharge to waste- and surface water (RMM Library E11.01). In principle, rubber and plastic processing are similar processes and both are covered by this scenario (EU, 2005). The exposure scenario is summarized in Table 9.12.

Table 9.12. Environmental exposure scenario for PVC and rubber processing

Information type	Data field	Explanation or citation
Short Title	ES3: PVC Processing	--
Description of activities and processes	Use of MCCP's as secondary plasticizers (with flame retardant properties) in PVC typically at a rate of 10-15 parts per hundred resin with a typical MCCP Cl content of 52% wt. Cl. Conversion of PVC in open, partially open, or closed systems.	RAR (EU, 2005); OECD ESD (2004a).
Contributing scenarios controlling environmental exposure	• Manufacture of substance (ERC 5)	Default ERC for industrial inclusion into a matrix.
Product characteristics	• Formulated into a matrix; dry process • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • MCCP similar in volatility to DEHP at process temperature	RAR (EU, 2005)
Amount used (local site)	110 ton/year	The RAR indicated a RCR for PVC formulation greater than 4 for compounding+conversion with partially open systems and use of 599 tonnes/annum (EU, 2005). Therefore a reduced maximum usage for safe use is required. The TGD A/B-Table fraction of main source of 0.05 based on assumed MCCP content in PVC of 10% is assumed. This equates to approximately 34189 tonnes/annum x 0.1 regional fraction x 0.05 = 171 tonnes/annum at the local site. Local uses greater than 171 tonnes/annum may be addressed by scaling.
...Fraction of tonnage to region	0.10	PVC formulation facilities are widely distributed. A default fraction to the region of 10% is assumed (OECD, 2004a).

Information type	Data field	Explanation or citation
...Fraction of main source	0.05	The TGD A/B-Table fraction of main source of 0.05 is based on assumed MCCP content in PVC of 10%.
Frequency and duration of use	300 d/y	Based on information available in RAR (EU, 2005)
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Conversion of PVC in open, partially open, or closed systems at elevated temperature.	RAR (EU, 2005)

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	5×10^{-5}	The typical MCCP Cl content is assumed to be 52% wt. Cl. For this weight content, MCCPs are estimated to be a factor of 1.4 times more volatile than DEHP (EU, 2005). However, the EU RAR indicated that the default ESD rates "may overestimate the actual emission rates from plastic processing in general, particularly at well controlled sites". Monitoring data also shows that emissions are lower than those assumed in the EU RAR (EU, 2008). Therefore, the DEHP (medium volatility) emission factors were used with no adjustment. The emission factors are derived from the OECD ESD for Plastic Additives. Emission factors are defined for raw handling, compounding and conversion. These factors assume that air is treated to remove fume. For compounding and conversion, the release is initially to air with 50% assumed to condense and ultimately released to wastewater. When information on the specific process is not available emission factors to air and water of 0.005% (closed), 0.015% (partially open) and 0.025% (open) are proposed in the ESD for DEHP. The ESD indicates a distribution of approximately 72% closed, 7% partially open and 21% closed. Data from industry representing a variety of air treatment methods showed low or non-measurable emissions (p. 33). The rate of emission for a site using 820 tonnes/annum was 6.4 kg/year equating to an emission factor of 8E-6. Therefore, the emission factor for closed systems (5E-5) is assumed representative and reasonably conservative of all uses.
...Fraction of applied amount lost from process/use to wastewater	5×10^{-5}	
...Absolute amount of waste released per year	8.5 kg/year (wastewater) 8.5 kg/year (air)	Release estimate based on well-controlled emissions and best practice with respect to treatment of air to remove fumes, exhaust recovery and incineration.
Technical conditions and measures at process level to prevent release	Exhaust recovery and treatment by thermal or catalytic oxidation.	CEFIC RMM Library W17.01. CEFIC RMM Library E12.12 or E12.13.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).

Information type	Data field	Explanation or citation
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.18.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.12. The PECs are presented in Table 9.13.

Table 9.10. Environmental PECs for PVC and rubber processing

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.77
Sediment (marine water) (mg/kg wet wt)	0.0937
Surface water (fresh) (mg/L)	0.0000601
Surface water (marine) (mg/L)	0.00000731
Agricultural soil (mg/kg wet wt)	0.595
Concentration in fish for secondary poisoning (mg/kg ww)	0.154
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	3.73
STP micro-organisms (mg/L)	0.000413

[a]PEC_{local} includes the contribution from all regional sources.

9.19. PVC and Rubber Service Life – environmental exposure

9.19.1. Exposure Scenario

MCCP's are used as secondary plasticizers (with flame retardant properties) in PVC typically at a content of 10-15 parts per hundred resin (phr). The nominal MCCP Cl content is approximately 52% wt. Cl. This scenario covers the service life of PVC products. The major use of MCCPs in PVC is flooring and some cushioned PVC products may have coatings that would reduce potential emission during the service life (EU, 2005). Therefore, a default emission factor for indoor uses is assumed to be appropriate. In principle, rubber and plastic service life emissions are similar and both are covered by this scenario (EU, 2005). The exposure scenario is summarized in Table 9.14.

Table 9.14. Environmental exposure scenario for PVC and rubber service life

Information type	Data field	Explanation or citation
Short Title	ES4: PVC Service Life (Indoor)	--
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, indoor (ERC 11a)	Default ERC for wide dispersive use of long life articles, low release, indoor
Product characteristics	• MCCP's incorporated into PVC matrix • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005)
Amount used (local use)	6.8 ton/year	Based on ERC 11a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 11a default.
...Fraction of main source	0.002	Based on ERC 11a default.
Frequency and duration of use	365 d/y	Based on ERC 11a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Indoor use	The major use of MCCPs in PVC is flooring and some cushioned PVC products may have coatings that would reduce potential emission during the service life (EU, 2005)

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	5.00E-04	Based on ERC 11a Default; see also RAR (EU, 2005)
...Fraction of applied amount lost from process/use to wastewater	5.00E-04	
...Absolute amount of waste released to per year (local)	3.4 kg/year (wastewater) 3.4 kg/year (air)	Release estimate based on ERC 11a default.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.19.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.14. The PECs are presented in Table 9.15.

Table 9.15. Environmental PECs for PVC and rubber service life

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.581
Sediment (marine water) (mg/kg wet wt)	0.384
Surface water (fresh) (mg/L)	0.0000454
Surface water (marine) (mg/L)	0.00003
Agricultural soil (mg/kg wet wt)	0.252
Concentration in fish for secondary poisoning (mg/kg ww)	0.136
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.85
STP micro-organisms (mg/L)	0.000136

[a]PEC_{local} includes the contribution from all regional sources.

9.20. Sealant/adhesive Formulation – environmental exposure

9.20.1. Exposure Scenario

MCCP's are used as plasticizers (with flame retardant properties) in adhesives and sealants typically at a concentration of 10-14%. The typical MCCP Cl content is 50-58% wt. Cl. Sealants and adhesives are formulated by mixing additives with a liquid viscous polymer (EU, 2005). The adhesives and sealants are moisture sensitive and manufactured in a manner to prevent contact with and release to water (EU, 2005). The process is conducted at approximately 40 °C and typically under vacuum. In line with the RAR for MCCPs, environmental release during both formulation and use of adhesives and sealants is negligible (EU, 2005). Solid waste is generated during cleaning between batches in formulation or during use must be disposed of properly in a permitted solid waste landfill. The exposure scenario is summarized in Table 9.16.

Table 9.16. Environmental exposure scenario for sealant/adhesive formulation and use

Information type	Data field	Explanation or citation
Short Title	ES5: Sealant/adhesive formulation	--
Description of activities and processes	Use of MCCP's as secondary plasticizers (with flame retardant properties) in adhesives and sealants typically at a content of 10 to 15% and The typical MCCP Cl content is 50-58% wt. Cl. The formulation process is conducted at approximately 40 °C and typically under vacuum.	RAR (EU, 2005)
Contributing scenarios controlling environmental exposure	• Formulation of mixtures (ERC 2) • Industrial inclusion onto a matrix (ERC 5) • Wide dispersive use, resulting in inclusion onto a matrix, outdoor (ERC 8f) • Wide dispersive use, resulting in inclusion onto a matrix, indoor (ERC 8c)	Default ERC for formulation and use of mixtures included onto a matrix.
Product characteristics	• Formulated into viscous liquid polymer matrix • Cures during use • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C)	RAR (EU, 2005)
Amount used (local site)	1445 tonnes/annum (ERC 2 or 5) 2.89 tonnes/annum (ERC 8f or 8c)	Based on ERC default methods with use widely dispersed and total use of 14447 tonnes/annum.
...Fraction of tonnage to region	0.1	Use distributed throughout Europe.
...Fraction of main source	1 (ERC 2 or 5) 0.002 (ERC 8f or 8c)	Based on ERC default methods.
Frequency and duration of use	300 d/y	Based on ERC default methods.

Information type	Data field	Explanation or citation
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Sealants and adhesives are formulated by mixing additives with a liquid viscous polymer. The process is conducted at approximately 40 °C and typically under vacuum. Solid waste is generated during cleaning between batches. Sealants and adhesives are applied at ambient temperature.	RAR (EU, 2005)
..Fraction of applied amount lost from process/use to waste gas	0	The release to water and air for this use is negligible as a result of the modest temperature (40°C) of the process and process conditions which prevent the possibility of contact with water (EU, 2005). Release during use is negligible as a result of curing of the matrix and low volatility of MCCP.
...Fraction of applied amount lost from process/use to wastewater	0	
...Absolute amount of waste released per year	0 kg/year (wastewater) 0 kg/year (air)	Release estimate based on no direct disposal of cleaning or solid wastes to water.
Technical conditions and measures at process level to prevent release	• Collection of disposal of solid waste generated during cleaning in a permitted landfill.	CEFIC RMM Library E14.03
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	None	None
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01

Information type	Data field	Explanation or citation
Conditions and measures related to municipal sewage treatment plant	None	None
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.20.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.16. The PECs are presented in Table 9.17.

Table 9.17. Environmental PECs for sealant/adhesive formulation

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.489
Sediment (marine water) (mg/kg wet wt)	0.0656
Surface water (fresh) (mg/L)	0.0000382
Surface water (marine) (mg/L)	0.00000512
Agricultural soil (mg/kg wet wt)	0.0842
Concentration in fish for secondary poisoning (mg/kg ww)	0.124
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.42
STP micro-organisms (mg/L)	6.98E-09

[a]PEC_{local} includes the contribution from all regional sources.

9.21. Adhesive/Sealant Service Life – Outdoor – environmental exposure

9.21.1. Exposure Scenario

MCCP's are used as plasticizers (with flame retardant properties) in adhesives and sealants typically at a concentration of 10-14%. In line with the RAR for MCCPs, environmental release during both formulation and use of adhesives and sealants is negligible (EU, 2005). However, the possibility of leaching and volatilization during the service life exists. This scenario covers the outdoor service life of adhesives and sealants. Uses of adhesives and sealants are assumed to be evenly divided between indoor and outdoor uses with a nominal lifetime of emissions of approximately 10 years. The exposure scenario is summarized in Table 9.18.

Table 9.18: Environmental exposure scenario for adhesive/sealant service life - outdoor

Information type	Data field	Explanation or citation
Short Title	ES6: Adhesive/Sealant Service Life (Outdoor)	--

Information type	Data field	Explanation or citation
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, outdoor (ERC 10a)	Default ERC for wide dispersive use of long life articles, low release, outdoor.
Product characteristics	• MCCP's incorporated into adhesive/sealant matrix • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005)
Amount used (local use)	1.4 ton/year	Based on ERC 10a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 10a default.
...Fraction of main source	0.002	Based on ERC 10a default.
Frequency and duration of use	365 d/y	Based on ERC 10a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Outdoor use	The RAR (EU, 2005) assumed that all adhesives were used in an outdoor setting. In principle, adhesives and sealants are used in both indoor and outdoor environments with an appreciable fraction having no contact with water.

Information type	Data field	Explanation or citation
Fraction of applied amount lost from process/use to waste gas	0.0005	Based on ERC 10a Default; see also RAR (EU, 2005)
...Fraction of applied amount lost from process/use to wastewater	0.008	The OECD Plastic Additive ESD (2004a) indicates an outdoor leaching rate of 0.16% to the environment per year for plasticizers. Assuming a nominal 10 year service life, the total service life emission rate is 0.16% x 10 years = 1.6%. This release to the environment was evenly divided between water and soil.
...Fraction of applied amount lost from process/use to soil	0.008	
...Absolute amount of waste released per year (local)	11.6 kg/year (wastewater) 11.6 kg/year (soil) 0.72 kg/year (air)	Release estimate based on ERC 10a default (air) and OECD ESD (water and soil).
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.21.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.18. The PECs are presented in Table 9.19.

Table 9.19. Environmental PECs for adhesive/sealant service life – outdoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.801
Sediment (marine water) (mg/kg wet wt)	0.0968
Surface water (fresh) (mg/L)	0.0000625
Surface water (marine) (mg/L)	0.00000756
Agricultural soil (mg/kg wet wt)	0.65
Concentration in fish for secondary poisoning (mg/kg ww)	0.164
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	3.87

STP micro-organisms (mg/L)	0.000459

[a]PEC_{local} includes the contribution from all regional sources.

9.22. Adhesive/Sealant Service Life – Indoor – environmental exposure

9.22.1. Exposure Scenario

MCCP's are used as plasticizers (with flame retardant properties) in adhesives and sealants typically at a concentration of 10-14%. In line with the RAR for MCCPs, environmental release during both formulation and use of adhesives and sealants is negligible (EU, 2005). However, the possibility of leaching and volatilization during the service life exists. This scenario covers the indoor service life of adhesives and sealants. Uses of adhesives and sealants are assumed to be evenly divided between indoor and outdoor uses with a nominal lifetime of emissions of approximately 10 years. The exposure scenario is summarized in Table 9.20.

Table 9.20. Environmental exposure scenario for adhesive/sealant service life - indoor

Information type	Data field	Explanation or citation
Short Title	ES7: Adhesive/Sealant Service Life (Indoor)	--
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, indoor (ERC 11a)	Default ERC for wide dispersive use of long life articles, low release, indoor.
Product characteristics	• MCCP's incorporated into adhesive/sealant matrix • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005)
Amount used (local use)	1.4 ton/year	Based on ERC 11a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 11a default.
...Fraction of main source	0.002	Based on ERC 11a default.
Frequency and duration of use	365 d/y	Based on ERC 11a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Indoor use	The RAR (EU, 2005) assumed that all adhesives were used in an outdoor setting. In principle, adhesives and sealants are used in both indoor and outdoor environments with an appreciable fraction having no contact with water.

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	0.0005	Based on ERC 11a Default; see also RAR (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.0005	
...Absolute amount of waste released to wastewater per year (local)	0.72 kg/year (wastewater) 0.72 kg/year (air)	Release estimate based on ERC 11a default (air) and OECD ESD (water and soil).
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.22.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.20. The PECs are presented in Table 9.21.

Table 9.21. Environmental PECs for adhesive/sealant service life – indoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.509
Sediment (marine water) (mg/kg wet wt)	0.0676
Surface water (fresh) (mg/L)	0.0000397
Surface water (marine) (mg/L)	0.00000527
Agricultural soil (mg/kg wet wt)	0.12
Concentration in fish for secondary poisoning (mg/kg ww)	0.127
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.51
STP micro-organisms (mg/L)	0.0000287

[a]PEC_{local} includes the contribution from all regional sources.

9.23. Metal Working Fluid Formulation – environmental exposure

9.23.1. Exposure Scenario

MCCP's are formulated in oil- and water-based (emulsion) metal working fluids (MWF) as an extreme pressure additive with chlorine content of 40 to 55% (EU, 2005). The typical paraffin content in neat oils is 5-10% although some formulations can contain higher amounts. In emulsions, a formulation of 5% paraffin is prepared and diluted at the use site to a concentration of approximately 0.25% (EU, 2005). MWF formulation is completed as a batch process typically at ambient temperatures with a maximum of 60°C. Formulation plants are assumed to be well controlled with oil capture and recovery systems resulting in an effluent concentration of 5 mg/L or less dissolved oil (EU, 2005). Releases from incidental spills are assumed to be eliminated by appropriate risk management measures consisting of closed sinks and basins to prevent discharge to waste- and surface water (RMM Library E11.01). The exposure scenario is summarized in Table 9.22.

Table 9.22. Environmental exposure scenario for metal working fluid formulation

Information type	Data field	Explanation or citation
Short Title	ES8: Metal Working Fluid Formulation	--
Description of activities and processes	MWF formulation is completed as a batch process typically at ambient temperatures with a maximum of 60 °C. The typical paraffin content in neat oils is 5-10%. In emulsions, a formulation of 5% paraffin is prepared and diluted at the use site to a concentration of approximately 0.25% (EU, 2005).	RAR (EU, 2005); OECD ESD (2004b).
Contributing scenarios controlling environmental exposure	• Formulation in mixtures (ERC 2)	Default ERC for formulation in mixtures.
Product characteristics	• Liquids at room temperature • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C)	RAR (EU, 2005)
Amount used (local site)	101 ton/year	The RAR (EU, 2005) indicates that the local MCCP use at a large blending plant is approximately 101 tonnes/annum, equating to a fraction of the main source of approximately 0.36 given default to region of 10% for widely dispersed use and total use of 2800 tons per year.
...Fraction of tonnage to region	0.10	Lubricant formulation facilities are widely distributed. A default fraction to the region of 10% is assumed (OECD, 2004b).

Information type	Data field	Explanation or citation
...Fraction of main source	0.268	The RAR (EU, 2005) indicates that the local MCCP use at a large blending plant is about 101 tonnes/annum, equating to a fraction of the main source of approximately 0.268 given default to region of 10% for widely dispersed use and total use of 3766 tons per year.
Frequency and duration of use	300 d/y	Based on information available in RAR (EU, 2005).
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	MWF formulation is completed as a batch process typically at ambient temperatures with a maximum of 60°C.	RAR (EU, 2005).
..Fraction of applied amount lost from process/use to waste gas	0	Release to air negligible based on low vapour pressure and operating temperatures (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	3×10^{-6}	The RAR (EU, 2005) indicates that at well controlled formulation sites with oil capture and recovery systems, the chlorinated paraffin content of the effluent is approximately 250 µg/L with a typical annual discharge of 1×10^6 L/year. This equates to an emission factor of (0.25 kg/year) / (100000 kg/year) = 3E-6.
...Absolute amount of waste released per year	0.3 kg/year (wastewater)	Release estimate based well controlled formulation sites with oil capture and recovery systems.
Technical conditions and measures at process level to prevent release	Oil capture and recovery systems with effluent concentration of 5 mg/L or less dissolved oil.	CEFIC RMM Library E13.04.

Information type	Data field	Explanation or citation
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Recovery and treatment of waste oils in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.23.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.22. The PECs are presented in Table 9.23.

Table 9.23. Environmental PECs for metal working fluid formulation

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.499
Sediment (marine water) (mg/kg wet wt)	0.0666
Surface water (fresh) (mg/L)	0.0000389
Surface water (marine) (mg/L)	0.0000052
Agricultural soil (mg/kg wet wt)	0.102

Concentration in fish for secondary poisoning (mg/kg ww)	0.126
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.47
STP micro-organisms (mg/L)	0.0000146

[a]PEC_{local} includes the contribution from all regional sources.

9.24. Metal Working Fluid Use - Emulsion – environmental exposure

9.24.1. Exposure Scenario

MCCP's are formulated in water-based (emulsion) metal working fluids (MWF) as an extreme pressure additive. In emulsions, a formulation of 5% paraffin is prepared and diluted at the use site to a concentration of approximately 0.25% (EU, 2005). During use, releases from incidental spills are assumed to be eliminated by appropriate risk management measures consisting of closed sinks and basins to prevent discharge to waste- and surface water (RMM Library E11.01). During use of emulsion MWFs, losses potentially occur as a result of misting, evaporation and dragout (swarf/workpiece). In addition, the whole system is replaced every 1 to 6 months (EU, 2005). The RAR assumed that the waste emulsion generated during system replacement was intermittently directly discharged to the environment. This scenario covers industrial and professional use of MWFs by taking into account worst case MCCP absolute release in kg/year. The exposure scenario is summarized in Table 9.24.

Table 9.24. Environmental exposure scenario for metal working fluid - emulsion

Information type	Data field	Explanation or citation
Short Title	ES9: Use of Emulsion Metal Working Fluid	--
Description of activities and processes	Use of MCCP's as extreme pressure additives in emulsion metal working fluids (MWF) diluted at the use site to a concentration of approximately 0.25% (EU, 2005).	RAR (EU, 2005)
Contributing scenarios controlling environmental exposure	• Industrial use of processing aids (ERC 4) • Wide dispersive use of processing aids (ERC 8a)	Default ERC for industrial and wide dispersive use of processing aids.
Product characteristics	• MCCPs liquids at room temperature • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • Formulation of 5% chlorinated paraffin diluted to 0.25% at the site	RAR (EU, 2005)

Information type	Data field	Explanation or citation
Amount used (local site)	0.125 ton/year	For emulsion use, the RAR (EU, 2005) indicates an annual release of approximately 6% to water or 7.5 kg/year MCCP. This corresponds to an annual use of 125 kg/year assuming 5 whole-system replacements. A usage of 125 kg/year corresponds to a fraction of the main source of (0.125 tonnes/annum) / (1243 tonnes/annum x 0.1) = 0.00101.
...Fraction of tonnage to region	0.10	Facilities using MWFs are widely distributed (OECD, 2004b). A default fraction to the region of 10% is assumed.
...Fraction of main source	0.00101	A usage of 125 kg/year corresponds to a fraction of the main source of (0.125 tonnes/annum) / (1243 tonnes/annum x 0.1) = 0.00101.
Frequency and duration of use	300 d/y	Based on information available in RAR (EU, 2005).
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Mist and evaporated vapours are enriched in water relative to the bulk solution as result of lower vapour pressure of MCCPs and releases to air are considered negligible (EU, 2005). The primary worst case sources of MCCP to water are overalls (2%), leaks (3%) work-piece dragout (1%).	RAR (EU, 2005)
..Fraction of applied amount lost from process/use to waste gas	0	Ultimate release at facility is to water due to low volatility of MCCP (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.06	The RAR (EU, 2005) indicates that the release to water from overalls, leaks and dragout at large facilities for emulsions is 6%. This emission factor assignment is based on elimination of waste oil discharge to the wastewater treatment plant (i.e. in accordance with Waste Oils Directive).

Information type	Data field	Explanation or citation
...Absolute amount of waste released per year	7.5 kg/year (wastewater)	Release estimate based on worst case release rate for well-controlled emissions and best practice with respect to recovery and treatment of waste oil.
Technical conditions and measures at process level to prevent release	• No direct release of spent MWF or residual oils to sewer • Disposal of spent MWF in accordance with the Waste Oils Directive, 75/439/EEC • Recycling/recovery and treatment of oils recovered from swarf	CEFIC RMM Library E14.02 or E14.03.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.24.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.24. The PECs are presented in Table 9.25.

Table 9.25. Environmental PECs for metal working fluid use - emulsion

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.737
Sediment (marine water) (mg/kg wet wt)	0.0904
Surface water (fresh) (mg/L)	0.0000575
Surface water (marine) (mg/L)	0.00000705
Agricultural soil (mg/kg wet wt)	0.533
Concentration in fish for secondary poisoning (mg/kg ww)	0.15
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	3.57
STP micro-organisms (mg/L)	0.000364

[a]PEC_{local} includes the contribution from all regional sources.

9.25. Metal Working Fluid Use – Neat Oil – environmental exposure

9.25.1. Exposure Scenario

MCCP's are formulated in oil-based metal working fluids (MWF) as an extreme pressure additive. The typical paraffin content in neat oils is 5-10% although some formulations can contain higher amounts. Releases from incidental spills are assumed to be eliminated by appropriate risk management measures consisting of closed sinks and basins to prevent discharge to waste- and surface water (RMM Library E11.01). Waste oils are assumed to be disposed of in accordance with the Waste Oils Directive, 75/439/EEC. This scenario covers industrial and professional use of MWFs by taking into account worst case MCCP absolute release in kg/year. The exposure scenario is summarized in Table 9.26. The PECs are presented in Table 9.27.

Table 9.26. Environmental exposure scenario for metal working fluid – neat oil

Information type	Data field	Explanation or citation
Short Title	ES10: Use of Neat Oil Metal Working Fluid	--
Description of activities and processes	Use of MCCP's as extreme pressure additives in neat oil metal working fluids (MWF) with a typical chlorinated paraffin content of 5-10% and maximum of 70%.	RAR (EU, 2005).
Contributing scenarios controlling environmental exposure	• Industrial use of processing aids (ERC 4) • Wide dispersive use of processing aids (ERC 8a)	Default ERC for industrial and wide dispersive use of processing aids.
Product characteristics	• MCCPs liquids at room temperature • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Typical chlorinated paraffin content of 5-10% and maximum of 70%.	RAR (EU, 2005).

Information type	Data field	Explanation or citation
Amount used (local site)	2.5 ton/year	The RAR (EU, 2005) indicates that the local MCCP use at a typical large-scale metal cutting/working plant is 2.5 tonnes/annum. Therefore, the fraction of the main source is approximately (2.5 tonnes/annum) / (2523 tonnes/annum x 0.1) = 0.00991.
...Fraction of tonnage to region	0.10	Facilities using MWFs are widely distributed (OECD, 2004b). A default fraction to the region of 10% is assumed.
...Fraction of main source	0.00991	A usage of 2.5 tonnes/annum corresponds to a fraction of the main source of (2.5 tonnes/annum) / 2523 tonnes/annum x 0.1) = 0.00991.
Frequency and duration of use	300 d/y	Based on information available in RAR (EU, 2005).
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	The primary worst case sources of MCCP to water are overalls (1 to 2%), leaks (1 to 3%) work-piece dragout (1%) and mist (2%). Leaks, mist and dragout losses are assumed controlled by risk management measure as described below.	RAR (EU, 2005).
..Fraction of applied amount lost from process/use to waste gas	0	Ultimate release at facility is to water due to low volatility of MCCP (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.01	The RAR (EU, 2005) indicates that the release to water from overalls at small and large facilities for neat oil is 2% and 1%, respectively. Leaks, releases from mist and dragout are assumed to be contained by risk management measures noted below. The highest absolute emissions at well controlled facilities will be at large facilities, and are conservatively considered in the quantitative exposure scenario.

Information type	Data field	Explanation or citation
...Absolute amount of waste released per year	25 kg/year (wastewater)	Release estimate based on well-controlled emissions and best practice with respect to housekeeping, elimination of discharges to sewers and recovery and treatment of waste oil.
Technical conditions and measures at process level to prevent release	• No direct release of spent MWF or residual oils to sewer • Disposal of spent MWF in accordance with the Waste Oils Directive, 75/439/EEC • Recycling/recovery and treatment of oils recovered from swarf	CEFIC RMM Library E14.02 or E14.03.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	• In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater. • In absence of control or losses from dragout, mist generation or residual oil discharge to sewer, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 50 kg/year or effluent oil concentration of 5 mg/L or less dissolved oil. • Potential MCCP wastewater emissions at well controlled facilities may be confirmed by measurement of adsorbable organic halide (AOX) as a surrogate for MCCP when there are no other appreciable sources of chlorinated substances in the effluent (EU, 2008).	• Without STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24). • With municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 50 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010

Information type	Data field	Explanation or citation
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.25.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.26. The PECs are presented in Table 9.27.

Table 9.23. Environmental PECs for metal working fluid use – neat oil

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	1.31
Sediment (marine water) (mg/kg wet wt)	0.148
Surface water (fresh) (mg/L)	0.000102
Surface water (marine) (mg/L)	0.0000115
Agricultural soil (mg/kg wet wt)	1.57
Concentration in fish for secondary poisoning (mg/kg ww)	0.21
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	6.24
STP micro-organisms (mg/L)	0.00121

[a]PEC_{local} includes the contribution from all regional sources.

9.26. Textile Flame Retardant and Waterproofing – environmental exposure

9.26.1. Exposure Scenario

MCCP additives including flame retardants are added during a coating process (OECD, 2004c). Typically, coatings such as flame retardants are fully fixed onto the textile process (OECD, 2004c) but a release to wastewater occurs in the residual liquor. The OECD ESD provides an approach to calculate the release to water for a typical textile processing facility. Textile processing is assumed to be conducted in accordance with Treatment with the Reference Document on Best Available Techniques for the Textile Industry (July 2003). The exposure scenario is summarized in Table 9.28.

Table 9.28: Environmental exposure scenario for formulation and use in textiles

Information type	Data field	Explanation or citation
Short Title	ES11: Textile flame retardant and waterproofing	--
Description of activities and processes	Addition of MCCP during the coating process (OECD, 2004c) with 100% fixation and release to wastewater as residual in the waste liquor.	OECD (2004c).
Contributing scenarios controlling environmental exposure	• Formulation of mixtures (ERC 2) • Industrial inclusion onto a matrix (ERC 5)	Default ERC for formulation and use of mixtures included onto a matrix.
Product characteristics	• Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L) • Fixed onto the matrix as a coating with MCCPs accounting for 5% of the coating	RAR (EU, 2005); OECD (2004c).
Amount used (local site)	4.8 tonnes/annum	The Textile Finishing Industry ESD Equation 3 indicates that if MCCP are assumed to be 5% of the coating with coating fraction of 0.25 (i.e. 25% of flame retardants are from the MCCP class), and fraction in the residual liquor of 0.01, the daily emission rate to water is 13 tonnes/day x 0.25 x 100 kg/t x 0.05 x 0.01 = 0.16 kg/day. This corresponds to an MCCP usage at the local site of about 4.8 tonnes/annum.
...Fraction of tonnage to region	0.1	Use distributed throughout Europe (OECD, 2004c).
...Fraction of main source	0.1	A usage of 4.8 tonnes/annum corresponds to a fraction of the main source of (4.8 tonnes/annum) / (482 tonnes/annum * 0.1) = 0.1.
Frequency and duration of use	300 d/y	Production assumed 6 days/week.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.

Information type	Data field	Explanation or citation
Other operational conditions affecting environmental exposure	Fixation of 100% of the coating to the textile is assumed.	OECD (2004c).
..Fraction of applied amount lost from process/use to waste gas	0	Due to the low volatility of MCCPs, environmental release will be to water. The Textile Finishing Industry ESD Equation 3 indicates a fraction in the residual liquor of 0.01.
...Fraction of applied amount lost from process/use to wastewater	0.01	
...Absolute amount of waste released per year	48 kg/year (wastewater)	Release estimate based on use of manufacturing practices consistent with OECD ESD (2004c).
Technical conditions and measures at process level to prevent release	Process conducted in accordance with the OECD ESD (2004c) and Reference Document on Best Available Techniques for the Textile Industry (July, 2003).	OECD (2004c); Textile Industry BREF (EU, 2003).
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.

Information type	Data field	Explanation or citation
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.26.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.28. The PECs are presented in Table 9.29.

Table 9.29. Environmental PECs formulation and use in textiles

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	2.07
Sediment (marine water) (mg/kg wet wt)	0.224
Surface water (fresh) (mg/L)	0.000162
Surface water (marine) (mg/L)	0.0000175
Agricultural soil (mg/kg wet wt)	2.96
Concentration in fish for secondary poisoning (mg/kg ww)	0.29
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	9.78
STP micro-organisms (mg/L)	0.00233

[a]PEC_{local} includes the contribution from all regional sources.

9.27. Textile Service Life – Outdoor – environmental exposure

9.27.1. Exposure Scenario

MCCP additives including flame retardants are added during a coating process (OECD, 2004c). Typically, coatings such as flame retardants are fully fixed onto the textile process, but in principle, release could occur during the service life. Uses of textiles are assumed to be evenly divided between indoor and outdoor uses. The exposure scenario is summarized in Table 9.30.

Table 9.30. Environmental exposure scenario for textile service life - outdoor

Information type	Data field	Explanation or citation
Short Title	ES12: Textile Service Life (Outdoor)	--
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, outdoor (ERC 10a)	Default ERC for wide dispersive use of long life articles, low release, outdoor
Product characteristics	• MCCP's incorporated into textile • Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005).
Amount used (local use)	0.048 ton/annum	Based on ERC 10a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 10a default.
...Fraction of main source	0.002	Based on ERC 10a default.
Frequency and duration of use	365 d/y	Based on ERC 10a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Outdoor use	In principle, textiles are used in both indoor and outdoor environments with a fraction of the indoor use having no contact with water.

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	0.032	Based on ERC 10a default.
...Fraction of applied amount lost from process/use to wastewater	0.0005	Based on ERC 10a default.
...Absolute amount of waste released per year (local)	1.5 kg/year (wastewater) 0.024 kg/year (air)	Based on ERC 10a default methods.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.27.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.30. The PECs are presented in Table 9.31.

Table 9.31. Environmental PECs for textile service life – outdoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.531
Sediment (marine water) (mg/kg wet wt)	0.0698
Surface water (fresh) (mg/L)	0.0000414
Surface water (marine) (mg/L)	0.00000545
Agricultural soil (mg/kg wet wt)	0.16
Concentration in fish for secondary poisoning (mg/kg ww)	0.13
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.62
STP micro-organisms (mg/L)	0.0000613

[a]PEC_{local} includes the contribution from all regional sources.

9.28. Textiles Service Life – Indoor – environmental exposure

9.28.1. Exposure Scenario

MCCP additives including flame retardants are added during a coating process (OECD, 2004c). Typically, coatings such as flame retardants are fully fixed onto the textile process, but in principle, release could occur during the service life. Uses of textiles are assumed to be evenly divided between indoor and outdoor uses. The exposure scenario is summarized in Table 9.32.

Table 9.32. Environmental exposure scenario for textile service life -indoor

Information type	Data field	Explanation or citation
Short Title	ES13: Textile Service Life (Indoor)	--
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, indoor (ERC 11a)	Default ERC for wide dispersive use of long life articles, low release, indoor.
Product characteristics	• MCCP's incorporated into textile • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005).
Amount used (local use)	0.048 ton/annum	Based on ERC 11a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 11a default.
...Fraction of main source	0.002	Based on ERC 11a default.
Frequency and duration of use	365 d/y	Based on ERC 11a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Indoor use	In principle, textiles are used in both indoor and outdoor environments with a fraction of the indoor use having no contact with water.

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	0.0005	Based on ERC 11a Default.
...Fraction of applied amount lost from process/use to wastewater	0.0005	
...Absolute amount of waste released to wastewater per year (local)	0.024 kg/year (wastewater) 0.024 kg/year (air)	Release estimate based on ERC 11a default methods.
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.28.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.32. The PECs are presented in Table 9.33.

Table 9.29. Environmental PECs for textile service life – indoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.49
Sediment (marine water) (mg/kg wet wt)	0.0657
Surface water (fresh) (mg/L)	0.0000382
Surface water (marine) (mg/L)	0.00000513
Agricultural soil (mg/kg wet wt)	0.0854
Concentration in fish for secondary poisoning (mg/kg ww)	0.125

Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.43
STP micro-organisms (mg/L)	0.000000957

[a]PEC_{local} includes the contribution from all regional sources.

9.29. Paint Formulation and Use – environmental exposure

9.29.1. Exposure Scenario

MCCPs are used as plasticizers in paints typically at a concentration of 5-15% and chlorine contents of 50 to 60% (EU, 2005). The typical use for MCCPs in these paints is in chlorinated rubber-based and vinyl copolymer paints particularly in weather resistant coatings for steel construction, ships, industrial flooring, road markings and swimming pools (EU, 2000). A bounding worst case estimate of release has been derived using default A-table emission factors for formulation and industrial use. However, releases to the atmosphere during formulation and use are expected to be negligible (EU, 2005). The possibility of leaching and volatilization during the service life exists. The exposure scenario is summarized in Table 9.34.

Table 9.34. Environmental exposure scenario for paint formulation and use

Information type	Data field	Explanation or citation
Short Title	ES14: Paint formulation and use	--
Description of activities and processes	Use of MCCP's as plasticizers in paints typically at a concentration of 5-15%.	RAR (EU, 2005).
Contributing scenarios controlling environmental exposure	• Formulation of mixtures (ERC 2) • Industrial inclusion onto a matrix (ERC 5) • Wide dispersive use, resulting in inclusion onto a matrix, outdoor (ERC 8f) • Wide dispersive use, resulting in inclusion onto a matrix, indoor (ERC 8c)	Default ERC for formulation and use of mixtures included onto a matrix.
Product characteristics	• Liquids at room temperature formulated into paint • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Typical concentration of 5-15%.	RAR (EU, 2005).
Amount used (local site)	3 tonnes/annum	According to the RAR (EU, 2005), the amount of paraffin formulated at a paint formulation site is approximately 3 tonnes/annum.
...Fraction of tonnage to region	0.1	Use distributed throughout Europe.
...Fraction of main source	0.043	A usage of 3 tonnes/annum corresponds to a fraction of the main source of (3 tonnes/annum) / (692 tonnes/annum * 0.1) = 0.043.

Information type	Data field	Explanation or citation
Frequency and duration of use	300 d/y	RAR (EU, 2005).
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	MCCPs are used in solvent based paints, primarily in industrial applications. Releases to water and air from formulation and industrial use are negligible because the chlorinated paraffin is associated with the solid phase.	RAR (EU, 2005).
..Fraction of applied amount lost from process/use to waste gas	0.001	The default A-Table emission factors for paint formulation of 0.001 (air) and 0.003 (water) were used in the RAR (EU, 2005). The default A-Table emission factors for industrial use of paint of 0 (air) and 0.001 (water) were used in the RAR (EU, 2005). These factor appreciably overestimate true emissions because MCCPs are used in solvent based paints and MCCPs are characterized by low water solubility and low vapour pressure (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.004	
...Absolute amount of waste released per year	8.9 kg/year (wastewater) 3.0 kg/year (air)	Release estimate based on no direct disposal of cleaning or solid wastes to water.
Technical conditions and measures at process level to prevent release	• Collection of disposal of solid waste generated during cleaning in a permitted landfill.	CEFIC RMM Library E14.03.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	In the absence of municipal wastewater treatment or in the case of direct discharge to surface water, physical and/or industrial waste treatment with removal efficiency of 97.1% or greater.	Without municipal STP, mechanical treatment and/or industrial waste treatment to achieve annual emissions less than 3.5 kg/year after treatment (CEFIC RMM Library codes E13.01, 13.03, 13.04 and/or 13.24).
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01.

Information type	Data field	Explanation or citation
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.29.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.30. The PECs are presented in Table 9.35.

Table 9.35. Environmental PECs for paint formulation and use

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.782
Sediment (marine water) (mg/kg wet wt)	0.095
Surface water (fresh) (mg/L)	0.0000611
Surface water (marine) (mg/L)	0.00000741
Agricultural soil (mg/kg wet wt)	0.617
Concentration in fish for secondary poisoning (mg/kg ww)	0.155
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	3.79
STP micro-organisms (mg/L)	0.000431

[a]PEC_{local} includes the contribution from all regional sources.

9.30. Paint Service Life – Outdoor – environmental exposure

9.30.1. Exposure Scenario

MCCPs are used as plasticizers in paints typically at a concentration of 5-15%. The typical use for MCCPs in these paints is in chlorinated rubber-based and vinyl copolymer paints (EU, 2005). In line with the RAR for MCCPs, environmental release during both formulation and use of paints is negligible (EU, 2005). However, the possibility of leaching and volatilization during the service life exists. Uses of paints are assumed to be evenly divided between indoor and outdoor uses with a nominal lifetime of emissions of approximately 10 years. The exposure scenario is summarized in Table 9.36.

Table 9.36. Environmental exposure scenario for paint service life - outdoor

Information type	Data field	Explanation or citation
Short Title	ES15: Paint Service Life (Outdoor)	--

Information type	Data field	Explanation or citation
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, outdoor (ERC 10a)	Default ERC for wide dispersive use of long life articles, low release, outdoor.
Product characteristics	• MCCP's incorporated into paint matrix • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005).
Amount used (local use)	0.069 ton/year	Based on ERC 10a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 10a default.
...Fraction of main source	0.002	Based on ERC 10a default.
Frequency and duration of use	365 d/y	Based on ERC 10a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Outdoor use	The RAR (EU, 2005) assumed that all paints were used in an outdoor setting. In principle, adhesives and sealants are used in both indoor and outdoor environments with an appreciable fraction having no contact with water.

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	0.0005	Based on ERC 10a Default; see also RAR (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.008	The OECD Plastic Additive ESD (OECD, 2004a) indicates an outdoor leaching rate of 0.16% to the environment per year for plasticizers. Assuming a nominal 10 year service life, the total service life emission rate is 0.16% x 10 years = 1.6%. This release to the environment was evenly divided between water and soil.
...Absolute amount of waste released per year (local)	0.55 kg/year (wastewater) 0.55 kg/year (soil) 0.03 kg/year (air)	Release estimate based on ERC 10a default (air) and OECD ESD (water and soil).
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.30.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.36. The PECs are presented in Table 9.37.

Table 9.37. Environmental PECs for Paint Service Life – Outdoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.504
Sediment (marine water) (mg/kg wet wt)	0.0671
Surface water (fresh) (mg/L)	0.0000393
Surface water (marine) (mg/L)	0.00000524
Agricultural soil (mg/kg wet wt)	0.111
Concentration in fish for secondary poisoning (mg/kg ww)	0.126
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.49
STP micro-organisms (mg/L)	0.000022

[a]PEC_{local} includes the contribution from all regional sources.

9.31. Paint Service Life – Indoor – environmental exposure

9.31.1. Exposure Scenario

MCCPs are used as plasticizers in paints typically at a concentration of 5-15%. The typical use for MCCPs in these paints is in chlorinated rubber-based and vinyl copolymer paints (EU, 2005). In line with the EU RAR for MCCPs, environmental release during both formulation and use of paints is negligible (EU, 2005). However, the possibility of leaching and volatilization during the service life exists. Uses of paints are assumed to be evenly divided between indoor and outdoor uses with a nominal lifetime of emissions of approximately 10 years. The exposure scenario is summarized in Table 9.38.

Table 9.38: Environmental exposure scenario for paint service life - indoor

Information type	Data field	Explanation or citation
Short Title	ES16: Paint Service Life (Indoor)	--
Contributing scenarios controlling environmental exposure	• Wide dispersive use of long life articles, low release, indoor (ERC 11a)	Default ERC for wide dispersive use of long life articles, low release, indoor
Product characteristics	• MCCP's incorporated into adhesive/sealant matrix • Low volatility (nominal vapour pressure of 2.7 x 10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005).
Amount used (local use)	0.069 ton/year	Based on ERC 11a default methods.
...Fraction of tonnage to region	0.10	Based on ERC 11a default.
...Fraction of main source	0.002	Based on ERC 11a default.
Frequency and duration of use	365 d/y	Based on ERC 11a default.
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	Indoor use	The RAR (EU, 2005) assumed that all paints were used in an outdoor setting. In principle, adhesives and sealants are used in both indoor and outdoor environments with an appreciable fraction having no contact with water.

Information type	Data field	Explanation or citation
..Fraction of applied amount lost from process/use to waste gas	5.00E-04	Based on ERC 11a Default; see also RAR (EU, 2005).
...Fraction of applied amount lost from process/use to wastewater	5.00E-04	
...Absolute amount of waste released to wastewater per year (local)	0.035 kg/year (wastewater) 0.035 kg/year (air)	Release estimate based on ERC 11a default (air) and OECD ESD (water).
Conditions and measures related to municipal sewage treatment plant	Removal efficiency of 97.1% (directed to sludge). Default effluent flow rate of 2000 m^3/day assumed.	Simple Treat 4.0 based on Coelhan 2010
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.31.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.38. The PECs are presented in Table 9.39.

Table 9.39. Environmental PECs for paint service life – indoor

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	0.49
Sediment (marine water) (mg/kg wet wt)	0.0657
Surface water (fresh) (mg/L)	0.0000382
Surface water (marine) (mg/L)	0.00000513
Agricultural soil (mg/kg wet wt)	0.0859
Concentration in fish for secondary poisoning (mg/kg ww)	0.125
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	2.43
STP micro-organisms (mg/L)	0.00000137

[a]PEC_{local} includes the contribution from all regional sources.

9.32. Production of Paper – environmental exposure

9.32.1. Exposure Scenario

MCCPs are used as a solvent in a small fraction (<1%) of paper products in a fraction of 3-4% by weight (EU, 2005). Based on industry knowledge, the production of mirocapsules containing MCCPs is performed in closed systems with little potential for release. Therefore, the primary release pathway for MCCPs use in paper occurs in paper recycling. The paper recycling scenario was used to represent emissions for this exposure scenario. MCCPs are carrier solvents for color formers, which are hydrolozed and released during pulping. Thus, MCCPs are assumed to enter the water phase during recycling with approximately 90% removed in sedimentation and a release to water of approximately 10% (EU RAR, 2005). Data from CEPI (http://www.cepi.org/taxonomy/term/14) indicated that 72.5% of all paper is recycled and that 83% is recycled in Europr. Thus, it is assumed that 61% of paper is recycled in Europe, or 72.5% x 83% = 61%.
Solid waste is generated during cleaning between batches in formulation or during use must be disposed of properly in a permitted solid waste landfill. The exposure scenario is summarized in Table 9.40.

CEPI does not report virign and recycled paper and board facilities separately, but utilization of recycled paper in paper and board manufacture is approximately 52.4% (http://www.cepi.org/system/files/public/documents/publications/statistics/2018/210X140_CEPI_Brochure_KeyStatistics2017_WEB.pdf). As of 2017, CEPI reports that there were 737 paper and board facilities in Europe. It was consevatively assumed that approximately half of the mills utilized recycled paper, or approximately 370 sites.

Table 9.40. Environmental exposure scenario for use of MCCP in paper

Information type	Data field	Explanation or citation
Short Title	ES17: Paper manufacture and recycling	--
Description of activities and processes	Use of MCCPs as a solvent in paper typically at a content of 3 to 4%. Primary manufacture is in a closed process, however, emission to water occurs during recovery of pulp for recycled papermaking.	RAR (EU, 2005)
Contributing scenarios controlling environmental exposure	• Industrial inclusion onto a matrix (ERC 5)	Default ERC for formulation and use of mixtures included onto a matrix.
Product characteristics	• Low volatility (nominal vapour pressure of 2.7×10^{-4} Pa at 20 °C) • Low solubility (0.027 mg/L)	RAR (EU, 2005)
Amount used (local site)	0.45 tonnes/annum	The distribution of 150 tonnes/annum accross 370 paper mill sites indicates that a local site will process at most 0.45 tonnes/annum of MCCP.
...Fraction of tonnage to region	0.1	Use distributed throughout Europe.
...Fraction of main source	0.03	A usage of 0.45 tonnes/annum corresponds to a fraction of the main source of (0.45 tonnes/annum) / 150 tonnes/annum x 0.1) = 0.03.
Frequency and duration of use	300 d/y	Based on ERC default methods.

Information type	Data field	Explanation or citation
Environment factors not influence by risk management	Flow rate of receiving water in standard town of 18000 m^3/day.	Based on TGD Chapter R.16.
Other operational conditions affecting environmental exposure	• MCCPs are processed in closed systems in carbon copy manufacture with negible release • MCCPs are carrier solvents for color formers, which are hydrolozed and released during recycled papermaking pulping	RAR (EU, 2005)
..Fraction of applied amount lost from process/use to waste gas	0	The primary release pathway for MCCPs use in paper occurs in paper recycling. The paper recycling scenario was used to represent emissions for this exposure scenario. MCCPs are carrier solvents for color formers, which are hydrolozed and released during pulping. Thus, MCCPs are assumed to enter the water phase during recycling with approximately 90% removed in sedimentation in facility treatement and a release to water of approximately 10% (EU RAR, 2005).
...Fraction of applied amount lost from process/use to wastewater	0.1	
...Absolute amount of waste released per year	45 kg/year (wastewater)	Release estimate based on no direct disposal of cleaning or solid wastes to water.
Technical conditions and measures at process level to prevent release	• Collection of disposal of solid waste generated during cleaning in a permitted landfill.	CEFIC RMM Library E14.03
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	None	None
Organizational measures to prevent/limit release from site	• Closed sinks/ basins to prevent discharge to waste- and/or surface water • General good hygiene and housekeeping	CEFIC RMM Library E11.01 and W27.01

Information type	Data field	Explanation or citation
Conditions and measures related to municipal sewage treatment plant	None	None
Conditions and measures related to external treatment of waste for disposal	Treatment of waste in accordance with the Reference Document on Best Available Techniques for Waste Treatment Industries (August, 2006).	Waste Treatment Industries BREF (EU, 2006b).

9.32.2. Exposure Estimate

Substance-specific parameters have been derived from the RARs (EU, 2005, 2007) and cited in UK (2008). Environmental exposure was assessed using EUSES version 2.1.1. The operational conditions, risk management measures and release factors are defined in Table 9.40. The PECs are presented in Table 9.41.

Table 9.41. Environmental PECs for paper applications

Compartment	PEC local[a]
Sediment (fresh water) (mg/kg wet wt)	1.97
Sediment (marine water) (mg/kg wet wt)	0.214
Surface water (fresh) (mg/L)	0.000154
Surface water (marine) (mg/L)	0.0000167
Agricultural soil (mg/kg wet wt)	2.77
Concentration in fish for secondary poisoning (mg/kg ww)	0.279
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	9.3
STP micro-organisms (mg/L)	0.00218

[a]PEC_{local} includes the contribution from all regional sources.

9.33. Environmental regional PECs

Table 9.42. Environmental PECs for regional exposure

Compartment	$PEC_{regional}$[a]
Sediment (fresh water) (mg/kg wet wt)	0.977
Sediment (marine water) (mg/kg wet wt)	0.131

Surface water (fresh) (mg/L)	0.0000382
Surface water (marine) (mg/L)	0.00000512
Agricultural soil (mg/kg wet wt)	0.86
Concentration in fish for secondary poisoning (mg/kg ww)	Not applicable. Local Only.
Concentration in earthworm for secondary poisoning (mg/kg earthworm)	Not applicable. Local Only.
STP micro-organisms (mg/L)	Not applicable. Local Only.

[a]$PEC_{regional}$ includes modelled releases from all exposure scenarios. Predicted regional concentrations greater than predicted local concentrations for the individual exposure scenarios result from calculation methodologies used in EUSES."

9.34. Comparison of Model and Measured Values

The results of the refined model were compared with measured environmental data presented in the RAR (EU, 2005) and several identified studies. The most complete dataset in the EU RAR was a study in the UK assessing the levels of MCCPs in industrial areas conducted in the summer of 1998. A comparison of the model results in this report to the measured data indicates good agreement between the model and the measured values in the RAR (Table 9.43). For example, the regional sediment concentration of approximately 1 mg/kg wet weight predicted by the model is close to the average of 0.7 mg/kg wet weight for areas upstream of STP plants in industrial areas. It is noted that the measured data for sediment may reflect historical sources and also other interference from other chlorinated compounds such that the model is likely over predicting regional MCCP concentration to a greater extent than implied by the comparison.Twenty-nine studies that measured for MCCPs in sediment, water, and biota have been identified and have been fully assessed as part of a MCCP monitoring literature review, which is provided in the Excel spreadsheet attached in Section 13.2 of the registration dossier. A subset of 22 studies were summarized in data tables by media. Studies were eliminated if unreliable analytical techniques were used or if the study was a review paper or repeated data. This subset was further refined to include only those that were deemed relevant as a basis of comparison to the PNECs and modelled concentrations. A complete description of this decision process is provided in the Excel spreadsheet attached in Section 13.2 of the registration dossier. Table 9.43 provides a summary of measured concentrations included in the comparison to the PNECs.

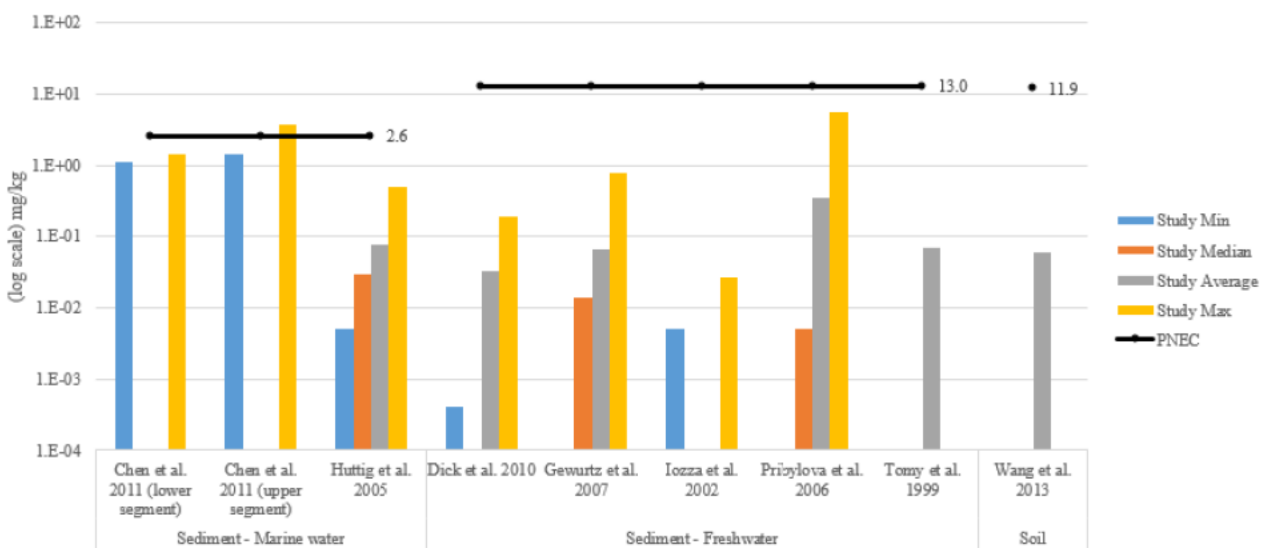
Table 9.43. Comparison of EUSES environmental exposure scenario results to selected measured values from several studies and PNECs.

Media	Measured Concentrations	Model – Local	Model Regional	PNEC	Data Source	Notes
Sediment – Marine Water	5×10^{-3} to 3.8 mg/kg dry weight	0.07 to 0.4 mg/kg wet weight (0.2 to 1.0 mg/kg dry weight)	0.13 mg/kg wet weight (0.34 mg/kg dry weight)	2.6 mg/kg dry weight	Huttig et al. (2005), Chen et al. (2011)	Generally in agreement with the local model results.
Sediment – Freshwater	Non detect to 5.6 mg/kg dry weight	0.5 to 2.1 mg/kg wet weight (1.3 to 5.4 mg/kg dry weight)	0.98 mg/kg wet weight (2.5 mg/kg dry weight)	13 mg/kg dry weight	Dick et al. (2010), Gewurtz et al. (2007), Iozza et al. (2002), Pribylova et al. (2006), Tomy et al. (1999)	Generally below the sediment PNECs. Only exception was the max marine water sediment concentration measured in a heavily industrialized area in China (Pearl River Delta, Chen et al. [2011]).
Soil	5.9×10^{-2} mg/kg dry weight	0.08 to 3.0 mg/kg wet weight (0.09 to 3.3 mg/kg dry weight)	0.86 mg/kg wet weight (0.96 mg/kg dry weight)	11.9 mg/kg dry weight	Wang et al. (2013)	Measured concentration was below the soil PNEC.
Freshwater	9.0×10^{-7} to 0.28 µg/L	0.04 to 0.16 µg/L	0.04 µg/L	1 µg/L	Dick et al. (2010), Houde et al. (2008)	Good agreement with regional and local model result.

Media	Measured Concentrations	Model – Local	Model Regional	PNEC	Data Source	Notes
						Well-below the freshwater PNEC.
WWTP	Non detect to 4.6×10^{-3} mg/L	7 x 10^{-9} to 0.002 mg/L	-	80 mg/L	Coelhan et al. (2009)	Well-below the WWTP PNEC.

Measured sediment concentrations were generally in agreement with local sediment model result. In addition, concentrations measured in freshwater were in agreement with the local and regional model result for surface water. Concentrations were generally well-below the PNECs with the exception of one maximum concentration measured in marine water sediment in a highly industrialized area in China (Figure1).

Figure 1. Measured concentrations in sediment and soil and comparison to PNECs



The concentrations from the recently assessed literature are generally similar to or less than the concentration scompiled in the 2005 RAR (Table 9.44). For example the maximum concentration of MCCP in sediment compiled in the 2005 RAR was 5.2 mg/kg wet weight, as compared to a maximum of 2.1 mg/kg wet weight when focusing on recent studies of adequate reliability

Table 9.44. Summary of selected measured values compiled in RAR (EU, 2005).

Media	Measured Concentrations	Data Source	Notes
Sediment	Upstream of STP averages 0.7 mg/kg ww with range of < 0.1 to 5.2 mg/kg wet weight. Downstream of STP concentrations up to 25 mg/kg ww were observed.	RAR (EU, 2005) Table 3.32. UK data	Good agreement with regional result. Some local downstream measured data may include historical sources or short and long-chain chlorinated paraffins or other interferences.

Media	Measured Concentrations	Data Source	Notes
Surface water (dissolved)	< 0.1 µg/L	RAR (EU, 2005) Table 3.25. UK data	Good agreement with regional and local result.
Soil receiving sewage sludge	< 0.088 mg/kg wet weight	RAR (EU, 2005) Table 3.38. UK data	EU RAR report notes that the half-life in soil is likely about 2 years. Use of this half-life (in lieu of infinite half life) would result in better agreement between model and measured values.
Earthworm	< 0.1 to 1.7 mg/kg fresh weight	RAR (EU, 2005) Table 3.38. UK data	Reasonable agreement relative to PNECoral of 10 mg/kg fresh weight.