Substance name: Alkanes, C_{10-13}, chloro
EC number: 287-476-5
CAS number: 85535-84-8

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT FOR IDENTIFICATION OF ALKANES, C_{10-13}, CHLORO AS A SUBSTANCE OF VERY HIGH CONCERN

Adopted on 8 October 2008

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FIGURES

Substance Name: Alkanes, C_{10-13}, chloro

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- *The substance is identified as a PBT substance according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).*
- *The substance is identified as a vPvB substance according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).*

Summary of the evaluation:

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

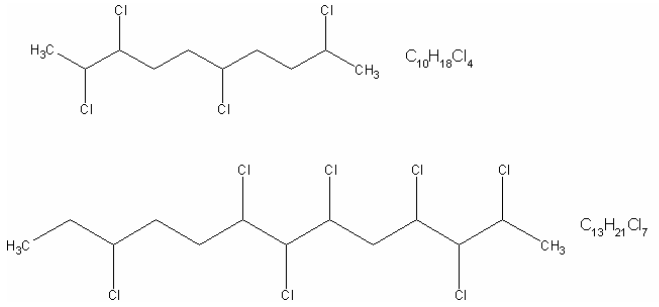
This evaluation is based on the properties of the substance itself.

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers 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 CLASSIFICATION AND LABELLING

2.1 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

3 ENVIRONMENTAL FATE PROPERTIES

3.1 Degradation

3.1.1 Stability

Second order reaction rate constants have been calculated for C_{10-13}, 49-71% wt Cl, chlorinated paraffins as 2.2-8.2×10^{-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).

3.1.2 Biodegradation

3.1.2.1 Screening tests

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 manometric 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^oC and comparing this to the theoretical amount of CO_2 that would form, 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 microorganisms A - acclimated microorganisms / - no significant BOD

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).

3.1.2.2 Simulation tests

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 continuously supplied to the aerobic chambers glass tubing located centrally above the water surface. The headspace of the anaerobic chambers was continually purged with nitrogen 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 25 mm and the water:sediment volume ratio was 3.3:1 (total volume of overlying water was 525 ml). 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.

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	-	-	-	<0.4	84.1	0.6	84.7
			14	0.3	0.2	-	0.9	110.4	0.6	112.4
			35	0.7	0.6	-	1.2	91.9	0.1	93.7
			56	0.4	2.1	-	1.4	108.6	0.1	112.6
			77	0.2	3.2	-	1.3	99.1	0.2	104.0
			98	0.2	3.9	-	1.1	85.5	0.1	90.8
		Marine	0	-	-	-	<0.3	69.2	1.2	70.4
			14	<0.1	0.4	-	2.1	81.8	2.3	86.6
			35	<0.1	2.6	-	5.2	56.3	1.6	65.7
			56	<0.1	5.8	-	4.4	77.7	0.8	88.7
			77	0.1	9.5	-	5.3	69.8	0.5	85.2
			98	<0.1	13.4	-	4.5	63.9	1.6	83.4
	C_{13}, 65% wt. Cl	Freshwater	0	-	-	-	<0.3	100.5	1.3	101.8
			14	<0.1	0.3	-	0.6	96.3	0.6	97.8
			35	<0.1	0.4	-	0.5	76.5	0.2	77.6
			56	<0.1	0.9	-	0.6	97.8	0.1	99.4
			77	<0.1	1.1	-	0.6	101.9	0.2	103.8
			98	<0.1	3.3	-	0.6	103.8	0.1	107.8

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
Aerobic	C_{13}, 65% wt. Cl	Marine	0	-	-	-	<0.3	101.1	1.5	102.6
			14	<0.1	0.1	-	1.0	59.2	2.4	62.7
			35	<0.1	1.3	-	2.0	63.7	0.9	67.9
			56	<0.1	3.3	-	2.5	57.4	1.9	65.1
			77	<0.1	4.6	-	2.5	78.0	0.2	85.3
			98	<0.1	5.8	-	2.3	71.2	1.6	80.9
Anaerobic	C_{10}, 65% wt. Cl	Freshwater	0	-	-	-	0.2	89.9	1.4	91.5
			77	<0.1	0.7	0.1	1.5	82.8	0.2	85.1
			78	<0.1	0.8	<0.1	1.7	78.0	0.2	80.5
			86	<0.1	0.1	0.1	1.8	97.0	0.2	99.0
			87	<0.1	0.9	<0.1	1.9	103.7	0.3	106.7
		Marine	0	-	-	-	0.3	46.9	2.4	49.5
			82	<0.1	0.5	<0.1	10.8	81.5	0.4	93.2
			83	<0.1	0.8	<0.1	10.1	76.9	<0.1	87.8
			97	<0.1	2.0	<0.1	11.6	64.6	0.4	78.6
			98	<0.1	1.9	<0.1	11.0	64.1	0.2	77.2

Table 4 continued overleaf.

Table 4 continued

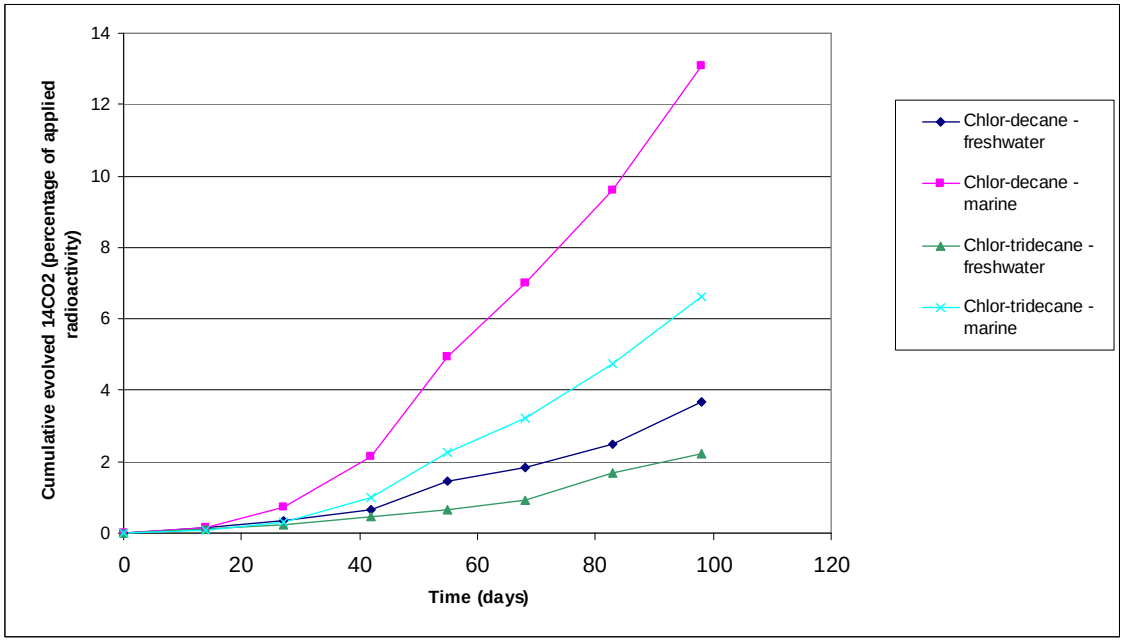
Conditions	Test substance	Sediment	Time (days)	% Distribution of ^{14}C-label (as a percentage of the applied dose)						
				Volatiles	CO_2 (cumulative)	Methane	Overlying water	Sediment	Vessel surfaces[a]	Total mass balance
Anaerobic	C_{13}, 65% wt. Cl	Freshwater	0	-	-	-	0.3	76.5	0.6	77.4
			79	<0.1	0.2	<0.1	0.5	76.7	0.2	77.6
			80	<0.1	<0.1	<0.1	0.7	92.7	<0.1	93.6
			92	<0.1	0.2	<0.1	0.9	92.1	0.4	93.6
			93	<0.1	0.4	<0.1	0.9	100.0	1.0	102.2
		Marine	0	-	-	-	0.2	41.2	5.4	46.8
			84	<0.1	<0.1	<0.1	5.6	69.6	0.7	75.7
			85	<0.1	<0.1	<0.1	4.8	76.4	<0.1	81.3
			99	<0.1	1.2	<0.1	5.7	89.8	2.8	99.8
			100	<0.1	1.4	<0.1	6.5	61.9	<0.1	71.2

Notes: - Not determined.

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

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.

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 substances; this could be assumed to be representative of a C_{10-13}, 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 ($\leq$ 2% 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 89-100% in the experiments with freshwater sediments and 75-80% 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.

3.1.3 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.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

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.

3.2.2 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 **Error! Reference source not found.**). 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.

3.3 Bioaccumulation

3.3.1 Aquatic bioaccumulation

3.3.1.1 Bioaccumulation estimation

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).

3.3.1.2 Measured bioaccumulation data

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 $C_{10\text{-}12}$, 58% wt Cl for 60 days. The concentrations were determined by means of a ^{14}C-labelled chlorinated n-undecane (59.1% wt Cl, 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^{o}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.

A subsequent study by Madeley and Maddock (1983c) found no adverse effects or deaths in groups of rainbow trout during a 99 day depuration phase following 168 days exposure to a 58% chlorinated short chain length (C_{10-12}) paraffin at mean measured concentrations of 3.4 and 17.2 µg/l (this study was carried out as part of an investigation of the effects of short-chain chlorinated paraffin exposure on growth of trout). This indicates that the effects seen by Madeley and Maddock (1983b) during depuration were not repeatable.

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^{o}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).

Other supporting information

A significant amount of monitoring data is available for short-chain chlorinated paraffins. Data for air, water, sediment and soil are presented in Section 1.9 and include levels found in remote regions such as the Arctic. For example, Tomy et al. (1997b and 1999) reported the following levels of short-chain chlorinated paraffins in surface sediments from two Arctic lakes: 1.6 µg/kg dry weight from Lake Ya Ya and 4.5 µg/kg dry weight from Hazen Lake. Short-chain chlorinated paraffins have also been found in air from the Arctic. Bidleman et al. (2001) found concentrations at Alert ranged from 1.07 to 7.25 pg/m3 between January 1994 and January 1995.

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.

Short-chain chlorinated paraffins have been found in the blubber of marine mammals from remote regions. Tomy (1997, as reported in Tomy 1998) found concentrations of 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.

Short-chain chlorinated paraffins have been detected in human breast milk. Tomy (1997) found that SCCPs (around 60–70% chlorine by weight) were present at a concentration of 11–17 µg/kg lipid (mean concentration 13 µg/kg lipid) in human breast milk from Inuit women living on the Hudson Strait in northern Quebec, Canada. Thomas and Jones (2002) detected short-chain chlorinated paraffins in 12 out of 22 samples of human breast milk at 4.5-110 µg/kg lipid. These findings are indicative of bioaccumulation through the food chain, especially in northern Quebec, since food would be the major or only source of environmental exposure for the Inuit.

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.	The actual identity of the residues was difficult to assign and it was not clear what types of chlorinated paraffins were present.

Reference	Summary of findings	
	Results	**Comments**
	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	
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.
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	The analytical detection limit was relatively high (in the range 16-740 µg/kg lipid depending on the sample size).

Reference	Summary of findings	
	Results	**Comments**
	lipid but not detected in cow's milk (detection limit 1.2 µg/kg lipid).	
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.) from Middle Sister Island in western Lake Erie. Both areas sampled are industrialised areas.	

3.3.2 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 and in human breast milk. This provides supporting evidence that the substance can be taken up by organisms in the environment.

3.4 Secondary poisoning

The EU Risk Assessment Report (EU, 2000) describes several long-term studies in rats and mice. In a 13-weeks study where rats were dosed by gavage, a dose-related increase in relative liver weight was observed as from the lowest dose of 313 mg/kg/day (NTP, 1986). In another 13 weeks study (Serrone et al, 1987), rats were given short-chain chlorinated paraffins via the diet or via gavage (in separate studies) at doses of 10, 100, or 625 mg/kg/day. Dose-dependent increases in absolute and relative liver and kidney weights were observed as from doses of 100 mg/kg/day. While the original interpretation considered these effects as adaptive, more recent interpretations consider them as

adverse effects and, as from this dose, also microscopic changes in liver, kidney and thyroid were observed, a NOAEL of 10 mg/kg/day can be derived.

The US NTP has also conducted two long-term studies (13 weeks and 2 years) on mice (NTP, 1986). In the 13 weeks study, a significantly increased relative liver weight was observed at doses of 250 mg/kg/day and higher. In the 2 years carcinogenicity study, employing doses of 125 and 250 mg/kg/day, clinical signs of intoxication (decreased activity, prominent backbones, abnormal breathing) were observed at both dose levels and survival was decreased in top dose females. Other effects included dose-related increases in hepatocellular carcinomas and adenomas, and in thyroid follicular cell carcinomas and adenomas.

In conclusion, effects on the liver, thyroid, and kidney have been shown to occur in mammalian species exposed to short-chain chlorinated paraffins. The effects are manifested as organ weight increases and histological changes after exposure for weeks or months, but may turn into carcinomas and adenomas after chronic exposure. An overall NOAEL of 10 mg/kg/day can be derived from the 13 weeks studies. No NOAEL can be obtained from the chronic studies. At chronic exposure situations, such as occurring for the marine mammals, a NOAEL of 10 mg/kg/day may not be sufficiently protective.

One proper developmental toxicity study in rats (described in EU, 2000) showed developmental effects at high dose levels, also causing severe maternal effects. Short-chain chlorinated paraffins are known to transport via milk to offspring. There are no fertility studies conducted with short-chain chlorinated paraffins, and there is thus a data gap when it comes to potential effects on pups, e.g., during lactation. However, the structural analogue medium-chain chlorinated paraffins (C14-C17 52% chlorination) has been shown to exert a very specific inhibitory effect on the blood clotting system in rats, which is manifested at the sensitive life-stages at and after birth as severe haemorrhaging, leading to mortality both in pups and the dams (IRDC, 1985) (CXR Biosciences Ltd., 2006). Pup mortality was observed at 74 mg/kg/day, giving an overall NOAEL of 47 mg/kg/day for the pups. The NOAEL for the dams was 100 mg/kg/day. Given the very similar physico-chemical properties and toxicity profiles of short- and medium-chain chlorinated paraffins, it is possible that short-chain chlorinated paraffins may exert toxicity during the reproductive cycle by affecting the blood clotting system, especially in newborn mammals.

To summarise the potential toxicological effects of short-chain chlorinated paraffins on (e.g., marine) mammals, it may affect the liver, the thyroid hormone system, and the kidneys, e.g., by causing hepatic enzyme induction and thyroid hyperactivity, which in the long-term can lead to carcinogenicity in these organs. In addition, based on read across from medium-chain chlorinated paraffins, short-chain chlorinated paraffins may affect the survival of pups via effects on the clotting system. Based on the available database, an overall NOAEL of 10 mg/kg/day is deduced. It is not clear whether this NOAEL also covers chronic exposure situations.

In conclusion, short-chain chlorinated paraffins is toxic to mammals, and there is a potential for secondary poisoning of, e.g., marine mammals.

4 ENVIRONMENTAL HAZARD ASSESSMENT

4.1 Aquatic compartment (including sediment)

4.1.1 Toxicity test results

4.1.1.1 Fish

Short-term toxicity to fish

Not relevant for this dossier.

Long-term toxicity to fish

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.

A further study by Madeley and Maddock (1983c) investigated the effects of long-term exposure to short-chain chlorinated paraffins on growth of rainbow trout. In the study groups of rainbow trout were exposed for 168 days to a 58% chlorinated short chain length (C_{10-12}) paraffin at mean measured concentrations of 3.4 and 17.2 µg/l. Following the exposure period, the fish were observed for a further 99 days (depuration period) in order to investigate further the deaths that had been noted in the above study by Madeley and Maddock (1983b). During the 168 day exposure period, no significant mortalities, behavioural effects or adverse effects on fish growth were observed compared with the control (an enhancement in the growth in the 17.2 µg/l exposure group compared with the control group was apparent by the end of the study). Therefore the NOEC for growth from this study was determined to be 17.2 µg/l. Similarly no mortalities or behavioural effects were evident during the depuration phase indicating that the effects seen by Madeley and Maddock (1983b) were not repeatable.

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.

4.1.1.2 Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Not relevant for this dossier.

Long-term toxicity to aquatic invertebrates

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_{10-12}, 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_{10-12}, 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.

4.1.1.3 Algae and aquatic plants

As reported in EU, 2000, 96-hour EC50s for the algae *Skeletonema costatum* and *Selenastrum capricornutum* (now known as *Pseudokirchneriella subcapitata*) range from 0.043 to 3.7 mg/l, with the marine alga *Skeletonema costatum* appearing to be more sensitive to short chain chlorinated paraffins than the fresh water alga *Selenastrum capricornutum* . A 96h NOEC of 12.1 µg/l was reported in a 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.

4.2 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.

5 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

5.1 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 both a P substance and 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. 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). Therefore it can be concluded that short-chain chlorinated paraffins meet the toxicity criterion.

The substance is considered to be toxic (T).

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

It is concluded that the substance meets the criteria for both a PBT substance and a vPvB 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 (P and vP). The substance has a measured bioconcentration factor in fish of 7,816 l/kg (B and vB) and a 21-day NOEC of 0.005 mg/l with *Daphnia magna* (T).

In addition, short-chain chlorinated paraffins have been detected in a wide range of environmental samples (air, sediment, water, wastewater, fish and marine mammals) and in the remote Arctic. Evidence for the bioaccumulation of short-chain chlorinated paraffins is further supported by the high concentrations of short-chain chlorinated paraffins measured in marine mammals and aquatic freshwater biota (e.g. beluga whales, ringed seals and various fish). High concentrations of short-chain chlorinated paraffins have also been measured in the breast milk of Inuit women in Northern Quebec. The substance has been proposed 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 (http://chm.pops.int/Convention/POPsReviewCommittee/Chemicalsunderreview/Riskprofiles/tabid/244/language/en-US/Default.aspx)

6 OTHER INFORMATION

The 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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