1 June 2009

Background document for alkanes,C_{10-13},chloro (SCCPs)

Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV

1. Identity of the substance

Chemical name:	alkanes, C_{10-13},chloro
EC Number:	287-476-5
CAS Number:	85535-84-8
IUPAC Name:	alkanes, C_{10-13}, chloro

2. Background information

2.1. Intrinsic properties

Alkanes, C_{10-13},chloro was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a PBT and vPvB substance pursuant to Article 57 (d) and (e) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

The exact volume of alkanes, C_{10-13}, chloro (SCCPs) currently manufactured in the EU is unknown but is estimated to be in the range of 1,000 – 4,000 t/y (BRE, 2008) with a most probable volume around 1,500 t/y.

No quantitative information is available on the amount of SCCPs imported into or exported from the EU. Imports of SCCPs into the EU from the United States and Asia appear however to be very small compared with the EU production (EC, 2008; BRE, 2008).

The available information points to a reduction in consumption of SCCPs in the EU and several other countries. Directive 2002/45/EC restricts since January 2004 the placing of SCCPs on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 % in metal working fluids and for fat liquoring of leather. Sales are therefore decreasing and SCCPs are mainly

replaced by Medium Chain Chlorinated Paraffins (MCCPs). The change to MCCPs has already occurred for the majority of uses for which this is possible (BRE, 2008).

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

Manufacture currently takes place at 4 sites in the EU located in Italy, Romania, Slovakia and the United Kingdom (BRE, 2008).

The maximum releases to the environment of SCCPs from the manufacturing sites in the United Kingdom and Italy are thought to be less than 0.01 to 0.027 t/y at each site (EC, 2008). The emissions from the production plant in Slovakia are reported to be effectively zero as the plant uses *"zero discharge technology"*. No emission information is available for the Romanian site (BRE, 2008).

About 50-100 employees may be potentially exposed to SCCPs within the EU at manufacturing sites (EC, 2000). As the production of SCCPs involves the use of closed systems and batch production measures, occupational exposure is expected to be intermittent and may occur during sampling, plant cleaning, filter cleaning, drumming and tanker loading operations.

2.2.2.2. Uses and releases from uses

No definite information on the amount of SCCP used is available, but the actual tonnage used in the EU seems to be lees than 1,000 t/y with major amounts being used for rubber (less than 600 t/y in 2004) and sealants (including adhesives, less than 300 t/y in 2004) and small amounts used in other areas. Uses in other areas comprise, e.g., paints and coating of textiles (both uses in 2004 were less than 100 t/y each) (BRE, 2008). Technical function of the SCCPs is in most cases flame retardant and/or plasticiser. In the case of textile coating SCCPs may as well be used for water proofing. The SCCPs are mixed into the rubber, sealant, paint or textile coating preparations. It is not clear to which extend they are bound to these matrices.

Directive 2002/45/EC restricts the marketing and use of SCCPs for metal working fluids and fat liquoring as substances or as constituents of other substances or preparations in concentrations higher than 1%. Therefore, it is theoretically possible that SCCPs are used in these applications provided that the concentration present is less than 1%. However such use would not be expected because of technical limitations. For example, for the SCCP to be effective, concentrations of typically 5-10% are needed in oil-based metal cutting fluids and typically 20% of the leather fat liquoring mix (EC, 2000). Thus it is doubtful that any products are supplied for these applications with SCCP contents less than 1%. One possible exception to this is in emulsion-based metal working fluids where the final chlorinated paraffin concentration in the final emulsified fluid can be less than l% (BRE, 2008). However the supplied lubricants typically have chlorinated paraffin contents of 5% and up to around 8% and are then diluted before use and so again it is unlikely that lubricants supplied with less than 1% SCCP contents would be effective after dilution. Therefore, although it cannot be completely ruled out that SCCPs are still supplied in products for leather fat liquoring or metal working, this possibility is considered unlikely.

The releases of SCCPs estimated to occur to the environment are summarised in Table 1. Releases from the lifecycle of SCCPs are estimated to be in the range of approximately 22 – 45 t/y and releases of SCCPs resulting from their presence as impurity in MCCPs amount to ≈33 t/y. Hence, the overall environmental emissions from manufacture, formulation and use of SCCPs in 2004 are estimated to be in the range of 55 – 80 t/y [1].

Table 1: Estimates of release of SCCPs in EU15 in 2004 (BRE, 2008)

Lifecycle stage	**Estimated release (tonnes/year)**			
	Surface water	**Waste water**	**Air**	**Industrial/ urban soil**
Manufacture	<0.037			
Formulation of rubber		<0.1	<0.1	
Formulation of textile backcoatings		<0.5		
Formulation of sealants		Negligible	negligible	
Formulation of paints		Negligible	negligible	
Processing of rubber		<0.5	<0.5	
Processing (application) of textile backcoatings		<0.5 (to waste water or waste)		
Use of sealants		Negligible	negligible	
Industrial application of paints		<0.1		
Service-life articles * (rubber goods, building and construction materials (sealants), textiles, and articles painted with paints and coatings)	4.7-9.5	7.4-19.6	0.6-1.8	8.7-13.9
Consumer use of preparations (paints and sealants)		Negligible	negligible	
Total from SCCPs lifecycle	**4.7-9.5**	**7.4-19.6**	**0.6-1.8**	**8.7-13.9**
Impurity in medium-chain chlorinated paraffins	<8.9	<13.1	<1.7	<9.7
Overall total	**<13.6-<18.4**	**<20.5-<32.7**	**<2.3-<3.5**	**<18.4-<23.6**

* The estimations for releases during service life include releases at disposal

[1] More recent confidential information from industry indicates that the actual releases from the EU27 are of the same order as those provided in table 1.

The number of people occupationally exposed to SCCPs in the EU is unknown (EC 2000). However, according to the available information, it is estimated that the numbers occupationally exposed during all formulation processes (rubber, textiles, paints and coatings and adhesives and sealants) in the EU at that time could be of the order of several thousands Similarly, it was estimated that the number of people occupationally exposed during the industrial use of paints, adhesives and sealants would be of the order of thousands (EC, 2000).

Information on releases at the workplace is not available. However, the exposure of workers was estimated using the EASE Model (EC 2000). Resulting estimates are summarised in Table 2.

Table 2: Worker exposure estimations by the EASE model (EC, 2000)

Lifecycle stage	**Exposure by inhalation (mg/m3) 8h TWA**	**Dermal exposure [1] ($mg/cm^2/day$)**
Use as flame retardant in rubber formulations *(Formulation and processing)*	11-63	0.1-1
Formulation of textile back coatings	0-2.1	0.1-1
Processing (application) of textile back-coatings	0-2.1	0.03-0.3
Formulation of sealants	0-2.1[2] 11-63[3]	0.1-1
Use of sealants	0.32[4]	0.01-0.1
Formulation of paints	0-2.1	0.1-1
Industrial application of paints	0.32	0.01-0.1

1 Dermal exposure of hands and forearms. It is expected that this value would be considerably reduced by the use of personal protective equipment
2 Low temperature mixing processes (the majority of cases)
3 Formulation of hot melt adhesives
4 Inhalation exposure where sealants are applied by spray. Inhalation exposure during other industrial application of sealants is expected to be insignificant as SCCPs have very low vapour pressures (EC, 2000).

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) the supply chain

There are 4 sites located in Italy, UK, Slovakia and Romania thought to be main producers of SCCPs in the EU in recent years (BRE, 2008).

The main use of SCCPs in rubber is in conveyor belts for mining. The highest production of rubber conveyor belts appears to occur in Germany, Poland, Greece and Romania and so the highest use (or number of sites of use) is assumed to occur in these countries (BRE, 2008). However, conveyor belts are produced in the majority of EU countries and so use in other countries is also likely. The current use of SCCPs in this application, and the number and location of sites where SCCPs are used is unclear.

The main areas of the EU where back coating of textiles is carried out include the UK and Germany but the process is also likely to be carried out in other parts of the EU. The total number of sites is estimated at less than 14 for formulation sites and less than 42 for sites applying back-coatings (processing sites). The current use of SCCPs

in this application, and the number and location of sites where SCCPs are used is unclear.

The number and location of sites where SCCPs are used in the formulation of sealants and adhesives is unknown. According to the available information, there is currently little or no use of SCCPs in this application. If this was the case, the number of formulation sites is likely to be very low, however, the available information indicates that use of SCCPs in sealants is still a major use (BRE, 2008). In the latter case the potential number of formulation sites and in particular the sites where SCCP containing sealants are used could be relatively large and widespread throughout the EU.

Based on the available information it appears that there is currently little or no use of SCCPs in paints and sealants in the EU and so the number of current formulation sites is likely to be very low. However, if SCCPs are used in paints and coatings the potential number of sites of use would be expected to be relatively large and widespread throughout the EU (CEPE, 2008). The major users of such paints are professional painters and specialist applicators, although it is possible that some DIY paints containing chlorinated paraffins may be used by the general public (EC 2008).

The supply chains related to the identified uses of SCCPs except rubber and textiles seem to be fairly short, not very complicated and associated with a relatively limited number of downstream users. The rubber and textile articles containing SCCPs are for limited and specialised uses. The users of articles made of recycled conveyer belts may present several industry branches, however, the available information does not indicate that these uses specifically require SCCP containing rubber.

According to the available information, it is likely that the formulation step involves a limited number of companies. A higher number of article producers and end-users (both industrial and professional) of the articles and preparations containing SCCPs are involved in the supply chains. However, these preparation and articles containing SCCPs are used in a limited number of specialised applications.

2.3. Availability of information on alternatives

The information on possible alternatives is summarised in Table 3. There appears to be information available on alternative substances to SCCPs for many of the uses. Furthermore the available information indicates substitution of SCCPs is already ongoing for some of these uses. However, it is not clear whether there is information available on alternatives and their suitability for all specific applications.

There is no information available on alternative techniques to avoid SCCPs.

Table 3: Summary of information on potential alternatives to the use of SCCPs (BRE, 2008)

Use	Alternative	Toxicity	Ecotoxicity	Cost	Availability	Use pattern	Performance
Rubber	MCCPs	Reproductive toxicant, effects on liver, kidney	R50-53; not readily biodegradable	Similar cost of substance, possible higher use rate; additional one-off costs	Commercially available	Similar to SCCPs	Technically viable alternative
	LCCPs	Possible carcinogenicity and reproductive effects	Not readily biodegradable; does not meet B and T criteria	Higher cost of substance; additional one-off costs.	Commercially available	Similar to SCCPs	Technically viable alternative
	Cresyl diphenyl phosphate	Toxicity to liver, kidney and blood	Does not meet P, B or T criteria	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting
	Tertbutylphenyl diphenyl phosphate	Possible liver, kidney and adrenal toxicity	Does not meet P and B criteria; provisional classification R50	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting
	Isopropylphenyl diphenyl phosphate	Low toxicity	Does not meet P and B criteria; acute aquatic toxicity <1 mg/l	Significantly higher substance costs; additional one-off costs	Commercially available	Probable use in PVC rather than rubber	Currently used in PVC belting
Textiles	MCCPs	Reproductive toxicant, effects on liver, kidney	R50-53; not readily biodegradable	Similar cost of substance, possible higher use rate; additional one-off costs	Commercially available	Similar to SCCPs, possible higher use rate	Technically viable alternative
	LCCPs	Possible carcinogenicity and reproductive effects	Not readily biodegradable; does not meet B and T criteria	Higher cost of substance; additional one-off costs.	Commercially available	Similar to SCCPs	Technically viable alternative

Use	Alternative	Toxicity	Ecotoxicity	Cost	Availability	Use pattern	Performance
	Decabromodiphenylether	Neurotoxicant	Not readily biodegradable , low to moderate bioaccumulation potential	Significantly higher substance cost than SCCPs; additional one-off costs. Requires diantimony trioxide	Commercially available	25% by weight (in conjunction with ATO)	Technically viable alternative
	Hexabromocyclododecane	Developmental effects	Meets the criteria in article 57(d) and (e) of the REACH Regulation.	Significantly higher substance cost than SCCPs; additional one-off costs. Requires diantimony trioxide	Commercially available	25% by weight (in conjunction with ATO)	Technically viable alternative
	Ethane, 1-2 bis(pentabromophenyl)	Limited data, but likely to be of low toxicity	Not readily biodegradable, may be persistent	Significantly higher substance cost than SCCPs; additional one-off costs. Requires diantimony trioxide	Commercially available	Typical loading 10-30 g/m^2	Technically viable alternative
Sealants, adhesives, paints, coatings	MCCPs	Reproductive toxicant, effects on liver, kidney	R50-53; not readily biodegradable	Similar cost of substance, possible higher use rate; additional one-off costs	Commercially available	Similar to SCCPs	Technically viable alternative
	LCCPs	Possible carcinogenicity and reproductive effects	Not readily biodegradable; does not meet B and T criteria	Higher cost of substance; additional one-off costs.	Commercially available	Similar to SCCPs	Technically viable alternative
	Phthalates	Possible developmental effects	Readily biodegradable; generally no effects at solubility		Commercially available		Do not provide flame retardancy

2.4. Existing specific Community legislation relevant for possible exemption

Directive 2002/45/EC restricts the placing of SCCPs on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 % in metal working fluids and for fat liquoring of leather.

2.5. Any other relevant information (e.g. for priority setting)

No data available.

3. Conclusions and justification

3.1. Prioritisation

According to the available information the actual tonnage of SCCPs used in the EU is less 1,000 tonnes/year.

Formulation of preparations and manufacture of articles containing SCCPs appear to happen in a limited number of sites. However, all known uses of preparations and articles, i.e. use of rubber articles containing SCCPs, use of textiles with back coatings containing SCCPs, use of sealants, adhesives and paints containing SCCPs are likely to be widespread and associated with a high potential for release of the substance and therefore can be considered as wide dispersive. The same conclusion can be drawn for use of articles made from recycled rubber belts containing SCCPs.

Given that SCCPS is a PBT and vPvB substance, with wide dispersive uses of the preparations and articles containing it and involving relatively high volumes, ECHA recommends to include alkanes, $C_{10\text{-}13}$, chloro (SCCPs) in Annex XIV.

3.2. Recommendation for Annex XIV entry

3.2.1. Transitional arrangements

Based on the available information, it is anticipated that the preparation of applications will require a collaborative effort by a number of actors. Supply chains related to some of the uses are fairly simple while others include more levels. The affected actors represent several different industry sectors and professional user groups. However, most of the uses are highly specialised.

Furthermore, the information already available on potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for. On the other hand, some of the information available on alternatives suggests that the potential applicants may need to assess more complicated situations to conclude whether or not transfer to alternatives is feasible.

Hence, in light of the available information, ECHA recommends a somewhat longer period for preparing applications than the minimum and the following transitional arrangements:

- *Latest application date*:
  27 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  45 months after the entry into force of the Decision to include the substance in Annex XIV

3.2.2. Review periods for certain uses

Neither the available information for SCCPs nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of SCCPs.

3.2.3. Exempted (categories of) uses

Recommendation:

ECHA recommends to exempt from the authorisation requirement the placing on the market and use of SCCPs in preparation in concentration at or lower than 1 % by weight where the preparation is intended for a use in metalworking or fat liquoring of leather.

Justification:

Exemption for use in metalworking or fat liquoring of leather:
Directive 76/769/EEC sets out the restrictions on the uses of substances as well as specific exemptions to these restrictions. These restrictions (and their exemptions) are incorporated in Annex XVII of the REACH Regulation which will replace the entries in Directive 76/769/EEC from 1 June 2009. The recitals of Directive 76/769/EEC and the directives amending it provide that these restrictions have an objective to protect human health and/or the environment. Directive 76/769/EEC could therefore constitute specific Community legislation imposing minimum requirements relating to the protection of human health and the environment for the use of a substance within the meaning of Article 58(2) of the REACH Regulation. Furthermore, recital 80 of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction.

On this basis, ECHA considers that where an entry in Annex XVII exempts a specific use of a substance from the restrictions, Article 58(2) could be used to exempt that specific use from authorisation in the two following situations:

i) Annex XVII includes a restriction on a specified use of a substance and this restriction specifies condition(s) under which the restriction does not apply

ii) Annex XVII includes a generic ban on a substance and a specified use is exempted from this generic ban. Such an exemption can be subject to further conditions.

Entry 42 of Annex XVII provides that SCCPs may not be placed on the market as substances or constituent of other substances or in preparations for use in metalworking or in fat liquoring of leather when the concentration is greater than 1 % by weight. Thus, use of SCCPs in these applications in preparation in concentrations at or lower than 1 % is permitted.

In its draft recommendation ECHA considered that as the restriction in Directive 76/769 permits the use of SCCPs in these applications in preparations in concentrations at or lower than 1 %, such use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation.

In its opinion of 20 May 2009 ECHA's Member State Committee (MSC) considered that further legal interpretation is required in order to take a position whether this use of SCCP should be exempted from authorisation.

Having examined the opinion of the MSC ECHA still considers that from a legal point of view this use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation. Indeed, unlike the exemption from restrictions for use of substances in artists' paints which addressed a category of substances, the restriction (and conditions for exemption) of the use of SCCPs specifically identified the substance that is subject to the restriction.

ECHA however urges the European Commission to review this analysis made by ECHA and to clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of the REACH Regulation.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of SCCPs.

ECHA did not see grounds for recommending general exemptions for SCCPs for the reasons set out in the "*Responses to comments*" document.

3.2.4. Application of authorisation to product and process oriented research and development (PPORD)

Neither the available information for SCCPs nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development (PPORD) on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of SCCPs in PPORD from authorisation

3.3 Possible route for authorisation

The substance meets the criteria in article 57(d) and (e). Therefore, pursuant to article 60(3) of REACH Regulation, it would appear that an authorisation can only be granted in accordance with article 60(4) of the REACH Regulation ('socio-economic route').

4. References

EC (2000): European Union Risk Assessment Report: Alkanes, C_{10-13}, chloro. 1st Priority List Volume 4. European Commission, Joint Research Centre, EUR 19010 EN.

EC (2008): European Union Risk Assessment Report: Alkanes, C_{10-13}, chloro. Updated Version 2008. 1st Priority List Volume 81. European Commission, Joint Research Centre, EUR 23396 EN.

BRE (2008): Data on manufacture, import, export, uses and releases of substance Alkanes, C10-13, chloro (SCCPs) as well as information on potential alternatives to its use
Report prepared for ECHA.

CEPE (2008): Personal communication (e-mail dated 22 October 2008).