Annex XV

Proposal for identification of a substance as a CMR, PBT, vPvB or a substance of an equivalent level of concern

June 2008

Submitted by:

UK REACH Competent Authority

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: **Alkanes, C_{10-13}, chloro**

(The name 'short chain chlorinated paraffins' is used to refer to Alkanes, C_{10-13}, chloro CAS No. 85535-84-8 in this dossier.)

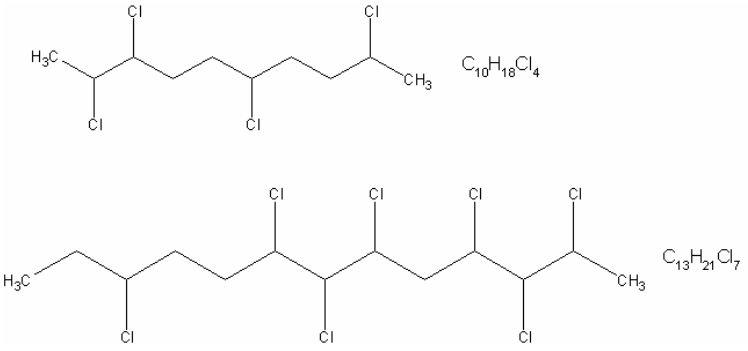
EINECS number: **287-476-5**

EINECS name: Alkanes, C_{10-13}, chloro

CAS number: 85535-84-8

Molecular formula: $C_xH_{(2x-y+2)}Cl_y$, where x = 10-13 and y = 1-13

Structural formula: Example structures



Purity: Alkanes, C_{10-13}, chloro are complex substances with varying chlorine contents and carbon chain lengths in the range of 10 – 13.

Impurities: Aromatics (50-100 ppm)

It is proposed to identify the substance as a Persistent, Bioaccumulative and Toxic (PBT) substance according to Article 57 (d).

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria, or is considered to be a substance of an equivalent level of concern

It is concluded that the substance meets the criteria for a PBT substance. Environmental degradation simulation studies have demonstrated that the mineralisation half-life in both freshwater and marine sediment is >180 days (vP). The substance has a measured bioconcentration factor in fish of 7,816 l/kg (vB) and a 21-day NOEC of 0.005 mg/l with *Daphnia magna* (T).

This proposal is based on the properties of the substance itself.

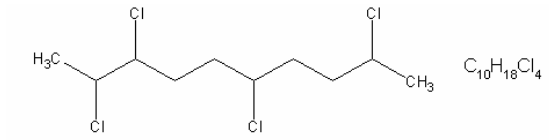
Registration number(s) of the substance or of substances containing the substance:

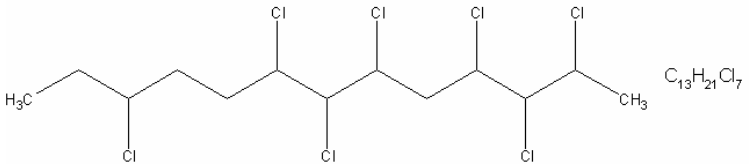
JUSTIFICATION

1 IDENTIFICATION OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifier of the substance

Name: Alkanes, C_{10-13}, chloro
EC Number: 287-476-5
CAS Number: 85535-84-8
IUPAC Name: Alkanes, C_{10-13}, chloro
Molecular Formula: $C_xH_{(2x-y+2)}Cl_y$, where x = 10-13 and y = 1-13
Structural Formula:





Molecular Weight: 320-500 approx.
Synonyms: Alkanes, chlorinated; alkanes (C_{10-13}), chloro-(50-70%); alkanes (C_{10-12}), chloro-(60%); chlorinated alkanes, chlorinated paraffins; chloroalkanes; chlorocarbons; polychlorinated alkanes; paraffins-chlorinated.

NOTE: Around 40 CAS numbers have been used to describe the whole chlorinated paraffin family at one time or another. Some of these are now historical, and others may be in use for the sole purpose of compliance with national or regional chemical inventories. It is possible that some cover Alkanes, C_{10-13}, chloro, and those that might are listed in Table 1 below (the list is not meant to be exhaustive).

Table 1: Substances that might contain short-chain chlorinated paraffins

Substance	CAS no.	EINECS no.
Alkanes, C6-18, chloro	68920-70-7	272-924-4
Alkanes, C10-12, chloro	108171-26-2	-
Alkanes, C10-14, chloro	85681-73-8	288-211-6
Alkanes, C10-21, chloro	84082-38-2	281-985-6
Alkanes, C10-26, chloro	97659-46-6	307-451-5
Alkanes, C10-32, chloro	84776-06-7	283-930-1
Alkanes, C12-13, chloro	71011-12-6	-
Alkanes, C12-14, chloro	85536-22-7	287-504-6
Paraffins (petroleum), normal C>10, chloro	97553-43-0	307-202-0
Alkanes, chloro	61788-76-9	263-004-3

This illustrates a problem in using CAS numbers to describe complex substances. It may be that some refer to products derived from feedstocks other than n-paraffins, or are monochlorinated.

The CAS number that is listed in IUCLID (85535-84-4) is taken to represent the commercial substance. The name 'short chain chlorinated paraffins' is used to refer to Alkanes, C_{10-13}, chloro CAS No. 85535-84-8 in this dossier.

1.2 Composition of the Substance

Alkanes, C_{10-13}, chloro are UVCB substances (Substances of Unknown or Variable Composition, complex reaction products or Biological materials) with varying chlorine contents (up to around 70% by weight) and carbon chain lengths (between C_{10} and C_{13}). Any impurities in commercial chlorinated paraffins are likely to be related to those present in the n-paraffin feedstocks, in which the major non-paraffinic impurity is a small proportion of aromatics, generally in the range 50-100 ppm. Various stabilisers (for example epoxidised vegetable oil at <0.5% by weight) are often added to commercial chlorinated paraffins in order to improve the thermal stability or light stability (EU, 2000).

1.3 Physico-Chemical properties

Table 2 Summary of physico-chemical properties

REACH ref Annex, §	Property	Value	Reference/comment
V, 5.1	Physical state at 20 C and 101.3 KPa	Clear to yellowish liquid to semi-solid	EU (2000). Depends on chlorine content.
V, 5.2	Melting / freezing point	-30 to +21°C	EU (2000). Pour points, no distinct melting point. Value depends on chlorine content.
V, 5.3	Boiling point	>200°C	EU (2000). Decompose with release of hydrogen chloride.
V, 5.5	Vapour pressure	0.021Pa at 40°C	EU (2000). Value for a 50% chlorine content product.
V, 5.7	Water solubility	0.15-0.47 mg/l at 20°C	EU (2000). Value for a 59% chlorine content product.
V, 5.8	Partition coefficient n-octanol/water (log value)	4.39-8.69 "typical" value ~6	EU (2000). Value depends on chlorine content.
VII, 5.19	Dissociation constant	Not relevant	

2 MANUFACTURE AND USES

Not relevant for this type of dossier.

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

Short chain chlorinated paraffins are classified as follows in Annex I of Directive 67/548/EEC.

N: R50-53

Xn: Carc. Cat. 3; R40

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

Second order reaction rate constants have been calculated for $C_{10\text{-}13}$, 49-71% wt Cl, chlorinated paraffins as $2.2\text{-}8.2\times10^{-12}$ cm^3 $molecule^{-1}$ s^{-1} for reaction with hydroxyl radicals. Assuming an atmospheric concentration of hydroxyl radicals of 5×10^5 molecules/cm^3, allows atmospheric half-lives of 1.9-7.2 days to be estimated (EU, 2000).

4.1.2 Biodegradation

Standard test systems

The biodegradability of a C_{10-12}, 58% wt Cl, chlorinated paraffin has been tested in the OECD Guideline 301C, Modified MITI I ready biodegradation test. The substance was tested at concentrations of 20 and 100 mg/l using a sludge concentration of 30 mg/l. No oxygen uptake, as measured in a manomeric biological oxygen demand (BOD) apparatus, was observed over a 28 day period. Analysis for residual chlorinated paraffin in the test vessels showed that 98% of the chlorinated paraffin initially added remained, confirming that no biodegradation had taken place (Street *et al*., 1983). Therefore, the substance is not readily biodegradable. However, it should be noted that the concentrations tested are well above the apparent solubility of the substance.

A C_{10-12}, 58% wt Cl, chlorinated paraffin has been tested in the OECD Guideline 302B, Inherent biodegradability: Modified Zahn-Wellens Test. Degradation was followed by monitoring CO_2 evolution over 28 days at 22±1°C and comparing this to the theoretical amount of CO_2 that would be evolved, assuming complete biodegradation. The chlorinated paraffin was tested at concentrations of 50 mg C/l (≡137.4 mg/l) and 25 mg C/l (≡68.7 mg/l) and the initial activated sludge concentration was 200 mg/l. The degradation seen during the 28 day period was 7.4% and 16% at the two concentrations respectively. Therefore, the substance is not inherently biodegradable. However, it should be noted that the concentrations tested are well above the apparent solubility of the substance. The high concentration was shown not to have any effect on the biodegradation of aniline, indicating that the chlorinated paraffin was not toxic to the microorganisms present (Mather *et al.*, 1983).

The same C_{10-12}, 58% wt Cl chlorinated paraffin has also been tested in a modified OECD Guideline 303A Coupled Units test. In this case, the commercial chlorinated paraffin was mixed with a ^{14}C-labelled chlorinated n-undecane (59.1% wt Cl) and this was continuously added to the units as an emulsion. The units had a hydraulic retention time of 6 hours and the initial chlorinated paraffin concentration was 10 mg/l. The units were initially seeded with secondary effluent (0.1% vol/vol) and were operated for 51 days (33 days were allowed for establishment of equilibrium conditions). The chlorinated paraffin was found to have no effect on DOC removal within the system, indicating that it was not toxic at the concentration used. The mean concentration (determined by radioactivity measurements) of chlorinated paraffin in the effluent was 0.7 mg/l, indicating an equilibrium removal of 93%. The removal was mainly by adsorption onto the sludge (mean concentration found on sludge was 68,000 mg/kg) rather than biodegradation. It was thought that the chlorinated paraffin found in the effluent was associated with the suspended matter (Street and Madeley, 1983).

Other test systems

Madeley and Birtley (1980) found that under aerobic conditions, microorganisms previously acclimated to specific chlorinated paraffins showed a greater ability to degrade the compounds than non-acclimated microorganisms. In the first series of experiments, microorganisms were obtained from soil near to a chlorinated paraffin production plant. The microorganisms were acclimatised to chlorinated paraffins (concentration 20-50 mg/l as an emulsion) in shake flasks over an 8 week period. The biodegradation of the chlorinated paraffins was then studied over a 25 day period using BOD tests (chlorinated paraffin concentration 2-20 mg/l). The second set of biodegradation experiments were carried out in a

similar way using non-acclimated microorganisms from the effluent of a laboratory activated sludge unit treating domestic waste. The results of the experiment, expressed as BOD (g O_2/g chlorinated paraffin) are shown in Table 3 (for comparison, the theoretical oxygen demand (ThOD) for $C_{11}H_{20}Cl_4$ (48% Cl) can be calculated as 1.63 g O_2/g chlorinated paraffin). As can be seen from the results, only the 49% wt Cl short chain length chlorinated paraffin exerted an appreciable BOD.

Table 3 Results of BOD experiments using acclimated and non-acclimated microbial populations

Chlorinated paraffin	Type of inoculum	BOD (g O_2/g chlorinated paraffin)				
		5 day	10 day	15 day	20 day	25 day
C_{10-13}, 49% wt Cl	NA	0.02	0.08	0.12	0.20	0.29
	A	0.25	0.46	0.55	0.65	1.02
C_{10-13}, 60% wt Cl	NA	/	/	/	/	/
	A	/	/	/	/	/
C_{10-13}, 70% wt Cl	NA	/	/	/	/	/
	A	/	/	/	/	/

Notes: NA - non-acclimated microorganismsA - acclimated microorganisms

Fisk *et al.* (1998) estimated half-lives for biodegradation of 13 days for ^{14}C-labelled $C_{12}H_{20.1}Cl_{5.9}$ (55.9% wt. Cl) and 30 days for $C_{12}H_{16.2}Cl_{9.8}$ (68.5% wt. Cl) in an aerobic sediment system containing oligochaetes (*Lumbriculus variegatus*). The extent of degradation was determined at day 0 and day 14 of the experiments based on the difference between toluene-extractable ^{14}C measurements (taken to represent unchanged chlorinated paraffin) and total ^{14}C measurements for the sediment. However, the results of this test should be treated with caution as the identity of the ^{14}C present in the samples was not determined, and it was assumed that the non-extractable ^{14}C represented metabolites. It should also be noted that as the analysis was based on the amount of ^{14}C present in the sediment, these data show that little mineralization of the short-chain chlorinated paraffins was occurring.

Omori *et al.* (1987) studied the biodegradation of C_{12}, 63% wt Cl chlorinated paraffin using a variety of microbial cultures. Degradation was studied by monitoring the release of chloride ion from the chlorinated paraffin. Firstly the degradation of the chlorinated paraffin was studied using resting cell cultures of *Pseudomonas aeruginosa*, *Achromobacter delmarvae*, *A. cycloclastes*, *Micrococcus* sp. and *Corynebacterium hydrocarboclastus* grown on glycerol and incubated for 24 hours at 30^{o}C. These bacteria had been shown to dechlorinate 1-chlorohexadecane as well as some other mono- and dichlorinated alkanes. Little or no dechlorination of the C_{12}, 63% wt chlorinated paraffin was seen using these bacteria. Dechlorination of the chlorinated paraffin was shown to occur using bacterial strains isolated from soil (using enrichment cultures with n-hexadecane as sole carbon source). In these experiments, the isolated bacteria were incubated for 48 hours at 30^{o}C with the chlorinated paraffin and n-hexadecane. The highest degree of dechlorination was achieved using a mixed culture of 4 strains of bacteria isolated from soil. Around 21% dechlorination, as measured by chloride ion release, was observed after 36 hours incubation of the chlorinated paraffin and n-

hexadecane (Omori *et al.*, 1987). These results show that dechlorination of short chain length chlorinated paraffins may occur in a cometabolic process.

Allpress and Gowland (1999) identified a bacterium (*Rhodococcus* sp.) that was able to grow using various chlorinated paraffins as the sole source of carbon and energy. The bacterium was isolated from stream water from an industrial area of the United Kingdom using a minimal salts medium containing 1% by volume of a C_{14-17}, 45% wt. Cl chlorinated paraffin product. The ability of this bacterium to utilise short-chain chlorinated paraffins was investigated by inoculating minimal salts medium containing one of two short-chain chlorinated paraffins (a C_{10-13}, 49% wt. Cl product and a C_{10-13}, 63% wt. Cl product) at a concentration of 1% by volume and determining the chloride release compared with controls over 71 days incubation at 20^{o}C. The test media also contained anti-bumping granules to aid dispersion of the test substance within the media. Only the C_{10-13}, 49% wt. Cl product was utilised by the bacterium with 49% of the chlorine present in the chlorinated paraffins being released as chloride after 71 days. The C_{10-13}, 63% wt. Cl product showed little or no increase in chloride ion levels above the control values during the experiment. Several other chlorinated paraffins were tested using this system and it was concluded that the *Rhodococcus* sp. identified in the study was able to utilise chlorinated paraffins as sole source of carbon and energy, but little or no utilisation occurred with chlorinated paraffins with high degrees of chlorination (at or above around 59-60% wt. Cl).

Simulation studies in freshwater and marine sediment

Further studies investigating the biodegradation of short-chain chlorinated paraffins in both freshwater and marine sediments under aerobic and anaerobic conditions have been carried out by Thompson and Noble (2007). Two substances were used in the tests, a ^{14}C-labelled n-decane, 65% wt. Cl product and a ^{14}C-labelled n-tridecane, 65% wt. Cl product. The test substances were synthesised by chlorination of the respective uniformly ^{14}C-labelled n-alkanes mixed with the appropriate unlabelled n-alkanes. The purity of the chlorinated products was >98% and the two test substances had average molecular formulas of $C_{10}H_{14.9}Cl_{7.1}$ (65.0% wt. Cl) and $C_{13}H_{18.8}Cl_{9.2}$ (64.9% wt. Cl) respectively.

The freshwater sediment was collected from the Grand Western Canal in Devon (UK) and the marine sediment was collected from the Dart Estuary in Devon. Both sampling sites were considered to be remote from sources of significant industrial contamination. The samples were collected through the water column using a grab sampler. The marine sediment samples were separated into the superficial aerobic sediment and the subsurface anaerobic sediment. This separation was not possible for the freshwater sediment and so a single sediment sample was collected and used for both the aerobic and anaerobic experiments. Samples of overlying water were collected from the same locations as the sediments. The sediments were sieved (2 mm) to remove stones and other debris and stored for between six and seven days under refrigeration prior to use in the tests.

The freshwater sediment had a pH of 7.1, a redox potential of 231 mV (Eh; at the time of collection), an organic carbon content of 4.5-4.8% and consisted of 56% sand, 21% silt and 23% clay. The overlying water from the freshwater sediment sampling site had a pH of 8.6 and a redox potential of 460 mV (Eh; at the time of collection). The aerobic layer of the marine sediment had a pH of 7.5, a redox potential of 279 mV (Eh; at the time of collection), an organic carbon content of 4.1% and consisted of 8% sand, 51% silt and 41% clay. The anaerobic layer of the marine sediment had a pH of 7.8, a redox potential of 216 mV (Eh; at the time of collection), an organic carbon content of 4.1% and consisted of 8% sand, 51% silt

and 41% clay. The overlying water from the marine sediment sampling site had a pH of 7.8, a redox potential of 356 mV (Eh, at the time of sampling) and a salinity of 26.5‰.

The test method used was based on the OECD 308 Test Guideline (Aerobic and anaerobic transformation in aquatic sediment systems). The sediments were acclimated to the test conditions for twenty two days prior to addition of the test substance. During the acclimation the test chambers (1 litre glass bottles) each contained an equivalent dry weight of 75 g freshwater sediment or 65 g marine sediment and 525 ml of the overlying water and the chambers were incubated at 16°C. Air was supplied to the aerobic chambers at a rate of 20-30 ml/min (air was provided via glass tubing located centrally above the water surface). The headspace of the anaerobic chambers was continually purged with nitrogen at a similar rate during the acclimation period. To start the biodegradation phase of the test, the relevant test substance was added to the chambers adsorbed onto 5 g of dry sediment. The spiked dry sediment was prepared by adding 0.5 ml of a stock solution of the relevant chlorinated paraffin in acetone to 5 g of dry sediment and allowing the acetone to evaporate. The spiked dry sediment was then mixed into the bulk sediment using a magnetic stirring bar. The final depth of sediment in the test chambers was 22 mm and depth of the overlying water was 90 mm (water/sediment volume ratio of approximate 3.1). Control sediments were prepared in the same manner but using acetone without the test substance. A total of 156 test vessels were prepared (sixteen vessels each for the eight combinations of test substance (C_{10}/C_{13}), sediment (marine/freshwater) and conditions (aerobic/anaerobic) and twenty eight control vessels). During the biodegradation phase, the headspace of the aerobic chambers was continually purged with air (as during the acclimation phase) and volatile organic products and $^{14}CO_2$ were collected from the exhaust air. The anaerobic chambers were operated as static closed systems during the biodegradation phase of the test (no trapping systems for methane were available that would be effective if the headspace was continually purged), with the chambers being flushed with nitrogen overnight only following the initial addition of the test substance. The initial concentrations of the test substance were in the range 6.2 to 8.7 mg/kg dry weight. The duration of the tests were 98 days (aerobic conditions) and 86-100 days (anaerobic conditions) and the test chambers were again incubated at 16°C throughout the duration of the tests.

The microbial biomass present in the test systems was determined both at the start and end of the test. The microbial biomass at the start of the test was determined to be 268 µg C/g in the freshwater aerobic sediment, 286 µg C/g in the freshwater anaerobic sediment, 220 µg C/g in the marine aerobic sediment and 216 µg C/g in the marine anaerobic sediment. At the end of the study the microbial biomass in the control sediments was 400 µg C/g in the freshwater aerobic sediment, 380 µg C/g in the freshwater anaerobic sediment, 250 µg C/g in the marine aerobic sediment and 160 µg C/g in the marine anaerobic sediment. The corresponding microbial biomass in the treated sediments was 420, 440, 280 and 160 µg C/g respectively in the experiments with the chlorinated decane and 400, 400, 250 and 160 µg C/g respectively in the experiments with the chlorinated tridecane. These data indicate that neither test substance was toxic to the microbial biomass at the concentrations used.

At various timepoints during the test, duplicate vessels from each treatment group were sacrificed and analysed to determine the distribution of total ^{14}C and the overall mass balance. The results of the experiments are summarised in Table 4.

For the experiments carried out under aerobic conditions, $^{14}CO_2$ was found to be evolved over the 98 day test period. The cumulative formation of $^{14}CO_2$ (as a percentage of the total

radiolabel added to the test system) is shown graphically in Figure 1. Both substances showed a higher rate of mineralisation in the marine sediment than in the freshwater sediment, and the chlorinated decane was mineralised at a faster rate than the chlorinated tridecane. The highest amount of $^{14}CO_2$ evolved was around 13% in the experiments with the chlorinated decane in the marine sediment.

Table 4 Biodegradation of short-chain chlorinated paraffins in freshwater and marine sediment

Conditions	Test substance	Sediment	Time (days)	% Distribution of ^{14}C-label (as a percentage of the applied dose)						
				Volatiles	CO_2 (cumulative)	Methane	Overlying water	Sediment	Vessel surfaces[a]	Total mass balance
Aerobic	C_{10}, 65% wt. Cl	Freshwater	0	-	-	-	<0.35	82.2	0.58	83.1
			14	0.29	0.20	-	0.90	108	0.55	110
			35	0.72	0.61	-	1.20	89.8	0.10	92.4
			56	0.36	2.14	-	1.40	106	0.07	110
			77	0.22	3.21	-	1.32	96.9	0.23	102
			98	0.18	3.88	-	1.07	83.6	0.12	88.8
		Marine	0	-	-	-	<0.29	69.2	1.16	70.7
			14	0.024	0.35	-	2.06	81.8	2.27	86.5
			35	0.054	2.64	-	5.17	56.3	1.61	65.7
			56	0.071	5.78	-	4.42	77.7	0.84	88.8
			77	0.12	9.51	-	5.33	69.8	0.46	85.2
			98	0.073	13.4	-	4.49	63.9	1.55	83.4
	C_{13}, 65% wt. Cl	Freshwater	0	-	-	-	<0.30	98.2	1.33	99.8
			14	0.0048	0.25	-	0.57	94.2	0.56	95.5
			35	0.0058	0.42	-	0.53	74.8	0.19	75.9
			56	0.0072	0.90	-	0.59	95.6	0.12	97.2
			77	0.0053	1.08	-	0.62	99.6	0.17	101
			98	0.0037	3.33	-	0.63	102	0.08	106

Table 4 continued overleaf.

Table 4 continued

Conditions	Test substance	Sediment	Time (days)	% Distribution of ^{14}C-label (as a percentage of the applied dose)						
				Volatiles	**CO_2** (cumulative)	Methane	**Overlying water**	**Sediment**	**Vessel surfaces[a]**	**Total mass balance**
		Marine	0	-	-	-	<0.25	101	1.49	103
			14	0.0044	0.08	-	1.00	59.2	2.43	62.7
			35	0.0044	1.32	-	2.00	63.7	0.93	67.9
			56	0.0013	3.30	-	2.50	57.4	1.85	65.0
			77	0.0044	4.62	-	2.46	78.0	0.18	85.3
			98	0.0033	5.81	-	2.34	71.2	1.56	80.9
Anaerobic	C_{10}, 65% wt. Cl	Freshwater	0	-	-	-	0.22	87.8	1.4	89.5
			77	0.0030	0.66	0.14	1.49	81.0	0.090	83.3
			78	0.0036	0.77	0.084	1.74	76.3	0.090	78.9
			86	0.0030	0.062	0.10	1.79	94.8	0.090	96.9
			87	0.0030	0.85	0.090	1.89	101	0.23	104
		Marine	0	-	-	-	0.28	46.9	2.38	49.5
			82	0.0036	0.50	0.069	10.8	81.5	0.42	93.3
			83	0.0057	0.79	0.072	10.1	76.9	0.094	87.9
			97	0.0062	2.00	0.063	11.6	64.6	0.41	78.7
			98	0.0057	1.86	0.066	11.0	64.1	0.19	77.2

Table 4 continued overleaf.

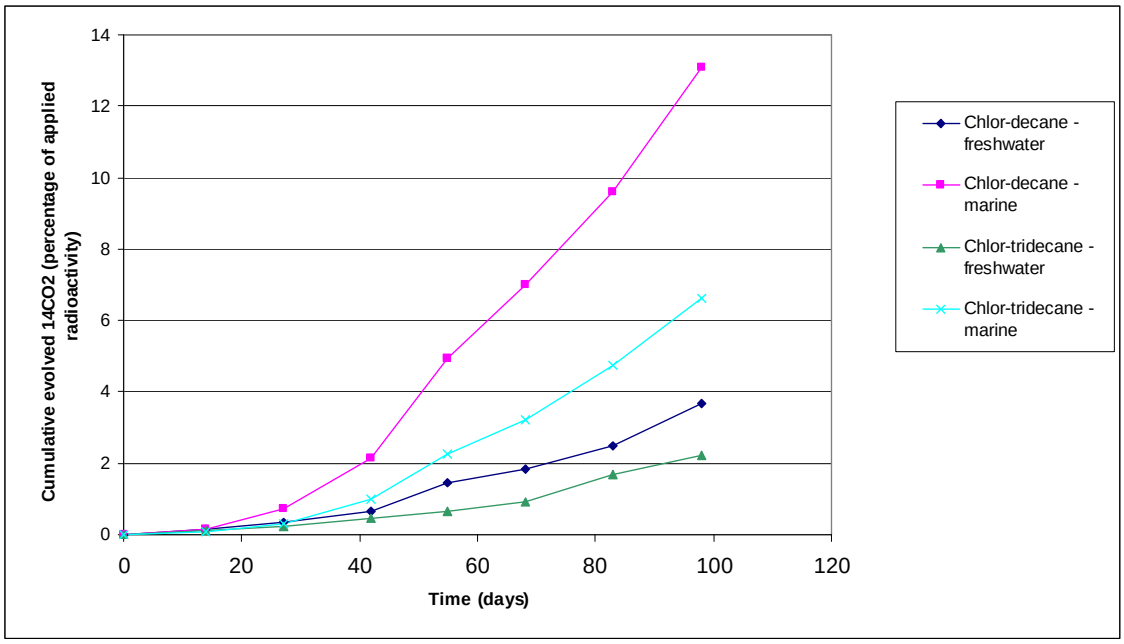
Table 4 continued

Conditions	Test substance	Sediment	Time (days)	% Distribution of ^{14}C-label (as a percentage of the applied dose)						
				Volatiles	**CO_2** (cumulative)	Methane	**Overlying water**	**Sediment**	**Vessel surfaces[a]**	**Total mass balance**
	C_{13}, 65% wt. Cl	Freshwater	0	-	-	-	0.25	74.8	0.57	75.6
			79	0.0026	0.17	0.053	0.54	74.9	0.20	75.9
			80	0.0027	0.054	0.068	0.68	90.6	0.15	91.5
			92	0.0032	0.20	0.090	0.88	90.0	0.37	91.6
			93	0.0026	0.41	0.069	0.87	100	0.95	102
		Marine	0	-	-	-	0.19	41.2	5.38	46.7
			84	0.0044	0.073	0.054	5.64	69.6	0.46	75.9
			85	0.0035	0.046	0.056	4.80	76.4	0.12	81.5
			99	0.0022	1.19	0.055	5.69	89.8	3.10	99.8
			100	0.0035	1.35	0.054	6.46	61.9	1.38	71.1

Notes: - Not determined.

a) Analysis of solvent extracts from the walls of the test vessels after emptying.

Figure 1 **Mineralisation of ^{14}C-labelled short-chain chlorinated paraffins in aerobic sediments**



First order rate constants and half-lives for mineralisation were estimated from the $^{14}CO_2$ evolution data. The estimated half-lives were around 1,340 days for the chlorinated decane in freshwater sediment, 335 days for the chlorinated decane in marine sediment, 1,790 days for the chlorinated tridecane in freshwater sediment and 680 days for the chlorinated tridecane in marine sediment. The mean half-live (average of the two substance; this could be assumed to be representative of a $C_{10\text{-}13}$, 65% wt. Cl product) was determined to be around 1,630 days in freshwater sediment and 450 days in marine sediment. It should be noted, however, that there was a considerable lag phase before mineralisation commenced (around 40-50 days; see Figure 1) and these half-lives were calculated after the lag phase. In addition, it should be noted that the actual extent of mineralisation seen in some experiments was relatively small and in all cases was <50% and so the calculated half-lives are extrapolated beyond the available data.

Under anaerobic conditions, no significant formation of ^{14}C-labelled methane was noted during the test (the amount of methane formed was <0.1% of the applied radioactivity). In addition only a limited amount of ^{14}C-labelled CO_2 was formed (≤ 1.3% of the applied radioactivity). Therefore it was concluded that there was insufficient degradation under the anaerobic conditions with which to estimate the rate constant for the reaction.

The mean mass balance determined in this study was around 90-98% in the experiments with freshwater sediments and 78-84% in the experiments with marine sediments. The mass balance in the freshwater sediment studies was generally satisfactory. Thompson and Noble (2007) thought that it was probable that the generally lower mass balance seen in the marine sediments reflected an underestimate of the amount of radioactivity present in the sediment by the analytical method used. As low mass balances were apparent in the marine sediment at the start of the study, a further experiment was carried out to investigate if there was any systematic loss of the test substance during the spiking procedure. This revealed no source of loss prior to addition of the test substance to the sediment.

The dissolved oxygen concentration in the overlying water of the control vessel was generally in the range 30-70% of the air saturation value during the test for both sediments under aerobic conditions (a few, isolated values were outside this range). For the anaerobic sediments, the dissolved oxygen levels of the overlying water in the control sediments were generally lower, but more variable, than found under aerobic conditions, with values of 1-25% and 0.6-65% of the air saturation value being found in the freshwater and marine sediments respectively. It was thought that these values were affected by the need to open the bottles periodically in order to make pH and oxygen readings, and this inevitably allowed oxygen to be introduced into the test system (the higher values for the dissolved oxygen readings were generally associated with such sampling times).

The redox potentials of the aerobic freshwater sediment systems during the test (after the acclimated phase) was in the range 269 to 957 mV (Eh) in the overlying water and -188 to -31 mV (Eh) in the sediment. The ranges in the aerobic marine system were 413 to 605 mV (Eh) in the overlying water, but somewhat higher in the sediment (-161 to 44 mV (Eh)). For the anaerobic sediment systems, the redox potentials for the overlying water were in the range -146 to 671 mV (Eh) in the freshwater system and -22 to 614 mV (Eh) in the marine system. The corresponding redox potentials in the anaerobic sediment phase were in the range -234 to -216 mV (Eh) in the freshwater system and -172 to 98 in the marine sediment system.

As relatively high levels of dissolved oxygen were present in the water phase of the anaerobic tests at various points during the incubation, it is likely that the actual conditions in this test cycled between aerobic and anaerobic conditions. It is also interesting to note that the redox potentials of the bulk sediment phase were generally similar (predominantly negative values for the redox potential) under both aerobic and anaerobic conditions. This is not necessarily surprising as the OECD 308 test guideline is designed to simulate an aerobic water column over an aerobic sediment layer that is underlain with an anaerobic gradient.

No parent compound analysis was carried out in this test and so the extent of primary degradation was not determined. Overall the results show that although mineralisation of the test substance occurred under aerobic conditions, the rate of mineralisation was low, with a mean half-life under aerobic conditions of around 1,630 days in freshwater sediment and around 450 days in marine sediment. Little or no mineralisation was evident under anaerobic conditions over the timeframe of this study.

4.1.3 Summary and discussion of persistence

Short-chain chlorinated paraffins are not readily biodegradable in standard ready biodegradation tests. In addition, although some degradation was seen in a standard inherent biodegradation test, the extent of degradation seen was only up to around 16% and so short-chain chlorinated paraffins cannot be considered as inherently biodegradable within the meaning of that test system, although interpretation is difficult due to the low water solubility of the substance.

A substance is considered to be persistent (P) if it has a half-life >60 days in marine water or > 40 days in fresh- or estuarine water, or >180 days in marine sediment or >120 days in freshwater or estuarine sediment or soil. A substance is considered to be very persistent (vP) if it has a half-life > 60 days in marine, fresh- or estuarine water or >180 days in marine sediment, freshwater or estuarine sediment or soil.

The results of a biodegradation simulation study with both freshwater and marine sediment are available. Two substances were tested, a C10, 65% wt. Cl substance and a C13, 65% wt. Cl substance. Under aerobic conditions the mineralisation half-life was determined to be around 1,340

days for the C10, 65% wt. Cl substance in freshwater sediment, 335 days for the C10, 65% wt. Cl substance in marine sediment, 1,790 days for the C13, 65% wt. Cl substance in freshwater sediment and 680 days for the C13, 65% wt. Cl substance in marine sediment. The mean half-live (average of the two substances, this could be assumed to be representative of a C10-13, 65% wt. Cl product) was determined to be around 1,630 days in freshwater and 450 days in marine sediment.

No information is available with which to estimate a reliable mineralisation half-life for soil or surface water or for short-chain chlorinated paraffins with chlorine contents other than 65% by weight. Based on the available data it is concluded that short-chain chlorinated paraffins meet the criteria for a vP substance.

4.2 Environmental distribution

4.2.1 Adsorption

The substance has a high log Kow value, with values ranging from around 4.4 up to around 8.7 depending on the chlorine content and carbon chain length, and a value of 6 was chosen for the EU risk assessment (EU, 2000). In addition the substance has only limited solubility in water (around 0.15-0.47 mg/l; EU, 2000). These properties indicate that, in water, the substance is likely to absorb onto sediment. Therefore the persistence in sediment is more relevant to this proposal than persistence in water.

4.2.2 Volatilisation

Not relevant for this dossier.

4.2.3 Elimination in wastewater treatment plants

The high log Kow value for short-chain chlorinated paraffins indicate a high removal during waste water treatment by adsorption onto sewage sludge. This has been confirmed experimentally in a Coupled Units test where an equilibrium removal of 93% by adsorption onto sludge was found (see Section 4.1.2). This indicates that the persistence in soil is a relevant consideration for the PBT properties of this substance as a result of spreading of sewage sludge on agricultural land.

4.3 Bioaccumulation

4.3.1 Screening data[1]

A high bioaccumulation potential for short-chain chlorinated paraffins is indicated by the high log Kow values determined for several short-chain chlorinated paraffin products (see Section 1.3).

4.3.2 Measured bioaccumulation data[2]

Madeley and Maddock (1983a) exposed rainbow trout (*Oncorhynchus mykiss*) to measured concentrations of 0.033, 0.1, 1.07 and 3.05 mg/l of a C_{10-12}, 58% wt Cl for 60 days. The concentrations were determined by means of a ^{14}C-labelled chlorinated n-undecane (59.1% wt Cl,

[1] For example, log K_{ow} values, predicted BCFs

[2] For example, fish bioconcentration factor

radiolabelled in the 6 position) mixed into the commercial product. In addition, parent compound analysis was also undertaken at various times during the test. Whole body bioconcentration factors (BCFs) of 1,173-7,816 were determined based on radioactivity measurements in the fish and BCFs of 574-7,273 were determined based on the parent compound analysis. The BCFs were found to increase with decreasing exposure concentration (this might be explained by the fact that two of the exposure concentrations are above the solubility for chlorinated paraffins) (Madeley and Maddock, 1983a).

Madeley and Maddock (1983b), again using rainbow trout (*Oncorhynchus mykiss*), found high levels of accumulation in the liver and viscera after exposure to measured concentrations of 3.1 and 14.3 µg/l of a short chain length (C_{10-12}), 58% chlorinated paraffin. Exposure was for 168 days at 12°C using a flow-through system. The bioconcentration was measured by means of a ^{14}C-labelled chlorinated n-undecane (59.1% wt Cl, radiolabelled in the 6 position) mixed into the commercial product. Lower bioconcentration factors were observed in the flesh (BCF=1,300-1,600) as compared to liver (2,800-16,000) and viscera (11,700-15,500) and the whole fish BCF was estimated to be 3,600-5,300. These bioconcentration factors were based on the amount of ^{14}C-labelled material present in the various organs. A limited number of parent compound analyses were also carried out at various times during the tests, and these indicated that some of the ^{14}C-label present in the liver and viscera may not have been the parent chlorinated paraffin. Therefore, these measured BCFs are likely to represent maximum values. During depuration (168 days), the following half-lives were determined for the chlorinated paraffin: liver 9.9-11.6 days; viscera 23.1-23.9 days; flesh 16.5-17.3 days; and whole body 18.7-19.8 days. The relatively short half-life observed in the liver is believed to be indicative of rapid metabolism and excretion of the test substance. On days 63-70 of depuration, fish previously exposed to chlorinated paraffins refused to feed and developed behavioural abnormalities. Deaths occurred in both groups previously exposed to chlorinated paraffins and all fish previously exposed to 14.3 µg/l died by day 70 of depuration. In the lower exposure group all abnormal effects ceased after day 70 of depuration. Although no explanation could be found for these events, there were no effects seen at this time or any other time in the control populations and the presence of disease or parasites was eliminated as a possible cause.

Bengtsson *et al.* (1979) studied the uptake and accumulation of several short chain length chlorinated paraffins by bleak (*Alburnus alburnus*). The fish were exposed to 125 µg/l of a chlorinated paraffin (C_{10-13}, 49% wt Cl; C_{10-13}, 59% wt Cl; C_{10-13}, 71% wt Cl) in brackish water ($7^{o}/_{oo}$) for 14 days at 10°C under semi-static conditions (renewed every 2nd or 3rd day). After exposure, the depuration of the chlorinated paraffins was studied for an additional 7 days. The concentration of chlorinated paraffin in the fish was measured by a neutron activation analysis method that determines the total amount of chlorine present (later unpublished work using a mass spectrometry based method specific for chlorinated paraffins showed good agreement with these concentrations (Bengtsson and Baumann-Ofstad, 1982)). All three chlorinated paraffins were taken up by the fish but uptake was greatest for the lower chlorinated grades over the 14 day exposure period (whole body BCFs of around 800-1,000 can be estimated from the data for the 49% wt Cl and 59% wt Cl compounds, whereas the BCF was around 200 for the 71% wt Cl compound). High levels of chlorinated paraffin were still detected in the fish after the 7 day depuration period.

Fisk *et al.* (1999) studied the uptake of two ^{14}C-labelled short-chain chlorinated paraffins by eggs and larvae of Japanese medaka (*Oryzias latipes*) as part of a 20-day embryo-larval toxicity study. The substances tested had average formulas of $C_{10}H_{15.3}Cl_{6.7}$, 63.7% wt. Cl and $C_{12}H_{19.5}Cl_{6.5}$, 58.5% wt. Cl. The measured exposure concentrations used were 4.7, 50, 370, 2,200 and 5,100 µg/l for the C_{10} chlorinated paraffin and 0.7, 9.6, 55 and 270 µg/l for the C_{12} chlorinated paraffin. The resulting concentrations in the larvae at approximately 3-days post hatch were 12, 100, 1,000, 3,000, and 3,500 mg/kg respectively for the C_{10} chlorinated paraffin and 0.74, 7.1, 62 and 460 mg/kg

respectively for the C_{12} chlorinated paraffin. The resulting BCF values were 690-2,700 l/kg for the C_{10} chlorinated paraffin and 740-1,700 for the C_{12} chlorinated paraffin, with the BCF for the C_{10} chlorinated paraffin appearing to increase with decreasing exposure concentrations. The two highest measured exposure concentrations for the C_{10} chlorinated paraffin appear to be higher than the experimental water solubility of short-chain chlorinated paraffin (typically 150-470 μg/l) and so the results at these higher exposure concentrations may have been affected by the presence of undissolved test substance (the BCFs for these two concentrations are 690-1,364 l/kg compared with BCFs of 2,000-2,700 l/kg at the three lower concentrations). Similar results were found for the eggs. Further details of this study are given in Section 3.2.1.1. The exposure period in this experiment is relatively short and no indication is available as to whether equilibrium was reached.

Very high BCFs have been determined for a C_{10-12}, 58% wt Cl chlorinated paraffin in common mussels (Mytilus edulis). The chlorinated paraffin was mixed with a 14C-labelled chlorinated n-undecane (59.1% Cl, 14C-labelled in the 6 position) and concentrations were determined by measurement of radioactivity (both water and mussel). Some parent compound analyses were also carried out at various times during the experiment and the concentrations obtained agreed with those obtained from the 14C radioactivity measurements. Mussels were exposed to the chlorinated paraffin at a concentration of 2.35 μg/l for 147 days followed by 98 days depuration or a concentration of 10.1 μg/l for 91 days followed by 84 days depuration using a flow-through system. Accumulation of the chlorinated paraffin was found to be greatest in the digestive gland, with BCFs being measured as 226,400 and 104,000 at the low and high exposure concentrations respectively. Whole mussel BCFs were determined as 40,900 and 24,800 at the low and high exposure concentrations respectively. All tissues expelled the test compound at a similar rate, with half-lives for the whole mussel being calculated as 9.2-9.9 days for the high exposure group and 13.1-19.8 days for the low exposure group. The high exposure concentration (10.1 μg/l) was found to cause a significant number of deaths during the test; 33% of the original 130 exposed mussels died either during the exposure period (23%) or depuration period (10%). Mortalities at the low exposure concentration were not significantly different from controls (Madeley *et al.*, 1983a). Similarly high BCFs (5,785-25,952) have also been measured in mussels after 60 days exposure to a 58% wt Cl short chain length chlorinated paraffin at concentrations of 0.013-0.93 mg/l (Madeley and Thompson, 1983).

As well as these BCF studies, a number of studies have shown that short-chain chlorinated paraffins can be taken up by fish from the diet. These studies are summarised in EU (2000).

4.3.3 Other supporting information

A significant amount of monitoring data is available for short-chain chlorinated paraffins. These indicate that short-chain chlorinated paraffins are present in a wide range of aquatic organisms, including fish and marine mammals, at locations both close to industrial sources and in more remote areas. Data are summarised in Table 5. The interpretation of some of these data is complicated by the fact that many of the studies have measured total chlorinated paraffins or C_{10-20} chlorinated paraffins and may not relate directly to the levels of short-chain chlorinated paraffins present, however more recent studies have used methods that unambiguously identify short-chain chlorinated paraffins.

Table 5 Summary of available monitoring data for short-chain chlorinated paraffins in biota

Reference	Summary of findings	
	Results	**Comments**
Bennie *et al.* (2000)	Short-chain chlorinated paraffins detected in beluga whale blubber (fifteen females at 4.6-60.7 mg/kg wet wt. and ten males at 27.6-85.6 mg/kg wet wt.), beluga whale liver (three females at 0.54-38.5 mg/kg wet wt. and three males at 4.61-8.52 mg/kg wet wt.), carp (three individuals at 0.12-1.25 mg/kg wet wt.) and rainbow trout (ten individuals at 0.45-5.33 mg/kg wet wt.).	The authors indicated that the method used (involving low resolution mass spectrometry) may be more subject to interferences from other organohalogen compounds than some of the methods used in other analyses. Some of these samples appear to have been the same as those analysed by Muir *et al.* (2001), which results in concentrations one to two orders of magnitude lower in beluga than found by Bennie *et al.* (2000). Therefore the results of Bennie *et al.* (2000) are considered uncertain.
Borgen *et al.* (2001)	Short-chain chlorinated paraffins (with 5-10 chlorine atoms/molecule) were detected in freshwater fish from various locations in Norway. The concentrations found were 108-1,692 µg/kg lipid in trout muscle, 500-592 µg/kg lipid in arctic char muscle and 226-3,700 µg/kg lipid in burbot liver.	
Campbell and McConnell (1980)	C_{10-20} chlorinated paraffins found in marine fish, mussels, predatory freshwater fish, seals, seabirds' eggs, seabirds' livers, human food stuffs (dairy products, vegetable oils and derivatives, fruit and vegetables) and also sheep (close to a source of release).	The levels refer to C_{10-20} chlorinated paraffins and it is not possible to distinguish the contribution from short-chain chlorinated paraffins.
CEFAS (1999)	Short-chain chlorinated paraffins possibly present in freshwater fish and benthos near to sources. Range of concentrations <0.05-0.7 mg/kg wet wt. in benthos and <0.1-5.2 in fish. Also possibly detected in earthworms at <0.1-1.7 mg/kg wet wt. from locations where sewage sludge containing chlorinated paraffins was applied to soil	The actual identity of the residues was difficult to assign and it was not clear what types of chlorinated paraffins were present.
Environment Agency Japan (1991).	Chlorinated paraffins not detected in 108 samples of fish from Japan.	The type of chlorinated paraffin analysed for was not specified. The detection limit was relatively high (0.5 mg/kg wet wt.)
Greenpeace (1995)	C_{10-24} chlorinated paraffins detected in mackerel (271 µg/kg lipid), fish oil (herring; 62 µg/kg lipid), margarine (98 µg/kg lipid), porpoise (16-114 µg/kg lipid), fin whale (963 µg/kg lipid), pork (69 µg/kg lipid), cows milk (74 µg/kg lipid) and mothers' milk (45 µg/kg lipid).	The analytical method determined the levels of C_{10-24} chlorinated paraffins. The C_{10-13} chlorinated paraffins were found to account for only a small percentage of the total in mackerel, fish oil, porpoise and fin whale, around 7% in human milk, 11.5% in margarine, 21% in cows' milk and 30% in pork.
Jansson *et al.* (1993)	Chlorinated paraffins of unspecified chain length detected in fish (570-1,600 µg/kg lipid), seal (130-280 µg/kg lipid), rabbit muscle (2,900 µg/kg lipid), reindeer suet (140 µg/kg lipid) and osprey muscle (530 µg/kg lipid).	The chain length of the chlorinated paraffins was not specified. The chlorinated paraffins had between 6 and 16 chlorine atoms per molecule.

Reference	Summary of findings	
	Results	**Comments**
Metcalfe-Smith *et al.* (1995; as reported in Tomy, 1998)	Short-chain chlorinated paraffins (60-70% wt. Cl) were not detected (<3,500 µg/kg dry wt.) in white suckers from the St. Lawrence River, downstream of a chlorinated paraffin manufacturing plant.	
Muir *et al.* (2001)	Short-chain chlorinated paraffins detected at mean concentrations of 940 µg/kg wet wt. and 850 µg/kg wet wt. in blubber samples of female and male beluga respectively from the St. Lawrence Estuary, 116 µg/kg wet wt. and 168µg/kg wet wt. in blubber samples of female and male beluga respectively from South Eastern Baffin Island, 2,630 µg/kg wet wt. in carp from Hamilton Harbour, 59 µg/kg wet weight in lake trout from Niagara-on-the-Lake and 73 µg/kg wet wt. in lake trout from Port Credit.	
Murray *et al.* (1987)	Short-chain chlorinated paraffins detected in mussels downstream of a chlorinated paraffin manufacturing site at 280 µg/kg compared with 7-22 µg/kg upstream of the discharge.	
Stern *et al.* (1997)	Short-chain chlorinated paraffins detected in marine mammals from various regions of the Arctic. The levels found were: beluga (western Greenland) 199 µg/kg wet wt.; beluga (Mackenzie Delta) 296 µg/kg wet wt.; seal (Ellesmere Island) 526 µg/kg wet wt.; walrus (western Greenland) 426 µg/kg wet wt. Beluga from the St Lawrence River Estuary had levels of 785 µg/kg wet wt. The same study also found short-chain chlorinated paraffins at levels of 10.6-16.5 µg/kg lipid in 3 samples of human milk taken from women living in settlements along the Hudson Strait.	Some of these results could be the same as reported in Tomy (1997).
Thomas and Jones (2002)	Short-chain chlorinated paraffins detected in 12 out of 22 samples of human breast milk at 4.5-110 µg/kg lipid. Also detected in butter samples at 1.2-2.7 µg/kg lipid but not detected in cow's milk (detection limit 1.2 µg/kg lipid).	The analytical detection limit was relatively high (in the range 16-740 µg/kg lipid depending on the sample size).
Tomy (1997; as reported in Tomy 1998)	Short-chain chlorinated paraffins (60-70% wt.) were detected in blubber from marine mammals from Canada and Greenland. The levels found were 370-1,363 µg/kg dry wt. in beluga from the St. Lawrence River, 106-253 µg/kg dry wt. in beluga from northwest Greenland, 178-302 µg/kg dry wt. in beluga from Hendrickson Island, 362-490 µg/kg dry wt. in walrus from northwest Greenland and 374-767 µg/kg dry wt. in ringed seal from southwest Ellesmere Island. Also detected at 11-17 µg/kg lipid in human breast milk from Inuit women living on the Hudson Strait.	Some of these results could be the same as reported in Stern *et al.* (1997).
Tomy *et al.* (1997)	Short-chain chlorinated paraffins (with chlorine contents around 60-70% wt.) were found in yellow perch (1,010 µg/kg wet wt.) and catfish (241 µg/kg wet wt.) from the mouth of the Detroit River and Lake Erie and zebra mussels (651 µg/kg wet wt.)	

Reference	Summary of findings	
	Results	Comments
	from Middle Sister Island in western Lake Erie. Both areas sampled are industrialised areas.	

4.3.4 Summary and discussion of bioaccumulation

Short-chain chlorinated paraffins have a bioconcentration factor (BCF) of 7,273 l/kg for (freshwater) fish based on parent compound analysis and 7,816 l/kg based on ^{14}C measurements (and so may represent accumulation of metabolites as well as short-chain chlorinated paraffins)

There are several other fish bioconcentration factors (of variable reliability) below this value (but some of which are above the 2,000 l/kg cut-off). Some data are also available for marine fish. A BCF value of 800-1,000 l/kg has been measured for a brackish water species (*Alburnus alburnus*) but here the exposure period was relatively short (14 days) and it is not clear if steady state was reached in this time. In addition, BCF values in the range 5,785-40,900 l/kg have been determined for a marine mollusc (*Mytilis edulis*) (although this might not represent a true BCF due to possible ingestion of the substance adsorbed to particles).

In addition to the laboratory accumulation data, short-chain chlorinated paraffins have been found to be present in a range of biota in the environment, including marine top predators. This provides supporting evidence that the substance can be taken up by organisms in the environment.

4.4 Secondary poisoning

Not relevant for this dossier.

5 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for this dossier.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

Not relevant for this dossier.

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

Acute toxicity

Not relevant for this dossier.

Long-term toxicity

During fourteen day exposures to 125 µg/l of short chain length paraffins (C_{10-13}, 49% Cl; C_{10-13}, 59% Cl; C_{10-13}, 71% Cl) behavioural effects including sluggish movements, lack of shoaling and abnormal posture were noted in the bleak *Alburnus alburnus*. These effects were reversible after two days in clean brackish water (Bengtsson *et al.*, 1979).

Madeley and Maddock (1983a) assessed the toxicity of chlorinated paraffin compounds to the rainbow trout *Oncorhynchus mykiss*. A 58% chlorinated short chain length (C_{10-12}) paraffin was used at mean measured concentrations of 0.033, 0.1, 0.35, 1.07 and 3.05 mg/l. Significant mortality was observed in the highest three concentrations. LT_{50}s (median lethal times) were calculated for these three concentrations as 44.7, 31.0 and 30.4 days respectively. Madeley and Maddock (1983b) exposed rainbow trout to the same chlorinated paraffin as part of a bioconcentration study for 168 days at concentrations of 3.1 and 14.3 µg/l followed by a 105 day depuration period. By day 70 of the depuration period all trout previously exposed to 14.3 µg/l and 50% of those exposed to 3.1 µg/l had died. No explanation (e.g. presence of disease or parasite) could be found for these events seen in the bioconcentration test.

Hill and Maddock (1983a) found that hatchability and survival of larvae of the sheepshead minnow *Cyprinodon variegatus* was unaffected by 28 day exposure to measured concentrations of 54.8, 22.1, 6.4, 4.1 and 2.4 µg/l of a 58% chlorinated short chain length n-paraffin. The results of this study reveal that all concentrations tested elicited a significant increase in larval growth compared to the acetone control. In a second study, sheepshead minnow larvae were exposed to 620.5, 279.7, 161.8, 71.0 and 36.2 µg/l of the same chlorinated paraffin for 32 days. In this study, larvae from the highest exposure group were significantly smaller than those from the acetone control; however, at lower exposure concentrations (71.0 and 36.2 µg/l) larvae were significantly larger than controls. The highest no observed effect concentration (NOEC) in this study was 279.7 µg/l. No effect on survival or hatchability was observed (Hill and Maddock, 1983b).

A toxicity test using embryos of Japanese medaka (*Oryzias latipes*) is also available (Fisk *et al*., 1999). This study used a series of four short-chain chlorinated paraffins with single carbon chain lengths and known chlorine contents ($C_{10}H_{15.5}Cl_{6.5}$ 63.0% wt. Cl, $C_{11}H_{18.4}Cl_{5.6}$ 56.9% wt. Cl, ^{14}C-$C_{10}H_{15.3}Cl_{6.7}$ 63.7% wt. Cl and ^{14}C-$C_{12}H_{19.5}Cl_{6.5}$ 58.5% wt. Cl). In the experiment, fertilised eggs from the fish were individually exposed to each test substance in 1.8 ml vials with teflon-lined caps. Exposure to the C_{10} 63.0% wt. Cl substance and the ^{14}C-C_{10} 63.7% wt. Cl labelled substance at concentrations of 9.6 mg/l and 7.7 mg/l respectively caused 100% mortality in the eggs within either 10-12 days (C_{10} 63.0% wt. Cl substance) or 2 days (^{14}C-C_{10} 63.7% wt. Cl labelled substance). No significant deaths or recognisable lesions occurred in the eggs from any other treatment, but larvae exposed to the higher concentrations of all four short-chain chlorinated paraffins were lethargic (with little or no movement) and in many cases these larvae also had large yolk sacs.

The hatching success in the exposed and control vials was low and variable, and in almost all cases unhatched eggs were still alive on the last observation day (day 20). Further observation on day 40 indicated that the majority of eggs had hatched by this time. The average hatching time in this study was >15 days, which was longer than normal for this species (11-13 days). It was thought that the variable hatching rate was unlikely to be related to the chlorinated paraffin exposure.

Based on the results of this study, the following NOECs and LOECs were derived from the data by the authors.

$C_{10}H_{15.5}Cl_{6.5}$	NOEC = 62 µg/l	LOEC = 460 µg/l
^{14}C-$C_{10}H_{15.3}Cl_{6.5}$	NOEC = 50 µg/l	LOEC = 370 µg/l

$C_{11}H_{18.4}Cl_{5.6}$	NOEC = 57 µg/l	LOEC = 420 µg/l
^{14}C-$C_{12}H_{19.5}Cl_{6.5}$	NOEC = 9.6 µg/l	LOEC = 55 µg/l

The authors indicated that these data were fully consistent with narcosis as the mechanism of toxicity caused by short-chain chlorinated paraffins in this study.

This study is similar in some ways to the OECD 210 fish early life-stage test, but falls short of the current guidelines in some areas as follows.

- This study was carried out for approximately 3 days post-hatch, but the OECD guideline recommends a test duration of 30 days post-hatch for *Oryzias latipes*.
- The test was carried out as a static test in sealed vials - no indication was given as to whether the dissolved oxygen level was maintained at a suitable level throughout the test period.
- The rate of hatching was slow in controls and so it is difficult to determine if any effects were seen on this endpoint.
- The number of eggs/test concentration was only 10 compared with at least 60 recommended in the OECD guidelines.

7.1.1.2 Aquatic invertebrates

Acute toxicity

Not relevant for this dossier.

Long-term toxicity

In 21 day tests with *Daphnia magna* EC_{50}s ranged from 0.101 to 0.228 mg/l and NOECs ranged from 0.005 to 0.05 mg/l (EU, 2000). The lowest of these NOECs was obtained with a $C_{10\text{-}12}$, 58% chlorinated paraffin using a flow-through test system (Thompson and Madeley, 1983a). Complete mortality occurred at 16.3 µg/l after 6 days. LC_{50} values were calculated as follows: 24, 18, 14 and 12 µg/l for 3, 4, 5, and 6 to 21 days respectively. There was no mortality of parent *Daphnia* at 8.9 µg/l, but 37% of the offspring were found to be dead when removed from the exposure vessel, as compared to 6% and 9% in the control and solvent control. This was considered to be a significant effect. No effect on survival, reproduction or growth was seen at 5 µg/l. The NOEC of 5 µg/l for the 58% chlorinated short chain length paraffin means that this species is the most sensitive aquatic species tested.

The second instar of the midge *Chironomus tentans* was exposed to a $C_{10\text{-}12}$, 58% chlorinated paraffin over the whole 49 day life cycle at concentrations of 61 to 394 µg/l. No significant toxicological response was found except for halting adult emergence at 121 and 394 µg/l. This led to a maximum acceptable toxicant concentration (MATC) for this paraffin of between 78 and 121 µg/l, with a geometric estimated value for the MATC of 97 µg/l. The NOEC for this study is 61 µg/l (E & G Bionomics, 1983).

Thompson and Madeley (1983b) studied the toxicity of a 58% chlorinated short chain length paraffin to the mysid shrimp *Mysidopsis bahia*. The chronic toxicity of this compound was studied in 28 day exposures to concentrations of 0.6, 1.2, 2.4, 3.8 and 7.3 µg/l. Significant mortalities were observed in some of the groups during the test but these were not treatment related. There was no

treatment-related effect on reproductive rate (offspring per female) or growth over the 28 day test period. A no effect level was determined as 7.3 µg/l.

Madeley and Thompson (1983) studied the toxicity of the 58% chlorinated short chain length paraffin (C_{10-14}) to the mussel *Mytilus edulis* over a period of 60 days. Tests were carried out at measured concentrations of 0.013, 0.044, 0.071, 0.13 and 0.93 mg/l (nominal concentrations were 0.018, 0.056, 0.1, 0.32 and 3.2 mg/l). There was significant mortality at 0.071, 0.13 and 0.93 mg/l with LT50s of 59.3, 39.7 and 26.7 days for the three exposure concentrations respectively. There was no significant mortality observed at concentrations of 0.013 and 0.044 mg/l; reductions in filtration rate were reported but these were not measured quantitatively. The 60-day LC_{50} was estimated to be 0.074 mg/l based on measured concentrations.

A further study on mussels *Mytilus edulis* using a 58% chlorinated short chain length chlorinated paraffin has been carried out by Thompson and Shillabeer (1993). The study was carried out as a follow up to a bioaccumulation study and only two exposure concentrations were used. Groups of 30 mussels were exposed to measured concentrations of 2.3 µg/l or 9.3 µg/l in seawater for 12 weeks in a flow-through system. No mortalities were seen in any of the exposure groups or controls, but growth (as assessed by increase in shell length and tissue weight) was significantly reduced in the group exposed to 9.3 µg/l. No significant effects were seen in the group exposed to 2.3 µg/l.

7.1.1.3 Algae and aquatic plants

A NOEC of 12.1 µg/l was reported in a 10-day study with the marine algae *Skeletonema costatum* (Thompson and Madeley, 1983c). The toxic effects seen with the marine alga were transient, with no effects being seen at any concentration after 7 days exposure.

Toxicity tests with the freshwater alga *Scenedesmus subspicatus* have been carried out by Koh and Thiemann (2001). Two commercial short-chain chlorinated paraffins, a C_{10-13}, 56% wt. Cl product and a C_{10-13}, 62% wt. Cl product, were tested. The method used was based on DIN 38 412, part 9. Acetone was used as a co-solvent in the test (0.1 ml/l in the test solutions) and a stock solution of either 200 µg/l for the C_{10-13}, 56% wt. Cl substance or 100 µg/l for the C_{10-13}, 62% wt. Cl substance was prepared for use in the test. Few other test details are reported. The undiluted solution of both chlorinated paraffins was found to have no effect on growth (biomass) or growth rate of the alga over 72 hours. Thus the NOEC is ≥0.2 mg/l for the C_{10-13}, 56% wt. Cl substance and ≥0.1 mg/l for the C_{10-13}, 62% wt. Cl substance.

7.1.1.4 Summary of aquatic toxicity data

There are reported long-term no observed effect concentrations (NOEC) for freshwater fish, *Daphnia magna* and algae. The lowest NOEC was from a 21 day multi-generation study on *Daphnia magna* using a 58% chlorinated short chain paraffin (C_{10-12}). The study was considered valid. The 21-day NOEC was 0.005 mg/l.

In addition to the freshwater toxicity data, several marine/estuarine data are also available. There are NOECs available for fish (sheepshead minnow *Cyprinodon variegatus*), invertebrate (mysid shrimp *Mysidopsis bahia*) and algae. The lowest NOEC was found for *Mysidopsis bahia* at 0.007 mg/l. In addition to this there are indications of effects on growth (as assessed by increase in shell length and tissue weight) in mussels (*Mytilus edulis*) at 0.0093 mg/l. Thus the marine data is similar to the freshwater data in that invertebrates appear to be the most sensitive species.

8 PBT, vPvB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

8.1 Comparison with criteria from Annex XIII

Persistence

A substance is considered to be persistent (P) if it has a half-life >60 days in marine water or > 40 days in fresh- or estuarine water, or >180 days in marine sediment or >120 days in freshwater or estuarine sediment or soil. A substance is considered to be very persistent (vP) if it has a half-life > 60 days in marine, fresh- or estuarine water or >180 days in marine sediment, freshwater or estuarine sediment or soil.

The results of a biodegradation simulation study with both freshwater and marine sediment are available. Under aerobic conditions the mineralisation half-life was determined to be around 1,340 days for the C10, 65% wt. Cl substance in freshwater sediment, 335 days for the C10, 65% wt. Cl substance in marine sediment, 1,790 days for the C13, 65% wt. Cl substance in freshwater sediment and 680 days for the C13, 65% wt. Cl substance in marine sediment. The mean half-live (average of the two substances, this could be assumed to be representative of a C10-13, 65% wt. Cl product) was determined to be around 1,630 days in freshwater and 450 days in marine sediment. Based on the available data it is therefore concluded that short-chain chlorinated paraffins meet the criteria for a vP substance.

The substance is considered to be persistent (P) and very persistent (vP).

Bioaccumulation

A substance is considered to be bioaccumulative (B) if it has a bioconcentration factor (BCF) >2,000 l/kg or very bioaccumulative (vB) if it has a BCF >5,000 l/kg. The highest measured BCF value for (freshwater) fish with short chain chlorinated paraffins is around 7,816 l/kg (see Section 4.3). This value was based on 14C measurements (and so may represent accumulation of metabolites as well as short-chain chlorinated paraffins), but a similar value of 7,273 l/kg was determined in the same study based on parent compound analysis. Therefore, the available BCF data indicate that short-chain chlorinated paraffins meet both the bioaccumulative (B) and the very bioaccumulative (vB) criteria. In addition, short-chain chlorinated paraffins have been found to be present in marine top predators (see Table 5).

The substance is considered to be bioaccumulative (B) and very bioaccumulative (vB).

Toxicity

A substance fulfils the toxicity criterion (T-) when:

– the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or

– the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or

– there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

The lowest NOEC for short-chain chlorinated paraffins is 0.005 mg/l for Daphnia magna. In addition effects on growth in marine mussels (*Mytilus edulis*) have been seen at a concentration of 0.0093 mg/l (see Section 7.1). Therefore it can be concluded that short-chain chlorinated paraffins meet the toxicity criterion.

The substance is considered to be toxic (T).

8.2 Assessment of substances of an equivalent level of concern

Not relevant to this dossier.

8.3 Emission characterisation

Short-chain chlorinated paraffins are used as a flame retardant in textiles and rubber, in paint and in adhesives and sealants. Predicted emissions to surface water, wastewater, air and soil are presented in the following section 'Information on Exposure'. As noted in this section, the release estimates are uncertain due to reductions in the use of short-chain chlorinated paraffins since the data was collected in 2001. However, there is no more recent data available.

8.4 Conclusion of PBT and vPvB or equivalent level of concern assessment

It is concluded that the substance meets the criteria for a PBT substance as outlined in Annex XIII. Biodegradation simulation studies have demonstrated that the mineralisation half-life in both freshwater and marine sediment is >180 days (vP). The substance has a measured bioconcentration factor in fish of 7,816 l/kg (vB) and a 21-day NOEC of 0.005 mg/l with *Daphnia magna* (T).

In addition, there are a number of data available showing that short-chain chlorinated paraffins have been detected in the remote Arctic and in marine biota (including top predators such as seals and whales). The substance appears to meet the screening criteria for consideration as a candidate persistent organic pollutant (POP) under the Stockholm Convention on Persistent Organic Pollutants and under the 1998 Protocol to the UNCECE Convention on Long-range Transboundary Air Pollution on Persistent Organic Pollutants.

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON EXPOSURE

The EU use pattern for short-chain chlorinated paraffins in 1994 was as follows (EU, 2000).

Metal working lubricants	9,380 tonnes/year
Rubber	1,310 tonnes/year
Paint	1,150 tonnes/year
Sealants	695 tonnes/year
Leather	390 tonnes/year
Textiles	183 tonnes/year
Other	100 tonnes/year
Total	13,208 tonnes/year

Subsequent marketing and use restrictions for two uses (metal working and use for fat liquoring of leather) have come into force in the European Union through Directive 2002/45/EC[3]. This Directive also states that all remaining uses of short-chain chlorinated paraffins will be reviewed by the European Commission before 1st January 2003.

Information on the trends in use of short-chain chlorinated paraffins since 1994 are available (EU, 2007) but is considered to be confidential owing to the limited number of companies now supplying short-chain chlorinated paraffins in the EU. Of the remaining applications covered in the 1994 survey, short-chain chlorinated paraffins are currently used as a flame retardant in textiles and rubber, in paint and in sealants and adhesives.

The release estimates are based on the consumption of short-chain chlorinated paraffins in 2001. The actual release estimates are subject to a large uncertainty. The use of short-chain chlorinated paraffins in the EU in 2003 was around three times lower than in 2001 (EU, 2007). This reduction in use will lead to a reduction in the regional and continental emissions.

Estimates of human (consumer or occupational) exposure are not considered relevant for this example dossier.

[3] O.J. No. L 177, 06/07/2002, p. 0021-0022

Table 1 Summary of environmental release estimates for short-chain chlorinated paraffins

Use	Comment	Estimated local release	Estimated regional release (kg/year)	Estimated continental release[a] (kg/year)
Production sites	Site specific information	<0.089 kg/day to waste water over 300 days	Confidential	Confidential
Use in rubber[b]	Compounding site (formulation)	7.5 kg/year (0.038-0.063 kg/day) to waste water; 2.5 kg/year (0.0125-0.021 kg/day) to air, over 118-200 days	Confidential	Confidential
	Conversion site (processing)	2.5-12.5 kg/year (0.0125-0.106 kg/day) to waste water; 2.5-12.5 kg/year (0.0125-0.106 kg/day) to air, over 118-200 days		
	Combined compounding and conversion site	10-20 kg/year (0.050-0.169 kg/day) to waste water; 5-15 kg/year (0.025-0.127 kg/day) to air, over 118-200 days		
Use in textiles	Formulation (compounding)	165 kg/year (0.55 kg/day) to waste water, over 300 days	Confidential	Confidential
	Processing (backcoating)	49.5-88.0 kg/year (0.75-1 kg/day) to waste water, over 66-88 days	Confidential	Confidential
Sealants/ adhesives	Formulation/use	Negligible	Confidential	Confidential
Paints and coatings	Formulation	Negligible	Confidential	Confidential
	Industrial application of paints (Processing)	6.48-13.0 kg/year (0.022-0.075) kg/day to waste water, over 300 days	Confidential	Confidential
	Application by general public (private use)	Negligible		
Volatile and leaching loss from products containing short-chain chlorinated paraffins over life-time	Volatile loss over life-time		286-1,057 kg/year to air	2,576-9,516 kg/year to air
	Leaching loss over life-time		4,363-11,878 kg/year to waste water	39,269-106,903 kg/year to waste water

Use	Comment	Estimated local release	Estimated regional release (kg/year)	Estimated continental release[a] (kg/year)
"Waste remaining in environment" over life-time and disposal			3,276-6,492 kg/year to urban/industrial soil 1,088-2,155 kg/year to surface water 4.4-8.7 kg/year to air	29,484-58,429 kg/year to urban/industrial soil 9,788-19,398 kg/year to surface water 39.2-77.9 kg/year to air
Total			299-1,092 kg/year to air 3,732-9,789 kg/year to wwtp[c] 2,021-4,602 kg/year to surface water[c] 3,276-6,492 kg/year to urban/industrial soil	2,695-9,832 kg/year to air 33,213-87,486 kg/year to wwtp[c] 18,091-41,270 kg/year to surface water[c] 29,484-58,429 kg/year to urban/industrial soil

Notes: a) Continental release = total EU release-regional release .

b) Estimates based on a worst case approach assuming release from rubber processing is similar to that from plastic processing. Other information is available which indicates that the total release from the processes may be much lower at <0.0042 kg/day over 118 days, probably to waste water. This figure will also be considered in the risk assessment.

c) Releases to waste water assume a 80% connection rate to wwtp, with 20% going directly to surface water.

1.1 Monitoring data

Monitoring data on short-chain chlorinated paraffins in the environment are reported in detail in the EU risk assessments (EU, 2000 and EU, 2007) and some of the more recent data is discussed below.

Levels of short chain chlorinated paraffins in water
Levels of C10-17 chlorinated paraffins in the effluent from a chlorinated paraffin production plant in Canada have been reported to be around 12.7 µg/l, but they were not detected in sediments downstream of the plant (Metcalfe-Smith et al., 1995; as reported in Tomy, 1998).

Further levels of short-chain chlorinated paraffins in final effluent from municipal waste water treatment plants in Canada have been reported by Muir et al. (2001). The waste water treatment plants were all located at the western end of Lake Ontario and the samples were collected in 1996. The levels were found to be higher in samples from industrial areas than in non-industrial areas and ranged from 0.060 – 0.448 µg/l. The concentration present in Lake Ontario surface water (samples taken in 1999 at 1 m depth from the west basin) was 1.75 ng/l (the equivalent concentration in 2000 was 0.77 ng/l; personal communication).

Tomy (1997; as reported in Tomy, 1998) found C10-13 chlorinated paraffins to be present in Red River, downstream of Winnipeg in Canada, at levels of around 0.02-0.05 µg/l.

An in depth study of the levels of short- and medium chain chlorinated paraffins in industrial areas of the United Kingdom has been carried out (CEFAS, 1999; Nicholls, 2001). The main purpose of the study was to determine the concentrations of chlorinated paraffins in surface water, sediment, biota and soil associated with their industrial use. Samples were collected during early summer 1998 and no short- or medium-chain chlorinated paraffins were detected (detection limit around 0.1 µg/l) in any of the surface water samples taken except in some samples from a site near to engineering (metal working) activity. These were identified as being short-chain length chlorinated paraffins and the concentration found was 0.2 -1.7 µg/l.

Levels of short chain chlorinated paraffins in sediment
The available data indicates that short-chain chlorinated paraffins are widely found in the sediment compartment, including samples taken from remote Arctic regions. The highest levels are generally associated with industrial activities.

Tomy et al. (1997a) reported that short chain chlorinated paraffins were present at a concentration of around 245 µg/kg dry weight in sediments from the mouth of the Detroit River at Lake Erie and Middle Sister Island in western Lake Erie. The samples were collected in August 1995.

Muir et al. (2001) determined the levels of short-chain chlorinated paraffins in surface sediment samples from harbour areas in western Lake Ontario. The samples were collected in 1996. The levels found were 24-27 µg/kg dry weight at Toronto inner harbour, 5.9 µg/kg dry weight at Humber River mouth (Toronto), 7.3 µg/kg dry weight at Port Credit Harbour, 27-41 µg/kg dry weight at Hamilton west harbour, 290 µg/kg dry weight at Hamilton Windemere Basin and 81 µg/kg dry weight at northest Hamilton. The highest levels were present at the most industrialised site sampled (Windemere Basin).

CSTEE (2002a) indicates that Marvin et al. (2002) reported that short-chain chlorinated paraffins were generally relatively evenly distributed in sediments from Lake Ontario and estimated that the average concentration was around 36 μg/kg dry weight. Muir et al. (2002) give the mean value for Lake Ontario in 1998 as 49 μg/kg dry weight for total short chain chlorinated paraffins (the mean values were 11.8 μg/kg dry weight for C10-chlorinated paraffins, 17.2 μg/kg dry weight for C11 chlorinated paraffins, 16.7 μg/kg dry weight for C12 chlorinated paraffins and 3.2 μg/kg dry weight for C13-chlorinated paraffins).

Tomy et al. (1997b and 1999) reported the following levels of short chain chlorinated paraffins in surface sediments from the Canadian mid-latitude and Arctic regions: 176 μg/kg dry weight and 8 μg/kg dry weight in samples from Lake Winnipeg (south and north respectively), 257 μg/kg dry weight in samples from Fox Lake (Yukon), 18 μg/kg dry weight in samples from Lake Nipigon (northwest Ontario), 1.6 μg/kg dry weight in samples from Lake Ya Ya and 4.5 μg/kg dry weight in samples from Hazen Lake (Arctic). The chlorine content of the chlorinated paraffins found was in the range 60-70% wt.

An in depth study of the levels of short- and medium chain chlorinated paraffins in industrial areas of the United Kingdom has been carried out (CEFAS, 1999; Nicholls, 2001). The main purpose of the study was to determine the concentrations of chlorinated paraffins in surface water, sediment, biota and soil associated with their industrial use. The sampling sites were chosen with regards to their proximity to known sources/users of medium chain chlorinated paraffins. Samples were collected during early summer 1998. Short-chain chlorinated paraffins were found to dominate in only a few of the samples but it should be noted that short-chain chlorinated paraffins were identified to be present in sediment close to a chlorinated paraffin production site (up to 24.2 mg/kg wet weight (mixture of short- and medium-chain chlorinated paraffins)) and a PVC and/or paint manufacturing site (up to 8.1 mg/kg wet weight (mixture of short- and medium-chain chlorinated paraffins)).

Stern et al. (2003; as reported in UNECE, 2003) have investigated the levels of short chain chlorinated paraffins in a lake sediment core taken from a lake on Devon Island, Nunavut, Canada. The levels of short-chain chlorinated paraffins in layers dating back to 1931 were low (<0.2 μg/kg dry weight), but were found to increase steadily in layers from 1943 onwards, reaching 0.8 μg/kg dry weight in the layer corresponding to 1956. The concentration was then found to decrease to <0.2 μg/kg dry weight between 1970 and 1980, but then showed an increasing trend up to 0.9 μg/kg dry weight in 1997 (the last year measured). These samples were taken from a very remote lake in the Arctic (75o34'N; 89°19'W) and provide evidence for transport to and deposition in the Arctic (UNECE, 2003). An unpublished draft report by Environment Canada (2003) reports the same trends (but slightly higher levels).

A sediment core taken in 1988 from the western basin of Lake Ontario (43°26'01''N, 79°24'00''W; the sample was taken approximately 40 km from the nearest sewage treatment plant) showed a maximum concentration of short-chain chlorinated paraffin of around 800 μg/kg dry weight (Environment Canada, 2003). The maximum concentration was found in the sediment layer corresponding to the 1970s but had fallen to around 390 μg/kg dry weight in the layer corresponding to 1996. Short-chain chlorinated paraffins could be determined in the layers dating back to 1913 (as short-chain chlorinated paraffins were not manufactured in Canada until the 1940s, the occurrence in the older layers was thought to be as a result of diffusion of residues through the sediment core or an artefact of sampling).

SFT (2002b) carried out a screening study for the concentrations of short-chain chlorinated paraffins in sediments associated with the effluents from waste dumps in Norway. In all, samples from five locations were analysed and short-chain chlorinated paraffins were found to be present in all five samples at a concentration of 0.33-19.4 mg/kg wet weight.

Levels of short chain chlorinated paraffins in soil

A monitoring survey of concentrations of short- and medium-chain chlorinated paraffins in sewage sludge, soil and earthworms associated with some uses of chlorinated paraffins in the United Kingdom has been carried out (CEFAS, 1999; Nicholls, 2001). The samples used in the study were collected in the early summer of 1998. The levels found in digested sewage sludge prior to application onto soil were in the range 2.9-93 mg/kg dry weight and the levels found in soil where the sludge was applied were generally not detected (<0.1 mg/kg dry weight which is equivalent to <0.088 mg/kg on a wet weight basis). In general it was not possible to identify exactly what type (short- or medium-chain) was present in the samples.

The levels of short-chain chlorinated paraffins in further sewage sludge samples from the United Kingdom have recently been determined (Stevens et al., 2003). Samples of digested sludge from 14 waste water treatment plants from domestic and/or urban and/or industrial areas were analysed. The total concentration of short-chain chlorinated paraffins found ranged between 6.9 and 200 mg/kg dry weight (mean level found was 42 mg/kg dry weight). The report concluded that theses findings were indicative of there being numerous ongoing diffuse sources of the substance.

Levels of short chain chlorinated paraffins in air

The available monitoring data indicate that short-chain chlorinated paraffins are widely found at low levels in the atmosphere, including remote Arctic environments. They are also present in household dust.

The levels of SCCPs in air have been determined in samples from a semi-rural site in the United Kingdom (sampled between May 1997 and January 1998), a semi-rural site in southern Ontario, Canada (sampled during summer 1990), and a remote area in the Canadian Arctic (sampled between September and December 1992) (Peters et al., 1998). The analytical method used could determine chlorinated paraffins with chain lengths between C_{10} and C_{13} with between 5 and 9 chlorine atoms per molecule. The mean total (vapour + particulate phase) levels found were 99±101 pg/m^3 at the semi-rural site in the United Kingdom, 543±318 pg/m^3 at the semi-rural site in southern Ontario and 20±32 pg/m^3 at the remote site.

Peters et al. (2000) determined the level of short-chain chlorinated paraffin in air at a semi-rural site in United Kingdom, over a 12-month period (samples taken at 2-weekly intervals). The arithmetic and geometric means found were 320±320 pg/m^3 and 160 pg/m^3 respectively. Around 95% of the short-chain chlorinated paraffins found were associated with the gaseous phase.

Tomy (1997; as reported in Tomy, 1998) found that short-chain chlorinated paraffins (60-70% wt. Cl) were present in air from Egbert, Canada at a concentration of 65-924 pg/m^3 (mean 543 pg/m^3). The samples were 24-hour composite samples collected daily over a 4-month period during the summer of 1990.

Muir et al. (2001) reported short-chain chlorinated paraffins to be present at a concentration of 249 pg/m^3 in air overlying the west basin of Lake Ontario. The sample was collected in June 1999.

The levels of short-chain chlorinated paraffins in air from the Arctic have been reported by Bidleman et al. (2001). The air samples were collected from January 1994 to January 1995. The concentrations of short-chain chlorinated paraffins in samples from Alert were found to be highest in the late summer months. The levels found ranged from 1.07 to 7.25 pg/m^3 and were dominated by the contributions from chlorodecanes (C_{10} fractions).

The levels of short-chain chlorinated paraffins in Arctic air have been investigated by Borgen et al. (2000). In this study samples (total volume 1,700-2,850 m^3) were collected during March to May 1999 at Mt. Zeppelin, Svalbard. The concentration of short-chain chlorinated paraffins (with 5-10 chlorine atoms/molecule) determined was 9.0 pg/m^3 on 26th March, 23 pg/m^3 on April 9th, 28 pg/m^3 on April 16th, 16 pg/m^3 on April 30th and 57 pg/m^3 on May 7th. The levels refer to the concentration in the vapour phase plus the particulate phase. The paper indicates that the levels found were of a similar order of magnitude to those in the field blank samples, but that the samples did contain higher amounts of the more volatile short-chain chlorinated paraffins than the blanks, indicating that transport of short-chain chlorinated paraffins by air may be occurring. The paper also indicated that the presence of contaminants such as phthalates may have caused some interference in the analysis, leading to an underestimate of the actual concentration of short-chain chlorinated paraffins.

A further study by Borgen et al. (2002) investigated the levels of short-chain chlorinated paraffins in ambient air from Bear Island in the Arctic. The samples (total volume sampled was 3,252-8,160 m^3) were collected during May to November 2000. The concentrations of short-chain chlorinated paraffins (with 5-10 chlorine atoms/molecule) found were 7.3 ng/m^3 on May 8th-15th, 10.6 ng/m^3 on June 1st-8th, 8.8 ng/m^3 on June 8th-15th, 7.1 ng/m^3 on June 15th-22nd, 1.8 ng/m^3 on June 22nd-29th, 4.3 ng/m^3 on August 10th-27th and 1.8 ng/m^3 on November 13th-21st. The levels again refer to the concentration in the vapour plus particulate phase.

Greenpeace (2003) have carried out a survey of the levels of short-chain chlorinated paraffins in dust samples collected from around 70 households in the United Kingdom. The samples were collected between the 30th October and 8th November 2002 from ten regional areas, and pooled samples (from 7 households in each region) were analysed for the presence of short-chain chlorinated paraffin. The substance was found to be present in eight out of ten pooled samples at a concentration of 1.9 to 13 mg/kg (ppm), with a mean value of 4.3 mg/kg (the analytical method used was considered to be only semi-quantitative for short-chain chlorinated paraffins due to the highly complex nature of the products and so the reported concentrations are only approximate; the detection limit of the method was around 0.12 mg/kg). In addition, a single dust sample from a household in Denmark and a single dust sample from a household in Finland were found to contain short-chain chlorinated paraffin at a concentration of 5.1 and 9.6 mg/kg respectively, which is similar to the range found in the United Kingdom. The results showed that short-chain chlorinated paraffins are widespread contaminants of the indoor environment.

SFT (2002b and 2004) determined the concentrations of short-chain chlorinated paraffins in three samples of moss from Norway. The samples were taken from Valvik (67.38^{o}N, 14.64^{o}E), Molde (62.73^{o}N, 07.00^{o}E) and Narbuvoll (62.38^{o}N, 11.47^{o}E). The samples were

collected in forest areas not closer than 300 m to the nearest road or building/house. The distance of each sampling site from the nearest village/town was at least 10 km. The concentration found was in the range 3-100 μg/kg wet weight. The report suggested that the presence in moss was indicative of transport of short-chain chlorinated paraffins via the atmosphere.

2 INFORMATION ON ALTERNATIVES

2.1 Alternative substances

As indicated above, the use of short-chain chlorinated paraffins in metal cutting/working fluids and leather fat liquors is now prohibited in the EU. No information is readily available on alternatives for the other applications, but it is possible that medium-chain chlorinated paraffins could be used in some cases (although it should be noted that medium-chain chlorinated paraffins are classified as dangerous to the environment, R50-53.).

2.2 Alternative techniques

No information has been located on alternative techniques.

3 RISK-RELATED INFORMATION

The PNEC for water was estimated as 0.5 µg/l based on the 21-day NOEC with *Daphnia magna* and an assessment factor of 10 (EU, 2000 and 2007).

The PNEC for sediment was estimated as 2.17 mg/kg wet weight using the equilibrium partitioning method (EU, 2007).

The PNEC for soil was estimated as 1.76 mg/kg wet weight using the equilibrium partitioning method (EU, 2000).

The PNEC oral was determined as 5.5 mg/kg food based on the available avian toxicity data and an assessment factor of 30 (EU, 2007).

No DNELs have been derived for this substance.

4 OTHER INFORMATION

This Annex XV dossier is based on information reviewed and agreed by the Technical Committee on New and Existing Chemicals following Council Regulation (EEC) 793/93 and Directive 67/548/EEC (July 2007) and by the Subgroup on Identification of PBT and vPvB Substances (May 2007).

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