United States
Environmental Protection Agency

Premanufacture Notification
Number: P-14-0683-0684
Office of Chemical Safety and
Pollution Prevention

TSCA NEW CHEMICALS REVIEW PROGRAM STANDARD REVIEW RISK ASSESSMENT ON

MEDIUM-CHAIN CHLORINATED PARAFFINS (PMN P-14-0683, P-14-0684)

This assessment was conducted under EPA's TSCA Section 5 New Chemicals Review Program. EPA is assessing Medium-Chain Chlorinated Paraffin (MCCP) and Long-Chain Chlorinated Paraffin (LCCP) chemicals as part of its New Chemicals Program. As with all Premanufacture Notice (PMN) submissions, EPA followed the approaches, methods and statutory provisions of TSCA section 5 for the chlorinated paraffin PMNs assessments.

CONCLUSIONS

Based on its assessment of the available hazard and exposure information on P-14-0683/0684, EPA/OPPT concludes the following pertaining to the potential manufacturing, processing and use of these PMN substances

1. Occupational Exposures: given the assumptions, data and scenarios evaluated in this assessment, there were no risks found for workers from either dermal or inhalation exposures.

2. General Population Exposures (from environmental releases): given the assumptions, data and scenarios evaluated in this assessment, there were no risks found to humans from environmental releases via exposure to drinking water or fish ingestion.

3. Environmental Assessment:
   a. Using estimated environmental concentrations, the PMN substances **may present an unreasonable risk following acute and chronic exposures to aquatic organisms.**

   b. Using available measured concentrations of MCCP congener groups in the environment as supporting information, the PMN substances:
      i. Are expected to partition to sediment and may partition to soil through land application of biosolids and,
      ii. May be released to the environment at levels at or above estimated concentrations of MCCP congener groups that **may present an unreasonable risk following acute and chronic exposures to aquatic organisms.**

4. PBT Assessment: The PMN substances **may be very persistent and very bioaccumulative**.

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1 INTRODUCTION

1.1 PMNS RECEIVED

Qualice submitted two Premanufacture Notices (PMNs) identified by EPA/OPPT as medium-chain chlorinated paraffins (MCCPs: P-14-0683 and P-14-0684) of varying chain lengths with the formula $C_xH_{(2x-y+2)}Cl_y$ and x equaling 14 to 17 and y equaling 6 to > 24. Table 1 lists basic information Qualice supplied on these two PMNs.

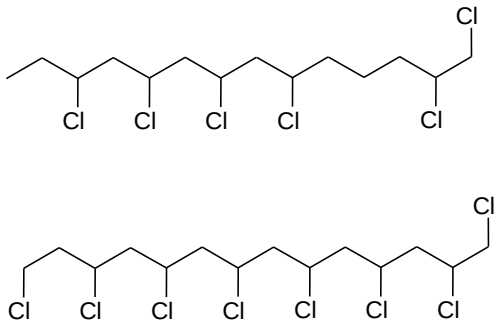
Table 1: Identification, Production Volume and Use of P-14-0683 and P-14-0684

PMN	Chemical Name	First Year/Third Year Production Volume (kg)	Uses	Log K_{ow}	Water Solubility
P-14-0683	Tetradecane, chloro	2,500,000/15,000,000	50% flame retardant in rubber products and 50% additive in lubricants	4.70 (E)	< 0.03 mg/L (E)
P-14-0684	Alkanes, C_{14-16}, chloro	2,500,000/15,000,000	50% flame retardant in rubber products and 50% additive in lubricants	4.70 (E)	< 0.03 mg/L (E)
E = Estimated					

Although the specific PMNs in this application are MCCPs, this standard review presents data and information on short-chain chlorinated paraffins (SCCPs) and long-chain chlorinated paraffins analogs. The continuum of carbon chain length and degree/percent of chlorination in all of the CPs and the relationship among them needs to be kept in mind.

1.2 CHEMISTRY

Shown below are the structures and chlorine content of P-14-0683 and P-14-0684. Note that P-14-0683 is 98% C_{14} and P-14-0684 is approximately 58% C_{14}, the remainder of the latter being higher chain lengths:



P-14-0683 C14 98%; alpha olefin 94%;

Cl level 92% 6 - 8 Cl atoms (52% - 60%)

P-14-0684 C14 58%; C15+ ~ 40%;

Cl level 92% 6 - 8 Cl atoms (52% - 60%)

CPs have an unknown or variable composition (classified as UVCB[1] compounds for TSCA Inventory purposes) of polychlorinated n-alkanes. The carbon chain length usually varies between 10 and 30 carbon atoms and the degree of chlorination can vary between 30 and 75 wt%. EPA/OPPT subdivides CPs according to their carbon chain length into the following categories:

1. Short chain CPs (SCCPs, $C_{10\text{-}13}$)
2. Medium chain CPs (MCCPs, $C_{14\text{-}17}$)
3. Long chain CPs (LCCPs, $C_{18\text{-}20}$)
4. Very long chain CPs (vLCCP, $C_{>20}$)

SCCPs and MCCPs exist as liquids at standard temperature and pressure. CPs with a carbon chain length ≥ 18 are subdivided based on their physical state, which is a function of chain length and chlorine content. The LCCPs and vLCCPs up to 70 wt% Cl are typically liquids (40 – 55 wt% Cl) while above 70 wt% Cl they are waxy solids.

CP products contain a variety of carbon chain lengths that have been chlorinated to different degrees (*i.e.*, variation in the number and position of the chlorine atoms on the carbon chain). The individual isomer content of commercial CPs is rarely identified because the number of possible individual congener groups is extremely large. Consequently, the physicochemical properties of CPs vary by carbon chain length and chlorine content. Increased molecular weight correlates to higher melting and boiling points, lower vapor pressures and water solubilities, and greater Log K_{ow} (logarithm of octanol:water partition coefficient). The MCCP products considered for this analysis are liquids with chlorination levels between 40 to 60 percent. The physicochemical properties of interest in this risk assessment include: physical form, water solubility, vapor pressure, and log K_{OW} (see Table 2).

Table 2: Physiochemical Information[a,b]

	wt% Cl	**Melting Point**	**Boiling Point**	**Vapor Pressure**	**Water Solubility**	**Log K_{OW}**
MCCPs	> 40	< 25°C (pour point)	> 200°C (dec)	< 0.036 Pa at 20°C	27 µg/L at 20°C	> 5.5 (measured) 8.30 (estimated)[c,d]

[a]Source: EURAR of MCCP (ECB, 2008)
[b]Because most CP products are liquids and the CPs begin decomposing at 200°C (*via* loss of HCl), melting point and boiling points are considered less important in characterizing hazard and risk.
[c]Value calculated using the KOWWIN Program (v1.68) available in EPA/OPPT's Estimation Programs Interface (EPI) Suite ™. This estimate was generated using a representative MCCP (*i.e.*, $C_{14}H_{24}Cl_6$, 52 wt% Cl) with the following SMILES notation: CCC(Cl)CC(Cl)CCCl)CC(Cl)CC(Cl)CC(Cl)C.
[d]The EURAR (ECB, 2008) cited Renberg's liquid chromatography to measure a log K_{OW} between 5.5 and 8.2 and then chose to use log K_{OW} = 7 as a representative log K_{OW} for MCCP 45 – 52 wt% Cl.

[1] UVCB are chemical substances whose composition is Unknown or Variable compositions, Complex reaction products and Biological materials.

Analytical challenges exist with evaluating CPs due to the sheer number of congener groups[2] that may be present in CP products. The existence of multiple chain lengths in the UVCBs such as P-14-0683 and P-14-0684 requires the use of analytical methods that separate congener groups based on retention time in a column and mass spectrum of the respective peaks. Several lines of evidence support the use of a representative SCCP or MCCP product as a surrogate for congener groups present in MCCP or LCCP commercial products, respectively.

Hüttig (2006) and Hüttig and Oehme (2006) reported that most commercial MCCP products were > 60 wt% of the C_{14} chain-length congener groups and the C_{15} chain-length congener groups comprised the majority of the remaining ~ 40 wt%. The authors found < 15 wt% C_{16} chain-length congener groups present in most commercial MCCP samples and little to no C_{17} chain-length congener groups. Additional studies have reported that the C_{14} and C_{15} chain-length congener groups are the predominant MCCPs present in environmental media and in human breast milk (Bayen et al., 2006; Chen et al., 2011; Reth et al., 2006; Wang et al., 2013). Some variation is possible in commercial products where the C_{14} and C_{15} chain-length congener groups may not be the predominant congener groups in a specific MCCP product; however, even in these products, the C_{14} and C_{15} chain-length congener groups may serve as reasonable worse case surrogates for the C_{16-17} chain-length congener groups, due to their greater bioavailability and mobility in environmental media (ECB, 2005).

These analyses, in conjunction with measured or estimated physicochemical and environmental fate properties, allow for the reasonable use of associating commercial products with CP levels found in environmental media and biota. For example, the experimental observation that MCCP ($C_{14} – C_{17}$) are abundant in sediment has been explained using known water solubility and vapor pressure values in conjunction with predicted degradation pathways (de Boer, 2010). EPA/OPPT determined that the toxic endpoints of interest were measured for only one CP (Cereclor S52®) commercial product. Therefore, this approach of relating one commercial product with other commercial products is critical for attributing the hazard characterization to CPs of different sources. Thus, available information (hazard and environmental monitoring data) on one commercial product (Cereclor S52®) is used as a representative CP for this assessment. Experimental data on SCCPs shows that these products are more toxic than the longer chain CPs (*e.g.*, MCCPs). Therefore, when endpoint specific data were lacking for the PMN, EPA/OPPT used measured data from SCCPs as surrogates for potential hazards and risks for the PMNs.

1.3 USES

Qualace reported that 50% of both P-14-0683 and P-14-0684 would be used in metal working fluid (MWF) lubricants as a heat and pressure stabilizer. The remaining 50% will be used as a flame retardant for rubber compounding. Chlorination rates for these MCCP are more constant for the rubber formulating applications (only using 52 – 53% Cl CP), while the amount of chlorine by weight is required for MWF varies based on the extreme conditions of the different metal working processes.

Table 3 provides the trade names, range of chlorination and percent PMN substance in the final use products.

[2] For this report, congener groups is used to recognize the existence of different chain lengths and degrees of chlorination that could be present in any given CP product.

Table 3: Trade Names, Percent Chlorination and PMN Concentration in Final Use Products

PMN	Trade Names	Percent Chlorination	Percent PMN in final Product
P-14-0683	CPAR MCCO	40-60	15% in lubricating oils and 10% in final rubber product
P-14-0684	CPAR MCCP		

2 ENVIRONMENTAL FATE

EPA/OPPT reviewed available information on the environmental fate of MCCPs and LCCPs in different environmental compartments and the properties that control transport (summarized in Appendix A). In addition, EPA/OPPT reviewed assessments performed by Canada (EC, 2008a) and the EU (EA, 2009; ECB, 2005) to inform its assessment.

2.1 ENVIRONMENTAL PERSISTENCE

Abiotic studies have shown that MCCPs are stable to hydrolysis and to direct photolysis in water and air. In laboratory studies using hydrocarbon solvents, CPs were shown to poorly absorb UV light and no direct photodegradation was observed. The atmospheric half-life has been estimated at 1 - 2 days (EA, 2009; ECB, 2005), based on estimated values for the second order rate constant with atmospheric hydroxyl radicals for MCCPs (40 and 56 wt% Cl). The persistence of MCCPs increases with carbon chain length and higher chlorine content (EA, 2009; ECB, 2005).

Existing biotic degradation data suggest there are a number of microbial species capable of degrading shorter chain, lower chlorinated MCCP congener groups. Longer and higher chlorinated chemicals also may be degraded, but at much slower rates (Allpress and Gowland, 1999; Muir, 2010; Omori et al., 1987). The results from laboratory studies of microbial metabolism, using both isolated species and mixed cultures of acclimated microbes, show that MCCPs and LCCPs may be degraded by direct metabolism or co-metabolism by some microbes and microbial consortia in soil, wastewater treatment systems, sediment, and other environmental media. Overall, the existing studies suggest that with microbial degradation, dechlorination and carbon chain cleavage may be possible in some media (see Table A-1); however the degree of degradation is generally low (Allpress and Gowland, 1999; Muir, 2010; Omori et al., 1987).

In general, MCCP and LCCP congener groups with longer chain lengths and higher degrees of chlorination are expected to be highly persistent in some environmental compartments. In contrast, shorter and less chlorinated congener groups are likely to degrade rapidly, especially in aerobic environments. Because persistence appears to increase with chain length, LCCPs are generally expected to be more persistent than MCCPs (EA, 2009; ECB, 2005).

Based on the review of available literature and studies submitted by various manufacturers, including confidential business information (CBI) not publically available, EPA/OPPT's conclusions regarding environmental persistence of MCCPs is consistent with those provided by Canada and the EU.

Canada's assessment (EC, 2008a),states:

"Information on physical properties of MCCPs, and especially LCCPs, is limited. Values used in this assessment are based on extrapolations mainly from SCCPs or QSARs. The analysis of SCCPs and MCCPs in sediment cores and associated calculations provide strong evidence for the persistence of these substances in the environment. Even though there are no data for persistence of LCCPs in sediment, based on biodegradation data which indicate increasing stability with increasing carbon chain length, it is reasonable to conclude that LCCPs are persistent in sediment."

The EU assessment on MCCPs states (ECB, 2005):[3]

"No standard ready or inherent biodegradation tests results are available for medium-chain chlorinated paraffins. From the available information, medium-chain chlorinated paraffins can be considered to be not biodegradable in such test systems and so a biodegradation rate MCCPs of 0 day-1 is used in the risk assessment.

There is evidence that some microorganisms may be capable of degrading MCCPs in the environment in acclimated or co-metabolic systems. The potential for biodegradation appears to increase with decreasing chlorine content. However, it is not possible from the available data to derive rate constants for biodegradation in soil, surface water and sediment systems. As a worst case approach, no biodegradation will be assumed in these media in the PEC calculations.

Hydrolysis is not expected to be a significant degradation process for medium-chain chlorinated paraffins in the environment. An atmospheric half-life of 1-2 days is estimated for reaction with hydroxyl radicals. A value for the rate constant for the reaction (k_{OH}) of 8 x 10^{-12} cm^3 $molecule^{-1}$ s^{-1} is used for the environmental modelling in the risk assessment."

EPA/OPPT generally concurs with these characterizations. In the absence of information on specific congener groups and data for MCCP products, EPA/OPPT concludes that at least some congener groups present in MCCP products are persistent to very persistent; with estimated half-lives in air exceeding 2 days and estimated half-lives in water or sediments exceeding 2 months (60 days) (ECB, 2005; EA, 2009)

2.2 BIOCONCENTRATION AND BIOACCUMULATION

Recent reviews of the potential for MCCPs to bioaccumulate have shown that, while data are limited, some congener groups are bioaccumulative or very bioaccumulative (EC, 2008a; ECB, 2005; Houde et al., 2008; Thompson and Vaughan, 2014). A summary of studies reviewed by EPA/OPPT is provided in Appendix A.

Based on EPA/OPPT's review of existing studies (Bengtsson et al., 1979; CPC, 1980, 1983a, 1983b; Fisk et al., 1999; Fisk et al., 1998; Houde et al., 2008; Madeley and Maddock, 1983a,

[3] Note, since the EU issued its assessment in 2005, standard inherent biodegradation studies were performed and are summarized in Appendix A.

1983b; Madeley and Thompson, 1983; Renberg et al., 1986; Thompson et al., 2000), EPA/OPPT concludes that bioconcentration varies with the chain lengths and degree of chlorination within the CP mixture and species evaluated. Shorter and less chlorinated chemicals are readily taken up by organisms but also may be excreted or degraded after absorption (Arnot, 2013). Longer and more highly chlorinated chemicals are typically not absorbed across cellular membranes and are not accumulated in tissues. Some MCCP chemicals with intermediate chain length and chlorination may be absorbed and retained. The available evidence for MCCP congener groups with intermediate chain lengths and chlorination suggests that some may have BCFs or BAFs greater than 1000 or 5000 (EC, 2008a; ECB, 2005, 2008). This suggests that some congener groups in MCCP products may be bioaccumulative or very bioaccumulative.

The Canadian assessment on MCCPs states (EC, 2008a):

> *"On the basis of the available information, and in particular the field BAF estimates, it is concluded that MCCPs are bioaccumulative substances…"*

EPA/OPPT generally concurs with these characterizations. In the absence of information on specific congener groups and data for MCCP products, EPA/OPPT concludes that at least some congener groups present in MCCP products are bioaccumulative to very bioaccumulative based on multiple lines of evidence, including: Log K_{ow} values, modeled BCFs, laboratory-measured BCFs, field-measured BAFs, field-measured BMFs, laboratory-measured biota-sediment bioaccumulation factors (BSAFs) and the presence of MCCPs in human and wildlife biota.

3 ECOLOGICAL HAZARD OVERVIEW

The available ecotoxicity data on MCCPs are summarized in Appendix B, along with the criteria EPA/OPPT used for identifying the highest quality studies. Ecotoxicity studies for MCCPs have been conducted in fish, aquatic invertebrates and plants, sediment and soil invertebrates, and terrestrial plants and invertebrates. Though no avian reproduction studies were available on MCCPs, a high quality study was available on a SCCP product ($C_{10\text{-}12}$, 58 wt% Cl) with similar physicochemical properties to MCCPs and was used for informing EPA/OPPT's hazard evaluation (ECB, 2000). EPA/OPPT concludes that the studies summarized in Table 4 were the highest quality for assessing potential hazards in the aquatic, sediment and terrestrial compartments.

Table 4: Summary of Aquatic, Sediment and Terrestrial Ecotoxicity Data for MCCPs

Test Substance	Test Organism (Species)	Test Guideline; Study type	End-point	Value[1]	Reference
Aquatic Invertebrates					
Cereclor S-52 (52% wt. Cl, C_{14-17})	Water flea (*Daphnia magna*)	OECD 202, 1984; Acute immobilization test	EC_{50}	0.0059	CPA (1996)
Cereclor S-52 (52% wt. Cl, C_{14-17})	Water flea (*Daphnia magna*)	OECD 202- Part II, 1984; Reproduction test	NOEC LOEC MATC	0.01 0.018 0.013	(Thompson, et al., 1997)
Sediment-Dwelling Invertebrates					
Cereclor S-52 (52% wt. Cl, C_{14-17})	Amphipod (*Hyalella azteca*)	OECD 218- Draft, 2001; 28-day prolonged sediment toxicity study	NOEC LOEC MATC	130 270 187	Thompson et al. (2002)
Terrestrial Invertebrates					
Cereclor S-52 (52% wt. Cl, C_{14-17})	Earthworm (*Eisenia fetida*)	OECD Guideline-Draft, 2000; 28-day reproductive toxicity test	NOEC LOEC MATC	79 280 149	Thompson et al. (2001d)
Terrestrial Vertebrates					
Commercial CP (58% wt. Cl, C_{10-12})	Mallard duck (*Anas platyrhynchos*)	EPA 560/6-82-002; 22-week reproduction test	NOEC LOEC	168 1000	ECB (2000)
[1] Units are mg/L for aquatic invertebrates, mg/kg dry weight sediment for sediment-dwelling invertebrates; mg/kg dry weight soil for earthworm study; and mg/kg diet for the duck study.					

Using the concentrations in the "value" column in Table 4 to represent hazard, the Agency derived concentrations of concern (COCs) by applying assessment factors of five or ten for acute or chronic exposures, respectively, which account for laboratory variability and represents species sensitivity distributions (following USEPA, 2012). The COCs derived for aquatic-, sediment-, and terrestrial-dwelling organisms are summarized in Table 5.

The most reliable and acceptable studies indicate that for MCCPs, the toxicity to aquatic organisms are from the CPA (1996) study for acute toxicity and the Thompson et al. (1997) study for chronic toxicity:

- Acute COC: The 48-hour EC_{50} value 0.0059 mg/L is divided by an assessment factor of 5 to yield an acute concentration of concern (CoC) of 0.00118 mg/L, or 0.001 mg/L, or 1 µg/L (1 ppb).
  Aquatic Acute COC = 1 ppb.
- Chronic COC: The chronic value 0.013 mg/L is divided by an assessment factor of 10 to yield 0.0013 mg/L or 1.3 µg/L or 1.3 ppb.
  Aquatic COC = 1 ppb.

The most reliable and acceptable value for the acute toxicity to aquatic sediment invertebrate organisms is based on the MCCP material from the Thompson et al. (2002) 28-d study. The 28-d sediment invertebrate GMATC value of 187 mg/kg dry wt sediment is used to assess hazard. Using methods in USEPA (2012):

- Acute COC: The chronic value 187 mg/kg dry wt. is multiplied by an acute to chronic ratio for invertebrates (10) to yield 1,870 mg/kg dry wt. This value is then divided by an assessment factor of 5 to yield 374 mg/kg dry wt.
  Aquatic Sediment Acute COC = 374 mg/kg dry wt sediment.
- Chronic COC: The 28-d sediment invertebrate GMATC of 187 mg/kg dry wt sediment is divided by an assessment factor of 10 to yield 18.7 mg/kg dry wt sediment.
  Aquatic Sediment COC = 18.7 mg/kg dry wt sediment.

The most reliable and acceptable value for acute toxicity to terrestrial invertebrates is based on the MCCP material from the Thompson et al. (2001a) study. The 28-d terrestrial invertebrate GMATC value of 149 mg/kg dry wt soil from this study will be used. Using methods in USEPA (2012):

- Acute COC: To calculate an acute concern concentration from the chronic value the value 149 mg/kg dry wt, is multiplied by an acute to chronic ratio for invertebrates (10) to yield 1,490 mg/kg dry wt. This value is then divided by an assessment factor of 5 to yield 298 mg/kg dry wt.
  Terrestrial Invertebrate Acute COC = 298 mg/kg dry wt.
- Chronic COC: The 28-d terrestrial invertebrate GMATC of 149 mg/kg dry wt is divided by an assessment factor of 10 to yield 14.9 mg/kg dry wt.
- **Terrestrial Invertebrate Chronic COC = 14.9 mg/kg dry wt.**

The most reliable and acceptable value for acute toxicity to terrestrial vertebrates is based on the MCCP material from the ECB (2001) study. The 22-week terrestrial vertebrate NOEC value of 168 mg/kg dry wt soil from this study will be used. Using methods in USEPA (2012):

- Acute COC: To calculate an acute concern concentration from the chronic value the value 168 mg/kg diet is multiplied by an acute to chronic ratio for invertebrates (10) to yield 1,680 mg/kg diet. This value is then divided by an assessment factor of 5 to yield 336 mg/kg diet.
  Terrestrial Vertebrate Acute COC = 336 mg/kg diet.
- Chronic COC: The 22-week terrestrial vertebrate NOEC of 168 mg/kg diet is divided by an assessment factor of 10 to yield 16.8 mg/kg diet.
  Terrestrial Vertebrate Chronic COC = 16.8 mg/kg diet.

Table 5: COCs for Environmental Toxicity of MCCPs

Compartment	Test organism	Endpoint	Value	Assessment factor	COC
Surface water	Water flea	EC_{50}	0.0059 mg/L	5	0.001 mg/L
		21-day MATC	0.013 mg/L	10	0.001 mg/L
Sediment	Amphipod	MATC	187 mg/kg dw	10	18.7 mg/kg dry wt. sediment
Terrestrial	Earthworm	28-day MATC	149 mg/kg dw	10	14.9 mg/kg dry wt. soil
	Mallard duck	22-week NOEC	168 mg/kg diet	10	16.8 mg/kg diet

4 HUMAN HEALTH HAZARD OVERVIEW

A summary of EPA/OPPT's evaluations on MCCPs is provided in section 4.1; individual study reviews are provided in Appendix C.

4.1 MCCP HEALTH DATA REVIEW

There is no information on inhalation absorption of MCCPs in humans or in animals. Based on their low vapor pressure and low water solubility, absorption following inhalation or dermal exposure is expected to be limited. Previous evaluations concluded that absorption by the inhalation and dermal routes of exposure will not exceed 50 or 1%, respectively (ECB 2005; EA 2009). Some MCCPs demonstrated moderate absorption and metabolism following oral exposure in animals. In general, absorption and metabolism are related to their carbon chain length and degree of chlorination; the longer the carbon chain length and the higher the degree of chlorination, the less absorption and metabolism.

No information is available on the toxicity of MCCPs in humans; however, the toxicology of these compounds has been evaluated in experimental animals. Studies in rats and rabbits have shown that MCCPs caused slight skin irritation and have low eye irritation potential. No evidence of skin sensitization was found when tested in guinea pigs. The liver, kidney and thyroid are the target organs of MCCPs in oral repeated dose studies in experimental animals (see Table C-1 in Appendix C). MCCPs induced increased liver weight, enzyme activity, and histopathological changes at high dose levels. Some of these hepatic effects are likely related to an increase in metabolic demand as an adaptive response, as well as to peroxisome proliferation, which are considered of limited toxicological significant to humans. However, liver necrosis was observed in a 90-day study in rats at 360 mg/kg-bw/day; this effect is considered relevant to humans. The reported effects in the kidney may have been produced by the parent compound or from metabolites. Mechanistic data cannot totally rule out that some kidney effects are relevant to humans. From the data available, a LOAEL of 625 mg/kg-bw/day based on histopathological changes in the kidneys of female rats is identified in a 90-day toxicity study, and a NOAEL of 23 mg/kg-bw/day based on increased kidney weight at 222 mg/kg-bw/day is identified from another 90-day study in rats (CXR, 2005). Repeated dose studies in rats reported some changes in histopathology and hormone levels of the thyroid. However, it may be concluded based on an

evaluation of the mechanistic data that the thyroid effects observed in rats is of little relevance to chronic toxicity in humans.

There is no information on the carcinogenicity of MCCPs; however, carcinogenicity studies on a SCCP and a vLCCP are available. These studies, along with the genotoxicity data on MCCPs, may be used to inform the carcinogenic potential of MCCPs. When administered by gavage, a SCCP (C_{12}, 60 wt% Cl) caused increased incidences of liver tumors in male and female rats, kidney tumors in male rats, and thyroid tumors in female rats. However, based on mechanistic considerations, these tumors are considered to be of little or no relevance to humans (details in ECB, 2008 and in Appendix C). An increased incidence of malignant lymphoma in male mice was reported at the highest dose of 5,000 mg/kg-bw/day in carcinogenicity studies of a vLCCP (C_{23}, 43 wt% Cl) in male and female rats and mice. However, malignant lymphoma is one of the more variable tumors in mice and has a viral origin in many cases. No increased incidence of malignant lymphoma was observed in the carcinogenicity study on an SCCP. Further, MCCPs are non-genotoxic. Therefore, it may be concluded that MCCPs are unlikely to pose a carcinogenic hazard to humans.

A series of range-finding and definitive prenatal developmental and reproductive toxicity studies were conducted in rats and rabbits with medium-chain chlorinated paraffins (MCCPs). These studies were conducted between 1981 and 1986. They appear to be valid toxicity studies, conducted according to the standard methodologies available at the time.

In several prenatal developmental toxicity studies with MCCPs conducted *via* gavage, no signs of maternal toxicity were seen at doses as high as 500 mg/kg-bw/day in rats and 100 mg/kg-bw/day in rabbits. Likewise, no signs of developmental toxicity were observed at doses as high as 5000 mg/kg-bw/day in rats and 100 mg/kg-bw/day in rabbits.

Two reproductive toxicity studies with MCCPs in rats have been conducted. A one-generation reproductive toxicity range-finding study showed that administration of approximately 100 and 400 mg/kg-bw/day MCCPs *via* the diet had no effect on fertility or other reproductive parameters; however, internal hemorrhaging and deaths in pups were observed at doses from 74 mg/kg-bw/day (1000 ppm) up to approximately 400 mg/kg-bw/day (6250 ppm). These effects in the pups were not seen in a more recent definitive one-generation reproductive toxicity study with exposure to MCCPs for 11-12 weeks to doses as high as 100 mg/kg-bw/day (1200 ppm). Internal hemorrhaging was not seen in the adult animals in either of these studies at doses as high as 400 mg/kg-bw/day (6250 ppm), or in another study in non-pregnant female rats repeatedly exposed to doses as high as 1000 mg/kg-bw/day. However, when dams were exposed to approximately 500 mg/kg-bw/day (6250 ppm) MCCPs during cohabitation, gestation, and lactation, signs of hemorrhaging were observed in dams that died at the time of parturition. Taken together, the results of these studies suggest that newborns during lactation and pregnant females at the time of parturition are a potentially sensitive subpopulation; with a possible LOAEL for internal hemorrhaging and deaths in pups at an oral dose of 74 mg/kg-bw/day.

Additional studies with MCCPs have been conducted in an effort to clarify the possible causes of the hemorrhaging in the pups. One (single-dose; 6250 ppm or 538 mg/kg-bw/day) study showed maternal death during parturition due to low levels of vitamin K and related hemorrhaging,

suggesting that the act of parturition places dams at higher risk. It was concluded from this study and a cross-fostering study that the fetus relies on clotting factors *via* mother's milk and severe deficiencies in vitamin K levels and related clotting factors in the pups results in hemorrhaging.

No guideline developmental neurotoxicity studies on MCCPs were located. It is not clear if any developmental neurotoxicity endpoints were measured in the available prenatal developmental/reproductive toxicity studies; none were explicitly stated. The only information available regarding behavior during development is from cage-side observations in pups through lactation day 21. In these cases, no dose-related differences were reported in F_1 post-weaning appearance or cage-side behaviors. While thyroid hormone induced effects were observed in adults, no data exist for developmental studies. Current studies do not evaluate developmental neurotoxicity following perinatal exposures.

In this assessment, the lowest NOAEL (90-day value of 23 mg/kg/d from the rat study described above; CXR, 2005) will be used to assess occupational and non-occupational (*i.e.*, general population) risks of MCCPs.

5 EXPOSURE INFORMATION

EPA/OPPT used the information in this section and our standard PMN approaches to estimate potential worker exposures from activities associated with manufacturing, processing and use of P-14-0683 and P-14-0684. Environmental releases from these activities were also estimated for use in assessing risk to both human health (general population) and the environment (aquatic organisms). In addition, EPA/OPPT reviewed the available information on measured environmental concentrations of MCCPs and LCCPs, which are not normally available for PMNs.

5.1 ENVIRONMENTAL MONITORING

For this assessment, environmental monitoring data consisting of measured levels of MCCPs in surface water, sediment and soil were used to characterize potential environmental exposure to MCCPs. These data are not amenable to determining the ultimate release source (*i.e.*, manufacturing, processing, or use) into the environment; however, they provide some insight on the geographical and temporal distribution of MCCPs. Appendix D contains information and data used in this risk assessment.

Studies published between 1980 and 2013 that reported environmental concentrations of MCCPs and were reviewed for this assessment. Monitoring studies from the early 1980s could not distinguish between the different chain lengths of CPs. The introduction of modern techniques, such as electron capture negative ion mass spectrometry (ECNI-MS) allowed for the detection of specific congeners, although difficulties with these methods have persisted (*e.g.*, detection of low chlorination congeners in samples). Tomy (2010) performed a round robin laboratory study of SCCPs that highlighted the inability of the ECNI-MS method to consistently measure a reference sample, with concentrations varying up to a factor of six. Subsequent work showed that significant errors (up to a factor of ten) could be introduced by the improper selection of the calibration standards (Coelhan et al., 2000). A more recent inter-laboratory study of SCCPs

found good agreement amongst the laboratories that used ECNI-MS (Pellizzato et al., 2009), but similar inter-laboratory studies for MCCPs or LCCPs have not been completed (Tomy, 2010).

The majority of the monitoring data were collected in Europe, and some more recent monitoring data were collected in China. Over time and across countries, industrial practices and effluent pre-treatment have varied. Some of the monitoring studies only published their final measured concentrations, and did not include the details of the analytical techniques and sampling locations. Generally, EPA/OPPT used studies sponsored by the environmental agencies, but full documentation is lacking for even these studies. The industrial sectors studied by other countries also are present in the US, suggesting that conditions in the US may be similar.

The level of detail provided in the studies varied. Some studies provided detailed information regarding sampling locations (*e.g.*, impacted sites), analytical methodology, and final sample results including detection limits, quantitation limits, and estimated values. In contrast, other studies provided only a summary of the results combined from a number of studies. These summaries also did not provide details of the data analysis to obtain sample results. In addition, certain studies reported concentrations within a given country but did not provide additional details about the exact sampling location. Given the disparate conditions (*i.e.*, number of sites sampled, temporal period over which samples collected, differing analytical methods, *etc*.) across the data sets, EPA/OPPT was unable to determine a central tendency or distribution for the data sets, and a range was used instead. Studies using older analytical techniques that did not distinguish CP congeners were not used in this assessment. Other nations' assessments that used newer, more reliable, analytical techniques were considered.

EPA/OPPT used the following selection criteria to identify the studies included in this assessment:

- Specific mention of MCCP/LCCP chain length;
- Use of modern analytical techniques to distinguish categories of CPs;
- At a minimum, general information on sampling location.

EPA/OPPT used the monitoring data summarized in Tables 6 for this assessment. When a limit of detection (LOD) value was reported for non-detectable results[4], EPA/OPPT used one half of the LOD value, as described in greater detail below.

Even though the existing monitoring data were limited in quality and quantity, and it remains unclear how well the measured data describe the potential range of US MCCP use scenarios, EPA/OPPT concluded that the data in Tables 6 represented the best available monitoring information for MCCPs. These data provide some evidence that MCCPs are released into the environment; however, these data reflect discrete locations and times, and the extent to which they are representative of the overall distribution of MCCPs is unknown.

[4] Examples would be "not detected" (ND), negligible, or with a "less than" qualifier.

Table 6: Summary of Measured Concentrations of MCCPs in Environmental Media and Biota

Media	n	Minimum	Unit	Maximum	Unit	References
Surface water (non-marine)	15	$<2.50\times10^{-10}$	mg/L	1.49×10^{-3}	mg/L	Coelhan (2010); EC (2008); Houde et al. (2008); IPCS (1996); Muir et al. (2003); USEPA (1988) Petersen et al., 2006[a]
Sediment (non-marine)	78	2.00×10^{-3}	mg/kg[b]	6.51×10^{1}	mg/kg dw	Borgen et al. (2003); Chen (2011); EC (2008); Iozza et al. (2008); IPCS (1996); Nicholls et al. (2001); Petersen et al. (2006); Pribylova et al. (2006); Tomy et al. (1998, 1999a,b); USEPA (1988)
Sediment (marine)	54	5.00×10^{-3}	mg/kg dw	1.64×10^{1}	mg/kg dw	Huttig et al. (2004); Huttig and Oehme (2005, 2006); Kemmlein et al. (2002); Muir et al. (2000)
Sludge	9	5.00×10^{-5}	mg/kg[b]	9.70×10^{3}	mg/kg dw	Stevens et al. (2003); Pribylova et al. (2006)
Soil	12	2.1×10^{-6}	mg/kg dw	8.5×10^{-2}	mg/kg dw	Iozza (2010); Wang et al. (2013)
Biota (aquatic)	120	$<2.00\times10^{-7}$	mg/kg	2.63	mg/kg ww	Bennie et al. (2000); EC (1993); EC (2008); Houde et al. (2008); IVL(2009); Kemmlein et al. (2002); Muir (2010); Muir et al. (2000); Muir et al. (2003); Reth et al. (2005, 2006); Tomy et al. (1999a); USEPA (1998)
Biota (terrestrial)	8	5.00×10^{-3}	mg/kg ww	3.70×10^{-1}	mg/kg ww	Reth et al. (2006)

[a]Petersen et al. (2006) reported results for two water samples; EPA/OPPT assumed these were non-marine surface water samples.
[b]The weight type was not reported (*i.e.*, wet, dry, or lipid weight).
Notes:
1. All values provided in the table above represent total MCCPs and not individual MCCP isomers.
2. The "n" value represents the number of media-specific MCCP monitoring data values that were compiled from various articles in the raw data table (provided in Appendix D).
3. In some cases, the minimum values in the table are preceded by "<". This indicates that the value reported in article was reported as a non-detect. In such cases, one half of the lowest reported detection limit was compiled as the 'minimum' reported monitoring data.
4. dw – dry weight and ww – wet weight

5.2 MODELED ENVIRONMENTAL RELEASES

EPA/OPPT used screening-level models to generate environmental release estimates for P-14-0683 and P-14-0684, which were used to calculate exposure concentrations for estimating risks to humans and aquatic organisms. EPA/OPPT used the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER ver.2) to estimate environmental releases from industrial processes; the results are provided in Appendix E. Inputs to the ChemSTEER ver. 2 release modeling were based on multiple sources, including information provided by Dover, published OECD Emission Scenario Documents, EPA/OPPT Generic Scenarios, and EPA/OPPT

models for estimating environmental releases. Table 7 provides a general summary of the release assessment.

Table 7: Summary of Estimated Release to Water

PMN	Chemical Name	Manufacturing	Processing	Use
P-14-0683	Tetradecane, chloro	Yes (one day/year)	Yes, from two processes	Yes, from two use types
P-14-0684	Alkanes, C_{14-16}, chloro			

Exposure pathways of interest for human health include drinking water, fish ingestion, and air stack emissions. For aquatic organisms, the exposure pathway of concern is from direct releases to water. EPA/OPPT assessed each of these pathways by using the ChemSTEER ver. 2 release estimates as inputs to the Exposure and Fate Assessment Screening Tool (E-FAST V2.0) for estimating industrial releases and concentrations in the foregoing exposure pathways. EPA/OPPT assumed that potential releases to water occurred from indirect discharges to publicly owned treatment works (POTW). The E-FAST V2.0 modeling applied an assumption of 90% removal of MCCPs at the POTW. Water concentrations were estimated using E-FAST V2.0's probabilistic dilution model (PDM), which predicts downstream chemical concentrations from industrial discharges. These values were reported as the central tendency for a median flow site, a low flow site, and the lowest seven-day average flow that occurs on average once every ten years (*i.e.*, 7Q10). These estimated water concentrations were compared to the COC of 1 µg/L for chronic aquatic invertebrates (see Table 5). Air stack emissions were estimated using generic scenarios, which assumed inhalation exposures occurring 100 meters downwind of a facility. EPA/OPPT used these estimated values for calculating human health and environmental risks of P-14-0683 and 0684.

The results of the E-FAST V2.0 modeling are provided in Appendix F. Table 8 presents the values used in the risk assessment. As explained in the footnotes to Table 8, the values represent reasonable worst-case scenarios based on the processing and use scenarios presented in Table 7. However, these estimates require consideration of two important caveats: (1) limited environmental monitoring data are available, and (2) MCCPs are expected to partition to particulates and sediment; however, the E-FAST V2.0 models do not account for this partitioning.

Table 8: E-FAST Modeling Values used[1]

Scenario[2]	Water Release - Human		Air Release - Human	Water Release – Aquatic Organisms[3]
	Drinking Water (mg/kg/d)	Fish Ingestion (mg/kg/d)	Stack Air LADD (mg/kg/d)	Range of Concentrations (µg/L)
Manufacturing	1.19×10^{-5}	6.22×10^{-5}	1.69×10^{-3}	one day/year
Proc1 – Formulation of MWFs[3]	1.48×10^{-4}	7.70×10^{-4}	3.23×10^{-3}	5.6 – 40 (206)
Proc2 – Compounding of rubber products	9.70×10^{-4}	5.07×10^{-3}	7.20×10^{-3}	35 – 257 (1310)
Use1 – Use of MWFs	1.39×10^{-4}	7.26×10^{-4}	5.55×10^{-4}	3 – 37 (333)
Use2 – Converting rubber products	4.81×10^{-5}	2.51×10^{-4}	7.50×10^{-3}	1 – 13 (110)

[1] Taken from Appendix F. Values represent the highest concentrations/estimated doses for chronic (*i.e.*, repeated exposure scenarios) for human health.
[2] MWF = metal working fluids.
[3] For PMNs, environmental risk was evaluated by performing a PDM as described above and in the E-FAST Manual (2007). The ranges encompass concentrations from the central tendency for a median flow site (*e.g.*, 5.6 µg/L) up to the central tendency for a low flow site (*e.g.*, 40 µg/L) – this example taken from the second row. The central tendency was calculated using the harmonic mean flow. The value in parentheses represents the 7Q10 (*e.g.*, 206 µg/L) value normally used to determine acute risk.

5.3 EXPOSURE ESTIMATES

5.3.1 Occupational Exposure Estimates

EPA/OPPT calculated screening-level workplace exposure estimates with ChemSTEER ver. 2.Table 9 provides a summary of the exposure estimates used in this risk assessment for evaluating worker exposures to P-14-0683 and P-14-0684; detailed information is provided in Appendix E.

Table 9: Summary of Occupational Exposure Estimates Used[1,2]

Route of Exposure	Mfg	Proc1 (MWF)	Proc 2 (Rubber)	Use 1 (MWF)	Use 2 (Rubber)
Inhalation (mg/day)	Negligible (due to low vapor pressure)		0.03 – 4.4	1.5 - 5.3	0.7 - 15
Dermal (mg/day)	1100 – 1200	340 – 2200	2200	260 - 370	Non-quantifiable[3]

[1] All values apply to P-14-0683 and P-14-0684

[2] The following represent the estimated number of sites and workers per scenario:

- Manufacturing (one site, three workers – 250 days/year)
- Proc 1 = Metalworking Fluid Processing (20 sites, 80 workers – 240 days/year)
- Proc 2 = Compounding of rubber products (six sites, 144 workers – 250 days per year)
- Use 1 = Metalworking fluid (3101 sites, 148,848 workers – 247 days/year)
- Use 2 = Converting of rubber products (16 sites, 768 workers – 250 days/year)

[3] PMN will be encapsulated in rubber sheets/blocks during handling of rubber raw material. While some surface contact may occur, dermal exposure to solids in this form is non-quantifiable.

5.3.2 Consumer Exposure Estimates

Qualace did not identify consumer uses in its PMN applications for P-14-0683 and P-14-0684; therefore, the Agency did not perform an assessment for these types of exposures.

6 RISK ASSESSMENT

6.1 Environmental Assessment

PMN risk assessments typically use modeled exposure values because new chemical substances are not in the stream of US commerce; however, for MCCPs, measured environmental data are available for some locations in the US and abroad. Though these data are not specific to P-14-0683 and 0684, the data contain MCCP congener groups that may be present in the PMN substances. However, EPA/OPPT used modeled exposure values as the principal source for its decision making because the modeled exposure values were generated using exposure scenarios that are representative of the types of uses and releases that may occur with P-14-0683 and 0684. In contrast, the measured environmental data are generally not amenable for identifying the types of uses or releases from which the measured congeners originated. Therefore, EPA/OPPT used these measured data as supporting information, along with modeled exposure values, to calculate potential environmental risks using the risk quotient (RQ) method.

The RQ method integrates the results of exposure and ecotoxicity data (USEPA, 1998).

An RQ is defined as:

$$RQ = \text{Environmental Concentration} \div \text{Effect Level}$$

where, the environmental concentration represents measured (see Table 6) or estimated (see Table 8) values for each compartment (*i.e.*, water, sediment, and soil), and the effect level represents the COC for aquatic, benthic, or terrestrial species (see Table 5).

An RQ greater than one serves as a benchmark for identifying whether aquatic concentrations of P-14-0683 and P-14-0684 may present an unreasonable risk to aquatic- and sediment-dwelling organisms.

6.1.1 Risk Estimates Using Environmental Monitoring Data

The RQs shown in Table 10 suggest that measured concentrations of MCCPs in water and sediment may present an unreasonable risk of acute and chronic injury to aquatic organisms and may present an unreasonable risk of chronic injury to sediment-dwelling organisms. However, several limitations must be noted about the monitoring studies and the level of uncertainty that they contribute to the basis of these findings. First, the reported concentrations represent minimum and maximum values that span, at a minimum, several orders of magnitude and translate to RQs of less than one (*i.e.*, no risk finding) or greater than one (*i.e.*, risk finding), respectively. Second, the temporal and geographical distributions of these data, along with the different types of uses and releases that may have served as the originating sources, make it impossible to describe the central tendency of these data. Finally, the frequency and magnitude of locations with relevant use and release scenarios to the PMN substances, which may result in environmental releases of MCCPs that exceed the relevant COCs, is unknown. In addition to these general limitations, there are specific limitations and uncertainties that preclude using these values as the sole source from which to inform potential environmental concentrations and risks that may result from the specific uses and releases associated with P-14-0683 and P-14-0684.

Table 10: Risk Quotients Calculated from Environmental Monitoring Data for Surface Water, Sediment and the Terrestrial Environment

	Environmental Concentration	**Effect Level (*i.e.*, COC)**	**RQs[1]**
Acute Risk Aquatic Species	$< 2.50\times10^{-10}$ to 1.49×10^{-3} mg/L	0.001 mg/L	$< 2.50\times10^{-7}$ to **1.49**
Chronic Risk Aquatic Species	$< 2.50\times10^{-10}$ to 1.49×10^{-3} mg/L	0.001 mg/L	$< 2.50\times10^{-7}$ to **1.49**
Chronic Risk Sediment-dwelling Species Non-marine Environment	0.002 to 65 mg/kg dw	18.7 mg/kg dw	1.07×10^{-4} to **3.5**
Chronic Risk Terrestrial Species	Insufficient Data	14.9 mg/kg dw[2]	Not calculated

[1]**Bolded values represent those that may present an unreasonable risk of injury.**
[2]The COCs for terrestrial invertebrates and vertebrates were 14.9 mg/kg dw and 16.8 mg/kg diet, respectively. Since these values were comparable, EPA/OPPT used the lowest value for calculating RQs for this compartment.

For surface water, EPA/OPPT based the aquatic risk findings for MCCPs on the highest concentration reported by Petersen et al. (2006). These authors collected two surface water samples from an undisclosed location(s) in Norway and measured the concentration of MCCP congener groups (*i.e.*, $C_{14\text{-}17}$). The authors reported a concentration of 1.49×10^{-3} mg/L for MCCP congener groups in one sample; however, a numerical value was not provided for the second sample, rather the distribution of congener groups was displayed in a bar graph. Based on the ordinate scale, the concentration of MCCP congener groups in the second sample was greater than zero, but less than 5.0×10^{-4} mg/L. Of the monitoring studies reviewed by EPA/OPPT (see

Appendix D), the Petersen et al. (2006) value of 1.49×10^{-3} is the only surface water concentration that resulted in an RQ greater than one. All other surface water concentrations are at least one order of magnitude below 1.49×10^{-3} mg/L (*i.e.*, RQs < 1).

For sediment concentrations, EPA/OPPT reviewed multiple studies, some of which reported values that exceeded the COC. Nicholls et al. (2001) reported the most relevant data for P-14-0683 and 0684. These authors measured concentrations of MCCPs at locations in the United Kingdom where specific industries were known to employ MCCPs in the use categories identified for the PMN substances (*e.g.*, lubricant in MWFs). Eight locations were sampled at three distances downstream (*i.e.*, 100 meters, 300 meters, and 1-2 kilometers) from the respective sewage treatment works. At four of the locations, at least one of the sampled downstream values exceeded the COC (*i.e.*, RQs > 1, risk finding). Though it is not possible to parse out the contribution of specific uses to the measured values, these data support that releases occur at locations with relevant uses to the PMN substances, which contribute to the environmental load of MCCP congener groups and in some cases result in RQs greater than one.

For soil concentrations, EPA/OPPT was unable to calculate RQs for terrestrial organisms due to the absence of relevant measured data from biosolid-amended soils. Though Iozza (2010) and Wang et al. (2013) reported measured levels of MCCPs in soil, the samples were collected from sites in remote alpine locations or industrialized areas, respectively. These data are relevant for assessing airborne deposition of MCCPs/LCCPs; however, the reported concentrations are of questionable relevance with informing concentrations of MCCPs/LCCPs that may occur in biosolid-amended agricultural soils.

Due to the foregoing limitations and resulting uncertainties with the measured environmental data, EPA/OPPT used these data in a limited capacity for estimating potential risks associated with the use categories identified for P-14-0683 and 0684. Specifically, these data were used as supporting information to inform the relevant pathways for estimating potential releases from relevant use categories for the PMN substances. A summary of the estimated release values and associated RQs that EPA/OPPT used as the primary basis for evaluating the potential risks of P-14-0683 and 0684 is presented in the following section.

6.1.2 Risk Estimates Using Modeled Exposures

The RQs shown in Table 11 suggest that the intended processes and uses for P-14-0683 and 0684 are expected to result in releases to surface water at concentrations that may present an unreasonable risk of injury to aquatic organisms.

It is noteworthy that these estimated concentrations are within the range of measured surface water concentrations reported for MCCP congener groups (Table 6). Though there is uncertainty whether the form (*i.e.*, dissolved or particle bound) of MCCP impacts the aquatic toxicity, the estimated values suggest that either form may exist. The median stream flow estimates are all below the reported water solubility for both PMN substances (Table 1). Since the available aquatic toxicity data support that dissolved MCCP congener groups cause toxicity, the median stream flow values suggest that the risk finding for this scenario is plausible. The low stream flow and 7Q10 flow scenarios estimate water concentrations that far exceed the estimated water solubility of P-14-0683 and P-14-0684. Under these scenarios, the MCCP congener groups would likely be bound to particulates and would eventually settle out in sediment. Nicholls et al.

(2001) provided support for this pathway and showed that sediment concentrations of MCCP congener groups generally increased with distance downstream from the source outfall. Based on the foregoing information, EPA/OPPT concludes the following: 1) the median stream flow values were adequate for determining that environmental releases of P-14-0683 and P-14-0684 may present an unreasonable risk of injury to aquatic organisms; and 2) it was unnecessary to estimate sediment concentrations of MCCP congener groups because any potential risks to sediment-dwelling organisms would be managed by addressing the risks identified for aquatic organisms.

Table 11: Risk Assessment of Aquatic Organisms Using Modeled Exposures[1]

Scenario	Estimated Water Concentrations (µg/L)[2]			RQs
	Median Stream Flow Scenario	Low Stream Flow Scenario	7Q10 Flow Scenario	
Proc1 – Formulation of MWFs[1]	5.6	40	206	5.6 – 206
Proc2 – Compounding of rubber products	35	257	1310	3.5 – 1310
Use1 – Use of MWFs	3	37	333	3 – 333
Use2 – Converting rubber products	1.1	12.8	110	1.1 - 110

[1]Taken from full model run of summary data presented in Appendix E (only summary table presented in Appendix). Full model runs are available on request.
[2]For PMNs, EPA/OPPT evaluated potential environmental risks by performing a PDM as described above and in the Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0 Documentation Manual (2007)", available at: http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf

6.2 Human Health

EPA/OPPT assessed potential risks to workers and the general population by calculating margins of exposure (MOE). This approach is performed according to the following equation:

MOE = Point of Departure (POD) ÷ Estimated human exposure

For the PODs, EPA/OPPT identified effect levels from an oral repeated dose toxicity study, which served as the basis for calculating human equivalent doses (HEDs). CXR (2005) reported a NOAEL of 23 mg/kg-bw/day based on increased kidney weight at 222 mg/kg-bw/day in male rats exposed through diet for 90 days to an MCCP congener group (C_{14-17}, 52 wt% Cl).

Using the effect levels of 23 mg/kg-bw/day, EPA/OPPT performed route-to-route extrapolations to develop HEDs for inhalation and dermal exposures in workers and for inhalation and oral exposures in the general population. EPA/OPPT did not assess oral exposures for workers, due to the unlikely nature of exposures occurring by this route. The respective HEDs served as the PODs for calculating MOEs, along with the previously reported estimated human exposure values for workers (Table 9) and the general population (Table 8).

EPA/OPPT compared the MOEs to a benchmark value that consisted of a multiplicative composite of three possible uncertainty factors (UFs): intraspecies variability (UF_H; default value = 10), interspecies variability (UF_A; default value = 10), and LOAEL-to-NOAEL extrapolation uncertainty (UF_L; default value =10). The UF_H and UF_A may each be subdivided to account for toxicokinetics (TK; default value = 3.16) and toxicodynamics (TD; default value = 3.16). When effect levels from experimental animal studies are converted to HEDs, the Agency's default approach is to reduce the TK subfactor of UF_A to 1 (*i.e.*, $UF_A = TK \times TD = 1 \times 3.16 \approx 3$).

EPA/OPPT interpreted MOEs that were equal to or below a benchmark value (*e.g.*, MOE $\leq$ 1000 [$UF_H \times UF_A \times UF_L = 1000$]) as an indication that the scenario(s) may present an unreasonable risk of injury to human health, whereas the MOEs that were above the benchmark value as a low risk finding. In the following sections, more detailed descriptions are provided on: 1) converting effect levels to route- and exposure-specific HEDs; 2) determining the appropriate UFs for the benchmark value, and 3) evaluating risk estimates for workers and the general population.

6.2.1 Workers

EPA/OPPT performed route-to-route extrapolations to convert the oral NOAEL of 23 mg/kg-bw/day (*i.e.*, MCCP congener groups to an HED value for inhalation exposures to workers (*i.e.*, $HED_{INHAL\text{-}WORKER}$) using the following equation:

$$HED_{INHAL\text{-}WORKER} = NOAEL_{ORAL} \times (1 \div sRV_{RAT}) \times (ABS_{ORAL\text{-}RAT} \div ABS_{INHAL\text{-}HUMAN}) \times (sRV_{HUMAN} \div wRV)$$

where,

$NOAEL_{ORAL}$ = 23 mg/kg-bw/day
sRV_{RAT} = rat standard respiratory volume for 8-hours = 0.38 m^3/kg bw
$ABS_{ORAL\text{-}RAT}$ = percent absorption by the oral route in rats = 50%
$ABS_{INHAL\text{-}HUMAN}$ = percent absorption by inhalation in humans = 50%
sRV_{HUMAN} = human standard respiratory volume for 8-hours = 6.7 m^3
wRV = worker respiratory volume for 8-hours = 10 m^3

Using this algorithm, the oral NOAEL of 23 mg/kg-bw was calculated to be an $HED_{INHAL\text{-}WORKER}$ values of 41 mg/m^3.

EPA/OPPT calculated the HED values for dermal exposures to workers (*i.e.*, $HED_{DERM\text{-}WORKER}$) based on the following equation:

$$HED_{DERM\text{-}WORKER} = NOAEL_{ORAL} \times (ABS_{ORAL\text{-}RAT} \div ABS_{DERMAL\text{-}HUMAN}) \times (BW_{RAT} \div BW_{HUMAN})^{1/4}$$

where,

$NOAEL_{ORAL}$ = 23 mg/kg-bw/day
$ABS_{ORAL\text{-}RAT}$ = percent absorption by the oral route in rats = 50%
$ABS_{DERM\text{-}HUMAN}$ = percent absorption by the dermal route in humans = 1%
BW_{RAT} = rat bodyweight = 0.250 kg

BW_{HUMAN} = human bodyweight = 71.8 kg

The resulting $HED_{DERM\text{-}WORKER}$ values equal 4600 mg/kg-bw/day for MCCP congener groups.

EPA/OPPT used the foregoing HED values to inform the appropriate application of UFs to derive benchmark values. For MCCP congener groups, a benchmark value of 30 was applied. This value consisted of the following individual UFs. A default UF_H of 10 was applied due to the absence of experimental data to inform the TK and TD subfactors of this UF. A reduced UF_A of 3 was applied to account for a TK subfactor of 1 after converting the effect levels to HEDs (i.e., the use of allometric scaling). The UF_A of 3 accounted for the remaining uncertainty associated with TD variability. Thus, the acceptable MOE would be 30 (10 times 3).

EPA/OPPT used the $HED_{INHAL\text{-}WORKER}$ and $HED_{DERM\text{-}WORKER}$ values for calculating the respective MOEs using the estimated exposure values presented in Table 9. As shown in Table 12, the MOEs for P-14-0683 and P-14-0684 all exceeded the respective benchmark value of 30, which indicate a finding of no risk to workers for the processes and uses evaluated in this assessment.

Table 12: Occupational MOEs for P-14-0683 and P-14-0684

Exposure Route	Exposure Scenario[1]	Margins of Exposure (Benchmark MOE = 30)
Inhalation	Manufacturing	No exposure
	Proc 1 – MWF Processing	No exposure
	Proc 2 – Compounding rubber	186 – 27,333
	Use 1 – MWF	155 – 547
	Use 2 Converting rubber	55 - 1171
Dermal	Manufacturing	27,523 – 30,025
	Proc 1 – MWF Processing	15,013 – 97,141
	Proc 2 – Compounding rubber	15,013
	Use 1 – MWF	89,265 – 127,031
	Use 2 Converting rubber	Non-quantifiable
[1]Processing 1= Formulation of metal working fluids, Processing 2 = compounding of rubber products, Use 1 = use of metal working fluids, Use 2 = converting rubber products		

6.2.2 General Population (from Environmental Releases)

EPA/OPPT converted the oral NOAEL of 23 mg/kg-bw/day to an HED value for oral exposures to the general population (*i.e.*, $HED_{ORAL\text{-}GENPOP}$) using the following equation:

$$HED_{ORAL\text{-}GENPOP} = NOAEL_{ORAL} \times (ABS_{ORAL\text{-}RAT} \div ABS_{ORAL\text{-}HUMAN}) \times (BW_{RAT} \div BW_{HUMAN})^{1/4} \times (5 \text{ days} \div 7 \text{ days})^{a}$$

where,

$NOAEL_{ORAL}$ = 23 mg/kg-bw/day
$ABS_{ORAL\text{-}RAT}$ = percent absorption by the oral route in rats = 50%

$ABS_{ORAL\text{-}HUMAN}$ = percent absorption by the oral route in humans = 50%
BW_{RAT} = rat bodyweight = 0.250 kg
BW_{HUMAN} = human bodyweight = 71.8 kg
[a]A duration-specific adjustment was only applied to the oral LOAEL of 100 mg/kg-bw/day because the animals were gavaged five days per week.

For assessing inhalation exposures to the general population, EPA/OPPT performed route-to-route extrapolations to convert the oral NOAEL of 23 mg/kg-bw/day to an HED value for inhalation exposures to the general population (*i.e.*, $HED_{INHAL\text{-}GENPOP}$) using the following equation:

$$HED_{INHAL\text{-}HUMAN} = NOAEL_{ORAL} \times (1 \div sRV_{RAT}) \times (ABS_{ORAL\text{-}RAT} \div ABS_{INHAL\text{-}HUMAN}) \times (5 \text{ days} \div 7 \text{ days})^{a}$$

where,

$NOAEL_{ORAL}$ = 23 mg/kg-bw/day
sRV_{RAT} = rat standard respiratory volume for 8-hours = 1.15 m^3/kg bw
$ABS_{ORAL\text{-}RAT}$ = percent absorption by the oral route in rats = 50%
$ABS_{INHAL\text{-}HUMAN}$ = percent absorption by inhalation in humans = 50%
[a]A duration-specific adjustment was only applied to the oral LOAEL of 100 mg/kg-bw/day because the animals were gavaged five days per week.

For the oral NOAEL of 23 mg/kg-bw/day, the $HED_{INHAL\text{-}GENPOP}$ value is equal 20 mg/m^3.

The same benchmark value of 30 was used for evaluating the general population MOEs. These benchmark values consisted of the same individual UFs and rationale discussed previously for workers.

EPA/OPPT used the $HED_{ORAL\text{-}GENPOP}$ and $HED_{INHAL\text{-}GENPOP}$ values for calculating the respective MOEs using the estimated exposure values presented in Table 8. As shown in Table 13, the MOEs for P-14-0683 and P-14-0684 all exceeded the respective benchmark values, which indicate a finding of no risk to the general population for environmental exposures that may occur due to the processes and uses evaluated in this assessment.

Table 13: General Population MOEs for P-14-0683 and P-14-0684 [1]

Scenario	Water Release		Air Release
	Drinking Water MOE[2] (Benchmark MOE = 30)	Fish Ingestion MOE (Benchmark MOE = 30)	Stack Air MOE (Benchmark MOE = 30)
Manufacturing	7.7×10^6	1.5×10^6	1.2×10^4
PROC1:Formulation of MWFs	6.2×10^5	1.2×10^5	6.2×10^3
PROC2: Compounding Rubbers	9.5×10^4	1.6×10^4	2.8×10^3
USE1: Use of MWF	6.6×10^5	1.3×10^5	3.6×10^4
USE2: Converting Rubber	1.9×10^6	3.7×10^5	2.7×10^3

[1]Taken from Appendix E. Values represent the highest concentrations/estimated doses (reported as the lifetime average daily dose, or LADD) for chronic (*i.e.*, repeated exposure scenarios) for human health.
[2] MOE = margin of exposure. In this risk assessment, MOEs of greater than 30 is acceptable.

7 CONCLUSIONS

Based on its assessment of the available hazard and exposure information on P-14-0683/0684, EPA/OPPT concludes the following pertaining to the potential manufacturing, processing and use of these PMN substances

5. Occupational Exposures: given the assumptions, data and scenarios evaluated in this assessment, there were no risks found for workers from either dermal or inhalation exposures.

6. General Population Exposures (from environmental releases): given the assumptions, data and scenarios evaluated in this assessment, there were no risks found to humans from environmental releases via exposure to drinking water or fish ingestion.

7. Environmental Assessment:
   a. Using estimated environmental concentrations, the PMN substances **may present an unreasonable risk following acute and chronic exposures to aquatic organisms.**

   b. Using available measured concentrations of MCCP congener groups in the environment as supporting information, the PMN substances:
      iii. Are expected to partition to sediment and may partition to soil through land application of biosolids and,
      iv. May be released to the environment at levels at or above estimated concentrations of MCCP congener groups that **may present an unreasonable risk following acute and chronic exposures to aquatic organisms.**

8. PBT Assessment: The PMN substances **may be very persistent and very bioaccumulative**.

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9 APPENDICES

Appendix A ENVIRONMENTAL FATE AND BIOACCUMULATION STUDY SUMMARIES

A-1 ENVIRONMENTAL PERSISTENCE

A-1-1 Abiotic Degradation

Generally, CPs are stable to hydrolysis and to direct photolysis in air and water, though very limited data exist on hydrolysis and direct and indirect photolysis in soil, water, or air. In studies using aliphatic hydrocarbon solvents, CPs were shown to be poor absorbers of UV light and no direct photodegradation was observed (Friedman and Lombardo, 1975; Lombardo et al., 1975). Koh and Thiemann (2001) studied photolysis of aqueous solutions for CPs products with chain lengths ranging from C_{10} to C_{24} including an MCCP product, Hoechst CP52, with chain lengths from C_{12} to C_{18} and an average of 52 wt% Cl. A mercury vapor lamp with main radiation wavelengths of 254, 302, 313, 366,405/408, and 436 was used in batch experiments. Following a 5 hour radiation time, estimated atmospheric degradation rates showed photolysis half-lives of less than 20 hours based on measurement of free chloride and analysis of degradation products. The MCCP product had a $T_{1/2}$ of 12.8 hour in aqueous solution. The addition of peroxide or acetone increased the photolysis rate suggesting that indirect photolysis may be significant. The authors also reported that longer chain CPs were formed during this study and speculated that recombination of smaller alkyl radicals could occur under some conditions.

Thermal degradation data for MCCPs and LCCPs are limited, but studies of SCCPs and Polyvinyl chlorides suggest MCCPs are degraded rapidly at 250 - 350 °C (Bergman et al., 1984). Dehydrohalogenation may lead to the formation of a large number of aliphatic and aromatic compounds. Chlorine radical formation can lead to production of highly chlorinated aromatics including polychlorinated biphenyls. Higher Cl content results in production of greater numbers and amounts of chlorinated aromatics (Bergman et al., 1984).

A-1-1-1 Fate in Air

As noted above, CPs lack structural components that absorb light in the UV or visible spectrum, so direct photolysis is not expected to occur. The atmospheric half-life has been estimated at 1 - 2 days (EA, 2009; ECB, 2005), based on estimated values for the second order rate constant for reaction with atmospheric hydroxyl radicals for MCCPs with lower chlorine contents between 40 and 56 wt%. EPA/OPPT also estimated atmospheric half-lives for MCCPs (40 and 70 Cl wt%) calculated using EPI Suite™/AOPWIN™ (v. 1.92a) that range from about 1 to > 4 days (see Table_Apx A-1). MCCPs with the shorter chain lengths and higher chlorine contents were calculated to be more persistent.

MCCPs have low estimated vapor pressures (4.5×10^{-8} to 2.27×10^{-3} Pa at 20 - 25°C) and a Henry's law constant (HLC) (0.014 - 51.3 Pa × m^3/mol for $C_{14\text{-}17}$ congener groups) and are not expected to partition to air. They may be transported associated with particulate matter, and have been reported in indoor and outdoor air and house dust (Barber et al., 2005; Fridén et al., 2011; Hilger et al., 2013). Wide spread soil contamination and occurrence in artic samples suggest that

MCCPs behave similarly to other chlorinated persistent organic pollutants (POPs) with high production volumes and releases, and are subject to long range transport (Dick et al., 2010; Medeiros et al., 2011; Tomy et al., 2000).

Table_Apx A-1: Estimated Atmospheric Half Lives Using EPI Suite™/AOPWIN™ (v. 1.92a) for Varying MCCP Chain Length and Chlorination Percents Based on Wt.

Chain Length	40 Cl Wt%	70 Cl Wt%
C_{14}	1.0	4.4
C_{15}	0.8	3.0
C_{16}	0.8	3.0
C_{17}	0.8	2.9

A-1-2 Biodegradation

EPA/OPPT reviewed studies from the open literature and submitted to the Agency including those described in the Canada and EU assessments and referenced in Table_Apx A-2 (EC, 2008a; ECB, 2005) to determine biodegradation under a variety of environmental conditions. Some of these studies used modified test conditions to enhance or maximize biodegradation. EPA/OPPT concurs with the EU's conclusions that under these modified test conditions, C_{14} 41.3% by wt. Cl and a C_{14} 45.5% by wt. Cl substances are readily biodegradable. C_{15} 51% by wt. Cl were found to be inherently degradable and possibly readily degradable in modified OECD 301 and 301D tests. This suggests that CPs with these chain lengths and shorter, and this degree of chlorination and lower, are inherently degradable. More highly chlorinated and longer carbon chain CPs ($C_{14\text{-}17}$ 51.7% by wt. Cl, C_{14} 55% by wt. Cl, C_{14} 60.2% by wt. Cl, and $C_{14\text{-}17}$ 63.2% by wt. Cl) biodegraded over a range of 2-54% in 28 days to 4-57% at up to 60 days. The most highly chlorinated, (C14-17, 63.2 wt% Cl) biodegraded 5% in 28 days and 10% at 60 days in the enhanced biodegradation studies, suggesting that longer chain and higher chlorination can contribute to greater persistence under most environmental conditions. (Van Ginkel, 2014 a and b; Van Ginkel 2010 a-d; Van Ginkel and Louwerse 2010 a and b).

A-1-2-1 Fate in Wastewater Treatment

In its review of the available measured data on MCCPs in wastewater treatment from data in from other countries, EPA/OPPT determined that CPs are present in the majority of municipal waste water treatment plant (WWTP) influent (Coelhan, 2010; Nicholls et al., 2001; Stevens et al., 2003; Zeng et al., 2013). Low water solubility and relatively high partitioning coefficients suggest that most of the MCCPs and LCCPs entering WWTP systems will associate with solids. Some biodegradation of shorter chain, lower chlorinated MCCP congener groups may occur, while longer chain length, more chlorinated congener groups will be resistant to aerobic and anaerobic degradation. Shorter and lower chlorinated congener groups have higher vapor pressure and may be lost to the vapor phase during aeration. WWTP effluent also contains some particulate-associated MCCPs. Because of their low water solubility, little MCCP or LCCP will be in the dissolved phase, and the majority will be removed along with settled sludge. Once associated with the sludge, the CPs will generally be stable in sludge treatment and remain in the residual biosolids. Land application of biosolids will transfer the MCCPs and LCCPs to

agricultural and other soils (Nicholls et al., 2001; Stevens et al., 2003). Because 50 - 60% of biosolids in the US are land applied, the majority of MCCPs and LCCPs entering WWTPs may be released to the environment via application to soil, and may be transported from contaminated soil to other locations and media by soil erosion, runoff, and wind borne particulates, and volatilization.

A-1-2-2 Fate in Surface and Groundwater

Because they generally have low water solubility, high sorption coefficients, and tend to partition to solids, MCCPs and LCCPs released to surface water will partition to surficial sediment where they may be buried and removed from potential degradation processes. This explains what is found in the limited monitoring data that exist - MCCP concentrations in surface water are generally in the low pg/L range, while sediment concentrations are several orders of magnitude higher (EC, 2008a).

MCCPs may leach from soil and be transported to groundwater, but low solubility and high sorption will act to keep dissolved concentrations very low. Facilitated transport with colloids and particulates may occur so that MCCPs can be transported in groundwater, but in general, concentrations in this compartment are expected to be very low. MCCPs that are introduced to groundwater will tend to partition to the solid phase and not be mobile.

A-1-2-3 Fate in Soil

Existing monitoring data suggest that MCCPs are present in soil, probably as a result of atmospheric transport and deposition. Areas near sources, such as land receiving wastewater biosolids, manufacturing and processing facilities, and electronic waste processing and recycling facilities are shown to have higher levels (Wang et al., 2013). MCCPs are expected to be stable in soil, and once deposited, could remain/persist in the soil for years or decades. Burial and advective transport away from the site of deposition are the major dissipation processes. No data are available on soil photolysis, although aqueous photolysis data suggest that indirect photolysis may result in degradation to shorter and less chlorinated CP congener groups. No soil biodegradation data exists, but some strains of bacteria that can co-metabolize MCCPs have been identified (Allpress and Gowland, 1999). If degradation does occur, it is expected to be slow with $T_{1/2}$ of at least months to years.

Table_Apx A-2: Review of MCCP and LCCP Biodegradation Studies

Biodegradation Studies on MCCPs (C_{14-17}) and LCCPs ($C_{>18}$)					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length, wt% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
MCCPs					
Van Ginkel	2010d	C_{14} 45 wt% Cl	Closed bottle	28 days	Approximately 64% degraded in 28 days Based on oxygen demand
Van Ginkel	2010b	C_{14-17} 45.6 wt% Cl	Closed bottle	28 days	Approximately 51% in 28 days and 63% in 42 days degradation Based on oxygen demand
Van Ginkel	2010c	C_{14-17} 51.7 wt% Cl	Closed bottle	28 days	Approximately 27% degradation in 28 days and 57% after 60 days Based on oxygen demand
Van Ginkel	2010a	C_{14-17} 63.2 wt% Cl	Closed bottle	28 days	Approximately 5% degradation after 28 days and 10% after 60 days.
Van Ginkel and Louwerse	2010a	C_{14} 41.3-60.2 wt% Cl%	Closed bottle with river water and sludge inoculum	28 days	Approximately 66% (41.3 wt% Cl) to 11 (60.2 wt% Cl) degradation in 28 days respectively
Van Ginkel and Louwerse	2010b	C_{14} 41.3-50 wt% Cl	Batch reactor	21 and 105 days	41.3 wt% Cl: 79% degradation in 21 days and 94% at 105 days 50 wt% Cl: 14% degradation by 21 days 5 wt% Cl in 80 days based on quantitation of released chloride
Conclusions: Quantification of degradation was by oxygen uptake or chloride release. No information on the chemical distribution in the test material or degradates was provided. These studies used modified test conditions to enhance or maximize biodegradation. Under these modified test conditions, C_{14} 41.3 wt% Cl and a C_{14} 45.5 wt% Cl substances are readily biodegradable. More highly chlorinated and longer carbon chain CPs (C_{14-17} 51.7 wt% Cl, C_{14} 55 wt% Cl, C_{14} 60.2 wt% Cl, and C_{14-17} 63.2 wt% Cl) biodegraded over a range of 2 – 54% in 28 days to 4 – 57% at up to 60 days. The most highly chlorinated, (C_{14-17} 63.2 wt% Cl) biodegraded 5% in 28 days and 10% at 60 days in the enhanced biodegradation studies, suggesting that longer chain and higher chlorination can contribute to greater persistence under most environmental conditions.					
Van Ginkel	2014b	C_{15} 51 wt% Cl	Closed bottle (301D)	60 day	43% and 63% degradation at 28 and 60 days

Biodegradation Studies on MCCPs (C_{14-17}) and LCCPs ($C_{>18}$)					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length, wt% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
Van Ginkel	2014a	C_{15} 51wt% Cl	Closed bottle (301)	60 day	37% and 57% degradation at 28 and 60 days
Conclusions: Unlike the 2010 series of studies, these most recent biodegradation studies did not have significant protocol modifications and the C_{15} 51 wt% Cl were found to be inherently degradable and possibly readily degradable in OECD 301 and 301D tests.					
Madeley and Birtley	1980	C_{14-17} mixed product, 40 wt% Cl	BOD test	25 days	Approximately 15.5% degradation as measured by theoretical BOD in non-acclimated samples and 22.5% degradation in acclimated samples.[1]
Madeley and Birtley	1980	C_{14-17} mixed product, 45 wt% Cl	BOD test	25 days	Approximately 10% degradation as measured by theoretical BOD in non-acclimated samples and 30% degradation with acclimated soil microbes added.[1]
Madeley and Birtley	1980	C_{14-17} mixed product, 52 wt% Cl	BOD test	25 days	Approximately 4% degradation as measured by theoretical BOD in non-acclimated samples and 6% degradation with acclimated soil microbes added.[1]
Madeley and Birtley	1980	C_{14-17} mixed product, 58 wt% Cl	BOD test	25 days	No significant degradation
Conclusions: The data from Madeley and Birtley suggests the potential for biodegradation but has significant limitations. The BOD studies were done on mixed products. No attempt was made to determine which specific congeners were degraded or the reaction products. No identification of the congeners present was provided. The degradation was estimated from the BOD but other compounds may have contributed to the ThBOD in the bottles. BOD measurements are highly variable as evidenced by the decrease in the C_{20-30} 42% of > 50% between day 20 and 25. [1]The ThOD (theoretical oxygen demand) was estimated (ThOD (g O_2/g substance) = 16[2×c+0.5×(h-cl)]/mw; where c=number of carbon atoms, h=number of hydrogen atoms, cl=number of chlorine atoms and MW = molecular weight). This is questionable for a product containing mixture of congeners as was used in all studies.					
LCCPs					
Madeley and Birtley	1980	C_{20-30} mixed product, 42 wt% Cl	BOD test	25 days	Approximately 7.5% degradation as measured by theoretical BOD in non-acclimated samples and 23% degradation with acclimated soil microbes added.[1]

Biodegradation Studies on MCCPs (C_{14-17}) and LCCPs ($C_{>18}$)					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length, wt% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
Madeley and Birtley	1980	C_{25} "chlorinated pentacosane"	^{14}C on central carbon	8 weeks (mean)	11% of ^{14}C- released as CO_2. Non-acclimated microbes.
Conclusions: The data from Madeley and Birtley suggests the potential for biodegradation but has significant limitations. The BOD studies were done on mixed products. No attempt was made to determine which specific congeners were degraded or the reaction products. No identification of the congeners present was provided. The degradation was estimated from the BOD but other compounds may have contributed to the ThBOD in the bottles. BOD measurements are highly variable as evidenced by the decrease in the C_{20-30} 42% of > 50% between day 20 and 25. [1]The ThOD (theoretical oxygen demand) was estimated (ThOD (g O_2/g substance) = 16[2×c+0.5×(h-cl)]/mw; where c=number of carbon atoms, h=number of hydrogen atoms, cl=number of chlorine atoms and MW = molecular weight). This is questionable for a product containing mixture of congeners as was used in all studies.					
Hildebrecht	1972	C_{20-30} mixed product, 42 wt% Cl	BOD test	5 days	25% degradation. Degradation was estimated by the authors as the% of the theoretical BOD based on the total carbon content of the test solution. Substances other than the chlorinated paraffin contributed to this total carbon content.
Hildebrecht	1972	> C_{20-30} mixed product, 70 wt% Cl	BOD test	5 days	2% degradation. Degradation was estimated by the authors as the% of the theoretical BOD based on the total carbon content of the test solution. Substances other than the chlorinated paraffin contributed to this total carbon content.
Hildebrecht	1972	> C_{20-30} mixed product, 70 wt% Cl	BOD test	5 days	65% degradation. Degradation was estimated by the authors as the% of the theoretical BOD based on the total carbon content of the test solution. Substances other than the chlorinated paraffin contributed to this total carbon content.
Conclusions: As described by the (EA, 2009), Hildebrecht's results are questionable (Hildebrecht, 1972). This report is not available so it cannot be reviewed directly, but others have reported that it provided limited details. A surfactant, other carbon sources, and nutrients were added that may have contributed BOD. The extent of degradation was determined by the comparing the oxygen consumption					

Biodegradation Studies on MCCPs (C_{14-17}) and LCCPs ($C_{>18}$)					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length, wt% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
in the test with the theoretical oxygen demand (ThOD) based on oxidation to CO_2 of the total organic carbon present in the solution from all sources. This estimation of ThOD does not take into account oxygen consumption by other compounds or the unknown composition. Of the CPs in the mixture, as the UK report concludes, "It is not possible to draw definite conclusions as to the degradability of the chlorinated paraffins in these tests" (EA, 2009).					
Hoechst AG	1976 and 1977	C_{18-20}, 35 wt% Cl	BOD test	5 days	0.7% degradation
Hoechst AG	1976 and 1977	C_{18-20}, 44 wt% Cl	BOD test	5 days	< 1.2% degradation
Hoechst AG	1976 and 1977	C_{18-20}, 49 wt% Cl	BOD test	5 days	< 2.3% degradation
Hoechst AG	1976 and 1977	C_{18-20}, 52 wt% Cl	BOD test	5 days	< 0.6% degradation
Conclusions: The Hoechst reports from early industry studies are not available so it is not possible to directly review the data (Hoechst, 1976, 1977). Others (EA, 2009) have reported the limitations of the studies. Limited details of the studies were apparently reported by Hoechst. These tests were done on mixtures of congeners with unknown composition. They reported that the majority of the CPs were removed by sorption on to the solids so no degradation may have occurred that would have been detected as BOD. The tests were run for 5 days using non-acclimated sludge microbes so degradation may have been possible but had not yet occurred.					
Omori *et al.*	1987	$C_{24.5}H_{44.5}Cl_{6.5}$, 40.5 wt% Cl	Chloride release	48 hours	9.9% degradation using bacterial strain HK-3; 13% H15-4; 2.2% HK-6; 3.5% HK-8; 33% using mixed bacterial culture (HK-3, HK-6, HK-8 and HK-10)
Omori *et al.*	1987	$C_{24.5}H_{41}Cl_{10,}$ 50 wt% Cl	Chloride release	48 hours	3% degradation using bacterial strain HK-3; 9% H15-4; 1.8% HK-6; 2.6% HK-8
Omori *et al.*	1987	$C_{24.5}H_{30}Cl_{21,}$ 70 wt% Cl	Chloride release	48 hours	2.6% degradation using bacterial strain HK-3; 12% H15-4; 1.4% HK-6; 1.7% HK-8; 15% using mixed bacterial culture (HK-3, HK-6, HK-8 and HK-10)

Biodegradation Studies on MCCPs (C_{14-17}) and LCCPs ($C_{>18}$)					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length, wt% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
Conclusions: Omori et al. (1987) showed the potential for biodegradation using pure and mixed cultures in short (48 hour) incubations. No information on the starting mixtures were provided except average compositions. No data on the products were reported. Loss of Cl suggests dechlorination can occur and that lower Cl content or shorter chain lengths may be produced.					
Allpress and Gowland	1999	C_{18-20}, 48 wt% Cl	Chloride release	71 days	11% degradation using *Rhodococcus* sp. bacteria
Allpress and Gowland	1999	$C_{>20}$, 42 wt% Cl	Chloride release	71 days	14% degradation using *Rhodococcus* sp. bacteria
Conclusions: Allpress and Gowland (1999) also showed that CPs have the potential to biodegrade using pure culture. They used mixed congener products and did not provide any information on the composition of the starting material or the degradation products. They found that the *Rhodococcus* sp. was able to use CPs as carbon source as well as an energy source.					

[1]The ThOD (theoretical oxygen demand) was estimated (ThOD (g O_2/g substance) = 16[2×c+0.5×(h-cl)]/mw; where c=number of carbon atoms, h=number of hydrogen atoms, cl=number of chlorine atoms and MW = molecular weight). This is questionable for a product containing mixture of congeners as was used in all studies.

A-2 BIOCONCENTRATION AND BIOACCUMULATION

EPA/OPPT's review of measured data on bioaccumulation of MCCPs are somewhat limited and conclusions vary with type of CP product and species evaluated (Bengtsson et al., 1979; CPC, 1980, 1983a, 1983b; Fisk et al., 1999; Fisk et al., 1998; Houde et al., 2008; Madeley and Maddock, 1983a, 1983b; Madeley and Thompson, 1983; Renberg et al., 1986; Thompson et al., 2000).

The limited measured data on MCCPs and LCCPs, informed by data on SCCPs, suggests that bioaccumulation is a function of chain length and degree of chlorination (see Table_Apx A-3). Some MCCP chemicals with intermediate chain length and chlorination may be absorbed and retained. The available evidence for MCCP congener groups with intermediate chain lengths and chlorination suggests that some may have BCFs or BAFs greater than 1000 or 5000 (EC, 2008b; ECB, 2008). This suggests that some congener groups in MCCP products may be bioaccumulative or very bioaccumulative. In conclusion, some MCCP congener groups present in the products are both very persistent and very bioaccumulative.

Additional evidence for bioaccumulation of MCCPs is provided by Houde et al. (2008). Field-derived log BAFs for MCCPs (C_{14-15}), ranging from 6.5 to 7.3, were reported for several Lake Ontario aquatic species from multiple trophic levels. Canada's assessment of MCCPs also indicates that modeled BAFs for a number of MCCPs (using the Modified Gobas BAF Model with assumption of no metabolism), were all above 5000, suggesting high to very high bioaccumulation (EC, 2008a). Evidence of bioaccumulation in sediment-dwelling organisms is also provided in a study by Fisk et al. (1998). Biota-sediment accumulation factors (BASFs)

ranging from 0.6 to 4.4 were reported for oligochaetes, which indicate bioaccumulation of MCCPs from sediment to biota (USEPA, 2009).

The Houde et al. (2008) study also provides evidence of biomagnification of MCCPs. BMFs derived for food chains in Lake Ontario and Lake Michigan ranged from 1 to 15. More specifically, large BMFs were observed for all MCCP chain lengths in Lake Ontario, and for C_{14} MCCPs in Lake Michigan, indicating biomagnification. BMFs (2.4 – 7.7) were also above 1 for smelt and lake trout in Lake Michigan.

In laboratory studies with rainbow trout and oligochaetes, lipid-normalized equilibrium BMFs estimated from a first-order bioaccumulation model for constant dietary exposure ranged from 0.4 - 5.0 (Fisk et al., 1996; Fisk et al., 2000; Fisk et al., 1998).

Most of the laboratory-based BCF studies (Bengtsson et al., 1979; CPC, 1980, 1983a, 1983b; Fisk et al., 1999; Fisk et al., 1998; Houde et al., 2008; Madeley and Maddock, 1983a, 1983b; Madeley and Thompson, 1983; Renberg et al., 1986; Thompson et al., 2000), were reported to have been conducted at MCCPs concentrations above the water solubility limit and hence likely underestimate the true BCF (summarized in Appendix C). Furthermore, acetone as a solvent in these tests, so they do not adhere to OECD guidelines. Nonetheless, some BCF values estimated from these studies indicate MCCPs are bioaccumulative (*e.g.*, bleak and rainbow trout (32-2856) and BCF of 6920 for common mussel).

Table_Apx A-3: Review of MCCP and LCCP Bioaccumulation Studies

Bioaccumulation studies on MCCPs (C_{14-17}) and LCCPs (> C_{18})					
MCCPs					
Study Authors	**Publication Date**	**MCCP/LCCP Chemicals Evaluated (*i.e.*, C-length,% Cl)**	**Method**	**Study Duration**	**Noteworthy Results and Implications**
Houde *et al.*	2008	C_{14-15} Only	BAF = ([predator]/[water (filtered)]); BMF) = [predator]/[prey]) where the concentrations in predator and prey are on a lipid basis	Three sampling periods: October 2000, June 2002, and July 2004.	Issues related to the temporal variability of water concentrations over the period of biota sampling (1999 – 2004) in this study have been raised (ECB, 2005; EC, 2008) contributing to uncertainties associated with the reported BAF values. Log BAF = Plankton: C14=6.2; C15=6.6; ∑=6.5 Alewife: C14=7.0; C15=6.8; ∑=6.9 Sculpin: C14=7.4; C15=7.2; ∑=7.3 Rainbow smelt: C14=7.4; C15=7.1; ∑=7.2 Lake trout: C14=6.8; C15=6.5; ∑=6.6 BMF (Lake Ontario) = 0.25 (lake trout – alewife); 0.14 (lake trout – smelt); 8.7 (sculpin –Diporeia) BMF (Lake Michigan) = 0.22 (lake trout – alewife); 0.94 (lake trout – sculpin); 0.88 (sculpin – Diporeia)

Thompson et al.; as summarized in ECB, 2005	2000	n-pentadecane-8-^{14}C, 51% Cl mixed with a non-radio-labelled C_{14-17}, 51% Cl chlorinated paraffin	Freshwater; flow-through; acetone solvent used;	35 days	Steady-state may not have been achieved, so kinetic BCF data considered more reliable. BCF = 860 L/kg at 35 days when exposed at 0.9 ug/L BCF = 265 L/kg at 35 days when exposed at 4.9 ug/L kinetic BCF = 1,087 L/kg at 35 days when exposed at 0.9 ug/L kinetic BCF = 349 L/kg at 35 days when exposed at 4.9 ug/L
CPC (Madeley et al.); as summarized in ECB, 2005	1983	commercial product mixed with a n-pentadecane-8-^{14}C chlorinated to a similar degree	freshwater; flow-through; rainbow trout; acetone solvent used	60 days	Concentrations above water solubility; hence, water concentrations may be overestimated and BCF underestimated. Uncertainty as to whether steady-state was reached. BCF = 32-45 l/kg on a wet weight basis when exposed at 1.05 mg/l; BCF = 42-67 l/kg on a wet weight basis when exposed at the 4.5 mg/l
CPC (Madeley and Pearson); as summarized in ECB, 2005	1980	C_{14-17}, 45% Cl	freshwater; flow-through; rainbow trout;	28 days	Measured water concentrations questionable; water concentrations may be overestimated and BCF underestimated. BCF = 50-60 l/kg based on nominal exposure concentrations BCF = 280-600 l/kg based on measured water concentrations
Madeley and Maddock; as summarized	1983	Total MCCPs	Bioconcentration factors. MCCPs concentrations were above the water	No Information	BCF = 32 – 2856 for common mussel, bleak and rainbow trout. May not have reached steady-state.

in ECB, 2005			solubility limit, using acetone as the co-solvent in the test solutions, and hence are not in compliance with OECD guideline requirements		
Fisk et al.	1999	Average formula: $C_{14}H_{23.3}Cl_{6.7}$, 55% Cl	freshwater; medaka eggs	20-days	Uncertainty as to whether steady-state was reached; hence BCFs probably represent lower limit of true value BCF = 32- 680 L/kg
Fisk et al.	1998	$^{14}C_{16}$ 35% Cl and $^{14}C_{16}$ 69% Cl	Lake sediments were spiked and worms added after 18 and 32	No Information	Kinetic BAF probably represents the upper limit of the true bioaccumulation factor $^{14}C_{16}$ 35% Cl 14-day BSAFss = 0.7 Kinetic BSAF = 4.4 $^{14}C_{16}$ 69% Cl 14-day BSAFss = 0.2 Kinetic BSAF = 0.6
Bengtsson et al.	1979	$C_{14\text{-}17}$, 50% Cl	seawater; semi-static; bleak; acetone solvent used	14 days	Measured water concentrations questionable; water concentrations may be overestimated and BCF underestimated. BCF ~ 40 L/kg
Madeley and Thompson; as summarized	1983	commercial $C_{14\text{-}17}$, 52% Cl	seawater; flow-through; mussel acetone solvent used	60 days	BCFs = 2,182 L/kg (parent compound analysis) or 2,856 L/kg (^{14}C-measurements) when exposed to 0.22 mg/l

in ECB, 2005					BCF = 339 L/kg (parent compound analysis) or 429 l/kg (^{14}C measurements) when exposed to 3.8 mg/l.
Renberg et al.	1985	$C_{16}H_{30.7}Cl_{3.3}$ (34% Cl) and $C_{12}H_{16}Cl_{9.8}$ (68.5% Cl) mixture synthesized with ^{14}C radiolabel	Flow through exposure to mussel (*Mytilus edulis*) C_{16} - 0.13 and 5.0 µg/L	C_{16} - 28 day uptake C_{12} - 21 day uptake followed by 28 day depuration	Steady state BCF about 7000 for C16 and 140,000 for C12 based on 14C quantification. No chemical specific analysis for CPs. Metabolism and accumulation of degradation products may have accounted for high values.
LCCPs					
Bengtsson et al.; as summarized in ECB, 2005	1979	$C_{18–26}$	concentrations were above the water solubility limit and hence are not in compliance with OECD guideline requirements	No Information	Concentrations above water solubility; hence, water concentrations may be overestimated and BCF underestimated. Uncertainty as to whether steady-state was reached. BCF reported = 8 – 16 L/kg

Appendix B ECOTOXICITY STUDY SUMMARIES

B-1 MCCP ECOTOXICITY DATA

B-1-1 Acute Fish Toxicity

(1) Mayer and Ellersieck (1986)

A series of 96-hour acute fish toxicity studies were conducted by the United States Geological Survey's Columbia National Fisheries Research Laboratory with Paroil 1048 by Mayer and Ellersieck (1986). Although the chemical composition of Paroil 1048 is not defined in Mayer and Ellersieck (1986), the Chlorinated Paraffins Environmental Hazard Criteria developed by the United Nations Environment Programme (IPCS, 1996); identified Paroil 1048 as a product of Dover Chemical Company with the average molecular formula of $C_{15}H_{26}Cl_6$ and a chlorine content of 50 – 52% Cl. The studies followed a test guideline that was similar to ASTM guidelines. Bluegill sunfish (*Lepomis macrochirus*) and yellow perch (*Perca flavescens*) were exposed to the test substance (100% commercial formulation) in a flow-through test system. Channel catfish (*Ictalurus punctatus*) and rainbow trout (*Oncorhynchus mykiss*) were exposed to the test substance in a static test system. A solvent was not used for this exposure. The average pH level was between 7.4 and 7.5 for all tests. Test temperature was 12°C for bluegill sunfish, rainbow trout, and yellow perch and was 20°C for channel catfish. Dilution water hardness was 44 mg $CaCO_3$/L in the rainbow trout and channel catfish test system and 314 mg $CaCO_3$/L for the bluegill sunfish and yellow perch test system. Reported effect levels are considered to be nominal with LC_{50} values of > 10 mg/L for bluegill sunfish, channel catfish, and yellow perch and > 0.011 mg/L for rainbow trout; all values are greatly above the limit of solubility. Using a weight-of-evidence approach, these studies were considered acceptable to characterize the acute fish toxicity endpoint.

96-hr LC_{50} = No effects at saturation (NES)

(2) Linden et al. (1979)

A 96-hour acute fish toxicity study was published by Linden et al. (1979). Groups of 10 bleak (*Alburnus alburnus*) were exposed to six nominal unspecified concentrations of Cereclor S52 ($C_{14\text{-}17}$, 52% Cl), Chloroparaffin huls 40G ($C_{15.5}$, 40% Cl), and Witaclor 50 ($C_{14\text{-}17}$, 50% Cl) under static test conditions. Salinity was 7 ppt, pH was 7.8, temperature was 10°C, and dissolved oxygen was considered by study authors to be satisfactory. EPA/OPPT requires reporting of dissolved oxygen concentrations to determine study adequacy. EPA/OPPT also does not consider the test species, the bleak, a standard test species. The 96-hour fish LC_{50} values were > 10,000 mg/L, > 5,000, and > 5,000 for Cereclor S52, Chlorapraffin huls 40G, and Witaclor 50. Given effect levels observed in Mayer and Ellersieck (1986) and the reported water solubility of medium chain paraffins, these studies were considered acceptable to characterize the acute saltwater fish toxicity endpoint as 'no effects at saturation'.

96-hr LC_{50} = NES

B-1-2 Acute Aquatic Invertebrate Toxicity

(1) CPA (1996)

A 48-hour acute *Daphnia magna* toxicity study was conducted by CPA (1996) according to OECD TG 202 with GLP compliance using a static test system. The test substance was identified as Cereclor S52, a C_{14-17} chlorinated paraffin with 52% chlorination that contained 0.3% epoxy soya bean oil stabilizer as well as a small amount of radio labeled n-pentadecane-8-14C (51% chlorinated). Four replicates of 5 *D. magna* Straus (< 24 hours old) were exposed to nominal concentrations of 0 (dilution water control), 0 (solvent control), 0.0032, 0.0056, 0.01, 0.018, 0.032, 0.056, and 0.1 mg/L test substance in acetone (0.1 mL/L). Test solutions were prepared by adding the appropriate stock solution to dilution water while continuously and vigorously stirring with a magnetic follower. Appearance of test solutions was not provided. Corresponding mean measured concentrations determined by radiochemical methods were 0.0025, 0.0041, 0.0094, 0.015, 0.024, 0.047, and 0.095 mg/L. Daphnid loading was 25 daphnids/L. Over the course of the study dissolved oxygen concentrations remained between 9 and 9.2 mg/L, pH remained within 8 and 8.1, and temperatures were 20 ± 1°C. Dilution water had a total water hardness of 248 mg $CaCO_3$/L. At 48 hours, 0%, 45%, 90%, 75%, 85%, 100%, and 100% immobilization was observed at the mean measured concentrations of 0.0025, 0.0041, 0.0094, 0.015, 0.024, 0.047, and 0.095 mg/L, respectively. Red coloration on parts of the exoskeleton was observed in animals exposed to each of the test substance treatments, which the laboratory notes as being of an uncertain significance. The mean measured 48-hour EC_{50} was determined to be 0.0059 mg/L. The study was acceptable.
48-hr EC_{50} = 0.0059 mg/L

(2) Koh and Thiemann (2001)
A 48-hour acute Daphnia magna toxicity study was conducted at the University of Bremen, Department of Physical and Environmental Chemistry with CP 52 (C_{12-18}, 52% chlorination) according to DIN 38412 by Koh and Thiemann (2001). Study methods were not fully characterized. Additional communications with the study author Wolfram Thiemann clarified that a static test system was used with nominal test concentrations. Based on communications with the study author, local (Bremen, Germany) tap water was used without adjustments. Presumed pH was between 5 and 6 and water hardness was between 35.7 and 53.5 mg $CaCO_3$/L. Ambient laboratory air temperature was around 21°C. The solvent acetone was used to maintain test substance in solution. Floating effects at the surface of the water were observed in individual cases due to undissolved oil slicks, but communications with the study author noted that there was no significant loss of daphnids due to mechanical trapping since most daphnid swam away from these occasional slicks observed at the higher test concentrations. The 48-hour EC_{50} was 0.052 mg/L. Given the consistently high toxic effect levels observed in other daphnid studies, this study was considered acceptable to support the characterization of the acute daphnid toxicity endpoint.
48-hr EC_{50} = 0.052 mg/L

(3) CPA (1994)
A 48-hour acute *Daphnia magna* toxicity study was conducted by CPA (1994) according to OECD TG 202 with GLP compliance using a static test system. The test substance was identified as Cereclor S52, a C_{14-17} chlorinated paraffin with 52% chlorination that was mixed with an equal weight of radio labeled n-pentadecane-8-14C (51% chlorinated). Four replicates of 5 *D. magna* (< 24 hours old) were exposed to 0% (dilution water control), 6.3%, 12.5%, 25%, 50%, and 100% of stock solution containing test substance. The test substance was prepared in solution by: 1.) combining 0.75 g test substance and 25 mL acetone to a borosilicate glass conical flask, 2.) evaporation of the acetone using a stream of nitrogen, 3.) addition of 1.5 L dilution water, 4.) stirring for three days, and 5.) filtration of the aqueous phase. Radiochemical methods were used to determine the concentration of test substance in solution. Nominal

concentrations of 0 (dilution water control), 0.14, 0.28, 0.55, 1.1, and 2.2 mg/L were within 86 – 100% of measured concentrations. Concerns regarding test solution preparation methods and analytical technique were identified by the submitter that included increasing the level of more soluble impurities (*i.e.*, short chain chlorinated paraffins), questionable analytical monitoring results due to the presence of radio-labeled impurities, and abnormally low recovery of the chlorinated paraffin into hexane. Over the course of the study dissolved oxygen concentrations remained between 8 and 9 mg/L, pH remained within 8 and 8.1, and temperatures were 20 ± 1 °C. Dilution water had a total water hardness of 237 mg $CaCO_3$/L. Observed immobilization was limited to the highest test concentration (100% solution) with 55% immobilization.
The study is unacceptable since EPA/OPPT agrees that methods used to prepare the test solution and analyze the test concentrations were questionable.

(4) Frank (1993); Frank and Steinhauser (1994)
The following study summary (Frank, 1993; Frank and Steinhauser, 1994), provided in the ECB (2005) MCCP risk assessment, was considered supportive of the aquatic invertebrate hazard determination. The chlorinated paraffin used in these studies was a commercial C_{14-17} product with a 52% by weight chlorine content. Daphnia magna were exposed to nominal concentrations of either 100 mg/L or 10,000 mg/L. The 100 mg/L solution was sonicated for 1 hour and then left to stand in the dark for 48 hours before use. The 10,000 mg/L solution also stood for 48 hours in the dark before use, but this time without sonication. After this period, both solutions were filtered firstly with glass filters and then with membrane filters to remove undissolved test substance. The concentrations of medium-chain chlorinated paraffin in the water soluble fractions were then determined by AOX (adsorbable organic halogen) analysis (detection limit of 10 µg/L Cl was equivalent to around 20 µg/L of the chlorinated paraffin). This analysis showed that the concentration of chlorinated paraffin present in the water soluble fraction was around 0.404 - 0.500 mg/L for the 10,000 mg/L nominal solution and 0.071 - 0.142 mg/L for the 100 mg/L stock solution. The acute (48-hour) toxicity tests were carried out using dilutions of the two prepared water soluble fractions. The method used was DIN 38 412, Teil 11, which is equivalent to OECD 202.

In the tests using the water soluble fraction from the 100 mg/L nominal solutions no toxicity was seen at concentrations up to the undiluted stock solution (*i.e.*, no effects up to around 0.071-0.142 mg/L). In experiments using the water soluble fraction from the 10,000 mg/L stock solution, an EC_0 of 0.140 mg/L (also reported as 0.100 - 0.110 mg/L in the paper) and an EC25 of 0.423 mg/L (also reported as 0.420-0.470 mg/L in the paper) was determined (maximum mortality seen was 25%) (Frank, 1993). The latter results for the 10,000 mg/L stock solution were reported by Frank and Steinhauser (1994) as EC_0 = 0.140 mg/L and EC_{25} = 0.339 mg/L, and it was noted that some of the Daphnia were floating on the surface of the test solution. In the later study (Frank and Steinhauser, 1994), the results of further acute toxicity studies were reported using the same test method. An EC_{50} of 0.037 mg/L and an EC_0 of 0.009 mg/L were determined using the water soluble fraction from the 100 mg/L stock solution and no toxic effects were seen in tests with the water soluble fraction from the 10,000 mg/L stock solution (approximately $EC_0 \geq 0.525$ mg/L). The authors noted that the effects seen in the acute tests showed poor reproducibility, probably because effects were seen only around the water solubility limit of the substance. However, the authors thought that the possibility of undissolved droplets affecting the results could be ruled out, as floating Daphnia were only sporadically observed in the test.
The results of these studies should be treated with caution, as the effects were mainly seen in the saturated solutions only. **48-hour EC_{50} = 0.037 mg/L; 100 mg/L stock**

(5) Thompson and Gore (1999)
The following study summary (Thompson and Gore, 1999), provided in the ECB (2005) MCCP risk assessment, was considered supportive of the aquatic invertebrates hazard determination. The acute toxicity of C_{14-17}, 52% wt. Cl substance was tested using the freshwater crustacean *Gammarus pulex* and the freshwater daphnid, *Daphnia magna*. The medium-chain chlorinated paraffin used was dissolved in acetone and then added to beakers in two separate studies containing either *G. pulex* or *D. magna* to give nominal concentrations of 0.1, 0.32, and 1.0 mg/L. A control and solvent control (containing 0.1 mL/L acetone) were also run. The tests were carried out for 96 hours at 15 ºC, with the solutions being renewed after 48 hours. The water used in the study had a hardness of 220 mg/L as $CaCO_3$ and had a pH of 8.0 - 9.2. No mortalities of the *G. pulex* were seen in any of the test substance solutions or control. One animal died in the solvent control. Therefore, no significant toxic effects were seen with the medium-chain chlorinated paraffin over the concentration range tested. This contrasted markedly to the situation when *D. magna* were exposed using the same test system at 20°C over 48 hours, where complete immobilization was seen at the lowest test concentration (0.1 mg/L). The high immobilization rate observed in *D. magna* in this study appears consistent with the other studies and *G. pulex* appear to be a less sensitive to medium chained chlorinated paraffins then *D. magna*.

(6) Tarkpea et al. (1981)
The Tarkpea et al. (1981); as quoted in IPCS (1996) summary, provided in the ECB (2005) MCCP risk assessment, was considered supportive of the aquatic invertebrates hazard determination. The results of tests with the brackish water harpacticoid Nitocra spinipes have been reported (Tarkpea et al., 1981). No other details of the test were reported but the test method was probably the same as reported by Tarkpea et al. (1981), where a static method was employed using water of salinity 7‰ at a temperature of 20 - 22°C without aeration, probably using acetone as co-solvent.
The results are considered supportive to address aquatic invertebrate acute toxicity.
96-hour LC_{50} = 9 mg/L (C14-17, 45% wt Cl)
96-hour LC_{50} >10,000 mg/L (C14-17, 52% wt. Cl)

B-1-3 Algae Toxicity

(1) Thompson, Smyth, et al. (1997)
A 96-hour algae toxicity study was conducted by Thompson, Smyth, et al. (1997) according to OECD TG 201 with GLP compliance using a static test system. The test substance was a commercial product of a C_{14-17} chlorinated paraffin with 52% chlorination that contained 0.3% epoxy soya bean oil stabilizer as well as a small amount of radio labeled n-pentadecane-8-14C (51% chlorinated). *Selenastrum capricornutum* were exposed to nominal concentrations of 0 (dilution water control), 0 (solvent control), 0.1, 0.18, 0.32, 0.56, 1, 1.8, and 3.2 mg/L test substance in the solvent acetone. Six replicates were tested for the solvent control and three replicates were tested for each treatment and the dilution water control. A mean measured concentration of 0.49, 0.77, and 1.2 mg/L was determined using radiochemical analysis for the nominal concentrations of 1, 1.8, and 3.2 mg/L, respectively, but effects were reported based on nominal test concentrations. At the start of the test, the pH was 7.4 - 7.5, but had reached 10.0 - 10.3 by the end of the test. The shift in pH was thought to be a function of the high control growth rates observed in the test according to the study summary and may have affected the outcome of the study; however, the section-by-section coefficient of variation for the solvent control remained below 35% indicating acceptable control growth rates throughout the duration

of the study. The maximum inhibition in the growth rate and biomass seen was 3% and 18%, respectively, but a dose response relationship was not seen. Both the 72-hour and 96-hour EC_{50} values based on growth rate and biomass calculations were > 3.2 mg/L (nominal) or > 1.2 mg/L (mean measured). The nominal NOEC was 0.1 mg/L and the nominal LOEC based on 18% biomass inhibition was 0.18 mg/L. A MATC of 0.134 mg/L was calculated by EPA/OPPT as the geometric mean of the NOEC and LOEC. The study was considered acceptable.
72-hr E_rC_{50} = NES
72-hr E_bC_{50} = NES
72-hr $NOEC_b$ = 0.1 mg/L
72-hr $LOEC_b$ = 0.18 mg/L
72-hr MATC = 0.134 mg/L

(2) Koh and Thiemann (2001)
A 72-hour algae toxicity study was conducted by the University of Bremen, Department of Physical and Environmental Chemistry with CP 52 (C_{12-18}, 52% chlorination) according to DIN 38412 by Koh and Thiemann (2001). Study methods were not fully characterized. Additional communications with the study author Wolfram Thiemann clarified that a static test system was used with nominal test concentrations. *Scenedesmus subspicatus* were exposed to the test substance and cell density was determined using a particle counter. Based on communications with the study author, local (Bremen, Germany) tap water was used without adjustments. Presumed pH was between 5 and 6 and water hardness was between 35.7 and 53.5 mg $CaCO_3$/L. Ambient laboratory air temperature was around 21°C. The solvent acetone was used to maintain test substance in solution. Effects were calculated based on growth rate. No effects were observed up to 0.1 mg/L.
Due to deficiencies/missing details in the study methods, the study alone was not acceptable to characterize aquatic toxicity to plants.
72-hr NOEC = 0.1 mg/L (Highest Test Concentration)

B-1-4 Chronic Fish Toxicity

(1) CPC (1983b)
A 60-day fish toxicity study was conducted by Brixham Laboratories in 1983 with radio-labeled chlorinated (52%) n-pentadecane (Trade Name: Cereclor S52) under flow through testing conditions (CPC, 1983b). A full non-confidential study report was submitted under TSCA in 1983 as DCN 40-8332184 (OTS Fiche 0507258) (CPC, 1983b). Two replicates of 3 immature rainbow trout (Oncorhynchus mykiss, formerly Salmo gairdneri) per concentration were exposed to nominal concentrations of 0 (dilution water control), 0 (acetone control, 500 ppm), 1, or 5.6 mg/L in 500 ppm acetone. Corresponding mean measured concentrations were 0, 0, 1.05, and 4.5 mg/L. Test concentrations were determined by radio activity measurements. Flow rate of the test system was 0.25 mL/minute for exposure concentrations. No mortality or adverse sub-lethal behavioral effects were observed for the duration of the 60-day exposure period. Effects observed were limited to the highest test concentration and involved sluggish movements. The measured NOEC was identified as 4.5 mg/L. In addition to the hazard assessment, the submitter provided an assessment of bioconcentration which indicated that analytically determined exposure concentrations of 1.05 and 4.5 mg/L resulted in fish tissue concentrations of 34 and 190 µg/g wet weight, respectively. This study appears to have been previously reviewed by EPA/OPPT in 1985. The previous conclusion that "a fish full life cycle toxicity test or modification thereof is needed to address the effects of CPs present in fish eggs during embryonic development" is still relevant for MCCPs.

This study is considered unacceptable to characterize chronic population-level effects in fish.

(2) CPC, 1980
A 28-day fish toxicity study was conducted by Brixham Laboratories in 1978 with a $C_{14\text{-}17}$ chlorinated paraffin having 45% chlorination under unspecified testing conditions (CPC, 1980). The study report was submitted under TSCA in 1992 as DCN 88920006972 (OTS Fiche 0545375). Rainbow trout (Oncorhynchus mykiss) per concentration were exposed to nominal concentrations of 0 (dilution water control), 0.1, or 1 mg/L in acetone. The age and size of the rainbow trout used in the study were not specified in the study. The specific environmental conditions of the test, such as pH, temperature and water quality were not specified in the report. Concentrations of the chlorinated paraffin in the test water were measured using thin layer chromatography (TLC) analytical procedures resulting in mean measured concentrations of 0.01 and 0.18 mg/L. Mortality and behavior (response to food, general behavior, swimming behavior and pigmentation) were assessed during the 28-day study. Survival was 96.6 and 100% for the mean measured exposures of 0.01 and 0.18. No behavioral effects were seen over the course of the study.
The study was considered unacceptable to characterize the chronic fish toxicity endpoint since insufficient study details were provided including the age and/or the life-stages of the exposed organisms.

(3) Fisk et al. (1999)
A 20-day Japanese medaka (*Oryzias latipes*) embryo toxicity study was conducted with the formulation $C_{14}H_{24.9}Cl_{5.1}$, 48% Cl (composition: 10.5% 1, 2, 13, 14-tetrachlorotetradecane (42.3% Cl); 74.3% x, 1, 2, 13, 14-pentachlorotetradecane (47.7% Cl); 14.2% x, y, 1, 2, 13, 13-hexachlorotetradecane (52.6% Cl); 1.0% x, y, z, 1, 2, 13, 14-heptachlorotetradecane (56.4% Cl) by Fisk et al. (1999) under static testing conditions. Five sets of 10 vials containing 1 egg each were exposed to nominal concentrations of 0.001, 0.010, 0.100, 1, or 10 mg/L test substance starting after fertilization and terminating approximately 3 days post-hatch. No adverse effects were reported in exposed embryos.
The study was considered unacceptable primarily due to insufficient exposure duration and insufficient number of eggs per exposure concentration.

(4) Fisk et al. (1999)
A 20-day Japanese medaka (Oryzias latipes) embryo toxicity study was conducted with the formulation ^{14}C-$C_{14}H_{23.3}Cl_{6.7}$, 55% Cl (composition: 0.2% $C_{14}H_{26}Cl_4$ (42.3% Cl), 4.4% $C_{14}H_{25}Cl_5$ (47.7% Cl), 34% $C_{14}H_{24}Cl_6$ (52.6% Cl), 45% $C_{14}H_{23}Cl_7$ (56.4% Cl), 14% $C_{14}H_{22}Cl_8$ (59.9% Cl), and 1.9% $C_{14}H_{21}Cl_9$ (62.8% Cl)) by Fisk et al. (1999) under static testing conditions. Five sets of 10 vials containing 1 egg each were exposed to measured concentrations of 0.0014, 0.012, 0.120, 0.420, or 1.6 mg/L test substance starting after fertilization and terminating approximately 3 days post-hatch. No adverse effects were reported in exposed embryos. Concentrations of the test substance were found in larvae and eggs in a dose-dependent manner (with exception of the highest concentration) suggesting that the substance can diffuse through the egg shell. Corresponding measured concentrations in eggs were 0.04, 8.4, 63, 110, and 72 mg/kg and corresponding measured concentrations in larvae were 0.24, 8.2, 45, 84, and 51 mg/L.
The study was considered unacceptable primarily due to insufficient exposure duration and insufficient number of eggs per exposure concentration.

(5) Cooley et al. (2001) as summarized in ECB (2005)

The following summary provided in the 2005 European Chemical Bureau Risk Assessment of MCCP was considered supportive, but did not characterize all fish life-cycle stages (ECB, 2008). Cooley et al. (2001) studied the toxicity of $C_{14}H_{24.9}Cl_{5.1}$, 48% Cl [as described in (Fisk et al., 1999)] to juvenile rainbow trout (*Oncorhynchus mykiss*) through dietary exposure. Treatment groups of 10 fish were exposed to 0.78 and 2.9 mg/kg for 21 days and 0.082 mg/kg for 85 days. Three control groups were also run. Histological examination and analysis of the chlorinated paraffin concentration was performed in five fish per treatment after 21 days in the two higher test concentrations and in three fish per treatment after 85 days in the lowest test concentration. Three fish were also sacrificed from each low exposure group and the remaining control group (but were not analyzed) after 21 days of exposure. Quantitative histomorphological measurements were also carried out on livers and thyroid of the exposed fish in the middle exposure group after 21 days, and also the low exposure group after 85 days. The parameters investigated included hepatocyte nuclear diameter, hepatocyte volume index, nucleus:cytoplasm area ratio and thyroid epithelium cell height. Livers displaying mild hepatocyte necrosis and moderate to severe depletion of glycogen/lipids were reported for the 0.78 mg/kg exposure. At 2.9 mg/L abnormal behavior was observed from day 3 onwards. Quantitative effects following 21 days of exposure were limited to a significantly ($p = 0.05$) reduced mean hepatocyte volume in 2.9 mg/L exposure group.

This study is considered unacceptable to characterize chronic population-level effects in fish.

(6) Cooley et al. (2001)

Cooley et al. (2001) studied the toxicity of 14C-$C_{14}H_{23.3}Cl_{6.7}$, 55% Cl [as described in (Fisk et al., 1999)] to juvenile rainbow trout (Oncorhynchus mykiss) through dietary exposure. Treatment groups of 10 fish were exposed to 29 and 78 mg/kg for 21 days and 5.7 mg/kg for 85 days. Three control groups were also run. Histological examination and analysis of the chlorinated paraffin concentration was performed in five fish per treatment after 21 days in the two higher test concentrations and in three fish per treatment after 85 days in the lowest test concentration. Three fish were also sacrificed from each low exposure group and the remaining control group (but were not analyzed) after 21 days of exposure. Quantitative histomorphological measurements were also carried out on livers and thyroid of the exposed fish in the middle exposure group after 21 days, and also the low exposure group after 85 days. The parameters investigated included hepatocyte nuclear diameter, hepatocyte volume index, nucleus:cytoplasm area ratio and thyroid epithelium cell height. At 29 mg/kg abnormal behavior was observed from day 2 onwards and livers exhibited mild to moderate hepatocyte necrosis and moderate to severe depletion of glycogen lipids. Abnormal behavior from day 3 onward was also observed at 78 mg/kg.

This study is considered unacceptable to characterize chronic population-level effects in fish.

B-1-5 Chronic Aquatic Invertebrate Toxicity

(1) Thompson, Williams, et al. (1997)

A 21-day chronic Daphnia magna reproduction toxicity study was conducted by Thompson, Williams, et al. (1997) according to OECD 202, Part II using a static-renewal test system with renewal on Monday, Wednesday, and Friday of each week. The test substance was identified as Cereclor S52, a $C_{14\text{-}17}$ chlorinated paraffin with 52% chlorination that contained 0.3% epoxy soya bean oil stabilizer as well as a small amount of radiolabelled n-pentadecane-8-14C (51% chlorinated). Ten replicates of 1 Daphnia magna Straus (< 24 hours old) were tested per

exposure concentration, which did not comply with OECD 202, Part II requirements that at least 40 daphnid be tested per concentration. These small population sizes may have had an effect on significance testing to determine NOEC and LOEC values. Nominal concentrations were 0 (dilution water control), 0 (solvent control), 0.0056, 0.01, 0.018, 0.032, 0.056, and 0.1 mg/L test substance in acetone (0.025 mL/L). Results from the acute daphnid study by the same author do not appear to have been considered when selecting concentrations for this study. Test solutions were prepared by adding the appropriate stock solution to dilution water while continuously and vigorously stirring with a magnetic follower. Based on analysis of 4 renewal intervals (two 48-hour intervals and two 72-hour intervals, corresponding mean measured concentrations determined by radiochemical methods were 0.0037, 0.005, 0.01, 0.018, 0.032, and 0.065 mg/L and were 78 - 94% of nominal concentrations at the start of the renewal period and 7.3 - 61% of nominal concentrations at the end of the renewal period indicating a notable loss of test substance.. In the dilution water control, 20% mortality was observed. Overall, dilution water control and solvent control results were significantly different for reproductive parameters. The test was carried out at temperatures of 19.5 - 20.3°C, at pH levels of 7.41 - 8.13, and at dissolved oxygen concentrations of 6.2 - 9.2 mg/L. A measured 21-day parental LC_{50} value of 0.025 mg/L was reported, which shows less toxicity then what was reported in the corresponding acute toxicity study by the same author using the same test substance. A significant decrease in the number of live offspring was reported at the mean measured concentration of 0.018 mg/L and delayed release of first offspring (statistical significance not determined) was observed at higher concentrations. Percentage dead offspring reported was 0%, 0%, 5.9%, 20.4%, and 18.5% for the 0.0037, 0.005, 0.01, 0.018, 0.032, and 0.065 mg/L mean measured exposures. A mean measured NOEC and LOEC were determined to be 0.01 and 0.018 mg/L, respectively, resulting in a ChV (geometric mean of NOEC and LOEC) of 0.013 mg/L. The inability to maintain test concentrations during renewal periods, the intermittent analysis of test concentrations, and a smaller population size may have contributed to inconsistencies with the survivability results compared to the acute studies and may have affected subsequent reproductive results. Given the uncertainties of the test, reported effect levels may not represent a worst case scenario but do exhibit a clear dose response relationship with a clearly defined statistically significant effect level. Thus, the study is considered acceptable to characterize the chronic invertebrate endpoint given that secondary source studies including TNO (1993) (21-d NOEC = 0.004 - 0.008 mg/L), Frank (1993), and Frank and Steinhauser (1994) (21-d MATC = 0.006 mg/L) provided in the 2005 European Chemical Bureau Risk Assessment of MCCP (ECB, 2005) indicate even higher toxicity.

21-d NOEC = 0.01 mg/L
21-d LOEC = 0.018 mg/L
21-d MATC = 0.013 mg/L

(2) CPC (1983a)

A 60-day mussel toxicity study was conducted by Brixham Laboratories in 1983 with radio-labeled chlorinated (52%) n-pentadecane (Trade Name: Cereclor S52) under flow through testing conditions (CPC, 1983a). A full non-CBI study report was submitted under TSCA in 1983 as DCN 40-8332184 (OTS Fiche 0507258). Mussels (*Mytilus edulis*) were exposed to nominal concentrations of 0 (dilution sea water control), 0 (acetone control, 500 ppm), 0.56, or 5.6 mg/L in 500 ppm acetone. Two replicates of 50 mussels were tested for the dilution water and solvent controls and a single replicate of 50 mussels was exposed for each treatment concentration. Corresponding mean measured concentrations were 0, 0, 0.22, and 3.8 mg/L. Test solutions were cloudy at the higher test concentration. Test concentrations were determined by radio activity measurements. Flow rate of the test system was 0.25 mL/minute for exposure concentrations. Over the course of the study, water temperature ranged from 14.6 – 15.6°C, pH

ranged from 8.0 – 8.3, and the dissolved oxygen concentrations ranged from 6.1 – 8.25 mg/L. Dilution water salinity was 34 – 35.5 ppb, which is high by OPPTS standards. One mussel exposed to 0.56 mg/L dies, and two mussels exposed to controls died; this was not considered to be a test substance related effect. Decreases in filter feeding were observed at 5.6 mg/L. In addition, the submitter provided an assessment of bioconcentration, but this assessment does not appear to include a depuration phase. Overall, the 60 day NOEC and LOEC were 0.22 and 3.8 mg/L, respectively, based on reduced filtration. The study was acceptable to characterize mussel toxicity, but mussels are not considered a standard species to fulfill the chronic aquatic invertebrate toxicity endpoint.

60-d NOEC = 0.22 mg/L

60-d LOEC = 3.8 mg/L (reduced filtration)

(3) Frank (1993); Frank and Steinhauser (1994)

The following study summary for (Frank, 1993; Frank and Steinhauser, 1994), provided in the ECB (2005) MCCP risk assessment, was considered supportive of the aquatic invertebrates hazard determination. A 21-day chronic Daphnia magna reproduction toxicity study was conducted using a static-renewal test system (renewal 3 times/week). The test substance was identified as $C_{14\text{-}17}$ chlorinated paraffin with 52% chlorination, which was tested as a water soluble fraction of two stock solutions (dilutions used 1:2 to 1:32). Nominal test concentrations prepared from the 100 mg/L stock solution were 3.125, 6.25, 12.5, 25, and 50 mg/L. Nominal test concentrations prepared from the 10,000 mg/L stock solution were 312.5, 625, 1250, 2500, and 5000 mg/L. Analytical monitoring of test concentrations was conducted, but only the final effect levels were presented as measured concentrations. Methods for test solution preparation were not provided in the summary. The tests were carried out at 20°C and at pH 7.79 - 8.44.

In the experiments using the 100 mg/L stock solution the mortality seen in the exposed populations was 0% at 3.125 mg/L, 0% at 6.25 mg/L, 20% at 12.5 mg/L, 90% at 25 mg/L, and 100% at 50 mg/L. In the experiments using the 10,000 mg/L stock solution the mortality seen in the exposed populations was 0% at 312.5 mg/L, 30% at 625 mg/L, 70% at 1250 mg/L, and 100% at lower dilutions (>1250 mg/L). In the experiments using the 100 mg/L stock solution the average number of young/adult was 82 at 3.125 mg/L, 89 at 6.25 mg/L, 80 at 12.5 mg/L, 15 at 25 mg/L and 0 at 50 mg/L (all parents died). Similarly in the experiments using the 10,000 mg/L stock solution the average number of young/adult was 74 at 312.5 mg/L, 64 at 625 mg/L, 43 at 1250 mg/L, and 0 at 2,500 and 5,000 mg/L (all parents died). Based on these effects, survivability/mortality appears to be the more sensitive endpoint. Based on the known measured concentrations in the stock solutions and the dilution rates used the NOEC for mortality was around 0.0044-0.0089 mg/L for the 100 mg/L nominal stock solution experiments and 0.0126-0.0156 mg/L for the 10000 mg/L nominal stock solution experiments. The corresponding LOECs were 0.0089- 0.0178 mg/L (100 mg/L nominal stock) and 0.0253-0.0313 µg/L (10 g/L nominal stock). The MATC of 0.006 mg/L was calculated using the geometric mean from the most conservative NOEC (0.0044 mg/L) and LOEC (0.0089 mg/).

These data are considered supportive of the aquatic invertebrate hazard determination.

(4) TNO (1993)

The following study summary for TNO (1993) provided in the ECB (2005) MCCP risk assessment, was considered supportive of the aquatic invertebrates hazard determination. A 21-day chronic Daphnia magna reproduction toxicity study was conducted using a static-renewal test system (renewal 3 times/week). The test substance was identified as $C_{14\text{-}17}$ chlorinated paraffin with 52% chlorination. The test solutions were prepared by stirring 20 g of the test substance in 2 litres of heated water (60°C) with stirring and then filtration through a 0.8 µm and

0.2 µm filter. This resulting stock solution was referred to as a water soluble fraction, but given that each concentration was not independently prepared, the test solutions is considered by EPA/OPPT to be merely a mixed and filtered solution that was subsequently diluted. Following dilution of the stock solution, exposure concentrations were analytically determined using the extractable organic halogen method, but not provided in the study summary. The test was carried out at 20 ± 1°C and solutions were gently aerated from day 9 onwards. The pH of the test water varied between 7.7 and 8.3, the dissolved oxygen concentration was > 7 mg/L, and the hardness was 214 mg $CaCO_3$/L. Test solutions were clear. Although analytical results obtained were considered to be too erratic to allow precise determination of concentrations (according to the study summary in ECB (2005)), the NOEC was reported based on survivability and/or reproductive effects. A LOEC in mg/L was not reported in the summary, nor could EPA/OPPT extrapolate one. However, it is still unclear as to the levels of saturation of each solution the organisms were exposed to based on the extraction technique and nominal loading rates.
This study is not considered acceptable for determining hazard, thus the results were not used in this assessment.

B-1-6 Chronic Aquatic Sediment Invertebrate Toxicity

(1) Thompson et al. (2001a)
A 28-day prolonged sediment invertebrate toxicity study with spiked sediment was conducted by Thompson et al. (2001a) according to OECD 218 draft guideline (February 2000 version) using a static test system. The substance used in the test was commercial C_{14-17}, 52% wt. Cl substance containing no stabilizers (the substance was reported to have a C_{14-17} content of 99.06% with 0.67% of C_{10-13} chain length substances) that was mixed with a small amount of a radio labeled n-pentadecane-8-14C, 51% wt. Cl substance (radiochemical purity > 96.6%). Three replicates of 15 midge (*Chironomus riparius*) larvae (< 48 hours post hatch) were exposed to nominal concentrations of 0 (sediment control), 0 (solvent sediment control), 44, 140, 440, 1400, 4400, or 14,000 mg/kg dry wt. sediment. Corresponding mean measured concentrations of 0 (sediment control), 0 (solvent sediment control), 36, 110, 370, 1200, 3800, and 13,000 mg/kg dry wt. sediment were determined using radiochemical analysis. The sediment used in the test was an artificial sediment that did not fully adhere to the final OECD TG recommendations, but the composition of 10% sphagnum moss peat, 70% quartz sand, 20% kaolinite clay, and < 0.1% calcium carbonate are not considerably different. The sediment had a mean organic carbon content of 4.9% and a pH of 6.0. The sediment was spiked with the test substance by mixing a solution of the test substance in acetone with the dry sand component of the sediment and allowing the acetone to evaporate overnight under an air stream. Over the course of the study, temperature was maintained at 20 ± 1°C, pH levels were 6.2 - 7.6, and dissolved oxygen in overlying water was maintained at 7.3 - 8.6 mg/L. Time to first emergence, mean emergence time, mean number emerged per replicate, and sex ratio was assessed for each exposure group. Statistically significant effects (Dunnett's procedure, $p = 0.05$) were limited to a decrease in mean number emerged per replicate in the 13,000 mg/kg dry wt. sediment exposed midges. The overall mean measured NOEC of 3,800 mg/kg dry wt. sediment corresponded to 1,460 mg/kg on a wet weight basis. Based on the mean measured NOEC and LOEC of 3,800 and 13,000 mg/kg dry wt. sediment, respectively, the MATC was 7,029 mg/kg dry wt. sediment. The study was acceptable.
28-d NOEC = 3,800 mg/kg dry wt sediment
28-d LOEC = 13,000 mg/kg dry wt sediment
28-d MATC = 7,029 mg/kg dry wt sediment

(2) Thompson et al. (2001b)

A 28-day prolonged sediment invertebrate toxicity study with spiked sediment was conducted by Thompson et al. (2001b) according to methods described in Phipps et al. (1993) using a static test system. The substance used in the test was commercial Cereclor S52 (C_{14-17}, 52% wt. Cl with no stabilizers). The substance was reported to have a C_{14-17} content of 99.06% with 0.67% of C_{10-13} chain length substances and was mixed with a small amount of a radio labeled n-pentadecane-8-14C, 51% wt. Cl substance (radiochemical purity > 96.6%). Six replicates of 10 oligochaete (*Lumbriculus variegatus*) adults were exposed to nominal concentrations of 0 (sediment control), 0 (solvent sediment control), 44, 140, 440, 1,400, 4,400, and 14,000 mg/kg dry wt. sediment. Corresponding mean measured concentrations of 0 (sediment control), 0 (solvent sediment control), 39, 130, 410, 1,300, 4,000, and 13,000 mg/kg dry wt. sediment were determined using radiochemical analysis. The sediment used in the test was an artificial sediment consisting of 10% sphagnum moss peat, 70% quartz sand, 20% kaolinite clay, and < 0.1% calcium carbonate. The sediment had a mean organic carbon content of 4.9% and a pH of 6.0. The test sediments were made up by adding the test substance to the sand phase as a solution in acetone, evaporating the acetone overnight and mixing the spiked sand with the rest of the sediment for 16 hours. Throughout the duration of the study, water temperature was maintained at 20 ± 1°C, pH remained between 6.3 and 7.9. Mortality and reproductive success were determined by total number of worms at study termination since differentiation of adult and young worms is difficult. Mean number of worms per replicate and mean total dry weight of worms per replicate was significantly different from controls (Dunnett's procedure, P = 0.05) at mean measured concentrations of 410 mg/kg dry weight sediment and greater. Thus, the NOEC and LOEC were 130 and 410 mg/kg dry wt. sediment and the ChV (geometric mean of the NOEC and LOEC) were 230.9 mg/kg dry wt. sediment. The study was acceptable.
28-d NOEC = 130 mg/kg dry wt sediment
28-d LOEC = 410 mg/kg dry wt sediment
28-d ChV = 230.9 mg/kg dry wt sediment

(3) Thompson et al. (2002)
A 28-day prolonged sediment toxicity study with amphipod *Hyalella azteca* in spiked sediment was conducted by Thompson et al. (2002) using a static-renewal test system with weekly renewals. The substance used in the test was a mixture of a commercial medium-chain chlorinated paraffin product (C_{14-17}, 52.5% wt. Cl) mixed with a small amount of a radio labeled chlorinated n-pentadecane-8-14C (51% wt. Cl). Six replicates per concentration of ten juvenile *Hyalella azteca* (~7-day-old) were exposed to 0 (sediment control), 0 (acetone sediment control), 38, 75, 150, 300, or 600 mg/kg dry weight sediment in acetone. The concentration of the test substance was measured in the sediment phase by radiochemical analysis with concentrations at the start of the exposure period of 85 - 97% of the nominal values and concentrations at the end of the 29-day exposure period of 78 - 90% of nominal. Results of the test were expressed as the arithmetic mean concentrations. The sediment used in the test was an artificial sediment consisting of 10% sphagnum moss peat, 70% quartz sand, 20% kaolinite clay, and < 0.1% calcium carbonate. The sediment had a mean organic carbon content of 4.9% and a pH of 6.0. The test sediments were made up by adding the test substance to the sand phase as a solution in acetone, evaporating the acetone overnight and mixing the spiked sand with the rest of the sediment and water. Over the course of the study, dissolved oxygen ranged from 7.7 to 8.4 mg/l, pH ranged from 7.0 to 7.6, water hardness ranged from 41 to 42 mg $CaCO_3$/l, and temperature ranged from 22.4 - 23.2°C. The endpoints investigated in the study included survival, growth (dry weight) and sexual development of females (proportion of gravid females). Controls responded adequately. For the survival endpoint, a statistically significant (p = 0.05) reduction in survival was seen at 470 mg/kg dry weight. A statistically significant (p = 0.05) reduction in mean weight was seen at 270 mg/kg dry weight. For the sexual development endpoint, there was

a statistically significant (p = 0.05) reduction in the proportion of gravid females in the 470 mg/kg dry weight treatment. The mean measured NOEC and LOEC for survival and reproductive toxicity was 270 and 470 mg/kg dry weight sediment, respectively. The mean measured NOEC and LOEC for growth was 130 and 270 mg/kg dry weight sediment, respectively, resulting in a MATC of 187 mg/kg dry weight sediment. The study is acceptable.
28-d NOEC = 130 mg/kg dry wt sediment
28-d LOEC = 270 mg/kg dry wt sediment
28-d MATC = 187 mg/kg dry wt sediment

B-1-7 Avian Toxicity

(1) Madeley and Birtley (1980)
An acute avian toxicity study conducted according to methods described in US EPA's Pesticide Program Guidelines for Registering Pesticides (FR 40, 123, 26913, 26915) was published by Madeley and Birtley (1980). Following a range-finding study, groups of 5 male and 5 female ring-necked pheasants (*Phasianus colchicus*) were exposed by gavage to 0 (control) or 24,606 mg/kg Cereclor S52 (C_{14-17}, 52% Cl) and then observed for 14 days. Based on reported tissue concentrations, the test substance is believed to have been absorbed by the ring-necked pheasant. Doses up to 24,606 mg/kg failed to produce any abnormal clinical signs or mortality. Thus, the LD_{50} was > 24,606 mg/kg Cereclor S52.
The study was acceptable. Acute LD_{50} > 24,606 ppm

(2) Madeley and Birtley (1980)
An acute avian toxicity study conducted according to methods described in US EPA's Pesticide Program Guidelines for Registering Pesticides (FR 40, 123, 26913, 26915) was published by Madeley and Birtley (1980). Following a range-finding study, groups of 5 male and 5 female mallard ducks (*Anas platyrynchos*) were exposed by gavage to 0 (control) or 10,280 mg/kg Cereclor S52 (C_{14-17}, 52% Cl) and then observed for 14 days. Based on reported tissue concentrations, the test substance is believed to have been absorbed by the mallard ducks. Doses up to 10,280 mg/kg failed to produce any abnormal clinical signs or mortality. Thus, the LD_{50} was > 10,280 mg/kg.
The study was acceptable. Acute LD_{50} > 10,280 ppm

(3) Madeley and Birtley (1980)
A sub-acute dietary avian toxicity study conducted according to methods described in US EPA's Pesticide Program Guidelines for Registering Pesticides (FR 40, 123, 26913, 26915) was published by Madeley and Birtley (1980). Following a range-finding study, groups of 5 male and 5 female ring-necked pheasants (Phasianus colchicus) were exposed to diets containing 0 (control), 1,000, or 24,063 ppm Cereclor S52 (C_{14-17}, 52% Cl) for 5 days. Three groups were exposed to the negative control and two groups were exposed to each of the treatment concentrations. Based on reported tissue concentrations, the test substance is believed to have been absorbed by the ring-necked pheasant. Good health was noted in all control and treatment groups. No abnormal effects were noted at necropsy. Thus, the LD_{50} was > 24,063 ppm.
The study was acceptable. 5-day LD_{50} > 24,063 ppm

(4) Madeley and Birtley (1980)
A sub-acute dietary avian toxicity study conducted according to methods described in US EPA's Pesticide Program Guidelines for Registering Pesticides (FR 40, 123, 26913, 26915) was published by Madeley and Birtley (1980). Following a range-finding study, groups of 5 male and 5 female mallard ducks (*Anas platyrynchos*) were exposed to diets containing 0 (control), 1,000,

or 24,063 ppm Cereclor S52 (C_{14-17}, 52% Cl) for 5 days. Three groups were exposed to the negative control and two groups were exposed to each of the treatment concentrations. Inferior food intake was noted for ducks, but weight gain was comparable to controls. Based on reported tissue concentrations, the test substance is believed to have been absorbed by the mallard ducks. Good health was noted in all control and treatment groups. No abnormal effects were noted at necropsy. Thus, the LD_{50} was > 24,063 ppm.

The study was acceptable. 5-day LD_{50} > 24,063 ppm

(5) Unpublished study reviewed in the ECB (2000)

The effects of C_{10-12}, 58% Cl chlorinated paraffin (mean-measured 29, 168, and 954 mg/kg-diet) on the reproduction of mallard ducks (*Anas platyrhynchos*) were evaluated over 22 weeks including a 9-week pre-egg-laying period without photostimulation, a 3-week pre-egg-laying period with photostimulation, and 10-week egg-laying period with photostimulation. There were no significant effects on adult body weight, food consumption, eggs laid, number of cracked eggs, mean egg weight, live 21-day embryos, hatchlings, 14-day old survivors, or day 0 and day 14 hatchling weights. A statistically-significant decrease in mean eggshell thickness of ~5% was observed in the mean-measured 954 mg/kg-diet treatment group compared to the control even though mean eggshell thickness in the 954 mg/kg-diet treatment group was within the range of normal values. In addition, a decrease in 14-day embryo viability of 10% was observed in the mean-measured 954 mg/kg-diet treatment group compared to the control. This decrease was not statistically significant over the entire 10-week egg-laying period but was statistically significant on weeks 3 and 6. The mean-measured NOEC and LOEC values were 168 and 954 mg/kg-diet, respectively, based on reproductive endpoints.

The study was acceptable. NOEC of 168 mg/kg-diet; LOEC of 954 mg/kg-diet.

B-1-8 Terrestrial Invertebrate Toxicity

(1) Thompson et al. (2001d)

A 28-day earthworm reproductive toxicity test was conducted by Thompson et al. (2001d) according to OECD guidelines. The substance tested was commercial C_{14-17}, 52% wt. Cl substance containing no stabilizers (the substance was reported to have a C_{14-17} content of 99.06% with 0.67% of C_{10-13} chain length substances) and a small amount of 14C-labelled n-pentadecane, 51% wt. Cl substance. Four replicates per concentration of 10 adult earthworm (*Eisenia fetida*) were exposed to nominal concentrations of 0 (soil control), 0 (solvent soil control), 100, 320, 1000, 3200, or 10,000 mg/kg dry wt. soil. Corresponding mean measured concentrations of 0 (soil control), 0 (solvent soil control), 79, ~280, 900, ~2,800, or 9,300 mg/kg dry wt. was determined using radiochemical analysis; concentrations identified as approximate (~) were approximated using the mean% of nominal (87%) determined in other treatments. Measured tissue concentrations in adults on day 28 were 169, 802, and 732 mg/kg wet weight for the 79, 900, and 9,300 mg/kg dry weight exposure groups. Measured tissue concentrations in juveniles on day 56 were 140 and 1,011 mg/kg wet weight for the 79 and 900 mg/kg dry weight exposure groups. The soil used in the test was an artificial soil consisting of 10% sphagnum moss peat, 70% quartz sand, 20% kaolinite clay, and 0.25% calcium carbonate. The soil had an organic carbon content of 4.7% and a pH of 6.66 - 7.09. Nominal test temperatures remained at 20 ± 1°C. The soils were prepared up by firstly adding the test substance in solution with acetone to a small portion of soil, evaporating out the acetone overnight under a stream of compressed air, and then mixing with the remainder of the soil. Before use, distilled water was added to the dry soil to provide a soil wet:dry ratio of 1.35. Following the 28-day parental exposure period, adult earthworms were removed, and vessels were incubated for an additional 28 days to allow hatching of any egg cocoons produced by parent. Effects assessed were parental survival, growth

as determined by change in weight of parents, and reproduction as determined by number of live offspring. A statistically significant (p = 0.05) reduction in parental survival (85%) was observed at 9,300 mg/kg dry wt. soil. A statistically significant (recalculated with Dunnett's Procedure, p = 0.05) reduction in parental weight was reported at 2800 mg/kg dry wt. soil. A statistically significant (recalculated with Dunnett's Procedure, p = 0.05) reduction in number of live offspring was reported at 280 mg/kg dry wt. soil. The MATC (geometric mean of the NOEC and LOEC) based on these values is 149 mg/kg dry wt. soil. In addition, the submitter assesses corresponding tissue concentrations in earthworms and determines that at nominal concentrations of 100 mg/kg dry wt. soil the concentration in parental earthworm tissue after 28 days is 850 mg/kg dry wt. and in juvenile worms after 56 days was 703 mg/kg dry wt. The study was acceptable.

28-d NOEC = 79 mg/kg dry wt soil
28-d LOEC = 280 mg/kg dry wt soil
28-d MATC = 149 mg/kg dry wt soil

B-1-9 Soil Microorganism Toxicity

(1) Thompson (2002)

A 28-day soil microorganisms toxicity test was conducted by Thompson (2002) according to OECD 216 (Soil Microorganisms: Nitrogen Transformation Test) with GLP compliance using a static test system. The substance tested was commercial C_{14-17}, 52% wt. Cl substance containing no stabilizers (the substance was reported to have a C_{14-17} content of 97.35% with 0.66% of C_{10-13} chain length substances). Three replicates of nitrogen producing bacteria per concentration were exposed to natural soil (sieved 0.2 mm) with an organic carbon content of 1.6% that was spiked with nominal concentrations of 25, 50, 100, 200, or 400 mg/kg dry wt. soil MCCP. Soil was amended by the addition of an organic nitrogen source referred to as lucerne meal and an amended and unamended control was tested concurrently with the test. Although a 13% decrease in nitrate production was observed in bacteria exposed to the highest test concentration (400 mg/kg dry wt. soil), there was no significant (p = 0.05) inhibition of nitrogen producing bacteria resulting in a 28-day EC_{50}, NOEC, and LOEC of > 400, 400, and > 400 mg/kg dry wt. soil. The study was acceptable.

28-d NOEC = 400 mg/kg dry wt soil
28-d LOEC > 400 mg/kg dry wt soil

B-1-10 Terrestrial Plant Toxicity

(1) Thompson et al. (2001c)

A 28-day seed germination and vegetative vigor study was conducted by Thompson et al. (2001c) to assess toxicity to wheat (Triticum aestivum; monocotyledon), oilseed rape (Brassica napus; ditcotyledon), and mung bean (Phaseolus aureus; dicotyledonous legume) using OECD guideline 208 (July, 2000 Revision). The substance tested was commercial C_{14-17}, 52% wt. Cl substance containing no stabilizers (the substance was reported to have a C_{14-17} content of 99.06% with 0.67% of C_{10-13} chain length substances) and a small amount of 14C-labelled n-pentadecane, 51% wt. Cl substance. For each species, four replicate pots per exposure concentration each containing 9 seeds were exposed for 28 days to nominal exposure concentrations of 0 (soil control), 0 (solvent soil control), 50, 158, 500, 1,580, or 5,000 mg/kg dry wt. Mean measured concentrations of 49, 520, and 5,800 mg/kg dry wt. soil were determined for the nominal test concentrations of 50, 500, and, 5,000 mg/kg dry weight soil; based on this observed stability, the submitter uses nominal test concentrations for effect level determination. The soils were prepared by firstly adding the test substance in solution with

acetone to dry silver sand, evaporating the acetone overnight, and mixing the spiked sand with the soil. Over the course of the study, temperatures were maintained between 16 and 31°C. Effects assessed were seed germination, emergence (% emerged plants on Day 14), vegetative growth (mean shoot dry weight per plant), and visual appearance of seedling. No statistically significant differences (p = 0.05) were observed in wheat, oilseed rape; however, control emergence for oilseed rape was below OECD recommendations of 70% suggesting issues with the test system and invalidating the oilseed rape test. A statistically significant reduction in growth was seen at 1,580 and 5,000 mg/kg dry wt. for mungbean when compared to soil control results, but not solvent control results. Since soil control and solvent control means were equal (two tailed T-Test) indicating no solvent interference, comparison of treatments was made to the soil control. Thus, the NOEC and LOEC for terrestrial plants was 500 and 1,580 mg/kg dry wt. soil and the MATC (geometric mean of the NOEC and LOEC) was 888.8 mg/kg dry wt. soil. The study was acceptable to characterize both monocot (wheat) and dicot (mung bean) seed germination and vegetative vigor; reproductive effects remain uncharacterized.
28-d NOEC = 500 mg/kg dry wt soil
28-d LOEC = 1,580 mg/kg dry wt soil
28-d MATC = 888.8 mg/kg dry wt soil

B-1-11 Conclusions

Sufficient data were available to characterize the acute fish, the acute aquatic invertebrate, the chronic aquatic invertebrate, the chronic aquatic sediment invertebrate, avian, and terrestrial plant toxicity endpoints for MCCPs. Data for other toxicity endpoints (i.e., chronic fish, aquatic plant, etc.) were inconclusive due to lack of study details, uncertainties in analytical methods, or test material preparation methods; thus, these data are included in order to characterize risk in a qualitative manner, but are used as supportive for the categories under which they are provided. Supporting data were included in order to provide a weight-of-evidence approach used to characterize some endpoints.

Most of the data provided in this review indicated several difficulties were encountered when testing in an aquatic environment. These included: (1) getting the material into solution, (2) measuring the material in solution, and (3) characterizing the effects for each study listed. Often there were many details of a given study omitted, prohibiting a full and robust review of the data. The (estimated) physical-chemical properties of MCCPs (water solubility values of approximately 30 μg/L and Log K_{ow} values between 4-8) suggest these materials may not partition to the aquatic media or elicit toxicity to aquatic organisms within the water column.

Appendix C HUMAN HEALTH HAZARD STUDY SUMMARIES

C-1 MCCP HEALTH DATA REVIEW

When evaluating the risks of workers from exposure to MCCPs based on the available repeated-dose toxicology studies, the EU's draft Risk Assessment Report (RAR) on MCCPs concluded that except metal working fluids (MWF) use, "*There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already*" (ECB, 2008).

Using the NOAEL (23 mg/kg-bw/day) of kidney toxicity identified in the 90-day oral study in rats (CXR, 2005), a MOS of 70,000 was estimated for dermal exposure of consumers resulting from wearing leather clothes treated with MCCP. For inhalation exposure of consumers using metal fluids containing MCCP, a MOS of 2,875 was obtained. Therefore, it was also concluded that: "*There is present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already*" (ECB, 2008).

C-1-1 Metabolism

There is no information on inhalation absorption of MCCPs in humans or in animals. Based on their low vapor pressure and low water solubility, absorption following inhalation or dermal exposure is expected to be limited. An *in vitro* study using human skin showed that after 24 hours, approximately 0.7% of a C_{15} chlorinated paraffin was absorbed (Scott, 1984; *cited in:* ECB, 2008). Oral studies (IRDC, 1984, CXR, 2005; *cited in:* ECB, 2008) showed that approximately 50% of a single dose of [8-^{14}C]-labeled C_{15} chlorinated paraffin (52 wt% Cl) was absorbed from the GI tract in rats. Excretion *via* feces was the major route of elimination of radiolabeled material. Elimination of radioactivity from body tissues occurred with an elimination half-life of approximately 2-5 days (liver and kidney) or approximately 2 weeks (adipose tissue).

C-1-2 Acute Toxicity

There is no information on the effects of a single exposure to MCCPs in humans. No deaths and only limited, non-specific clinical signs of toxicity resulting from exposure of rats to very high doses were observed in an acute oral toxicity study of MCCPs ($C_{14\text{-}17}$, 51-60 wt% Cl); the LD_{50} was reported to be > 4,000 mg/kg bw (Birtley *et al*., 1980; *cited in*: IPCS, 1996). Though no acute toxicity data are available for MCCP by the inhalation or dermal route of exposure, the low acute toxicity data for SCCPs by these routes suggest that MCCPs are likely to have low acute inhalation and dermal toxicity.

C-1-3 Irritation and Sensitization

No signs of skin irritation were seen with MCCPs ($C_{14\text{-}17}$, 45 wt% Cl), and only slight erythema on the shaved skin was reported in one rabbit at 24 hours exposed to MCCPs ($C_{14\text{-}17}$, 40 wt% Cl) (Chater, 1978; *cited in:* ECB, 2008). A mild skin irritancy response was reported in one of nine unpublished skin irritation studies of MCCPs ($C_{14\text{-}17}$, 51-60% Cl) in rats (Birtley *et al*., 1980; *cited in:* ECB, 2008). The material caused slight, transient eye irritation in rabbits (Birtley *et al*., 1980; Kuhnert *et al*., 1986; *cited in:* ECB, 2008).

No skin sensitization reactions were produced in guinea pig maximization tests conducted on MCCPs (C_{14-17}, 40-45 wt% Cl) (Murmann, 1988; Chater, 1978; *cited in:* ECB, 2008).

C-1-4 Repeated-dose Toxicity

There are a number of repeated dose toxicity studies (up to 90-days duration) of MCCPs (C_{14-17} 40 wt% Cl or 52 wt% Cl) in rats by oral exposure (CXR, 2005; Poon *et al*., 1995; IRDC, 1984; Birtley *et al*., 1980; and Wyatt *et al*., 1997; *cited in:* ECB, 2008). Though the quality and reliability of these studies differs, the liver, kidney, and thyroid were consistently established as the target organs. A summary of the results from these studies is provided in Table 1.

MCCPs caused an increase in liver weight in male rats at exposure levels of $\geq$ 100 mg/kg-bw/day) and in female rats at exposure levels of $\geq$ 32 mg/kg-bw/day. Liver enzyme induction was reported in male and female rats starting from 222 and 100 mg/kg-bw/day, respectively. Liver hypertrophy of trace to minimal severity was reported in male rats at dose levels of $\geq$ 100 mg/kg-bw/day and higher. Collectively, these changes are likely to be related to an increase in metabolic demand as an adaptive response and to peroxisome proliferation, both of which are considered of no or limited toxicological significance to humans. Though Poon *et al*. (1995) reported various histopathological effects in the liver of male and female rats at dose levels $\geq$ 36 mg/kg-bw/day, there are a number of deficiencies with this study, including the scoring and classification of histopathological findings and limited reporting of data, which preclude its utility in hazard evaluation. This conclusion is consistent with previous evaluations of this study (ECB, 2008). Further, despite the consistency of findings reported in the review article by Birtley *et al*. (1980) with other 90-day studies, these findings should be viewed cautiously because the original full study report is not available. Based on the available data, the studies by IRDC (1984) and CXR (2005) provide the most reliable data for identifying effect levels of MCCPs on the liver. For the purposes of this assessment, a NOAEL of 100 mg/kg-bw/day was chosen based on increases in absolute liver weight (*i.e.*, 22-26%), liver hypertrophy of trace severity, and enzyme induction (*i.e.*, 30% increase).

Kidney effects have been reported in a number of studies, with effect levels typically being observed at the limit doses. MCCPs (C_{14-17} 52 wt% Cl) caused significant increases (9-13%) in kidney weight at 222 mg/kg-bw/day (CXR, 2005; *cited in:* ECB, 2008), as well as "chronic nephritis" and tubular pigmentation in the kidney of female rats at 625 mg/kg-bw/day (IRDC, 1984, *cited in:* ECB, 2008). One study reported a dose-related increase in congestion starting at 32 mg/kg-bw/day; however, no information was provided on the incidence or severity of this effect (Birtley *et al*., 1980; *cited in:* ECB, 2008). An additional study reported minimal to mild hyaline-droplet like cytoplasmic inclusions, starting at $\geq$ 0.4 mg/kg-bw/day in male rats. This effect is considered of limited relevance to humans. The authors also reported minimal dose-related increases with inner medullary tubular dilation at an incidence of 1/10, 4/10, and 8/10 female rats at 4, 42, and 420 mg/kg-bw/day, respectively (Poon *et al*., 1995; *cited in:* ECB, 2008). Though this effect is considered relevant to humans, the study suffers from a number of limitations, which preclude utilizing it for hazard evaluation. However, based on the incidence reported by the authors, the NOAEL of 42 mg/kg-bw/day for kidney effects is consistent with the NOAEL of 23 mg/kg-bw/day reported in the CXR (2005) study. Therefore, a NOAEL of 23 mg/kg-bw/day was chosen for the kidney, based on increases in organ weight at the next highest dose level.

MCCPs (C_{14-17} 52 wt% Cl) have been reported to cause minimal to mild adaptive histopathological changes in the thyroid (*i.e.*, follicular cell hypertrophy and hyperplasia) in two

studies in rats starting at 50 ppm (4 mg/kg-bw/day) and above (Poon *et al*., 1995; IRDC, 1985). Decreased T_4 levels and increased TSH levels in the plasma were also seen at similar dose levels. As noted previously, these results have been drawn into question based on the scoring and classification for histopathology, the limited reporting of data, and the inconsistent findings from other more robust studies (ECB, 2008). Therefore, these studies will not be considered further for hazard identification. IRDC (1985) reported mild to moderate hypertrophy and hyperplasia in male rats at dose levels of $\geq$ 10 mg/kg-bw/day and higher, whereas changes in absolute organ weights of male and female rats were not observed except at the limit dose of 625 mg/kg-bw/day (IRDC, 1985; *cited in:* ECB, 2008). The remaining studies that evaluated thyroid hormone levels identified a decrease in plasma free T_3 in male rats, but not total T_3 or free/total T_4, and an increase in TSH in female rats at dose levels of 24.6 or 242 mg/kg-bw/day, respectively (CXR, 2005; *cited in:* ECB, 2008), or fluctuations in thyroid hormones in male or female rats at doses of $\geq$ 312 mg/kg-bw/day or higher (Wyatt *et al*., 1997; *cited in:* ECB, 2008). There is evidence that the thyroid effects observed are attributable to stimulation of this organ arising from a negative feedback effect arising from plasma T_4 depletion following increased excretion of this hormone. This depletion of plasma T_4 results from the induction of hepatic UDPG-transferase, increased glucuronidation, and ultimately excretion of T_4 following exposure to MCCPs. The pituitary responds to the decreased levels of T_4 by releasing more TSH, which in turn leads to increased production of T_4 by the thyroid. The continuous stimulation of the thyroid in response to the increased excretion of plasma T_4 is predicted to ultimately give rise to hypertrophy and hyperplasia in this organ. Humans, unlike rodents, possess T_4-globulin binding protein and are therefore less susceptible to plasma T_4 depletion and hence any resultant thyroid stimulation. The thyroid effects observed in rats are not considered to be of relevance to chronic human health at relevant levels of exposure, although these changes may be relevant for assessing potential adverse outcomes during reproduction and development, as discussed under section.

C-1-5 Genotoxicity

MCCPs ($C_{14\text{-}17}$ 40-52 wt% Cl) are not mutagenic to bacteria. Three *in vivo* bone marrow studies also show that MCCPs are not clastogenic (*cited in:* ECB, 2008). Therefore, it may be concluded that MCCPs possess a low potential to cause genotoxic effects.

C-1-6 Carcinogenicity

There is no information on the carcinogenicity of MCCPs. When administered by gavage, a SCCP (C_{12}, 60 wt% Cl) caused increased incidences liver tumors in male and female rats, kidney tumors in male rats, and thyroid tumors in female rats (NTP, 1986). However, on mechanistic considerations, these tumors are considered to be of little or no relevance to humans. This conclusion is consistent with previous carcinogenicity evaluations (ECB, 2008). An increased incidence of malignant lymphoma in male mice was reported at the highest dose of 5,000 mg/kg-bw/day in carcinogenicity studies of a LCCP (C_{23}, 43 wt% Cl) in male and female rats and mice. However, malignant lymphoma is one of the more variable tumors in mice and has a viral origin in many cases. No increased incidence of malignant lymphoma was observed in the carcinogenicity study on a SCCP (C_{12}, 60 wt% Cl). Based on structure-activity relationships and the absence of positive genotoxicity data on MCCPs, the available carcinogenicity studies on a SCCP and a LCCP suggest that MCCPs are not expected to pose a carcinogenic hazard to humans.

Table_Apx C-1: Summary of Results from 90-Day Studies in Rats Administered MCCPs

Strain (sample size)	*Test substance and dose levels*	*Target organ*	*Effect levels*
F-344 (10 rats/sex/group)[1]	C_{14-17}, 52 wt% Cl Dietary intake for ♂: 0, 2.38, 9.34, 23.0, or 222 mg/kg-bw/day. Dietary intake for ♀: 0, 2.51, 9.70, 24.6, or 242 mg/kg-bw/day.	Liver	♂ at 222 and ♀ at 242 mg/kg-bw/day, 13-31% ↑ in organ weight ♂ at 222 mg/kg-bw/day, minimal centrilobular hypertrophy in 9/10 animals ♂ at 222 mg/kg-bw/day, 82% ↑ in microsomal T_4-UDPGA-glucuronyl transferase activity ♀ at 100, 300, and 300 mg/kg-bw/day, 30, 30, and 252% ↑ in microsomal T_4-UDPGA-glucuronyl transferase activity, respectively
		Kidney	♂ at 222 and ♀ at 242 mg/kg-bw/day, 9-13% ↓ in organ weight ♂ at > 222 and ♀ at 242 mg/kg-bw/day, no treatment-related histopathology
		Thyroid	♂ at 222 mg/kg-bw/day, 17% ↑ in plasma TSH ♂ at 23.0 and 222 mg/kg-bw/day, 26% or 22% ↓ in plasma free T_3, respectively, but no effects on total T_3 or on free/total T_4 at any dose ♀ at > 242 mg/kg-bw/day, no effects on free/total T_3 or T_4 ♀at 24.6 and 242 mg/kg-bw/day, 20 and 39% ↑ in plasma TSH ♂at > 222 and ♀ at 242 mg/kg-bw/day, no treatment-related histopathology
Sprague-Dawley (10 rats/sex/group)[2]	C_{14-17}, 52 wt% Cl Dietary intake for ♂: 0, 0.4, 4, 36, or 360 mg/kg-bw/day. Dietary intake for ♀: 0, 0.4, 4, 42, or 420 mg/kg-bw/day.	Liver	♂ at 360 and ♀ at 420 mg/kg-bw/day, 28 and 48% ↑ in absolute and relative weights, respectively ♂ and ♀ at ≤ 4 mg/kg-bw/day, no treatment-related histopathology ♂at 36 and ♀ at 42 mg/kg-bw/day, minimal increase in anisokaryosis and vesiculation of the nuclei ♂ at 360 and ♀ at 420 mg/kg-bw/day, mild increase in anisokaryosis and vesiculation of the nuclei (7-10 animals) ♂ at 360 mg/kg-bw/day, ↑ in perivenous homogeneity ♀ at 42 and 420 mg/kg-bw/day, ↑ in perivenous homogeneity ♂ at 360 and ♀ at 420 mg/kg-bw/day, ↑ in single cell necrosis (incidence not reported)
		Kidney	♂ at 360 and ♀ at 420 mg/kg-bw/day, 11% ↑ in absolute and relative weights ♂ at ≥ 0.4 mg/kg-bw/day, minimal to mild hyaline-droplet like cytoplasmic inclusions, with significant accumulation at

Table_Apx C-1: Summary of Results from 90-Day Studies in Rats Administered MCCPs

Strain (sample size)	*Test substance and dose levels*	*Target organ*	*Effect levels*
			the limit dose ♀ at ≥ 4 mg/kg-bw/day, minimal dose-related inner medullary tubular dilation seen in 0/10, 0/10, 1/10, 4/10, and 8/10 animals
		Thyroid	♂ at 36 and 360 mg/kg-bw/day, minimal to mild morphological changes affecting the architecture (*i.e.*, reduced follicle sizes and collapsed angularity) and the epithelium (*i.e.*, increased height, cytoplasmic vacuolation, and nuclear vesiculation) ♀ at ≥ 4 mg/kg-bw/day, minimal to mild morphological changes affecting the architecture (*i.e.*, reduced follicle sizes and collapsed angularity) and the epithelium (*i.e.*, increased height, cytoplasmic vacuolation, and nuclear vesiculation)
F-344 (15 rats/sex/group)[3]	C_{14-17}, 52 wt% Cl Dietary intake for ♂ and ♀: 0, 10, 100, or 625 mg/kg-bw/day.	Liver	♂ and ♀ at 100 and 625 mg/kg-bw/day, 22-26% and 64-92% ↑ in absolute weight values, respectively ♂ at 100 and 625 mg/kg-bw/day, hypertrophy of trace severity seen in 1/15 and 13/15 animals, respectively ♀ at 625 mg/kg-bw/day, hypertrophy of trace severity seen in 13/15 animals
		Kidney	♂ and ♀ at 625 mg/kg-bw/day, 18% ↑ in absolute weight values ♂ at ≥ 10 mg/kg-bw/day, trace to mild nephritis seen in 1/15, 3/15, 4/15, and 10/15 animals ♀ at 625 mg/kg-bw/day, tubular pigmentation (9/14 animals)
		Thyroid	♂ at 625 mg/kg-bw/day, 50% ↑ in absolute weight values ♂ at ≥ 10 mg/kg-bw/day, mild to moderate hypertrophy observed in controls with a dose-dependent trend towards ↑ severity in treated animals ♂ at ≥ 10 mg/kg-bw/day, trace to mild hyperplasia with a dose-dependent trend towards ↑ severity
		Adrenal	♂ and ♀ at 625 mg/kg-bw/day, 25% ↑ in absolute weight values
Wistar-derived (24 rats/sex/group)[4]	C_{14-17}, 52 wt% Cl, containing epoxidized vegetable oil as a stabilizer Dietary intake for ♂: 0, 33, 167, or 333 mg/kg-bw/day.	Liver	♂ at 167 and 333 mg/kg-bw/day, 15 and 22% ↑ in relative weight values, respectively ♀ at 32, 160, and 320 mg/kg-bw/day, 11, 21, and 48% ↑ in relative weight values, respectively ♂ at 333 and ♀ at 320 mg/kg-bw/day, no histopathological abnormalities ♂ at ≥ 33 and ♀ at ≥ 32 mg/kg-bw/day, dose-related ↑ in proliferation of smooth endoplasmic reticulum (electron microscopy)

Table_Apx C-1: Summary of Results from 90-Day Studies in Rats Administered MCCPs

Strain (sample size)	*Test substance and dose levels*	*Target organ*	*Effect levels*
	Dietary intake for ♀: 0, 32, 160, or 320 mg/kg-bw/day.	Kidney	♂ and ♀ at limit dose, 15% ↑ in relative weight ♂ and ♀, dose-related ↑ in congestion (incidence and severity not reported) ♂ and ♀ at > limit dose, no histopathological abnormalities
F-344 (10 rats/sex/group)[5]	C_{14-17}, 40 wt% Cl Oral gavage for ♂ and ♀: 0, 312, or 625 mg/kg-bw/day	Liver	♂ and ♀ at 312 and 625 mg/kg-bw/day, 37 and 72% ↑ in relative weight, respectively, (absolute weight and bodyweight not presented) ♂ and ♀, dose-related ↑ in centrilobular hypertrophy (incidence and severity not reported) ♂ and ♀ at 312 and 625 mg/kg-bw/day, dose-related ↑ in β-oxidation from day 29 onwards (~2.7- and 3.3-fold ↑, respectively, at study termination) ♂ and ♀ at 312 and 625 mg/kg-bw/day, dose-related ↑ in UDPG-transferase activity from day 15 onwards (up to 100% ↑, respectively)
		Thyroid	♂ and ♀ at 312 and 625 mg/kg-bw/day, ↓ in levels of free and plasma T_3, which reached statistical significance on days 15 and 57 ♂ at 312 and 625 mg/kg-bw/day, ↑ TSH up to 2-fold on day 8 only ♀ at 312 and 625 mg/kg-bw/day, T_3 significantly ↑ by day 91 ♀ at 312 and 625 mg/kg-bw/day, total plasma T_4 significantly ↓ by up to 25% on day 57 ♂ and ♀ at 312 and 625 mg/kg-bw/day, ↑ follicular cell hypertrophy throughout the study, and accompanied by follicular cell hyperplasia on days 55 and 91 (incidence and severity not reported) ♂ and ♀ at 312 and 625 mg/kg-bw/day, significantly ↑ replicative DNA synthesis on day 29, but not on day 91

[1] CXR (2005), *cited in:* ECB (2008).
[2] Poon *et al*. (1995), *cited in:* ECB (2008).
[3] IRDC (1984), *cited in:* ECB (2008).
[4] Birtley *et al*. (1980), *cited in:* ECB (2008); note, this study was only summarized in the review by Birtley *et al*. (1980). The underlying original study report was not available.
[5] Wyatt *et al*. (1997), *cited in:* ECB (2008).

C-1-7 Developmental Reproductive Toxicity

A series of range-finding and definitive prenatal developmental and reproductive toxicity studies were conducted in rats and rabbits with medium-chain chlorinated paraffins (MCCPs). These studies were conducted between 1981 and 1986. They appear to be valid toxicity studies, conducted according to the standard methodologies available at the time. More recently, additional studies with MCCPs have been conducted in an attempt to determine the cause of hemorrhaging in the pups observed in a one-generation reproductive toxicity range-finding study.

In several prenatal developmental toxicity studies with MCCPs conducted *via* gavage, no signs of maternal toxicity were seen at doses as high as 500 mg/kg-bw/day in rats and 100 mg/kg-bw/day in rabbits. Likewise, no signs of developmental toxicity were observed at doses as high as 5000 mg/kg-bw/day in rats and 100 mg/kg-bw/day in rabbits.

Two reproductive toxicity studies with MCCPs in rats have been conducted. A one-generation reproductive toxicity range-finding study showed that administration of approximately 100 and 400 mg/kg-bw/day MCCPs *via* the diet had no effect on fertility or other reproductive parameters; however, internal hemorrhaging and deaths in pups were observed beginning from 74 mg/kg-bw/day (1000 ppm) up to approximately 400 mg/kg-bw/day (6250 ppm). These effects in the pups were not seen in a more recent definitive one-generation reproductive toxicity study with exposure to MCCPs for 11-12 weeks to doses as high as 100 mg/kg-bw/day (1200 ppm). Internal hemorrhaging was not seen in the adult animals in either of these studies at doses as high as 400 mg/kg-bw/day (6250 ppm), or in another study in non-pregnant female rats repeatedly exposed to doses as high as 1000 mg/kg-bw/day. However, when dams were exposed to approximately 500 mg/kg-bw/day (6250 ppm) MCCPs during cohabitation, gestation, and lactation, signs of hemorrhaging were observed in dams that died at the time of parturition. Taken together, the results of these studies suggest that newborns during lactation and pregnant females at the time of parturition are a potentially sensitive subpopulation.

The UK Risk Assessment (February, 2008) did not use the LOAEL of 74 mg/kg-bw/day (1000 ppm) from the one-generation reproductive toxicity range-finder study as a point of departure because the pup deaths at that dose were not statistically significant. The study itself used a limited number of animals and was intended for dose range-finding purposes only and, more importantly, the pup deaths were not repeated in a more recently conducted definitive study. With respect to developmental/reproductive toxicity, the UK Risk Assessment identified two subpopulations at risk: offspring during lactation and pregnant dams at parturition. The NOAELs from the definitive one-generation reproductive toxicity study (a maternal NOAEL ~ 47 mg/kg-bw/day (600 ppm) for effects on the offspring mediated *via* lactation; and a maternal NOAEL ~ 100 mg/kg-bw/day (1200 ppm) for effects on the dam during the time of parturition) were used to calculate risk. Assuming a conservative value of 50% oral absorption, the margin of safety (MOS) for effects on the offspring mediated *via* lactation and effects on the dam during the time of parturition were calculated for workers, consumers, and other scenarios. In all but one scenario (oil-based metal working fluids), the margins of safety were above 100 and in many cases, several fold above. In addition, margins of exposure were calculated for infants exposed *via* breast milk and *via* cow's milk, and in both instances, large MOEs (*i.e.*, > 100) were calculated.

Additional studies with MCCPs have been conducted in an effort to clarify the possible causes of the hemorrhaging in the pups. One (single-dose; 6250 ppm or 538 mg/kg-bw/day) study showed maternal death during parturition due to low levels of vitamin K and related hemorrhaging, suggesting that the act of parturition places dams at higher risk. It was concluded in data from this study and a cross-fostering study that the fetus relies on clotting factors *via* mother's milk and severe deficiencies in vitamin K levels and related clotting factors in the pups results in hemorrhaging.

No definitive developmental neurotoxicity studies on MCCPs were located. It is not clear if any developmental neurotoxicity endpoints were actually measured in the available prenatal developmental/reproductive toxicity studies; none were explicitly stated. The only information available regarding behavior during development is from cage-side observations in pups through LD 21. In these cases, no dose-related differences were reported in F_1 post-weaning appearance or cage-side behaviors.

In the prenatal developmental toxicity study in rats, the **LOAEL for maternal toxicity was 2000 mg/kg-bw/day based on clinical signs. The NOAEL for maternal toxicity was 500 mg/kg/day. The NOAEL for developmental toxicity was 5000 mg/kg-bw/day, the highest dose tested.**

In the prenatal developmental toxicity study in rabbits, no adverse, treatment-related effects were reported in the dams or the offspring. **The NOAEL for both maternal and developmental toxicity was 100 mg/kg-bw/day, the highest dose tested.**

In the reproduction range-finding study in rats, the **LOAEL for maternal toxicity was 6250 ppm (463 mg/kg-bw/day) based on reductions in body weight gains. The NOAEL for maternal toxicity was 1000 ppm (74 mg/kg-bw/day). The LOAEL for developmental toxicity was 1000 ppm (62/74 mg/kg/day) based on pup mortality associated with internal hemorrhages. The NOAEL for developmental toxicity was 100 ppm (6/8 mg/kg-bw/day). No effects on any reproductive parameters were reported. The NOAEL for reproductive toxicity was 6250 ppm (384/463 mg/kg-bw/day).**

In the one-generation reproduction toxicity study in rats**,** the **LOAEL for maternal toxicity was 1200 ppm (~100 mg/kg-bw/day) based on increases in liver weight; the NOAEL for maternal toxicity was 600 ppm (~ 47 mg/kg-bw/day). The NOAEL for developmental and reproductive toxicity was 1200 ppm (~ 84/99 mg/kg-bw/day), the highest dose tested.**

Basis for Conclusions

In a range-finding prenatal developmental toxicity study in pregnant Charles River COBS CD rats administered MCCPs ($C_{14\text{-}17}$, 52 wt% Cl) *via* gavage at dose levels of 0, 1000, 1500, and 2500 mg/kg-bw/day on gestation days (GD) 6-20, no effects were observed in the dams at doses up to 2500 mg/kg-bw/day (IRDC, 1983, 1984; *cited in:* ECB, 2008). As a result, doses greater than 2500 mg/kg-bw/day were selected for the definitive study.

In the definitive study, four groups of 25 pregnant Charles River COBS CD rats were administered MCCPs ($C_{14\text{-}17}$, 52 wt% Cl) *via* gavage at doses of 0, 500, 2000, and 5000 mg/kg-bw/day on GD 6-19 (IRDC, 1984; *cited in:* ECB, 2008). Unmated males and females were individually housed and acclimated for 21-days in an environmentally controlled room. At the end of the acclimation period, all animals were weighed and subjected to a detailed physical

examination. One female and one male rat were placed together for mating. Confirmation of mating was based on evidence of a copulatory plug or by vaginal smear for sperm. The day mating was confirmed was designated as day 0 of gestation. Test article was administered to pregnant females orally by gavage as a single daily dose on GD 6-19. During treatment, pregnant females were observed daily for mortality and clinical signs of toxicity. Any females not surviving to scheduled sacrifice were necropsied. Body weights were recorded on GD 0, 6, 9, 12, 16, and 20. All females were sacrificed on GD 20 and the uterus and ovaries excised for examination. The number and location of viable and nonviable fetuses, early and late resorptions, and the number of total implantations and corpora lutea were recorded. The uterus was weighed. The abdominal and thoracic cavities underwent gross examination. Maternal tissues were preserved for future histopathological analysis. Fetuses were weighed, sexed, tagged, and examined for external malformations and variations, including the palate and the eyes. The fetuses underwent visceral and skeletal examinations for malformations and developmental variations.

The only effects reported in dams consisted of an increased incidence in wet matted and yellow stained haircoat in the anogenital area at 5000 mg/kg-bw/day, and soft stool at $\geq$ 2000 mg/kg-bw/day. No treatment-related adverse effects were reported in offspring at doses up to 5000 mg/kg-bw/day. The LOAEL for maternal toxicity was 2000 mg/kg-bw/day based on clinical signs; the NOAEL for maternal toxicity was 500 mg/kg-bw/day. The NOAEL for developmental toxicity was 5000 mg/kg-bw/day, the highest dose tested.

In a range-finding prenatal developmental toxicity study in pregnant Dutch Belted rabbits administered MCCPs (C_{14-17}, 52 wt% Cl) *via* gavage at dose levels of 0, 100, 300, 1000, 2000, and 3000 mg/kg/day on GD 6-27, an increase in the number of abortions was observed at $\geq$ 1000 mg/kg/day (IRDC, 1982a; *cited in:* ECB, 2008). Body weight reductions in the dams were reported at 100 and 300 mg/kg/day. As a result, another range-finding prenatal developmental toxicity study in rabbits was initiated. This second range-finding study showed decreases in maternal weight gain at 80 and 160 mg/kg-bw/day (IRDC, 1982b; *cited in:* ECB, 2008).

Based on the results of these range-finding studies, dose levels of 10, 30, and 100 mg/kg-bw/day were selected for the definitive prenatal oral gavage developmental toxicity study (IRDC, 1983; *cited in:* ECB, 2008). In the definitive study, four groups of 16 pregnant Dutch Belted rabbits were administered 0, 10, 30, and 100 mg/kg-bw/day MCCPs (C_{14-17}, 52 wt% Cl) *via* gavage on GD 6-27. Unmated males and females were individually housed and acclimated for 50-days in an environmentally controlled room. As a result of a positive finding for parasites in stool samples collected during acclimation, all rabbits received sodium sulfamethazine in their drinking water for 16 days during the acclimation period. This treatment was terminated 4 weeks prior to study initiation and only rabbits testing negative for parasites were placed on study. At the end of the acclimation period, all animals were weighed and subjected to a detailed examination. Females were impregnated *via* artificial insemination. Three weeks prior to artificial insemination, females were given chorionic gonadotropin *via* an injection in a marginal ear vein in order to induce superovulation. Semen was collected from males of proven fertility and evaluated for motility. The day of artificial insemination was designated as day 0 of gestation. During treatment, pregnant females were observed for mortality and clinical signs of toxicity. Body weights were recorded on GD 0, 6, 12, 18, 24, and 28. Any females not surviving to scheduled sacrifice were necropsied. On GD 28, all surviving females were sacrificed and the uterus and ovaries excised for examination. The location and number of viable and nonviable fetuses, early and late resorptions, and the number of total implantations and corpora lutea were recorded. The uterus was weighed. The thoracic and abdominal cavities underwent gross

examination. Pooled samples of abdominal adipose tissue from 3 dams were frozen for future analysis. Each fetus was sexed, weighed, and examined for external malformations and variations, including the palate and the eyes, as well as visceral and skeletal examinations for malformations and developmental variations, including examination of the brain and the heart.

No adverse, treatment-related effects were reported in the dams or the offspring at doses up to 100 mg/kg-bw/day. The NOAEL for both maternal and developmental toxicity was 100 mg/kg-bw/day, the highest dose tested.

In a one-generation reproductive toxicity range-finding study, four groups of 5 male and 10 female Charles River COBS SC rats were administered MCCP (C_{14-17}, 52 wt% Cl) *via* the diet at 0, 100, 1000, and 6250 ppm (~ 0, 6, 62, and 384 mg/kg-bw/day, respectively, in males; and 0, 8, 74, or 463 mg/kg-bw/day, respectively, in females) (IRDC, 1985; *cited in:* ECB, 2008). F_0 animals were exposed to test substance from 28 days prior to mating until sacrifice; F_1 animals were treated from weaning until sacrifice, with additional potential exposures occurring *in utero* and during lactation. All F_0 males were sacrificed after the mating period. Following the premating period, each male was cohabited with two females for 10 days. Females were examined for evidence of copulation by means of vaginal smears and/or the appearance of a vaginal plug. The day evidence of copulation was determined was designated as day 0 of gestation. Direct dosing began at 83 days of age for the F_0 parents and at 21 days of age for the F_1 weanlings. The F_0 and F_1 animals were observed for clinical signs of toxicity, changes in general appearance and behavior, and mortality. In the F_0 adults, body weights and food consumption were measured weekly; in addition, body weights were measured in F_0 females on GD 0, 7, 14, and 20; and on lactation days (LD) 0, 7, 14, and 21. Estrous cyclicity was determined in F_0 females prior to mating, during mating, and prior to dosing. All F_0 females were allowed to deliver. The day the entire litter was found and delivery was judged to be complete was designated as LD 0. Gestation duration was calculated. Following delivery, all pups were examined for external malformations and the numbers of live births and stillbirths (litter size) was recorded for each dam. Pups were weighed, sexed, and examined externally on LD 0, 7, 14, and 21. Litter size was determined on LD 0, 4, 10, and 21. The number of male and female pups was recorded on LD 4. Litters were examined daily for survival. F_0 females were examined for behaviors in nesting and nursing. On LD 21, all dams were sacrificed and a gross necropsy performed, including examination of the uterine contents for implantation sites; and ten F_1 weanlings/sex/dose were sacrificed and necropsied. Five F_1 males and ten F_1 females/dose group were retained after LD 21 and sacrificed at 70 days (10 weeks) of age and necropsied. Due to high mortality in high-dose F_1 pups, the surviving F_1 pups in the high-dose group and an equal number of control pups were sacrificed on LD 6 and 7 and necropsied. Blood was collected *via* heart puncture and complete blood counts performed. Bone marrow smears were collected from the femur, and the abdominal contents of the pups with milk in the stomach were collected and frozen for future analyses.

Effects in the adults consisted of isolated reductions food consumption and body weight in the dams at 6250 ppm. Effects in the offspring consisted of significant reductions in pup survival at the high dose (none of the F_1 pups in the high-dose group survived until lactation day 21); and slight (11%, not statistically significant) decreases in pup survival, and labored breathing, subcutaneous hematoma, pale discoloration, blood around the orifices, pale liver, kidney, and spleen, and blood in the cranial cavity and brain beginning at the mid-dose. No dose-response, treatment-related adverse effects were reported in the offspring in the low dose group. Reductions in body weight in F_1 male and female pups occurred during LD 7, 14, and 21, but these reductions were not statistically significantly different from controls, and were seen only in

the low- and mid-dose groups but not the high-dose group. There were no dose-related differences in F_1 post-weaning appearance, behavior, food consumption, or clinical or anatomical pathology in the low- and mid-dose groups. Based on the results of this study, it was recommended that dosage levels in a two-generation reproduction toxicity study not exceed 1000 ppm. The LOAEL for maternal toxicity was 6250 ppm (~463 mg/kg-bw/day) based on reductions in body weight gains. The NOAEL for maternal toxicity was 1000 ppm (~74 mg/kg-bw/day). The LOAEL for developmental toxicity was 1000 ppm (~62/74 mg/kg-bw/day) based on pup mortality due to hemorrhaging. The NOAEL for developmental toxicity was 100 ppm (~6/8 mg/kg-bw/day). No effects on any of the reproductive parameters were reported. The NOAEL for reproductive toxicity was 6250 ppm (~384/463 mg/kg-bw/day).

In an effort to determine the cause of hemorrhaging in the pups at the high dose from the reproductive toxicity range-finding study, a screening level cross-fostering developmental toxicity study was conducted in Charles River COBS Wistar rats fed diets containing either 0 or 6250 ppm (~ 3125 mg/kg-bw/day) MCCPs (C_{14-17}, 52 wt% Cl) for 4 weeks prior to mating and throughout pregnancy in a series of groups (Hart *et al*., 1985; *cited in:* ECB, 2008). Offspring from two of these groups (pups from control females reared from treated females, and pups reared from their treated mothers) showed high-pup mortality associated with internal hemorrhages. Hematological assays in the pups from these two groups showed decreases in factor X, resulting in a disruption of a vitamin K-dependent clotting system (lower plasma vitamin K levels). It was concluded that the pup mortalities were due to internal hemorrhages caused by a decrease in the vitamin K-dependent hemostatic mechanism (not examined in this study), induced during lactational exposures *via* the milk from mothers receiving MCCPs.

Additional studies have been conducted to investigate two hypotheses in an effort to clarify the possible causes of the hemorrhaging in the pups.

The first hypothesis proposes that MCCPs induce a catabolism of vitamin K in lactating rats leading to decreased plasma concentrations and ultimately low levels of vitamin K in the milk pups receive (vitamin K controls the formation of several clotting factors in the liver). In order to test this hypothesis, a preliminary study (CXR Biosciences Ltd., 2003; *cited in:* ECB, 2008) was conducted in which three groups of 6 female adult Sprague-Dawley were administered MCCPs (C_{14-17}, 52wt% Cl) *via* gavage at doses of 0, 500, or 1000 mg/kg-bw/day for 21 days while being fed a normal diet or a vitamin K-deficient diet. Following exposures to MCCPs, significant decreases in plasma concentrations of a clotting factor were seen in rats fed a normal diet; however, these decreases did not affect prothrombin clotting times. Reductions of a clotting factor in both treated and control groups were also seen in animals fed a vitamin-K deficient diet. Plasma vitamin K levels were not affected by treatment in the normal diets, but they were lower in high-dose animals fed vitamin K-deficient diets. The results from this study suggested that MCCPs did not adversely affect the blood clotting system in adult female rats treated for 3 weeks up to a dose of 1000 mg/kg-bw/day; and the hemorrhaging effects in pups are unlikely to be mediated by reduced vitamin K levels in breast milk.

The second hypothesis proposes that MCCPs transferred to the pups through breast milk causes disruption of the pup clotting system. In order to test this hypothesis, a study (CXR Biosciences Ltd., 2004; *cited in:* ECB, 2008) was conducted in two groups of 16 male and 32 female Sprague-Dawley rats administered 0 or 6250 ppm (~ 0 and 513 and 538 mg/kg-bw/day in males and females, respectively) MCCPs (C_{14-17}, 52 wt% Cl) for 4 weeks prior to mating, during cohabitation, gestation, and lactation until study termination (at about 2 weeks after the first litters were born, due to high rate of pup mortality). Milk, blood, and liver samples from

lactating dams, and blood and liver samples from lactating pups were assessed for plasma vitamin K levels. Five dams died or were killed at the time of parturition (16% mortality). These deaths were considered to be treatment-related as there was no indication of obstruction or hindrance to delivery. The clinical necropsy of these dams showed effects suggestive of hemorrhaging in 3 out of the 5 dams and one male who died. Slight reductions in food consumption and body weight gains were observed during gestation and lactation. There were no effects on mating performance or duration of gestation. Concentrations of plasma vitamin K levels in adult females having gone through lactation and pregnancy was markedly decreased by treatment with MCCPs, which in turn produced a decrease in activity of the plasma clotting factors in treated dams. Prothrombin clotting times were not affected in the dams, suggesting that the functional reserve in these adult animals was sufficient. Pup plasma volumes were reportedly insufficient to measure vitamin K directly, but clotting factor activities were possible to analyze. No effects on litter size at birth or on pup mortality from birth to LD 4 were reported; however, after pup mortality increased significantly after LD 4. The majority of these pups showed internal hemorrhages at necropsy. It was concluded that data from this study and the cross-fostering study performed by Hart *et al*. (1985) suggest that the fetus receives sufficient vitamin K *via* the placenta, but after birth becomes severely deficient in vitamin K and related clotting factors and relies on these factors *via* mother's milk. In addition, the pups also receive considerable levels of MCCPs *via* lactation (through mother's milk) which may also contribute to further reducing the vitamin K levels. These severe deficiencies in vitamin K levels and related clotting factors in the pups results in hemorrhaging. It was also concluded that the act of parturition places dams at higher risk.

More recently, a definitive one-generation reproductive toxicity study was conducted to refine the NOAEL for effects in the offspring and to further explore the mechanisms of hemorrhaging (CXR, 2006; *cited in:* ECB, 2008). This study was reportedly conducted in compliance with OECD TG 421 and Good Laboratory Practice standards. Four groups of 12-17 male and female Sprague-Dawley rats were administered 0, 300, 600, and 1200 ppm (~ 0 and 21, 44, and 84 mg/kg-bw/day in males; and 0, 23, 47, and 99 mg/kg-bw/day in females) MCCPs (C_{14-17}, 52 wt% Cl) for 4 weeks prior to mating, during cohabitation, gestation, and lactation until study termination (for a total treatment of 11-12 weeks). Males were terminated on LD 4 (9 weeks of treatment) and females were allowed to litter and rear their offspring until PND 21. Females were sacrificed on LD 21. Adult males were assessed for signs of clinical toxicity, body weight, food consumption, and macropathology. Adult females were assessed for signs of clinical toxicity, body weight, food consumption, gestation length, parturition, liver weights, and macropathology. Mating performance and fertility were also evaluated. Offspring evaluations included clinical signs of toxicity, litter size, survival, sex ratio, body weight, and pathological examinations at necropsy. Milk, blood, and liver samples were obtained from selected offspring at specific time points between birth of litters and PND 21. In addition, blood, liver, and milk samples from a satellite group of five females and their litters from the control and high-dose group (1200 ppm) were collected for future analysis. Analysis of these samples was still pending at the time of the UK assessment.

No adverse effects were reported in the adult animals for clinical condition, body weight, body weight gain, food consumption, estrous cycling, mating performance, pre-coital interval, fertility, number of implantations, gestation lengths, or parturition. The only effect reported was for higher absolute and relative liver weights in high-dose females (1200 ppm; 99 mg/kg-bw/day). Likewise, no adverse effects were in the offspring at any dose level for litter size, sex ratio, offspring survival, body weights, body weight gains, macropathology and liver weights. No adverse effects were reported on pre- and post-natal survival and growth up to sacrifice

(weaning). Though no histopathology was performed, the body cavity and cranial cavity were opened and examined for any signs of hemorrhaging. None was reported. Based on the results of this study, the LOAEL for maternal toxicity was 1200 ppm (~100 mg/kg-bw/day) based on increases in liver weight; the NOAEL for maternal toxicity was 600 ppm (~ 47 mg/kg-bw/day). The NOAEL for developmental and reproductive toxicity was 1200 ppm (~ 84/99 mg/kg-bw/day), the highest dose tested.

Appendix D ENVIRONMENTAL MONITORING DATA

D-1 MCCP MONITORING DATA

D-1-1 Surface Water

It is known that over time, based on their molecular weight and physicochemical properties, MCCPs in surface water will partition to suspended particulates, sediment, sludge, or soil. Reported MCCP concentrations in surface water range from < 2.50×10^{-10} mg/L to 1.49 x 10^{-3} (Table_Apx D-1-1). Very little information is available on the specific sampling locations for many of the surface water measurements reported in Table_Apx D-1-1. Limited documentation is available on two of the studies (Petersen et al., 2006 and Muir, 2003). Two sources provide a review of the literature with very little details (IPCS, 1996 and EC, 2008b). Two studies do provide detailed information on the sampling approach, including location (Houde et al., 2008 and USEPA, 1988). The Petersen et al. (2006) study, which had the highest published concentration, reported results for water samples collected from different Norwegian locations. EPA/OPPT assumes that these samples were collected in non-marine waters. Three studies found were not used in this assessment (BUA, 1992; Hoechst, 1987; and Willis, 1994). However, all of the studies used in the assessment use modern analytical techniques, reference the specific CPs of interest, and provide, at a minimum, general information on the sampling location. Given the paucity of surface water data available, EPA/OPPT used measurements from the selected studies and used the minimum and maximum values in this assessment.

Measurements of dissolved (filtered) concentrations were generally ND with few exceptions. Concentrations measured in surface water were largely from studies that measured total water concentrations which included MCCPs sorbed to particulates. More recent monitoring studies (**Error! Reference source not found.**e_Apx D-1-1) have focused on measuring MCCPs in suspended solids, sediment pore water, and sediment.

Early analytical methods using thin layer chromatography (TLC) were used to measure CPs in surface water. However, this method has poor sensitivity and reproducibility, and provide false negative results. Current methods of quantification using gas or liquid chromatography coupled with a range of detectors (*i.e.*, mass spectrometry; MS) are more reliable. Nearly all of the water concentrations were measurements taken at a single point in time (*i.e.*, the samples were not time series samples). Absent more extensive monitoring data, the Agency assumed that the available data could be extrapolated to longer time periods for determination of a chronic exposure concentration.

MCCP concentrations in surface water, reported in **Error! Reference source not found.**e_Apx D-1-1, rely on test methods that filtered or pre-filtered samples before they were analyzed, which can underestimate environmental concentrations. Where appropriate, reported values were converted to a common unit, as presented in the table. For the purposes of this assessment, in the studies considered acceptable, EPA/OPPT used the lowest and highest reported concentrations (< 2.50×10^{-10} mg/L to 1.49 x 10^{-3}) to evaluate risks of potential concern to aquatic organisms.

Table_Apx D-1-1: Surface Water Concentrations of MCCPs, sorted by country

Media	Country	Location City, State or Province	Comments	Converted Concentration	Common Units	Analytical Method	References
Surface water	Canada	Lake Ontario	Maximum	2.60×10^{-9}	mg/L	NR	EC (2008b)
			<	2.50×10^{-10}	mg/L	GC-HRMS-MAB	Houde et al. (2008)
			<	1.00×10^{-8}	mg/L	GC-ECNI-MS	Muir et al. (2003)
			Maximum	4.70×10^{-8}	mg/L	GC-HRMS-MAB	Houde et al. (2008)
			Mean	9.00×10^{-10}	mg/L	GC-HRMS-MAB	Houde et al. (2008)
	Germany	River Lech at Langsweid	---	1.90×10^{-4}	mg/L	NR	IPCS (1996)
		River Lech at Rain	---	1.70×10^{-4}	mg/L	NR	IPCS (1996)
		River Lech at Gersthofen	---	9.00×10^{-5}	mg/L	NR	IPCS (1996)
		River Lech at Augsburg	<	2.50×10^{-5}	mg/L	NR	IPCS (1996)
		River Danube at Marxheim	---	7.00×10^{-5}	mg/L	NR	IPCS (1996)
			<	3.00×10^{-5}	mg/L	NR	IPCS (1996)
	Norway	NR	---	1.49×10^{-3}	mg/L	GC-ECNI-MS	Petersen et al. (2006)
	United Kingdom	Multiple locations	<	1×10^{-4}	mg/L	GC-ECNI-MS	Nicholls et al. (2001)
	United States	Sugar Creek, Ohio	<	7.50×10^{-5}	mg/L	GC-ECNI-MS	USEPA (1988)
	Central European Country	NR	<	5.00×10^{-5}	mg/L	GC-ECNI-MS	Coelhan (2010)

NR: Not recorded. Location description was not provided in the study.
--: Single sample value reported above the detection limit; therefore, no data qualifier required.
GC-HRMS-MAB: Gas chromatography-high resolution mass spectrometry with metastable atom bombardment ionization
GC-ECNI-MS: Gas chromatography in combination with electron capture negative ion mass spectrometry
Notes:
1. All values provided in the table above represent total MCCP and not individual MCCP isomers
2. In some cases, the minimum values in the table are preceded by "<". This indicates that the value reported in article was reported as a non-detect. In such cases, one half of the lowest reported detection limit was compiled as the 'minimum' reported monitoring data
3. All concentrations measured from impoundment lagoons and drainage ditches from the USEPA (1988) study have not been included as they are not considered as surface water concentrations
4. All concentrations measured from suspended solid matter fraction from influents from the Coelhan (2010) study have not been included as they are not considered as surface water concentrations

D-1-2 Sediment

MCCP sediment concentrations from marine and non-marine environments ranged from 5.00×10^{-3} to 1.64×10^{1} mg/kg dw and from 2.00×10^{-3} to 6.51×10^{1} mg/kg dw, respectively.

For the purposes of this assessment, in the studies considered acceptable, EPA used the lowest and highest reported marine and non-marine sediment concentrations (5.00×10^{-3} to 1.64×10^{1} mg/kg dw and 2.00×10^{-3} to 6.51×10^{1}, respectively) to evaluate risks of potential concern to sediment organisms (Table_Apx D-1-2). Where appropriate, reported values were converted to a common unit, as presented in the table.

Table_Apx D-1-2: Sediment Concentrations of MCCPs, Sorted by Country

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
Sediment (Marine)	Australia	NR	---	1.11	mg/kg dw	Kemmlein et al. (2002)
			---	1.17	mg/kg dw	Kemmlein et al. (2002)
			---	3.11	mg/kg dw	Kemmlein et al. (2002)
			---	1.64×10^{1}	mg/kg dw	Kemmlein et al. (2002)
	Canada	Hamilton Harbour (Windemere basin)	---	2.90×10^{-1}	mg/kg*	Muir et al. (2000)
	Germany	German Bight, North Sea	---	5.00×10^{-3}	mg/kg dw	Hüttig et al. (2004)
			---	9.00×10^{-3}	mg/kg dw	Hüttig et al. (2004)
			---	9.00×10^{-3}	mg/kg dw	Hüttig et al. (2004)
			---	1.30×10^{-2}	mg/kg dw	Hüttig et al. (2004)
			---	2.80×10^{-2}	mg/kg dw	Hüttig et al. (2004)
			---	1.46×10^{-1}	mg/kg dw	Hüttig et al. (2004)
		Baltic Sea	---	9.30×10^{-2}	mg/kg dw	Hüttig et al. (2004)
			---	1.15×10^{-1}	mg/kg dw	Hüttig et al. (2004)
			---	1.22×10^{-1}	mg/kg dw	Hüttig et al. (2004)
			---	2.11×10^{-1}	mg/kg dw	Hüttig et al. (2004)
			---	4.99×10^{-1}	mg/kg dw	Hüttig et al. (2004)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
		North and Baltic Sea	---	2.20×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	2.30×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	3.30×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	3.40×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	3.70×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	3.90×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	4.30×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	4.30×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	4.80×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	5.40×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	5.80×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	6.10×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	7.20×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	7.60×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	7.70×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	8.10×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	8.50×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)
			---	8.70×10^{-2}	mg/kg dw	Hüttig and Oehme (2006)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
			---	1.49×10^{-1}	mg/kg dw	Hüttig and Oehme (2006)
			---	1.49×10^{-1}	mg/kg dw	Hüttig and Oehme (2006)
			---	1.49×10^{-1}	mg/kg dw	Hüttig and Oehme (2006)
			---	2.75×10^{-1}	mg/kg dw	Hüttig and Oehme (2006)
			---	9.10×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	4.80×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.98×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.31×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.32×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	3.03×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.53×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.14×10^{-1}	mg/kg dw	Hüttig and Oehme (2005)
			---	4.00×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	2.70×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.80×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	1.90×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	3.00×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	3.20×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
			---	1.80×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
			---	2.40×10^{-2}	mg/kg dw	Hüttig and Oehme (2005)
Sediment (Non-marine)	Canada	Lake Erie	---	6.80×10^{-2}	mg/kg dw	Tomy and Stern (1999)
		Lake St Francis	Minimum	7.50×10^{-1}	mg/kg dw	EC (2008b)
			Maximum	1.2	mg/kg dw	EC (2008b)
	Czech Republic	NR	Minimum	2.00×10^{-3}	mg/kg*	Pribylova et al. (2006)
		Labe	Sum	1.80×10^{-2}	mg/kg dw	Pribylova et al. (2006)
			Sum	7.30×10^{-2}	mg/kg dw	Pribylova et al. (2006)
		Libis-Labe	Sum	1.6	mg/kg dw	Pribylova et al. (2006)
		Bilina	Sum	3.10×10^{-2}	mg/kg dw	Pribylova et al. (2006)
		Mala Becva	Sum	1.13×10^{-1}	mg/kg dw	Pribylova et al. (2006)
		Becva	Sum	1.20×10^{-1}	mg/kg dw	Pribylova et al. (2006)
		Morava	Sum	1.93×10^{-1}	mg/kg dw	Pribylova et al. (2006)
		Ohre	Sum	3.08×10^{-1}	mg/kg dw	Pribylova et al. (2006)
			Sum	6.00×10^{-1}	mg/kg dw	Pribylova et al. (2006)
			Sum	5.58	mg/kg dw	Pribylova et al. (2006)
		Morava	Sum	4.16×10^{-1}	mg/kg dw	Pribylova et al. (2006)
		Dyje	Sum	7.57×10^{-1}	mg/kg dw	Pribylova et al. (2006)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
		Drevnice	Sum	8.93×10^{-1}	mg/kg dw	Pribylova et al. (2006)
	Germany	Bodensee (middle)	<	5.00×10^{-3}	mg/kg dw	IPCS (1996)
			---	7.00×10^{-2}	mg/kg dw	IPCS (1996)
		River Lech	<	5.00×10^{-3}	mg/kg dw	IPCS (1996)
			---	3.25×10^{-1}	mg/kg dw	IPCS (1996)
			Maximum	7.00×10^{-1}	mg/kg*	Tomy et al. (1998)
		River Rhine	---	6.00×10^{-2}	mg/kg dw	IPCS (1996)
			---	8.50×10^{-2}	mg/kg dw	IPCS (1996)
			---	1.40×10^{-1}	mg/kg dw	IPCS (1996)
			Minimum	1.45×10^{-1}	mg/kg dw	IPCS (1996)
			Maximum	2.05×10^{-1}	mg/kg dw	IPCS (1996)
		River Elbe at Hamburg	Minimum	1.30×10^{-1}	mg/kg dw	IPCS (1996)
			Maximum	2.30×10^{-1}	mg/kg dw	IPCS (1996)
		River Main	Minimum	1.60×10^{-1}	mg/kg dw	IPCS (1996)
			Maximum	2.60×10^{-1}	mg/kg dw	IPCS (1996)
		Outer Alster, Hamburg	---	3.70×10^{-1}	mg/kg dw	IPCS (1996)
	Norway	NR	minimum	5.00×10^{-2}	mg/kg dw	Petersen et al. (2006)
			maximum	3.24	mg/kg dw	Petersen et al. (2006)
			---	2.7	mg/kg ww	Borgen et al. (2003)
			---	1.14×10^{1}	mg/kg ww	Borgen et al. (2003)
	South China	Pearl River Delta	Minimum	8.80×10^{-1}	mg/kg dw	Chen et al. (2011)
			Minimum	1.1	mg/kg dw	Chen et al. (2011)
			Minimum	1.4	mg/kg dw	Chen et al. (2011)
			Maximum	1.4	mg/kg dw	Chen et al. (2011)
			Maximum	3.8	mg/kg dw	Chen et al. (2011)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
			Mean	3.9	mg/kg dw	Chen et al. (2011)
			Mean	2.10×10^{1}	mg/kg dw	Chen et al. (2011)
			Maximum	3.80×10^{1}	mg/kg dw	Chen et al. (2011)
	Switzerland	Lake Thun	Minimum	5.00×10^{-3}	mg/kg dw	Iozza et al. (2008)
			Maximum	2.60×10^{-2}	mg/kg dw	Iozza et al. (2008)
		Lake Zurich	Maximum	5.00×10^{-3}	mg/kg*	Tomy et al. (1998)
	United Kingdom	NR	<	1.00×10^{-1}	mg/kg dw	Nicholls et al. (2001)
		South West Region: Grand Union Canal	---	3.00×10^{-1}	mg/kg dw	Nicholls et al. (2001)
			---	2.7	mg/kg dw	Nicholls et al. (2001)
			---	2.8	mg/kg dw	Nicholls et al. (2001)
		South West Region; Bristol Avon River	---	5.00×10^{-1}	mg/kg dw	Nicholls et al. (2001)
			---	6.00×10^{-1}	mg/kg dw	Nicholls et al. (2001)
			---	8.00×10^{-1}	mg/kg dw	Nicholls et al. (2001)
		North East Region: Hull River	---	1.0	mg/kg dw	Nicholls et al. (2001)
			---	1.35×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	1.1	mg/kg dw	Nicholls et al. (2001)
		South West Region: Colne River	---	1.4	mg/kg dw	Nicholls et al. (2001)
			---	2.0	mg/kg dw	Nicholls et al. (2001)
		West Midlands Region: Trent River	---	3.8	mg/kg dw	Nicholls et al. (2001)
			---	6.02×10^{1}	mg/kg dw	Nicholls et al. (2001)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
			---	6.51×10^{1}	mg/kg dw	Nicholls et al. (2001)
		North West Region: Hornsmill brook	---	5.6	mg/kg dw	Nicholls et al. (2001)
			---	1.25×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	1.83×10^{1}	mg/kg dw	Nicholls et al. (2001)
		North East Region: Hull River	---	1.0	mg/kg dw	Nicholls et al. (2001)
			---	1.1	mg/kg dw	Nicholls et al. (2001)
			---	1.35×10^{1}	mg/kg dw	Nicholls et al. (2001)
		East Midlands Region: Idle River	---	1.62×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	4.39×10^{1}	mg/kg dw	Nicholls et al. (2001)
		Northumberland Region: Skerne River	---	1.80×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	2.56×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	5.84×10^{1}	mg/kg dw	Nicholls et al. (2001)
		East Anglia Region: Lark River	---	3.22×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	4.50×10^{1}	mg/kg dw	Nicholls et al. (2001)
			---	6.04×10^{1}	mg/kg dw	Nicholls et al. (2001)
	United States	Detroit River	---	6.80×10^{-2}	mg/kg dw	Tomy et al. (1999)
		Sugar Creek, Ohio	Reported as trace with range of 1.5-5; used the average	3.25×10^{-3}	mg/kg dw	USEPA (1988)

Media	Country	Location	Comments	Converted Concentration	Common Units	References
		City, State or Province				
			Reported as trace with range of 1.5-5; used the average	3.25×10^{-3}	mg/kg dw	USEPA (1988)
			---	6.80×10^{-3}	mg/kg dw	USEPA (1988)
			---	8.20×10^{-3}	mg/kg dw	USEPA (1988)
			---	7.60×10^{-1}	mg/kg dw	USEPA (1988)
			---	2.10×10^{1}	mg/kg dw	USEPA (1988)
			---	3.40×10^{1}	mg/kg dw	USEPA (1988)
			---	5.00×10^{1}	mg/kg dw	USEPA (1988)

Note:

NR: Not recorded. Location description was not provided in the study.

--: Single sample value reported above the detection limit; therefore, no data qualifier required.

1. All values provided in the table above represent total MCCP and not individual MCCP isomers
2. In some cases, the minimum values in the table are preceded by "<". This indicates that the value reported in article was reported as a non-detect. In such cases, one half of the lowest reported detection limit was compiled as the 'minimum' reported monitoring data
3. dw. – dry weight and ww. – wet weight

D-1-3 Biosolids and Soil

CPs are detected more frequently and at higher concentrations in treated sewage sludge (*i.e.*, biosolids) than in soil. MCCP concentrations ranged from 5.00×10^{-5} to 9.70×10^{3} mg/kg dw in sludge and from 1.5×10^{-2} to 8.5×10^{-2} mg/kg dw in soil. It is unclear if the difference in MCCP concentrations in sludge and soil is related to the smaller sample sizes for these media compared to the typically larger data sets available for water and sediment. To determine the most reliable studies for its consideration, EPA/OPPT used the following criteria: designation of specific MCCP chain length and the appropriate analytical methodology. Thus, EPA/OPPT did not use information from other published studies reporting measured CPs in sludge and soil because they did not distinguish the CPs measured (*e.g.*, Nicholls et al., 2001); although they reported total CP concentrations at much lower levels ranging from 3.00×10^{-5} to 2.3 mg/kg dw. .

Stevens et al. (2003) measured MCCP concentrations in sludge samples obtained from 14 WWTPs in the UK. MCCP concentrations ranged from 3.00×10^{1} to 9.70×10^{3} mg/kg dw. The authors concluded that these very high concentrations were likely the result of releases from numerous and ongoing diffuse sources.

Although risk to terrestrial species was not calculated, EPA/OPPT notes that the lowest and highest reported biosolid and soil concentrations (5.00×10^{-5} to 9.70×10^{3} mg/kg dw and 1.5×10^{-2} to 8.5×10^{-2} mg/kg dw, respectively) represents a very large range (up to eight orders of magnitude (Table_Apx D-1-3).

Table_Apx D-1-3: Biosolid and Soil Concentrations of MCCPs

Location	Media	Concentration		Units	References
		Minimum	Maximum		
Switzerland	Soil	1.5×10^{-2}	8.5×10^{-2}	mg/kg dw	Iozza (2010)
China	Soil	2.1×10^{-6}	1.53×10^{-3}	mg/kg dw	Wang et al. (2013)
Czech Republic	Sewage Sludge	7.36×10^{-1}	2.30	mg/kg dw	Pribylova et al. (2006)
United Kingdom	Sewage Sludge	3.00×10^{1}	9.70×10^{3}	mg/kg dw	Stevens et al. (2003)
United States	Sewage Sludge	5.00×10^{-5}	5.00×10^{-5}	mg/kg dw	Pribylova et al. (2006)

D-1-4 Biota

EPA/OPPT reviewed available published literature and summarized MCCP concentrations in tissues of aquatic and terrestrial biota (Table D-4). Measured tissue concentrations for aquatic biota ranged from ND to 2.63 mg/kg ww (*i.e.*, beluga whales, seals, rainbow trout, carp, mackerel, arctic char, mussels, crustaceans, and plankton) and ranged from 5.00×10^{-3} to 3.70×10^{-1} mg/kg ww in terrestrial biota. The concentrations measured in the terrestrial studies did not designate the specific CP congener groups measured.

As a result of the Agency's evaluation, MCCPs were found in organisms across many different trophic levels indicating widespread environmental contamination (Table_Apx D-1-4). The data were insufficient for EPA/OPPT to draw conclusions about trends based on region, species, time, or other factors.

While EPA/OPPT determined the concentrations of MCCPs in aquatic and terrestrial biota range from ND to 2.63 mg/kg ww and from 5.00×10^{-3} to 3.70×10^{-1} mg/kg ww, respectively, in this assessment, the Agency did not use tissue concentrations to determine risks of potential concern for biota. Rather, it used the risk quotient (RQ) method and the conventional PMN approach as described in Section 6.

Table_Apx D-1-4: Biota Concentrations of MCCPs

Location	Media Description	Minimum	Units	Min Reference	Maximum	Units	Max Reference
Aquatic Biota							
Australia	Invertebrates	$2.32x10^{-5}$	mg/kg lw	Kemmlein et al. (2002)	$3.05x10^{-5}$	mg/kg lw	Kemmlein et al. (2002)
Canada	Mammals	$5.45x10^{-7}$	mg/kg ww	Bennie et al. (2000)	$8.00x10^{-5}$	mg/kg ww	Bennie et al. (2000)
	Fish	$2.57x10^{-7}$	mg/kg ww	Bennie et al. (2000)	2.63	mg/kg ww	Muir et al. (2000)
	Invertebrates	ND[1]	mg/kg ww	EC (1993)	ND[1]	mg/kg ww	EC (1993)
	Total	ND[1]	mg/kg ww	EC (1993)	2.63	mg/kg ww	Muir et al. (2000)
Europe	Fish	$7.00x10^{-3}$	mg/kg ww	Reth et al. (2006)	$4.70x10^{-2}$	mg/kg ww	Reth et al. (2006)
North Sea/Baltic Sea Region[2]	Fish	ND[3]	mg/kg ww	IVL (2009)	$2.6x10^{-1}$	mg/kg ww	Reth et al. (2005)
United States	Fish	$2.90x10^{-3}$	mg/kg ww	Tomy and Stern (1999)	$9.04x10^{-1}$	mg/kg ww	Tomy and Stern (1999)
	Invertebrates	$3.50x10^{-3}$	mg/kg ww	USEPA (1988)	$1.70x10^{-1}$	mg/kg ww	USEPA (1988)
	Total	$2.90x10^{-3}$	mg/kg ww	Tomy and Stern (1999)	$9.04x10^{-1}$	mg/kg ww	Tomy and Stern (1999)
United States / Canada - Great Lakes	Fish	$1.80x10^{-3}$	mg/kg ww	Muir et al. (2003)	$1.10x10^{-1}$	mg/kg ww	Muir et al. (2003)
	Invertebrates	$2.40x10^{-3}$	mg/kg ww	EC (2008a)	$1.60x10^{-2}$	mg/kg ww	Muir et al. (2003)
	Total	$1.80x10^{-3}$	mg/kg ww	Muir et al. (2003)	$1.10x10^{-1}$	mg/kg ww.	Muir et al. (2003)
Terrestrial Biota							
Europe	Birds	$5.00x10^{-3}$	mg/kg ww	Reth et al. (2006)	$3.70x10^{-1}$	mg/kg ww	Reth et al. (2006)

Notes:
Summary values represent total MCCP and not individual MCCP isomers.
[1] MCCPs were not detected in Invertebrates from Canada. Detection limit = 4.0×10^{-7} mg/kg; ½ DL = 2.0×10^{-7} (EC, 1993).
[2] North Sea/Baltic Sea Region includes the following countries: Estonia, Latvia, Lithuania, Norway, Poland, and Sweden.
[3] The minimum MCCP concentration value for fish from the North Sea/Baltic Sea Region was non-detect. The detection limit = 2.5×10^{-4} mg/kg; ½ DL = 1.25×10^{-4} (IVL 2009)

Appendix E ENGINEERING (ChemSTEER) REPORTS ON P-14-0683 AND P-14-0684

INITIAL REVIEW ENGINEERING REPORT

P-14-0684 C
P-14-0683, P-14-0684
CEB Staff Draft 8/26/2014 11:00:00 PM

ENGINEER:
PV (kg/yr): 15000000

Revision Notes/Assessment Overview:

SUBMITTER: Qualice, LLC (submitter)

USE: The uses are equally split between flame retardant/plasticizer in the rubber (50%) and lubricant in metal working fluids (MWFs) (50%). These uses are consistent with all the lit and previous cases submitted. Other potential uses are listed elsewhere. Lubricants can have more variety of chlorine content based on application needs, while rubber formulations have chlorine content more steady around the 52% levels. Related Cases Submitted Together: P-14-0683, P-14-0684.

OTHER USES: Generic uses MCCP: 1) Substances are used as a flame retardant/plasticizer in polymers; 2) used as lubricants in automotives 3) as components of solvent based paints, adhesives and sealants. The paints are specialty paints for applications where weather resistant coatings are needed, such as steel construction, industrial flooring, road marking, window sealants and pools; and 4) flame retardants / waterproofers to textiles.

MSDS: Yes **LABEL**: Yes

Gen Eqpt: Eng Controls: Under normal conditions of use, natural ventilation should effectively remove and prevent buildup of any vapor/mist/fume/dust generated from the handling of this product. // Eye/Face: If splashes are likely to occur, wear safety glasses with side-shields or a face shield with safety glasses. // Skin: Normal work clothing (long sleeved shirts and long pants) is recommended. If splashes are likely to occur, use apron or impervious suit, such as a Tyvek coverall. If liquid contact is likely to occur, manufacturer recommends nitrile gloves (ex: N-DEX Nitrile).
Respirator: No personal respiratory protective equipment normally required. If mist is generated (heating, spraying) and engineering controls are not sufficient, wear NIOSH certified organic vapor respirator with particulate filter.
Health Effects: Eye: Contact with eyes may cause irritation // Skin: Prolonged and/or repeated skin contact may result in mild irritation or redness // Inhalation: Avoid breathing vapors or mists of this product. May cause irritation of respiratory tract. // Ingestion: Small amounts (a tablespoonful) swallowed during normal handling operations are not likely to cause injury; swallowing amounts larger than that may cause injury.
TLV/PEL: - none established

CRSS: (7/17/2014 1:00:00 AM):
Chemical Name: Tetradecane, chloro derivs.
S-H2O: 0.000005 g/L @
VP: 2.0E-6 torr @
MW: 440 0.0%<500 0.0%<1000
Physical State and Misc CRSS Info:
Neat: liquid **Mfg:** liquid
Proc/Form: liquid **End Use:** 10 - 15% in final product. The stoicheometer of the process diagram would produce PMN products that are average molecular formula containing 6 - 8 chlorine atoms. The starting olefin is 98% C14 and 93% alpha oleffin. The typical MW is near 440 daltons for a Cl7 congener based on total PV of > 40 to < 70 wt% chlorine content.

Consumer Use: No

SAT (concerns): (7/17/2014 11:00:00 PM):

Related Cases and Misc SAT Info:
Same as P-12-0283. Analogs: P-12-0282, P-12-0357, P-12-0453 all MCCPs
Migration to groundwater: Slow

PBT rating: P3 **B**3 **T**2
Health: 1, No exposures needed
Eco: 3, Water (All releases to water with a CC = 1 ppb), XB Testing (Testing desired)

OCCUPATIONAL EXPOSURE RATING: 2-3D

NOTES & KEY ASSUMPTIONS:
Generated by the 06/07/2005 version of ChemSTEER. This is a consolidated set: P14-0683 & 0684. The two PMNs have identical volume, use rate, concentration and uses. PB ratings are P2B3; therefore, a full assessment is performed. This is an exposure-based case; all exposure criteria met; XB testing desired for Eco. //// Note P14-0684 was previously submitted as P12-0357 by Trinity, but the case was later withdrawn. //// The PMN is a MCCP product that is manufactured domestically and used in the following applications: 1) 50% as a flame retardant in rubber products; and 2) 50% as a lubricant in metal working fluids (MWFs). // The technical contact was called, see contact report for details. // Note, this IRER is consistent with past assessment of P12-0357 (same chemical as P14-0684, same uses), except that this IRER assesses a separate converting operation based on latest information provided by technical contact. Further, this IRER was prepared using the same methdology as the following past MCCP cases: P12-0277 through P12-0284, and P12-0453. //// For MFG: Submitter estimates were used for assessing submitter specified waste streams and standard models were used to assess equipment cleaning. Dermal exposure was assessed using standard models and inhalation exposure is expected to be negl. // For downstream processing and use operations: The release and exposure estimates were based on a combination of submitter provided data and data available in various literature sources. The literature sources include 1) previous EPA/OPPT assessments on chlorinated paraffins; 2) foreign risk assessments on MCCPs and LCCPs (e.g. EU risk assessments); 3) EPA/OPPT Generic Scenarios; and 4) OECD Emission Scenario Documents. Due to the uncertainty at multiple downstream use sites, the most conservative data were chosen when evaluating releases for downstream operations.

POLLUTION PREVENTION CONSIDERATIONS:
P2 claims were made for the MCCP being an alternative to the SCCP. P2 claims were also made for MCCP as an alternative for phthalates. While true neither merits recognition.

P2 REC: P2 claims were made for the MCCP being an alternative to the SCCP. P2 claims were also made for MCCP as an alternative for phthalates. While true neither merits recognition.

EXPOSURE-BASED REVIEW: Yes **(3 criteria met)**

1) # of workers exposed: 149,846 **>1000?** Yes
2) >100 workers with > 10 mg/day inhalation exposure: Yes
3) (a) >100 workers w/1-10 mg/day inh. exp. & >100 days/yr: Yes
(b) Routine Dermal Cont: > 250 workers & > 100 days/yr: Yes

MFG: Batch Manufacturing of PMN

Number of Sites/Location: 1 submitter site(s)

Qualice, LLC Hamlet NC 28345
Basis: Per submission, 1 submitter site, 375 bt/yr, 12 hr/bt, 20,000 kg/bt, PMN produced as a liquid at 100%. CS calculates 750 bt/yr based on submitted PV of 15,000,000 kg/yr. Assumed 3 processing lines per site.
Process Description: Feedstock charged to a reactor ---> chlorine gas in fed to reactor ---> byproduct gas is recovered and treated and produces waste PMN stream, bleach and HCl product ---> reaction forms PMN (liquid, 100%) --> QC sampling ---> stabilizer added ---> transfer to storage ---> loading PMN product (liquid, 100%) into tank trucks (90% of PV) or totes (10% of PV) (submission)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Incineration or Landfill
Conservative: 4.0E+2 kg/site-day over 1 day/yr from 1 sites or 4.0E+2 kg/yr
to: uncertain
from: Equipment Cleaning Losses of Liquids from Multiple Vessels
basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. The submission states that equipment cleaning is not performed between batches (not needed). As conservative, CEB assesses cleaning of equipment for 1 day/yr to address the possibility of equipment cleaning due to unforseen circumstances with releases to uncertain media.

Incineration
Output 2: 2.2E+1 kg/site-day over 250 day/yr from 1 sites or 5.4E+3 kg/yr
to: off-site incineration (submission)
from: Waste from Byproduct Gas Recovery
basis: User-Defined Loss Rate Model. The submission estimates 7.2 kg/bt of PMN is released to off-site incineration from waste PMN produced during byproduct gas recovery. CS calculates 3 bt/day resulting in a release of (7.2 x 3) = 21.6 kg/site-day.

Landfill
Output 2: 9.0E+0 kg/site-day over 250 day/yr from 1 sites or 2.2E+3 kg/yr
to: RCRA Subtitle D landfill (submission)
from: Carbon Waste from HCl Carbon Treatment
basis: User-Defined Loss Rate Model. The submission estimates 3 kg/bt of PMN is released to a RCRA subtitle D landfill from waste carbon produced HCl carbon treatment. CS calculates 3 bt/day resulting in a release of (3 x 3) = 9 kg/site-day.

RELEASE TOTAL

8.0E+3 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 6
Basis: The submission estimates up to 3 workers/site exposed to PMN at during various activities. As conservative, CEB assesses dermal exposure for all workers to liquid PMN at 100% during sampling (1-hand) and loading (2-hand) activities.

Dermal:

Exposure to Liquid
High End: 1.1E+3 mg/day over 250 days/yr
Number of workers (all sites) with Dermal exposure: 3
Basis: Sampling Liquid Product; EPA/OPPT 1-Hand Dermal Contact with Liquids Model.

Dermal:

Exposure to Liquid
High End: 2.2E+3 mg/day over 250 days/yr
Number of workers (all sites) with Dermal exposure: 3
Basis: Loading Liquid Product into Transport Containers; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

P-14-0684 C
P-14-0683, P-14-0684

PROC2: Compounding of Rubber Products (50% of PV)

Number of Sites/Location: 6 submitter site(s)
unknown site Mebane NC
unknown site Youngsville NC
unknown site Marysville OH
unknown site Hannibal MO
unknown site Calhoun GA
unknown site St. Mary's OH

Basis: Per submission, the PMN is used at 100% in rubber compounding at 6 customer sites. The technical contacts indicates the PMN may be present in rubber products from 10-15%. CEB assumes 15% to conservatively assess exposures and 250 days/yr based on 2004 ESD for Plastic Converting. CS calculates a use rate of 5,000 kg/site-day.

Process Description: PMN (liquid, 100%) unloaded from tank trucks ---> piped into mixer, mix with raw rubber and other additives at high temperature ---> molten rubber extruded into sheets, blocks and/or molds (PMN, 10-15% entrained in solid) and shipped to downstream sites (submission, CRSS, technical contact for P14-0683/684 and P12-0282)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The submission does not provide information on releases during the manufacture of rubber products. The methology used to assess the standard reviews for P12-0277 through P12-0284 (LCCP and MCCP products) was used to assess releases during this operation. The only exception being container cleaning releases which are estimated using information from the submitter and technical contact.

Air
High End: 1.2E+0 kg/site-day over 250 day/yr from 6 sites or 1.9E+3 kg/yr
to: water or air (ESD, 2010 EU CSR)
from: Fugitive Air Emission from Extrusion
basis: User-Defined Loss Rate Model. Per ESD, fugitive air emissions generated during rubber converting can be 0.05% with engineering controls depending on the type of coversion process (e.g. extrusion, injection molding, calendaring). The 2004 GS for Plastics Compounding estimates that 50% of air emissions will settle and be ultimately released to water while the other 50% remains in air. As conservative, CEB assesses fugitive air emissions at a loss rate of 0.05% with 50% to water and 50% to air.

Water
High End: 1.2E+0 kg/site-day over 250 day/yr from 6 sites or 1.9E+3 kg/yr
to: water or air (ESD, 2010 EU CSR)
from: Fugitive Air Emission from Extrusion
basis: User-Defined Loss Rate Model. Per ESD, fugitive air emissions generated during rubber converting can be 0.05% with engineering controls depending on the type of coversion process (e.g. extrusion, injection molding, calendaring). The 2004 GS for Plastics Compounding estimates that 50% of air emissions will settle and be ultimately released to water while the other 50% remains in air. As conservative, CEB assesses fugitive air emissions at a loss rate of 0.05% with 50% to water and 50% to air.

Water or Incineration or Landfill
High End: 5.0E-1 kg/site-day over 250 day/yr from 6 sites or 7.5E+2 kg/yr
to: water, incineration, or landfill (RM-2)
from: Spillage During Raw Material Handling
basis: User-Defined Loss Rate Model. A 2010 EU CSR assessment on MCCPs estimated these releases to be 0.01% of PV with releases to water or solid waste. .

Water or Incineration or Landfill
Conservative: 1.0E+2 kg/site-day over 250 day/yr from 6 sites or 1.5E+5 kg/yr
to: Uncertain

from: Equipment Cleaning Losses of from Multiple Vessels

basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. The 2004 GS for Plastics Compounding estimates releases from equipment cleaning using the EPA/OPPT model loss rate of 2%. Due to multiple unknow sites, release to uncertain media (water, incineration or landfill) is assumed.

Water or Incineration or Landfill
High End: 3.8E+1 kg/site-day over 1 day/yr from 6 sites or 2.3E+2 kg/yr
to: water, incineration or land (ESD)
from: Cleaning Liquid Residuals from Tank Trucks Used to Transport the Raw Material
basis: EPA/OPPT Bulk Transport Residual Model, CEB standard 0.2% residual. The submission states that tank trucks are reused and are not cleaned between uses. For P12-0357, technical contact stated that in a scenario where the they will need to be taken out of service, tank trucks will be sent to a third party truck washing facility. To account for the possibility of containers being removed from service, CEB assesses releases from container cleaning for 1 day/yr with releases to uncertain media.

RELEASE TOTAL

1.5E+5 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 144
Basis: The submission estimates 1 worker/site. The 2004 ESD for Plastic Compounding estimates up to 24 workers/site. CEB uses the ESD estimate as conservative.

Inhalation:

Exposure to Vapor
High End of Range: 4.4E+0 mg/day over 250 days/yr
Low End of Range: 3.0E-2 mg/day over 250 days/yr
Number of workers (all sites) with Inhalation exposure: 144
Basis: Fugitive Air Emission from Extrusion; User-defined Inhalation Model. The 2004 GS for Plastics Compounding suggests that inhalation exposure is negligible for non-volatile substances during compounding. A 2010 EU Risk Assessment on MCCP contains monitoring| data from plastic compounding operations is the EU. The monitoring data is based on 32 air samples from 4 sites. Results showed MCCP air concentrations ranging from <0. 003 to 0.44 mg/m3 with a median of 0.03 mg/m3 and a 90th percentile of 0.15 mg/m3. It is unknown whether these data represent area or personal monitoring data. As conservative, exposures estimates are presented based on the low and high of the range for these data and assuming up to 8 hr exposure duration. .

INHALATION MONITORING DATA REVIEW

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes
2) (a) Exposure level > 1 mg/day? Yes
(b) Hazard Rating for health of 2 or greater? No
Inhalation Monitoring Data Desired? Yes (both criteria met)

Dermal:

Exposure to Liquid
High End: 2.2E+3 mg/day over 250 days/yr
Number of workers (all sites) with Dermal exposure: 144
Basis: Unloading Liquid Raw Material from Tank Trucks; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

P-14-0684 C
P-14-0683, P-14-0684

PROC1: Formulation of Metalworking Fluids (50% of PV)

Number of Sites/Location: 10 submitter site(s)
unknown site Goshen NY
unknown site Harvey IL
unknown sites Cleveland OH
unknown sites Detroit MI
unknown sites Philadelphia PA
unknown site Mantua NJ
unknown site Milwaukee WI
unknown site Cincinnati OH
unknown site Crystal Lake IL
unknown site Linden NJ
Basis: Per submission, 20 MWF formulation sites, 150 kg PMN/bt, 240 exposure days/yr, PMN used as a liquid at 100%. For past case P12-0357, technical contact estimates the PMN will be in products at 10-15%. CEB assumes 100% PMN in raw material and 15% PMN in plastic product to conservatively assess exposures. CS calculates a use rate of 1,562.5 kg/site-day based on 240 day/yr operation.
Process Description: PMN (liquid, 100%) is unloaded from tanks trucks (90% of PV) and totes (10% of PV) ---> transfer to storage ---> feed into blending tank, mixed with base oils and other additives ---> packaging of metal working fluids containing PMN (10 - 15%) (submission, technical contact from P12-0357)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The submission states there are no releases during formulation of MWFs. The methology used to assesses the standard reviews for P12-0277 through P12-0284 and P12-0357 (LCCP and MCCP products) was used to assesses releases during this operation. The only exception being container cleaning releases which are estimated using information from the submitter and technical contact.

Water or Incineration or Landfill
High End: 3.8E+1 kg/site-day over 1 day/yr from 20 sites or 7.6E+2 kg/yr
to: uncertain
from: Cleaning Liquid Residuals from Totes and Tank Trucks Used to Transport the Raw Material
basis: EPA/OPPT Bulk Transport Residual Model, CEB standard 0.2% residual. The submission states that totes and tank trucks are reused and are not cleaned between uses. From contact report for P12-0357, the technical contact stated that in a scenario where the they will need to be taken out of service, totes would be sent to a third party handler for cleaning and disposal and tank trucks will be sent to a third party truck washing facility. To account for the possibility of containers being removed from service, CEB assesses releases from container cleaning for 1 day/yr with releases to uncertain media.

Water or Incineration or Landfill
Conservative: 1.6E+1 kg/site-day over 240 day/yr from 20 sites or 7.5E+4 kg/yr
to: Uncertain
from: Equipment Cleaning Losses of Liquids from a Mixing Tank
basis: EPA/OPPT Single Vessel Residual Model, CEB standard 1% residual. The submission does not address equipment cleaning at downstream formulation sites. Due to uncertainty at multiple downstream sites, CEB assesses releases to uncertain media using the standard model loss fraction assuming cleaning once per day.

Air
Output 2: 7.8E-2 kg/site-day over 240 day/yr from 20 sites or 3.8E+2 kg/yr
to: fugitive air (2002 EU RA, 2010 Japan RA)
from: Fugitive Air Emissions
basis: User-Defined Loss Rate Model. A 2010 Japanese RA for SCCPs suggests 0.005% release to air during MWF formulation. Due to uncertainty at multiple downstream use sites, CEB includes this release source using this estimate.

Incineration or Landfill

Output 2: 3.1E+1 kg/site-day over 240 day/yr from 20 sites or 1.5E+5 kg/yr
to: incineration or landfill (2002 EU RA)
from: Off-Spec Material
basis: User-Defined Loss Rate Model. Data from a 2002 EU RA estimates a 1-2% loss rate from disposal of off-spec batches released to solid waste. Due to uncertainty at multiple downstream use sites, CEB includes this release source using the high end estimate with releases to incineration or landfill.

RELEASE TOTAL

2.3E+5 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 80
Basis: The submission estimates 80 workers for all sites (avg 4 workers/site). As conservative, CEB assesses all workers are exposed to PMN at 100% (unloading) and 15% (loading).

Dermal:

Exposure to Liquid
High End: 2.2E+3 mg/day over 240 days/yr
Number of workers (all sites) with Dermal exposure: 80
Basis: Unloading Liquid Raw Material from Totes and Tank Trucks; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

Dermal:

Exposure to Liquid
High End: 3.4E+2 mg/day over 240 days/yr
Number of workers (all sites) with Dermal exposure: 80
Basis: Loading Liquid Product into Drums; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

P-14-0684 C
P-14-0683, P-14-0684

USE1: Use of Metalworking Fluids (50% of PV)

Number of Sites/Location: 1 submitter site(s)
unknown sites
Basis: The submission does not address the use of formulated MWFs containing the PMN. The lubricant products contain 10-15% PMN per contact report for P12-0357. CEB assumes 15% to conservatively assess exposures. The 2011 ESD for MWF Operations estimates 247 days/yr of operation. The ESD estimates the number of sites as: (7,500,000 kg/yr) / (4,260 gal/site-yr x 1 kg/L x 3.785 L/gal x 0.15) = 3,101 sites. Environmental releases are of concern for this PMN. As conservative, CEB assumes 247 days/yr of operation and the ESD estimate of 3,101 sites to maximize kg/site-day release. CEB also assumes 15% PMN in raw material and assumes no dilution as conservative. CS calculates a use rate of 9.7918 kg/site-day.
Process Description: Bulk MWF containing PMN (liquid, 10 - 15%,) is unloaded from transport containers ---> transfer to mixing vessel ---> possible dilution of if water-based MWF ---> transfer to metal shaping trough ---> metal shaping operation ---> shaped metal part is rinsed and dried ---> spent MWF is drained and discarded (ESD)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The submission does not provide information on releases during the use of MWFs. The ESD was used to assess releases during this operation.

Water or Incineration or Landfill
High End: 9.4E-1 kg/site-day over 18 day/yr from 3101 sites or 5.2E+4 kg/yr
to: water, incineration, or landfill (ESD)
from: Cleaning Liquid Residuals from Drums Used to Transport the Raw Material
basis: EPA/OPPT Drum Residual Model, CEB standard 3% residual. The submission does not address end use. Due to uncertainty at multiple downstream sites, these releases are assessed to uncertain media using a 3% loss rate per the ESD.

Water
Output 2: 1.0E+0 kg/site-day over 247 day/yr from 3101 sites or 8.0E+5 kg/yr
to: on-site WWTP or POTW (ESD)
from: Dragout Losses
basis: User-Defined Loss Rate Model. The 2011 ESD for MWF Operations estimates a loss rate of 11% from dragout with releases to on-site WWTP or POTW. These data are based on U.S. industry data collected during the development of effluent guidelines for the metalworking industry. Due to uncertainty at multiple downstream sites, CEB assesses dragout releases using the ESD estimate of 11% and accounting for upstream losses from container cleaning: (1-0.03) x 0.11 = 0.1067. Releases are assessed to water via on-site WWTP or POTW per submission and ESD.

Water or Incineration or Landfill
Output 2: 3.4E+0 kg/site-day over 247 day/yr from 3101 sites or 2.6E+6 kg/yr
to: water, incineration, or landfill (ESD)
from: Filter Media and Other Recycling Waste
basis: User-Defined Loss Rate Model. The 2011 ESD for MWF Operations estimates these releases to account for a 36% loss rate with releases to water, incineration, or landfill (water-based fluids) or incineration or landfill (straight-oil). Accounting for upstream container cleaning losses: (1-0.03) x 0.36 = 0.3492. CEB assesses these releases to water, incineration, or landfill based on uncertainty at multiple downstream use sites.

Water or Incineration or Landfill
Output 2: 4.4E+0 kg/site-day over 247 day/yr from 3101 sites or 3.3E+6 kg/yr
to: water, incineration, or landfill (ESD)
from: Spent Metalworking Fluid
basis: User-Defined Loss Rate Model. The 2011 ESD for MWF Operations also assesses 100% release with the spent MWF disposed to water (water-based fluids) or incineration or landfill (straight oil fluids) with at least onebath changeout occurring per day at a facility with multiple baths in use. Based on uncertainty at multiple

downstream use sites, CEB assesses the spent MWF to water, incineration, or landfill. Account for upstream losses, the loss rate is calculated as: (1-0.03) x (1-0.05-0.11-0.38) = 0.4462.

Air
Output 2: 4.7E-1 kg/site-day over 247 day/yr from 3101 sites or 3.6E+5 kg/yr
to: air (2002 EU RA)
from: Misting/Evaporation
basis: User-Defined Loss Rate Model. A 2002 EU RA for MCCP estimates misting/evaporation losses to range from 2 to 5% depending on the type of MWF begin used. Based on uncertainty at multiple downstream sites, CEB uses the most conservative estimate of 5% loss to air from misting/evaporation. Account for upstream losses from container cleaning: (1-0.03) x 0.05 = 0.0485

RELEASE TOTAL
7.2E+6 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 148848
Basis: The 2011 ESD for MWF Use estimates 48 workers/site. CEB assesses 48 workers/site as conservative, due to uncertainty at downstream use sites.

Dermal:

Exposure to Liquid
High End: 2.6E+2 mg/day over 247 days/yr
Number of workers (all sites) with Dermal exposure: 148848
Basis: Unloading Liquid Raw Material from Drums; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

Dermal:

Exposure to Mist
: mg/day over days/yr
: 3.7E+2 mg/day over 247 days/yr
Number of workers (all sites) with Dermal exposure: 148848
Basis: Exposure During Metalworking Operation; User-defined Dermal Model. The 2011 ESD for MWF Operations estimates an average dermal surface loading rate for MWFs of 2.9 mg/cm2-hr during metalworking operations. These data are more conservative than the EPA/OPPT 2-Hand Dermal Contact Model and are used to provide a conservative estimate of dermal exposure during MWF use due to uncertainty at downstream opeations. Per ESD, exposure is to fluid that has undergone a 10-fold dilution so PMN concentration is 15% x 10% = 1.5%.

Inhalation:

Exposure to Mist
High End of Range: 5.3E+0 mg/day over 247 days/yr
Typical: 1.5E+0 mg/day over 247 days/yr
Number of workers (all sites) with Inhalation exposure: 148848
Basis: Exposure During Metalworking Operation; User-defined Inhalation Model. The 2011 ESD for MWF Operations estimates typical mist concentrations ranging from 0.19 to 0.39 mg/m3 and high end concentrations ranging from 0.87 to 1.42 mg/m3 depending on the type of MWF used. These estimates are based on the geometric mean (typical) and 90th percentile data (high end) of data collected by NIOSH from 942 machinists at 79 shops across the U.S. A range of inhalation exposure estimates are based the high end for the range of geometric means and 90th percentiles. CEB assumes the PMN is 37.5% of the mist. (GS assumes that water conc. is 60% and the PMN is then estimated to be 15/40 = 37.5% of the mist. 0.39 mg/m3 x 37.5% = 0.146 mg/m3. 1.42 mg/m3 x 37.5% = 0.532 mg/m3.

INHALATION MONITORING DATA REVIEW

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes
2) (a) Exposure level > 1 mg/day? Yes
(b) Hazard Rating for health of 2 or greater? No
Inhalation Monitoring Data Desired? Yes (both criteria met)

P-14-0684 C
P-14-0683, P-14-0684

USE2: Converting of Rubber Products (50% of PV)

Number of Sites/Location: 1 submitter site(s)
unknown site(s)
Basis: Submission does not provide the number of rubber converting sites. Per 2004 ESD on Plastics Converting, 250 day/yr operation and a default plastic use rate of (38,738 MM kg/yr) / (12,191 sites) / (250 day/yr) = 12,710.36 kg/site-day (general plastics). CS calculates 16 sites.
Process Description: Rubber blocks, sheets or molds containing PMN (solid, 10 - 15%) are unloaded ---> forming (heating) ---> molding and shaping using various processes (injection molding, extrusion, casting, calendaring, etc.) ---> trimming ---> finishing ---> finished rubber article

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The 2004 Plastics Converting ESD is referenced for this operation.

Incineration or Landfill
Output 2: 4.8E+1 kg/site-day over 250 day/yr from 16 sites or 1.9E+5 kg/yr
to: landfill or incineration
from: Scrap Material
basis: User-Defined Loss Rate Model. The 2004 GS for Plastics Converting estimated these releases to be 2.5% of PV. Expected to be handled as solid waste with disposal to landfill or incineration considered most likely.

Incineration or Landfill
Output 2: 1.9E+1 kg/site-day over 250 day/yr from 16 sites or 7.5E+4 kg/yr
to: incineration or landfill
from: Cleaning Solid/ Powder Residuals from Containers Used to Transport the Raw Material
basis: EPA/OPPT Solid Residuals in Transport Containers Model, CEB standard 1% residual. Solid compounded plastic residuals considered most likely to be handled as solid waste with disposal to landfill or incineration.

Incineration or Landfill
Conservative: 3.8E+1 kg/site-day over 250 day/yr from 16 sites or 1.5E+5 kg/yr
to: incineration or landfill
from: Equipment Cleaning Losses of Liquids from Multiple Vessels
basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. Converted plastic residual material in equipment is considered most likely to be handled as solid waste and disposed by landfill or incineration.

Water or Incineration or Landfill
Output 2: 1.9E-1 kg/site-day over 250 day/yr from 16 sites or 7.6E+2 kg/yr
to: water, incineration or landfill
from: Dust Generation from Converting
basis: User-Defined Loss Rate Model. Per ESD, 0.01% loss of daily use rate. Particles are originally released to air but are expected to eventually settle to the ground. Dust particles are expected to be cleaned from equipment and floor with water or disposed directly to landfill.

Air
Output 2: 2.4E+0 kg/site-day over 250 day/yr from 16 sites or 9.5E+3 kg/yr
to: Water (50%) or Air (50%) (ESD)
from: Fugitive Air Emission from Converting
basis: User-Defined Loss Rate Model. Based on Plastics Converting GS (2004), Most plastic additives are

non-volatile; however, converting operations may be performed at elevated temperatures; thus slight volatilization may occur. A release of 0.25% of the daily use rate is estimated. Particles are originally released to air but subsequent condensation may result in losses to water. As a conservative estimate, 50% is assumed to be released to water and 50% is assumed to be released to the atmosphere. NOTE: The CSR estimates 0.05% loss for this activity.

Water
Output 2: 2.4E+0 kg/site-day over 250 day/yr from 16 sites or 9.5E+3 kg/yr
to: Water (50%) or Air (50%) (ESD)
from: Fugitive Air Emission from Converting
basis: User-Defined Loss Rate Model. Based on Plastics Converting GS (2004), Most plastic additives are non-volatile; however, converting operations may be performed at elevated temperatures; thus slight volatilization may occur. A release of 0.25% of the daily use rate is estimated. Particles are originally released to air but subsequent condensation may result in losses to water. As a conservative estimate, 50% is assumed to be released to water and 50% is assumed to be released to the atmosphere. NOTE: The CSR estimates 0.05% loss for this activity.

Water or Incineration or Landfill
Output 2: 1.9E-1 kg/site-day over 250 day/yr from 16 sites or 7.6E+2 kg/yr
to: water, incineration or landfill (RM-2_
from: Raw Material Spillage
basis: User-Defined Loss Rate Model. A 2010 EU CSR assessment on MCCPs estimated these releases to be 0.01% of PV with releases to water or solid waste. The 2010 EU CSR estimate is used as a basis to estimate releases from spillage.

RELEASE TOTAL

4.4E+5 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 768
Basis: Per 2004 ESD for Plastics Converting, 48 workers/site.

Inhalation:

Exposure to Mist
High End of Range: 1.5E+1 mg/day over 250 days/yr
Low End of Range: 7.0E-1 mg/day over 250 days/yr
Number of workers (all sites) with Inhalation exposure: 768
Basis: Inhalation Exposure during Converting; User-defined Inhalation Model. A 2008 EU RA on MCCPs and a 2010 EU CSR on MCCPs contains monitoring data from rubber manufacturing operations in the EU. The monitoring data suggest MCCP air concentrations ranging from 0.01 to 0.07 mg/m3 based on monitoring conducted at 1 site. It is unknown whether these data represent area or personal monitoring data. Based on uncertainty in multiple downstream use sites and the fact that these data are only basd on 1 site, CEB assesses exposures based on the high end of the EU data range (0.07 mg/m3) and the OSHA PEL (15 mg/m3 x 0.1 = 1.5 mg/m3).

INHALATION MONITORING DATA REVIEW

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes
2) (a) Exposure level > 1 mg/day? Yes
(b) Hazard Rating for health of 2 or greater? No
Inhalation Monitoring Data Desired? Yes (both c

Appendix F EXPOSURE SCENARIO ESTIMATES

(E-FAST Model Run)

INITIAL REVIEW EXPOSURE REPORT (IRExR)

Chemical ID: P-14-0683C
(P-14-0683 and P-14-0684)

Results Table: Dose, Concentration, and Days Exceeded Results Summary

Exposure Scenario[1]	Water						Landfill	Stack Air		Fugitive Air	
Release activity(ies)[2]; exposure calculation(s)[3]	Drinking Water		Fish Ingestion		7Q10[4] CC = 1	PDM Days Exceeded	LADD	ADR	LADD	ADR	LADD
	ADR	LADD	ADR	LADD							
	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day	µg/l	# Days	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day
MFG: Max ADR: max acute eco	**1.60E-01**	---	**2.00E+00**	---	**7.39E+03**	---	---	**5.20E-01**	---	---	---
MFG: Max LADD	---	**1.19E-05**	---	**6.22E-05**	---	---	**3.89E-04**	---	**1.69E-03**	---	---
PROC 1: Max ADR: max acute eco	**1.54E-02**	---	**3.40E-01**	---	**6.96E+02**	---	---	**1.00E-01**	---	**1.96E-03**	---
PROC 1: PDM1	---	---	---	---	**2.06E+02**	**240**	---	---	---	---	---
PROC 1: Max LADD	---	**1.48E-04**	---	**7.70E-04**	---	---	**1.66E-03**	---	**3.23E-03**	---	**4.34E-05**
PROC 2: Max ADR: max acute eco	**3.98E-02**	---	**8.90E-01**	---	**1.80E+03**	---	---	**1.70E-01**	---	**2.93E-02**	---
PROC 2: PDM1	---	---	---	---	**1.31E+03**	**250**	---	---	---	---	---
PROC 2: Max LADD	---	**9.70E-04**	---	**5.07E-03**	---	---	**3.70E-03**	---	**7.20E-03**	---	**6.95E-04**
USE 1: Max ADR: max acute eco	**7.87E-03**	---	**1.00E-01**	---	**3.69E+02**	---	---	**1.08E-02**	---	**1.17E-02**	---
USE 1: PDM1	---	---	---	---	**3.33E+02**	**245**	---	---	---	---	---
USE 1: Max LADD	---	**1.39E-04**	---	**7.26E-04**	---	---	**2.85E-04**	---	**5.55E-04**	---	**2.69E-04**
USE 2: Max ADR: max acute eco	**2.35E-03**	---	**3.22E-02**	---	**1.10E+02**	---	---	**1.30E-01**	---	**6.04E-02**	---
USE 2: PDM1	---	---	---	---	**1.10E+02**	**238**	---	---	---	---	---
USE 2: Max LADD	---	**4.81E-05**	---	**2.51E-04**	---	---	**3.86E-03**	---	**7.51E-03**	---	**1.39E-03**

[1] Exposure scenario titles consist of release activity followed by exposure calculation abbreviation.
[2] Release activities are from engineering report's Manufacturing (Mfg), Processing (Proc) and Use release activity labels. Multiple release activities are combined in one exposure scenario if their releases occur at same location.
[3] Exposure calculations are Acute Dose Rate (ADR), Lifetime Average Daily Dose (LADD), and Probabilistic Dilution Model (PDM). There may be one, two, or all three exposure calculations per exposure scenario. CC is the aquatic concentration of concern.
[4] This column displays concentration values for the 7Q10 streamflow, which is defined as the average daily streamflow of the seven consecutive days of lowest flow within a ten year period.

Results Table: Exposure Based (XB)/Persistent (P2B2) Criteria

Parameter	Exp Based	Persistent	Exceedance Value
Drinking (Surface) Water Dose (mg/kg/day)	No	No	
Fish Ingestion Dose (mg/kg/day)	Yes	Yes	**5.07E-03**
Inhalation Dose (mg/kg/day)	Yes	Yes	**7.51E-03**
Groundwater Dose (mg/kg/day)	Yes	Yes	**3.86E-03**
Surface Water Release After Treatment (kg/yr)	Yes	Yes	**7.03E+05**
Total Release After Treatment (kg/yr)	Yes	Yes	**7.28E+06**
Consumer Use?	No		

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:1 Number of Release Sites: 1.

Release Activity: MFG: Max ADR

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	400.00	0.00	422.00	0.00
	(kg/yr)	(kg/yr)	(kg/yr)	(kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	0.00/0.00	1.00	0.00
Per Site Release:	400.00	0.00/0.00	422.00	0.00
	(kg/site/day)	(kg/site/day)	(kg/site/day)	(kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 1 Number of Sites: 1 RELEASE ACTIVITY:MFG: Max ADR

SIC-CODE DESCRIPTION: Organic Chemicals Manufacture

SIC-CODE (S): 2865,2869 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	400.	40.00	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	2825.61	935.49	634.16	514.20	14.16	42.76	63.08	77.79
ALL	10	50.57	9.38	5.41	4.53	790.98	4264.39	7393.72	8830.02

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	2.13E-07	1.19E-05	mg/kg/day	1.11E-06	6.22E-05	mg/kg/day
$LADC_{pot}$	1.64E-05	9.17E-04	mg/L	1.19E-02	0.66	mg/kg
Acute						
ADR_{pot}	1.62E-03	0.16	mg/kg/day	3.57E-02	2.00	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 1 RELEASE ACTIVITY:MFG: Max ADR

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	1.	
Per Site Fugitive Release:	NA	kg/site/day
Fugitive Release Days per Year:	NA	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	NA	kg/yr
Max Annual Average Air Concentration (Fugitive):	0.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	0.00	$\mu g/m^3$
Per Site Stack Release:	422.00	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	422.00	kg/yr
Max Annual Average Air Concentration (Stack):	1.56	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	2840.00	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	1.21E-04	N/A	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	6.60E-04	N/A	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	0.52	N/A	NA	1 day	80.00	0.61

Stack Parameter Data			Fugitive Parameter Data	
Stack Height	10.00	m	Release Height:	N/A
Inside Stack Diameter:	0.10	m	Length of Release Opening:	N/A
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	N/A
Stack Gas Temperature:	293.00	K		

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:2 Number of Release Sites: 1.

Release Activity: MFG: Max LADD

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	400.00 (kg/yr)	2650.00 (kg/yr)	5900.00 (kg/yr)	0.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	1.00/0.00	1.00	0.00
Per Site Release:	400.00 (kg/site/day)	2650.00/0.00 (kg/site/day)	5900.00 (kg/site/day)	0.00 (kg/site/day)

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 2 Number of Sites: 1 RELEASE ACTIVITY:MFG: Max LADD

SIC-CODE DESCRIPTION: Organic Chemicals Manufacture

SIC-CODE (S): 2865,2869 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	400.	40.00	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	2825.61	935.49	634.16	514.20	N/A	N/A	N/A	N/A
ALL	10	50.57	9.38	5.41	4.53	N/A	N/A	N/A	N/A

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	2.13E-07	1.19E-05	mg/kg/day	1.11E-06	6.22E-05	mg/kg/day
$LADC_{pot}$	1.64E-05	9.17E-04	mg/L	1.19E-02	0.66	mg/kg
Acute						
ADR_{pot}	N/A	N/A	mg/kg/day	N/A	N/A	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

DRINKING WATER EXPOSURE ESTIMATES FROM LANDFILL RELEASES

SCENARIO #: 2 ACTIVITY: MFG: Max LADD

RELEASE DESCRIPTION:

EXPOSED POPULATION: Adult

NUMBER OF SITES	NON-SLUDGE LANDFILL RELEASE AND DAYS OF RELEASE (kg/site/day)/(days)	LANDFILLED SLUDGE[1] AND DAYS OF RELEASE (kg/site/day)/(days)	MIGRATION DESCRIPTOR[2]	ADSORPTION TO WASTEWATER SLUDGE (%)	DRINKING WATER TREATMENT (%)
1.	2650.00/1.00	0.00/0.00	Slow	0.00	0.00

[1] Landfilled sludge equals the fraction adsorbed to wastewater treatment sludge times the surface water pre-treatment release.

[2]

Migration Descriptor	Groundwater Concentration (GWC)	Log Koc (mg/L per kg release)	
Negligible		no migration	None
Negligible to slow	3.21E-6	> 4.5	
Slow			<4.5 to 3.5
	2.67E-5		
Moderate		<3.5 to 2.5	5.95E-5
Rapid			<2.5
	7.55E-5		

Exposure Units	Results	ASSUMPTIONS			
		ED (years)	AT (years)	BW (kg)	IR (L/day)
Cancer					
$LADD_{pot}$ (mg/kg/day)	3.89E-04	33.00	78.00	80.00	1.04
$LADC_{pot}$ (mg/L)	2.99E-02	33.00	78.00	NA	NA

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 2 RELEASE ACTIVITY:MFG: Max LADD

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	1.	
Per Site Fugitive Release:	NA	kg/site/day
Fugitive Release Days per Year:	NA	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	NA	kg/yr
Max Annual Average Air Concentration (Fugitive):	0.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	5900.00	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	5900.00	kg/yr
Max Annual Average Air Concentration (Stack):	21.80	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	1.69E-03	N/A	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	9.22E-03	N/A	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Stack Parameter Data			Fugitive Parameter Data	
Stack Height	10.00	m	Release Height:	N/A
Inside Stack Diameter:	0.10	m	Length of Release Opening:	N/A
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	N/A
Stack Gas Temperature:	293.00	K		

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:3 Number of Release Sites: 20.

Release Activity: PROC 1: Max ADR

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1080.00 (kg/yr)	0.00 (kg/yr)	1700.00 (kg/yr)	374.40 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	0.00/0.00	1.00	240.00
Per Site Release:	54.00 (kg/site/day)	0.00/0.00 (kg/site/day)	85.00 (kg/site/day)	7.80E-02 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 3 Number of Sites: 20 RELEASE ACTIVITY:PROC 1: Max ADR

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	54.	5.40	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	18.75	43.60	69.07	81.76
ALL	10	39.60	13.29	7.76	7.57	136.36	406.32	695.88	713.34

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	2.83E-07	2.05E-06	mg/kg/day	1.48E-06	1.07E-05	mg/kg/day
$LADC_{pot}$	2.17E-05	1.58E-04	mg/L	1.57E-02	0.11	mg/kg
Acute						
ADR_{pot}	1.65E-03	1.54E-02	mg/kg/day	4.73E-02	0.34	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 3 RELEASE ACTIVITY:PROC 1: Max ADR

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	20.	
Per Site Fugitive Release:	7.80E-02	kg/site/day
Fugitive Release Days per Year:	240.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	374.40	kg/yr
Max Annual Average Air Concentration (Fugitive):	0.56	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	10.70	$\mu g/m^3$
Per Site Stack Release:	85.00	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	1700.00	kg/yr
Max Annual Average Air Concentration (Stack):	0.31	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	570.00	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	2.43E-05	4.34E-05	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	1.33E-04	2.37E-04	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	0.10	1.96E-03	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:4 Number of Release Sites: 20.

Release Activity: PROC 1: PDM1

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	7.68E+04 (kg/yr)	0.00 (kg/yr)	0.00 (kg/yr)	0.00 (kg/yr)

		Non-sludge/Sludge		
Release Days/yr:	240.00	0.00/0.00	0.00	0.00
Per Site Release:	16.00 (kg/site/day)	0.00/0.00 (kg/site/day)	0.00 (kg/site/day)	0.00 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 4 Number of Sites: 20 RELEASE ACTIVITY:PROC 1: PDM1

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	240.	16.	1.60	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	5.56	12.92	20.47	24.22
ALL	10	39.60	13.29	7.76	7.57	40.40	120.39	206.19	211.36

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	2.01E-05	1.46E-04	mg/kg/day	1.05E-04	7.63E-04	mg/kg/day
$LADC_{pot}$	1.55E-03	1.12E-02	mg/L	1.12	8.14	mg/kg
Acute						
ADR_{pot}	4.89E-04	4.56E-03	mg/kg/day	1.40E-02	0.10	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC CODE EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 4 RELEASE ACTIVITY: PROC 1: PDM1

SIC CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

ASSOCIATED SIC CODES: Subset of 4952

SIC CODE RESULTS						
COC (µg/L)	Percent of Year COC Exceeded	Number of Days COC Exceeded	Release days/year	Loading (kg/site/day)	Waste Water Treatment (%)	High/Avg Analysis
1.00	66	240	240.00	16.00	90.00	High

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:5 Number of Release Sites: 20.

Release Activity: PROC 1: Max LADD

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	7.76E+04 (kg/yr)	2.26E+05 (kg/yr)	2.26E+05 (kg/yr)	374.40 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	1.00/0.00	1.00	1.00
Per Site Release:	3878.00 (kg/site/day)	1.13E+04/0.00 (kg/site/day)	1.13E+04 (kg/site/day)	18.72 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 5 Number of Sites: 20 RELEASE ACTIVITY:PROC 1: Max LADD

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	3878.	387.80	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	N/A	N/A	N/A	N/A
ALL	10	39.60	13.29	7.76	7.57	N/A	N/A	N/A	N/A

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	2.03E-05	1.48E-04	mg/kg/day	1.06E-04	7.70E-04	mg/kg/day
$LADC_{pot}$	1.56E-03	1.14E-02	mg/L	1.13	8.22	mg/kg
Acute						
ADR_{pot}	N/A	N/A	mg/kg/day	N/A	N/A	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

DRINKING WATER EXPOSURE ESTIMATES FROM LANDFILL RELEASES

SCENARIO #: 5 ACTIVITY: PROC 1: Max LADD

RELEASE DESCRIPTION:

EXPOSED POPULATION: Adult

NUMBER OF SITES	NON-SLUDGE LANDFILL RELEASE AND DAYS OF RELEASE (kg/site/day)/(days)	LANDFILLED SLUDGE[1] AND DAYS OF RELEASE (kg/site/day)/(days)	MIGRATION DESCRIPTOR[2]	ADSORPTION TO WASTEWATER SLUDGE (%)	DRINKING WATER TREATMENT (%)
20.	1.13E+04/1.00	0.00/0.00	Slow	0.00	0.00

[1] Landfilled sludge equals the fraction adsorbed to wastewater treatment sludge times the surface water pre-treatment release.

[2]

Migration Descriptor	Groundwater Concentration (GWC)	Log Koc (mg/L per kg release)	
Negligible		no migration	None
Negligible to slow	3.21E-6	> 4.5	
Slow			<4.5 to
3.5	2.67E-5		
Moderate		<3.5 to 2.5	5.95E-5
Rapid			<2.5
	7.55E-5		

Exposure Units	Results	ASSUMPTIONS			
		ED (years)	AT (years)	BW (kg)	IR (L/day)
Cancer					
$LADD_{pot}$ (mg/kg/day)	1.66E-03	33.00	78.00	80.00	1.04
$LADC_{pot}$ (mg/L)	0.13	33.00	78.00	NA	NA

REMARKS:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)		
SCENARIO #: 5	RELEASE ACTIVITY:PROC 1: Max LADD	
RELEASE DESCRIPTION:		
METHOD OF CALCULATION: Screen3		
EXPOSED POPULATION: Adult		
Number of Sites:	20.	
Per Site Fugitive Release:	18.72	kg/site/day
Fugitive Release Days per Year:	1.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	374.40	kg/yr
Max Annual Average Air Concentration (Fugitive):	0.56	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	1.13E+04	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	2.26E+05	kg/yr

Max Annual Average Air Concentration (Stack):	41.70	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	3.23E-03	4.34E-05	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	1.76E-02	2.37E-04	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:6 Number of Release Sites: 6.

Release Activity: PROC 2: Max ADR

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	838.20 (kg/yr)	0.00 (kg/yr)	831.00 (kg/yr)	1800.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	0.00/0.00	1.00	250.00
Per Site Release:	139.70 (kg/site/day)	0.00/0.00 (kg/site/day)	138.50 (kg/site/day)	1.20 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 6 Number of Sites: 6 RELEASE ACTIVITY:PROC 2: Max ADR

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	139.7	13.97	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	48.51	112.81	178.69	211.51
ALL	10	39.60	13.29	7.76	7.57	352.78	1051.17	1800.26	1845.44

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	7.31E-07	5.32E-06	mg/kg/day	3.82E-06	2.78E-05	mg/kg/day
$LADC_{pot}$	5.62E-05	4.09E-04	mg/L	4.07E-02	0.30	mg/kg
Acute						
ADR_{pot}	4.27E-03	3.98E-02	mg/kg/day	0.12	0.89	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 6 RELEASE ACTIVITY:PROC 2: Max ADR

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	6.	
Per Site Fugitive Release:	1.20	kg/site/day
Fugitive Release Days per Year:	250.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	1800.00	kg/yr
Max Annual Average Air Concentration (Fugitive):	8.98	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	160.00	$\mu g/m^3$
Per Site Stack Release:	138.50	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	831.00	kg/yr
Max Annual Average Air Concentration (Stack):	0.51	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	930.00	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	3.96E-05	6.95E-04	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	2.16E-04	3.80E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	0.17	2.93E-02	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:7 Number of Release Sites: 6.

Release Activity: PROC 2: PDM1

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1.53E+05	0.00	0.00	0.00
	(kg/yr)	(kg/yr)	(kg/yr)	(kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	250.00	0.00/0.00	0.00	0.00
Per Site Release:	101.70	0.00/0.00	0.00	0.00
	(kg/site/day)	(kg/site/day)	(kg/site/day)	(kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 7 Number of Sites: 6 RELEASE ACTIVITY:PROC 2: PDM1

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	250.	101.7	10.17	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	35.31	82.12	130.08	153.97
ALL	10	39.60	13.29	7.76	7.57	256.82	765.24	1310.57	1343.46

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	1.33E-04	9.67E-04	mg/kg/day	6.95E-04	5.05E-03	mg/kg/day
$LADC_{pot}$	1.02E-02	7.44E-02	mg/L	7.41	53.88	mg/kg
Acute						
ADR_{pot}	3.11E-03	2.90E-02	mg/kg/day	8.92E-02	0.65	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC CODE EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 7 RELEASE ACTIVITY: PROC 2: PDM1

SIC CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

ASSOCIATED SIC CODES: Subset of 4952

SIC CODE RESULTS						
COC (µg/L)	Percent of Year COC Exceeded	Number of Days COC Exceeded	Release days/year	Loading (kg/site/day)	Waste Water Treatment (%)	High/Avg Analysis
1.00	68	250	250.00	101.70	90.00	High

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:8 Number of Release Sites: 6.

Release Activity: PROC 2: Max LADD

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1.53E+05 (kg/yr)	1.51E+05 (kg/yr)	1.51E+05 (kg/yr)	1800.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	1.00/0.00	1.00	1.00
Per Site Release:	2.55E+04 (kg/site/day)	2.52E+04/0.00 (kg/site/day)	2.52E+04 (kg/site/day)	300.00 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 8 Number of Sites: 6 RELEASE ACTIVITY:PROC 2: Max LADD

SIC-CODE DESCRIPTION: POTW (Indust., includes POTWs which receive ind. disch.)

SIC-CODE (S): Subset of 4952 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	25500.	2550.00	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	288.00	123.84	78.18	66.05	N/A	N/A	N/A	N/A
ALL	10	39.60	13.29	7.76	7.57	N/A	N/A	N/A	N/A

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	1.33E-04	9.70E-04	mg/kg/day	6.97E-04	5.07E-03	mg/kg/day
$LADC_{pot}$	1.03E-02	7.46E-02	mg/L	7.43	54.04	mg/kg
Acute						
ADR_{pot}	N/A	N/A	mg/kg/day	N/A	N/A	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

DRINKING WATER EXPOSURE ESTIMATES FROM LANDFILL RELEASES

SCENARIO #: 8 ACTIVITY: PROC 2: Max LADD

RELEASE DESCRIPTION:

EXPOSED POPULATION: Adult

NUMBER OF SITES	NON-SLUDGE LANDFILL RELEASE AND DAYS OF RELEASE (kg/site/day)/(days)	LANDFILLED SLUDGE[1] AND DAYS OF RELEASE (kg/site/day)/(days)	MIGRATION DESCRIPTOR[2]	ADSORPTION TO WASTEWATER SLUDGE (%)	DRINKING WATER TREATMENT (%)
6.	2.52E+04/1.00	0.00/0.00	Slow	0.00	0.00

[1] Landfilled sludge equals the fraction adsorbed to wastewater treatment sludge times the surface water pre-treatment release.

[2]

Migration Descriptor	Groundwater Concentration (GWC)	Log Koc (mg/L per kg release)	
Negligible		no migration	None
Negligible to slow	3.21E-6	> 4.5	
Slow			<4.5 to 3.5
	2.67E-5		
Moderate		<3.5 to 2.5	5.95E-5
Rapid			<2.5
	7.55E-5		

Exposure Units	Results	ASSUMPTIONS			
		ED (years)	AT (years)	BW (kg)	IR (L/day)
Cancer					
$LADD_{pot}$ (mg/kg/day)	3.70E-03	33.00	78.00	80.00	1.04
$LADC_{pot}$ (mg/L)	0.28	33.00	78.00	NA	NA

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 8 RELEASE ACTIVITY:PROC 2: Max LADD

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	6.	
Per Site Fugitive Release:	300.00	kg/site/day
Fugitive Release Days per Year:	1.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	1800.00	kg/yr
Max Annual Average Air Concentration (Fugitive):	8.98	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	2.52E+04	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	1.51E+05	kg/yr
Max Annual Average Air Concentration (Stack):	93.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	7.20E-03	6.95E-04	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	3.93E-02	3.80E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:9 Number of Release Sites: 3101.

Release Activity: USE 1: Max ADR

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	5.44E+05 (kg/yr)	0.00 (kg/yr)	4.88E+05 (kg/yr)	3.60E+05 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	18.00	0.00/0.00	18.00	247.00
Per Site Release:	9.74 (kg/site/day)	0.00/0.00 (kg/site/day)	8.74 (kg/site/day)	0.47 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 9 Number of Sites: 3101 RELEASE ACTIVITY:USE 1: Max ADR

SIC-CODE DESCRIPTION: Metal Finishing

SIC-CODE (S): 34xx - 39xx EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	18.	9.74	0.97	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	300.46	107.45	67.50	55.59	3.24	9.06	14.43	17.52
ALL	10	23.74	4.69	2.64	2.27	41.03	207.68	368.94	429.07

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	8.79E-07	1.11E-05	mg/kg/day	4.59E-06	5.81E-05	mg/kg/day
$LADC_{pot}$	6.76E-05	8.56E-04	mg/L	4.90E-02	0.62	mg/kg
Acute						
ADR_{pot}	3.43E-04	7.87E-03	mg/kg/day	8.19E-03	0.10	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 9 RELEASE ACTIVITY:USE 1: Max ADR

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	3101.	
Per Site Fugitive Release:	0.47	kg/site/day
Fugitive Release Days per Year:	247.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	3.60E+05	kg/yr
Max Annual Average Air Concentration (Fugitive):	3.48	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	64.20	$\mu g/m^3$
Per Site Stack Release:	8.74	kg/site/day
Stack Release Days per Year:	18.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	4.88E+05	kg/yr
Max Annual Average Air Concentration (Stack):	0.58	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	58.90	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	4.50E-05	2.69E-04	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	2.46E-04	1.47E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	1.08E-02	1.17E-02	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:10 Number of Release Sites: 3101.

Release Activity: USE 1: PDM1

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	6.74E+06 (kg/yr)	0.00 (kg/yr)	0.00 (kg/yr)	0.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	247.00	0.00/0.00	0.00	0.00
Per Site Release:	8.80 (kg/site/day)	0.00/0.00 (kg/site/day)	0.00 (kg/site/day)	0.00 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 10 Number of Sites: 3101 RELEASE ACTIVITY:USE 1: PDM1

SIC-CODE DESCRIPTION: Metal Finishing

SIC-CODE (S): 34xx - 39xx EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	247.	8.8	0.88	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	300.46	107.45	67.50	55.59	2.93	8.19	13.04	15.83
ALL	10	23.74	4.69	2.64	2.27	37.07	187.63	333.33	387.67

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	1.09E-05	1.38E-04	mg/kg/day	5.69E-05	7.20E-04	mg/kg/day
$LADC_{pot}$	8.39E-04	1.06E-02	mg/L	0.61	7.68	mg/kg
Acute						
ADR_{pot}	3.10E-04	7.11E-03	mg/kg/day	7.40E-03	9.36E-02	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC CODE EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 10 RELEASE ACTIVITY: USE 1: PDM1

SIC CODE DESCRIPTION: Metal Finishing

ASSOCIATED SIC CODES: 34xx - 39xx

SIC CODE RESULTS

COC (µg/L)	Percent of Year COC Exceeded	Number of Days COC Exceeded	Release days/year	Loading (kg/site/day)	Waste Water Treatment (%)	High/Avg Analysis
1.00	67	245	247.00	8.80	90.00	High

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:11 Number of Release Sites: 3101.

Release Activity: USE 1: Max LADD

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	6.79E+06 (kg/yr)	6.03E+06 (kg/yr)	6.03E+06 (kg/yr)	3.60E+05 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	1.00/0.00	1.00	1.00
Per Site Release:	2190.52 (kg/site/day)	1943.52/0.00 (kg/site/day)	1943.52 (kg/site/day)	116.09 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 11 Number of Sites: 3101 RELEASE ACTIVITY:USE 1: Max LADD

SIC-CODE DESCRIPTION: Metal Finishing

SIC-CODE (S): 34xx - 39xx EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	2190.52	219.05	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	300.46	107.45	67.50	55.59	N/A	N/A	N/A	N/A
ALL	10	23.74	4.69	2.64	2.27	N/A	N/A	N/A	N/A

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	1.10E-05	1.39E-04	mg/kg/day	5.74E-05	7.26E-04	mg/kg/day
$LADC_{pot}$	8.45E-04	1.07E-02	mg/L	0.61	7.74	mg/kg
Acute						
ADR_{pot}	N/A	N/A	mg/kg/day	N/A	N/A	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

DRINKING WATER EXPOSURE ESTIMATES FROM LANDFILL RELEASES

SCENARIO #: 11 ACTIVITY: USE 1: Max LADD

RELEASE DESCRIPTION:

EXPOSED POPULATION: Adult

NUMBER OF SITES	NON-SLUDGE LANDFILL RELEASE AND DAYS OF RELEASE (kg/site/day)/(days)	LANDFILLED SLUDGE[1] AND DAYS OF RELEASE (kg/site/day)/(days)	MIGRATION DESCRIPTOR[2]	ADSORPTION TO WASTEWATER SLUDGE (%)	DRINKING WATER TREATMENT (%)
3101.	1943.52/1.00	0.00/0.00	Slow	0.00	0.00

[1] Landfilled sludge equals the fraction adsorbed to wastewater treatment sludge times the surface water pre-treatment release.

[2]

Migration Descriptor	Groundwater Concentration (GWC) (mg/L per kg release)	Log Koc
Negligible		no migration
Negligible to slow	3.21E-6	> 4.5
Slow	2.67E-5	<4.5 to 3.5
Moderate	7.55E-5	<3.5 to 2.5
Rapid		<2.5

None

5.95E-5

Exposure Units	Results	ASSUMPTIONS			
		ED (years)	AT (years)	BW (kg)	IR (L/day)
Cancer					
$LADD_{pot}$ (mg/kg/day)	2.85E-04	33.00	78.00	80.00	1.04
$LADC_{pot}$ (mg/L)	2.20E-02	33.00	78.00	NA	NA

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 11 RELEASE ACTIVITY:USE 1: Max LADD

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	3101.	
Per Site Fugitive Release:	116.09	kg/site/day
Fugitive Release Days per Year:	1.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	3.60E+05	kg/yr
Max Annual Average Air Concentration (Fugitive):	3.48	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	1943.52	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	6.03E+06	kg/yr
Max Annual Average Air Concentration (Stack):	7.17	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	5.55E-04	2.69E-04	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	3.03E-03	1.47E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:12 Number of Release Sites: 16.

Release Activity: USE 2: Max ADR

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1.11E+04 (kg/yr)	0.00 (kg/yr)	4.22E+05 (kg/yr)	9600.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	250.00	0.00/0.00	250.00	250.00
Per Site Release:	2.78 (kg/site/day)	0.00/0.00 (kg/site/day)	105.38 (kg/site/day)	2.40 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 12 Number of Sites: 16 RELEASE ACTIVITY:USE 2: Max ADR

SIC-CODE DESCRIPTION: Rubber Products Manufacture

SIC-CODE (S): 3011,3021,3031,3041 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	250.	2.78	0.28	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	255.71	132.96	84.15	69.21	1.09	2.09	3.30	4.02
ALL	10	21.78	4.48	2.52	2.35	12.76	62.05	110.32	118.30

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	4.10E-06	4.81E-05	mg/kg/day	2.14E-05	2.51E-04	mg/kg/day
$LADC_{pot}$	3.15E-04	3.70E-03	mg/L	0.23	2.68	mg/kg
Acute						
ADR_{pot}	7.92E-05	2.35E-03	mg/kg/day	2.75E-03	3.22E-02	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 12 RELEASE ACTIVITY:USE 2: Max ADR

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	16.	
Per Site Fugitive Release:	2.40	kg/site/day
Fugitive Release Days per Year:	250.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	9600.00	kg/yr
Max Annual Average Air Concentration (Fugitive):	18.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	330.00	$\mu g/m^3$
Per Site Stack Release:	105.38	kg/site/day
Stack Release Days per Year:	250.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	4.22E+05	kg/yr
Max Annual Average Air Concentration (Stack):	97.20	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	710.00	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	7.53E-03	1.39E-03	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	4.11E-02	7.62E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	0.13	6.04E-02	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:13 Number of Release Sites: 16.

Release Activity: USE 2: PDM1

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1.11E+04	0.00	0.00	0.00
	(kg/yr)	(kg/yr)	(kg/yr)	(kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	250.00	0.00/0.00	0.00	0.00
Per Site Release:	2.78	0.00/0.00	0.00	0.00
	(kg/site/day)	(kg/site/day)	(kg/site/day)	(kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 13 Number of Sites: 16 RELEASE ACTIVITY:USE 2: PDM1

SIC-CODE DESCRIPTION: Rubber Products Manufacture

SIC-CODE (S): 3011,3021,3031,3041 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	250.	2.78	0.28	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	255.71	132.96	84.15	69.21	1.09	2.09	3.30	4.02
ALL	10	21.78	4.48	2.52	2.35	12.76	62.05	110.32	118.30

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	4.10E-06	4.81E-05	mg/kg/day	2.14E-05	2.51E-04	mg/kg/day
$LADC_{pot}$	3.15E-04	3.70E-03	mg/L	0.23	2.68	mg/kg
Acute						
ADR_{pot}	7.92E-05	2.35E-03	mg/kg/day	2.75E-03	3.22E-02	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC CODE EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 13 RELEASE ACTIVITY: USE 2: PDM1

SIC CODE DESCRIPTION: Rubber Products Manufacture

ASSOCIATED SIC CODES: 3011,3021,3031,3041

SIC CODE RESULTS

COC (µg/L)	Percent of Year COC Exceeded	Number of Days COC Exceeded	Release days/year	Loading (kg/site/day)	Waste Water Treatment (%)	High/Avg Analysis
1.00	65	238	250.00	2.78	90.00	High

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683 Assessor:

ENVIRONMENTAL RELEASES

Scenario#:14 Number of Release Sites: 16.

Release Activity: USE 2: Max LADD

Release Description:	WATER	LANDFILL Non-sludge/Sludge	STACK	FUGITIVE
Total Releases:	1.11E+04 (kg/yr)	4.21E+05 (kg/yr)	4.21E+05 (kg/yr)	9600.00 (kg/yr)
		Non-sludge/Sludge		
Release Days/yr:	1.00	1.00/0.00	1.00	1.00
Per Site Release:	695.00 (kg/site/day)	2.63E+04/0.00 (kg/site/day)	2.63E+04 (kg/site/day)	600.00 (kg/site/day)

Remarks:

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

SIC-CODE BASED HUMAN AND AQUATIC EXPOSURES TO SURFACE WATER RELEASES

SCENARIO #: 14 Number of Sites: 16 RELEASE ACTIVITY:USE 2: Max LADD

SIC-CODE DESCRIPTION: Rubber Products Manufacture

SIC-CODE (S): 3011,3021,3031,3041 EXPOSED POPULATION: Adult

WWT REMOVAL (%)	RELEASE DAYS	PRETREATMENT RELEASE (kg/site/day)	POSTTREATMENT RELEASE (kg/site/day)	DWT (%)	BCF (L/kg)
90.00	1.	695.	69.50	0.00	724.00

AQUATIC EXPOSURE ESTIMATES - SURFACE WATER									
PLANT TYPE	% ILE FACILITY	STREAM FLOW (MLD)				STREAM CONC. (µg/l)			
		Harmonic Mean	30Q5	7Q10	1Q10	Harmonic Mean	30Q5	7Q10	1Q10
ALL	50	255.71	132.96	84.15	69.21	N/A	N/A	N/A	N/A
ALL	10	21.78	4.48	2.52	2.35	N/A	N/A	N/A	N/A

DRINKING WATER AND FISH INGESTION EXPOSURE ESTIMATES						
Exposure Units	Drinking Water Results		Drinking Water Units	Fish Ingestion Results		Fish Ingestion Units
	50%	10%		50%	10%	
Cancer						
$LADD_{pot}$	4.10E-06	4.81E-05	mg/kg/day	2.14E-05	2.51E-04	mg/kg/day
$LADC_{pot}$	3.15E-04	3.70E-03	mg/L	0.23	2.68	mg/kg
Acute						
ADR_{pot}	N/A	N/A	mg/kg/day	N/A	N/A	mg/kg/day

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

DRINKING WATER EXPOSURE ESTIMATES FROM LANDFILL RELEASES

SCENARIO #: 14 ACTIVITY: USE 2: Max LADD

RELEASE DESCRIPTION:

EXPOSED POPULATION: Adult

NUMBER OF SITES	NON-SLUDGE LANDFILL RELEASE AND DAYS OF RELEASE (kg/site/day)/(days)	LANDFILLED SLUDGE[1] AND DAYS OF RELEASE (kg/site/day)/(days)	MIGRATION DESCRIPTOR[2]	ADSORPTION TO WASTEWATER SLUDGE (%)	DRINKING WATER TREATMENT (%)
16.	2.63E+04/1.00	0.00/0.00	Slow	0.00	0.00

[1] Landfilled sludge equals the fraction adsorbed to wastewater treatment sludge times the surface water pre-treatment release.

[2]

Migration Descriptor	Groundwater Concentration (GWC)	Log Koc (mg/L per kg release)	
Negligible		no migration	None
Negligible to slow	3.21E-6	> 4.5	
Slow	2.67E-5	<4.5 to 3.5	
Moderate	7.55E-5	<3.5 to 2.5	5.95E-5
Rapid			<2.5

Exposure Units	Results	ASSUMPTIONS			
		ED (years)	AT (years)	BW (kg)	IR (L/day)
Cancer					
$LADD_{pot}$ (mg/kg/day)	3.86E-03	33.00	78.00	80.00	1.04
$LADC_{pot}$ (mg/L)	0.30	33.00	78.00	NA	NA

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 14 RELEASE ACTIVITY:USE 2: Max LADD

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	16.	
Per Site Fugitive Release:	600.00	kg/site/day
Fugitive Release Days per Year:	1.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	9600.00	kg/yr
Max Annual Average Air Concentration (Fugitive):	18.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	2.63E+04	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	4.21E+05	kg/yr
Max Annual Average Air Concentration (Stack):	97.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

Exposure Units	Results (Stack)	Results (Fugitive)	ASSUMPTIONS			
			ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	7.51E-03	1.39E-03	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	4.10E-02	7.62E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m

INITIAL REVIEW EXPOSURE REPORT

Chemical ID: P-14-0683

INHALATION EXPOSURE ESTIMATES (POST-TREATMENT)

SCENARIO #: 14 RELEASE ACTIVITY:USE 2: Max LADD

RELEASE DESCRIPTION:

METHOD OF CALCULATION: Screen3

EXPOSED POPULATION: Adult

Number of Sites:	16.	
Per Site Fugitive Release:	600.00	kg/site/day
Fugitive Release Days per Year:	1.00	days
% Removal via Fugitive Release:	0.00	%
Total Fugitive Release:	9600.00	kg/yr
Max Annual Average Air Concentration (Fugitive):	18.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration(Fugitive):	N/A	$\mu g/m^3$
Per Site Stack Release:	2.63E+04	kg/site/day
Stack Release Days per Year:	1.00	days
% Removal via Stack Release:	0.00	%
Total Stack Release:	4.21E+05	kg/yr
Max Annual Average Air Concentration (Stack):	97.00	$\mu g/m^3$
Max 24 Hour Average Air Concentration (Stack):	N/A	$\mu g/m^3$

			ASSUMPTIONS

Exposure Units	Results (Stack)	Results (Fugitive)	ED (years)	AT (years)	BW (kg)	Inh. Rate (m^3/hr)
Cancer						
$LADD_{pot}$ (mg/kg/day)	7.51E-03	1.39E-03	33.00	78.00	80.00	0.61
$LADC_{pot}$ (mg/m^3)	4.10E-02	7.62E-03	33.00	78.00	NA	NA
Acute						
ADR_{pot} (mg/kg/day)	N/A	N/A	NA	1 day	80.00	0.61

Inhalation Comments:

Stack Parameter Data			Fugitive Parameter Data		
Stack Height	10.00	m	Release Height:	3.00	m
Inside Stack Diameter:	0.10	m	Length of Release Opening:	10.00	m
Stack Gas Exit Velocity:	0.10	m/sec	Width of Release Opening:	10.00	m
Stack Gas Temperature:	293.00	K			

Meteorological and Terrain Information:

Surrounding Land Use:	Rural	
Terrain Height:	0.00	m
Distance to Residence of Interest:	100.00	m
Meteorological Class:	Full	
Stability Class:	NA	
Wind Speed:	NA	

Downwash Information:

Facility Length:	NA	m
Facility Width:	NA	m
Facility Height:	NA	m