NICNAS

National Industrial Chemicals Notification and
Assessment Scheme

Short chain chlorinated paraffins (SCCPs)

Priority Existing Chemical Assessment Report No. 16

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Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This Scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act), which came into operation on 17 July 1990.

The principal aim of NICNAS is to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS assessments are carried out in conjunction with Environment Australia and the Therapeutic Goods Administration, which carry out the environmental and public health assessments, respectively.

NICNAS has two major programs: the assessment of the health and environmental effects of new industrial chemicals prior to importation or manufacture; and the other focussing on the assessment of chemicals already in use in Australia in response to specific concerns about their health/or environmental effects.

There is an established mechanism within NICNAS for prioritising and assessing the many thousands of existing chemicals in use in Australia. Chemicals selected for assessment are referred to as Priority Existing Chemicals.

This Priority Existing Chemical report has been prepared by the Director (Chemicals Notification and Assessment) in accordance with the Act. Under the Act manufacturers and importers of Priority Existing Chemicals are required to apply for assessment. Applicants for assessment are given a draft copy of the report and 28 days to advise the Director of any errors. Following the correction of any errors, the Director provides applicants and other interested parties with a copy of the draft assessment report for consideration. This is a period of public comment lasting for 28 days during which requests for variation of the report may be made. Where variations are requested the Director's decision concerning each request is made available to each respondent and to other interested parties (for a further period of 28 days). Notices in relation to public comment and decisions made appear in the *Commonwealth Chemical Gazette*.

In accordance with the Act, publication of this report revokes the declaration of this chemical as a Priority Existing Chemical, therefore manufacturers and importers wishing to introduce this chemical in the future need not apply for assessment. However, manufacturers and importers need to be aware of their duty to provide any new information to NICNAS, as required under Section 64 of the Act.

For the purposes of Section 78(1) of the Act, copies of Assessment Reports for New and Existing Chemical assessments may be inspected by the public at the library of the National Occupational Health and Safety Commission. Summary Reports are published in the *Commonwealth Chemical Gazette*, which are also available to the public at the NOHSC library.

Copies of this and other PEC reports are available on the NICNAS website. Hardcopies are available from NICNAS either by using the prescribed application form at the back of this report, or directly from the following address:

GPO Box 58

Sydney

NSW 2001

AUSTRALIA

Tel: +61 (02) 9577 9437

Fax: +61 (02) 9577 9465 or +61 (02) 9577 9465 9244

Other information about NICNAS (also available on request) includes:

- NICNAS Service Charter;
- information sheets on NICNAS Company Registration;
- information sheets on PEC and New Chemical assessment programs;
- safety information sheets on chemicals that have been assessed as Priority Existing Chemicals;
- subscription details for the NICNAS Handbook for Notifiers; and
- subscription details for the Commonwealth Chemical Gazette.

More information on NICNAS can be found at the NICNAS Web site:

http://www.nicnas.gov.au

Other information on the management of workplace chemicals can be found at the website of the National Occupational Health and Safety Commission:

http://www.nohsc.gov.au

Overview

Short chain chlorinated paraffins (SCCPs) were declared Priority Existing Chemicals (PECs) for preliminary assessment on 7 March 2000 due to the widespread uses and concern about their long term health and environmental impacts as these chemicals persist in the environment have been shown to be bioaccumulative.

In Australia, SCCPs are mainly used in manufacturing of metal working fluids and a range of products such as fillers, adhesives and coating materials used in the building industry. Other minor uses include manufacture of pigment dispersants, rubber and leather treatment products. The formulated products are either used directly or further diluted or mixed with other components by end users. The final concentration of SCCPs in the products ranges from 1 to 15%. Some of the final products containing SCCPs such as adhesives, paints and sealants may be available to the general public.

SCCPs have the greatest potential for environmental release of the chlorinated paraffins, and also exhibit the highest toxicity of polychlorinated *n*-alkanes (PCAs). Their release into the environment could occur during production, storage, transportation, industrial use of manufactured products, release from plastics, paints and sealants in which they are incorporated, and leaching, runoff or volatilisation from landfills, sewage sludge or other waste disposal sites.

When released to the environment, the compounds are expected to be stable and degrade only slowly. However, they will bind strongly to soils and sediments. There is a high potential for bioaccumulation, supported by the limited available data. Long range transport through the air also appears to occur.

Available data indicates SCCPs do not demonstrate acute toxicity to fish, however, they do show toxicity to fish in chronic tests. However, they may be considered highly toxic to aquatic invertebrates. Toxicity was observed within the limits of solubility although there is a possibility the effects could be physical, particularly in the case of Daphnia. SCCPs may also be considered highly toxic to algae, although in instances, the EC_{50} values exceeded the highest mean measured concentrations of the test substance employed in the study. No data are available for sediment dwelling organisms. This is an area for further consideration as it is likely to receive significant exposure in localised areas.

Occupational exposure may occur from any of the uses and also during transportation and disposal. Potential inhalation exposure to workers when formulation occurs at high temperatures, in the use of metal working fluids and during spraying of paint, coatings, adhesives and leather treatment products containing SCCPs has been identified. Exposure to the general public may occur from use of products available to the public and also via contaminated food due to the potential bioaccumulation of SCCPs.

SCCPs are absorbed significantly by oral administration (up to 60%), but poorly through the skin. Available data show that the degree of chlorination affects the absorption, distribution and excretion of SCCPs.

SCCPs exhibit very low acute toxicity by all three routes in animals. Mild skin and eye irritation were observed in some animal studies. Available human data indicate that SCCPs do not cause skin irritation and are not sensitisers.

Repeated dose animal studies showed the principal signs of toxicity were effects in the liver, thyroid and kidney. However, mechanistic information has indicated that the liver and thyroid effects are probably not relevant to human health.

SCCPs are not mutagenic. Carcinogenicity studies in animals indicate that the principal tumour sites are the liver, thyroid and kidney. The characteristic patterns in the results and probable underlying mechanisms indicate that in the liver chronic tissue damage was caused by peroxisome proliferation and that in the thyroid there was long-term hormonal stimulation, potentially consequent to the liver effects. The Organisation for Economic Cooperation and Development (OECD) consideration of the likely underlying mechanisms for these tumours suggests that they are not relevant to human health. However, the mechanism for kidney tumours is not yet clear and hence SCCPs are classified as Category 3 carcinogens.

The occupational risk assessment conducted by the OECD in its Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) concluded that at present there is no need for further risk reduction measures beyond those that are already being applied in the European Union (EU), as use of SCCPs is appropriately controlled and the potential exposure of workers is not considered to be a cause for concern. The industries using SCCPs and the industrial processes in Australia are similar to those described in the OECD report. Therefore, the potential for occupational exposure of workers in Australia to SCCPs is likely to be low. It is recommended that NOHSC adopt the EU classification as soon as possible and appropriate control measures should be used to minimise exposure during processes where inhalation and skin contact of SCCPs may occur.

The potential for release to the aquatic compartment through inappropriate disposal of extreme pressure lubricants used in metal working fluids may be high. There are no data on sediment dwelling organisms, and these may be subject to localised high exposure. Based on the reasonable worst case assessment of 50% disposal to sewer, the potential for environmental risks is of concern.

Use of SCCPs in lubricants, building materials, surface coatings, rubber products and leather finishing products is not considered to present a significant hazard to public health. However, due to the potential for SCCPs to bioaccumulate, exposure of the general public via contaminated food is possible and environmental releases of SCCPs should be kept at a minimum.

It is recommended that a full (risk) assessment of the use of SCCPs in metal work is needed for the environment, unless new data comes forward indicating acceptable releases to sewer. Further assessment work for workers and the public is not recommended at this time.

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Acronyms and Abbreviations

AICS	Australian Inventory of Chemical Substances
BCF	bioconcentration factor
BUA	Beratergremium für Umweltrelevante Alstoffe
C	carbon
CAA	Clean Air Act
Cl	chlorine
CO_2	carbon dioxide
DNA	deoxyribonucleic acid
EA	Environment Australia
EC	European Communities
EC_{50}	median effective concentration
EHC	Environmental Health Criteria
EU	European Union
FDA	Food and Drug Authority
g	gram
GLP	good laboratory practice
h	hour
H_2O	water
HCl	hydrochloride
HPV	High Production Volume
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
ITC	Interagency Testing Committee
kg	kilogram
K_{oc}	partition coefficient to organic carbon
K_{ow}	octanol/water partition coefficient
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose

LT_{50}	median lethal time
MATC	maximum acceptable toxicant concentration
µg	microgram
mg	milligram
µm	micrometer
MSDS	Material Safety Data Sheet
MTL	Master Testing List
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration (USA)
OSPAR	Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic
Pa	pascals
PCAs	polychlorinated n-alkanes
PECs	Priority Existing Chemicals
PPE	personal protective equipment
ppm	parts per million
SCCPs	short chain chlorinated paraffins
SIAR	SIDS Initial Assessment Report
SIDS	Screening Information Data Set
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
T_4	thyroxine
TDI	tolerable daily intake
TGA	Therapeutic Goods Administration
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
TSH	thyroid-stimulating hormone
UDPG	uridine diphosphate glucuronosyl

UK	United Kingdom
UK HSE	United Kingdom Health and Safety Executive
US EPA	United States Environmental Protection Agency
vol	volume
wt	weight
WHO	World Health Organization

1. Introduction

1.1 Declaration

Short chain chlorinated paraffins (SCCPs), were declared Priority Existing Chemicals (PECs) for preliminary assessment under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act), as amended, by a notice in the *Chemical Gazette* of 7 March 2000.

The reason for the declaration was "the widespread use of SCCPs and concern about their long term health and environmental impacts as these chemicals are not biodegradable and have been shown to be bioaccumulative".

1.2 Scope of the assessment

The Act prescribes which matters may be taken into account and addressed in a preliminary assessment. Risk assessment and risk management are not covered in preliminary assessments. However, as an outcome of a preliminary assessment, the Act requires the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to determine the significance of the assessment findings for risk. If the findings indicate that there may be a significant risk of adverse health or environmental effects, then a full (risk) assessment may be recommended.

Chlorinated paraffins are characterized by the carbon-chain length range of their *n*-alkanes. SCCPs contain between 10-13 carbon molecules.

This is a preliminary assessment focussing on manufacture/import volumes and identifying downstream uses.

1.3 Objectives

The purpose of the assessment was to:

- determine manufacture/importation volumes;
- identify likely or potential uses of SCCPs in Australia;
- review the properties of SCCPs;
- determine the potential for public and occupational exposure and exposure to the environment resulting from use;
- review and summarise the health and environmental effects; and
- determine whether or not the significance for risk is such that a full (risk) assessment should be undertaken.

1.4 Sources of information

Information for the assessment was obtained from a number of sources.

Industry

In accordance with the Act, manufacturers and importers of SCCPs and importers of mixtures containing SCCPs were required to apply for assessment and supply information. Data supplied by industry included:

- quantities imported in the past two years;
- known uses of the chemicals and products containing the chemicals;
- Material Safety Data Sheet (MSDS) and labels; and
- a list of end users.

Importers/manufacturers on-sell SCCPs and were unable to provide data on potential exposure and disposal during use of the chemicals. An external consultant, Professor Ian Rae, was commissioned to facilitate data collection and to investigate use patterns and occupational, public and environmental exposure resulting from use of SCCPs in Australia.

Literature review

The major sources of information on the toxicology of SCCPs were a Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) prepared by the United Kingdom Health and Safety Executive (UK HSE) in 1997 and finalised in 1999 through the Organisation for Economic Cooperation and Development (OECD) SIDS Program (OECD, 1999) and the World Health Organization (WHO) Environmental Health Criteria (EHC) monograph 181 for chlorinated paraffins published under the International Programme on Chemical Safety (IPCS, 1996). A large number of unpublished reports were included in these reviews. A search of publicly available databases was carried out to identify recent data (post-1997) if any. The OECD SIDS report was also used as the basis for the environmental fate and toxicity summary.

1.5 Peer review

During all stages of preparation, the report has been subjected to internal peer review by NICNAS, Environment Australia (EA) and Therapeutic Goods Administration (TGA). External peer review was not undertaken because the primary sources of the hazard information are internationally agreed report that underwent significant international peer review in which Australia actively participated.

2. Background

Chlorinated paraffins were first produced commercially in the 1930s. They are manufactured by the chlorination of specified normal paraffin fractions obtained from petroleum refining. Ordinary commercial chlorinated paraffins are mixtures which contain several homologous *n*-alkanes corresponding to their manufacture from *n*-paraffin fractions with several different degrees of chlorination.

Substances of this type were used extensively for the first time during the 1939-45 World War when they were applied to cotton fabrics employed by the military as flame retardants. They are thermally unstable beyond about 175°C, although the incorporation of other substances as stabilisers may raise this ceiling. The SCCPs possess other properties, besides flame retardancy, which make them valuable as industrial products. They are employed as extreme pressure lubricants and as dispersing agents which promote good mixing of, for example, pigment in plastic material (Government of Canada, 1993).

2.1 International perspective

It has been reported that less than 15,000 tonnes per year of SCCPs are currently manufactured by two companies in Europe (OECD, 1999). Some SCCPs (CAS No. 63449-39-8, 68920-70-7, 85535-84-8) are listed in the OECD Representative List of High Production Volume (HPV) chemicals i.e. production volume of 1,000 tonnes or more in at least one OECD country.

The environmental toxicity of SCCPs to sensitive aquatic species became apparent in the 1970s. Concerns about the health and environmental safety implications of SCCPs have resulted in a number of overseas regulations and controls that have impacted on the use of these chemicals.

OECD Clearing House

An OECD Clearing House on SCCPs, which included Canada, Denmark, Finland, Germany, Sweden, UK and US, was initiated in 1993. Status reports on SCCPs activities have been provided periodically since then. The most recent status report was from an expert meeting on SCCPs held in Switzerland in November 1999 to discuss existing and planned member country risk management activities. The details are described below.

United States (US)

The US Environmental Protection Agency (US EPA) regulates chlorinated paraffins under the Toxic Substances Control Act (TSCA), requiring the reporting of general health effects of the compounds. TSCA's Interagency Testing Committee (ITC) has designated chlorinated paraffins as priority chemicals and added them on its Master Testing List (MTL) in 1994. The US EPA also regulates chlorinated paraffins under the Clean Air Act (CAA; Section 112): Standards that regulate specific categories of stationary sources that emit (or have potential to emit) one or more hazardous air pollutants. The US Food and Drug Authority

(FDA) regulates chlorinated paraffins as indirect food additives, adhesives and components of other products which may come into contact with foods.

The US EPA conducted a risk assessment of SCCPs in 1993. It concluded that metal working fluids constitute the major source of human and environmental exposure, that current environmental releases appear to pose no widespread risk to aquatic organisms and that there is a possible cancer risk to metal working fluid workers. It was recommended to list SCCPs on the Toxic Release Inventory (TRI) and to refer the occupational risk of cancer to the Occupational Safety and Health Administration (OSHA). To date, SCCPs have not been listed on the TRI. The OSHA regulates chlorinated paraffins under the Hazard Communication Standards and as a chemical hazard in laboratories.

European Union (EU)

In 1994, under the framework of the Existing Substances Regulation (793/93/EC), SCCPs were included in the EU's first priority list of substances for which a risk assessment should be developed. A risk assessment report was produced by UK HSE in 1997. The report was approved by the European Environment Council in July 1999 and was published in the *Official Journal of the European Communities* (EC) in November 1999. This report was the basis for the OECD SIDS report (OECD, 1999). Based on the report, the EU classified SCCPs as Carcinogen Category 3 (substances which cause concern for humans owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment), with risk phrase R40 (possible risk of irreversible effects). The EU is considering marketing and use restrictions for SCCPs particularly in applications providing high emissions such as metal working and leather processing.

According to the OECD report, the use of SCCPs in EU countries has decreased by approximately 70% since 1994, particularly in the metal working and leather areas. For example, in Germany an overall reduction in their use in metal working fluids of around 50% has occurred and their use has practically been discontinued in water-oil emulsions. In Sweden the use of all chlorinated paraffins in metal working fluids has been reduced by 80% overall and is expected to reduce further. In Switzerland SCCPs are not used in consumer products.

Canada

SCCPs were assessed under the Canadian Environmental Protection Act in 1993 and were declared "toxic" as defined in Section 11(c) of the Act. Environment Canada is currently examining new Canadian data to determine if SCCPs present an immediate or long-term harmful effect on the environment. The draft risk assessment indicates that SCCPs are likely to be persistent and bioaccumulative and that there is a potential risk to the aquatic environment. The assessment is expected to be completed and available for public comment in year 2001. The Canadian government is consulting with industries on possible risk management measures. A final decision regarding the management of SCCPs will be made following the review of these data.

Other

In 1995, the Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) led by Sweden adopted a decision on phasing out use of SCCPs as metal working fluids, plasticizers in paint, coating and sealants and flame retardants in rubber, plastics and textiles. Reporting on the progress in implementing the decision by Contracting Parties was scheduled for the year 2000. It was reported at the OECD Clearing House meeting that the decision has been almost implemented in several Member states.

Industry

A number of companies throughout the OECD countries voluntarily labelled SCCPs as "dangerous to the environment" before such labelling was required. In Germany, industry has begun an intensive effort to use metalworking fluids that are chlorine-free. Voluntary agreements between a few governments (Germany, Sweden) and their industries to limit releases are in place or under discussion.

2.2 Australian perspective

SCCPs are not listed in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) (Australian Health Ministers' Advisory Council, 1999), nor the National Occupational Health and Safety Commission's (NOHSC) *List of Designated Hazardous Substances* (NOHSC, 1999). No Australian exposure standard has been established. The materials are not classified as dangerous goods according to the Australian Code for the Transport of Dangerous Goods by Road and Rail. There are no specific public, occupational health or environmental regulatory controls in Australia.

2.3 Assessments by overseas national or international bodies

Reviews of the health and environmental effects of SCCPs have been carried out by the International Agency for Research on Cancer (IARC, 1990), Beratergremium für Umweltrelevante Altstoffe (BUA, 1992), Government of Canada (1993), the WHO International Programme on Chemical Safety (IPCS, 1996) and the US National Toxicology Program (NTP 9th Report on Carcinogens, 1999). SCCPs have been assessed under the OECD SIDS Program (1999) (see Section 1.3). The health effects of SCCPs and conclusions of these reviews are discussed in Section 8.4.

3. Applicants

Following declaration of SCCPs as PECs, five companies and two interested parties applied for assessment of the chemicals. The applicants supplied information on import quantities, uses, human and environmental exposure, MSDS and labels of the chemicals. In accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989*, NICNAS provided the applicants with a draft copy of the report for comments during the statutory consultation phases of the assessment.

The applicants were, as follows:

Australia Council of Trade Unions
393 Swanston St.
Melbourne
VIC 3000

Australian Manufacturing Workers Union
3/440 Elizabeth St.
Melbourne
VIC 3000

Clariant Australia Pty Ltd.
PO Box 23
Chadstone
VIC 3148

HB Fuller Company Australia Pty Ltd.
16-22 Redgum Drive
Dandenong South
VIC 3175

Orica Australia Pty Ltd.
1 Nicholson St.
Melbourne
VIC 3001

PCA Hodgson Pty Ltd.
19-25 Anne St.
St Marys
NSW 2760

Swift Pty Ltd.
PO Box 600
Abbotsford
VIC 3067

4. Chemical Identity and Composition

Short chain chlorinated paraffins contain between 10 to 13 carbon molecules. This assessment covers SCCPs generally, however the following substances were specifically cited in the declaration notice.

Chemical Name	**CAS Number**
Alkanes, C_{6-18}, chloro	68920-70-7
Alkanes, C_{10-13}, chloro	85535-84-8
Alkanes, C_{12-13}, chloro	71011-12-6
Alkanes, C_{12-14}, chloro	85536-22-7
Alkanes, C_{10-14}, chloro	85681-73-8
Alkanes, C_{10-12}, chloro	108171-26-2

Most of the C_{10-13} chloroparaffins are imported under CAS Number 85535-84-8 which is specific for this group of substances. There were no notifications relating to the other five classes, however these were included in this assessment as these chemicals may be imported under exempt categories or in articles.

Some material is imported under CAS Number 63449-39-8, paraffin waxes and hydrocarbon waxes, chlorinated, C_{10-13}. This is a generic classification which covers both short and long chain chlorinated paraffins and is included on the Australian Inventory of Chemical Substances (AICS).

4.1 Chemical identity

The chemical identities of SCCPs are listed in Table 1.

Table 1 - Chemical identity of SCCPs

Chemical Name	CAS Numbers	EINECS Number	AICS Listed	Other Names	Trade Names	Molecular Formula	Structural Formula	Molecular Weight
Alkanes, C_{6-18}, chloro	68920-70-7	272-924-4	Yes	Alkanes, C_{6-18}, chloro Alkanes, (C=6-18), chloro Chlorinated *n*-paraffin (C_6-C_{18}) Chlorinated *n*-paraffins (C_6-C_{18})	N/A	Unspecified	Unspecified	Unspecified
Alkanes, C_{10-13}, chloro	85535-84-8	287-476-5	Yes	Alkanes, C_{10-13}, chloro Alkanes, (C=10-13), chloro Chloro alkanes, C_{10-13} C_{10-13} chloro alkanes	Cereclor 50LV PCA 60 PCA 70 Witachlor149 Witachlor 171P	Unspecified	Unspecified	320-500 (g/mole)
Alkanes, C_{12-13}, chloro	71011-12-6	N/A	No	Alkanes, C_{12-13}, chloro Alkanes, (C=12-13), chloro	N/A	Unspecified	Unspecified	Unspecified
Alkanes, C_{12-14}, chloro	85536-22-7	287-504-6	No	Alkanes, C_{12-14}, chloro Alkanes, (C=12-14), chloro	N/A	Unspecified	Unspecified	Unspecified
Alkanes, C_{10-14}, chloro	85681-73-8	288-211-6	No	C_{10-14} chloroalkanes Alkanes, (C=10-14), chloro Chloro alkanes, C_{10-14} Chloro C_{10-13} alkanes	N/A	Unspecified	Unspecified	Unspecified
Alkanes, C_{10-12}, chloro	108171-26-2	N/A	No	Chlorinated paraffins (C_{12}, 60% chlorine)	N/A	Unspecified	Unspecified	Unspecified

Table 1 - Chemical identity of SCCPs (Cont.)

Chemical Name	CAS Number	EINECS Number	AICS Listed	Other Names	Trade Names	Molecular Formula	Structural Formula	Molecular Weight
Paraffin waxes and hydrocarbon waxes, chlorinated	63449-39-8	264-150-0	Yes	Chlorinated paraffin Chlorinated paraffin waxes Chlorinated wax Paraffin waxes, chlorinated Hydrocarbon waxes, chlorinated Paraffin waxes, chloro- Chloroparaffin waxes	A70(wax) Adekacizer E 410 ADK Cizer E 450 Aquamix 108 Arubren CP Cereclor Cereclor 48 Cereclor 51L Chlorcosane Chlorez 700HMP Chlorez 760 Chloroflo 35 Chlorowax Chlorowax 170 CP 52 (wax) CPW 7 CW 35 Diablo 700X Enpara L 50 Paroil 140 Paroil 150 HVH Paroil 170HV Plastichlor Toyoparax 40 Unichlor	Unspecified	Unspecified	Unspecified

N/A, not available.

5. Physical and Chemical Properties

5.1 Physical and chemical properties

SCCPs with 10 to 13 carbon atoms are liquids with a faint, sweetish characteristic odour.

The available data relate to commercial SCCPs which are complex mixtures. SCCPs do not have well-defined melting or boiling points, but these are expected to be higher for those materials containing more chlorine, as evidenced by the pour point data in Table 2. Pour point is the lowest temperature at which oil or other liquid will pour under given conditions. SCCPs have very low water-solubility but are readily soluble in organic solvents.

Table 2 - Physical properties of SCCPs (Sweet, 1993)

Property	**Percentage Chlorine in Material (%)**			
	50	**56**	**63**	**70**
Vapour pressure at 20^{o}C (Pa)	0.16	N/A	N/A	N/A
Specific Gravity at 20^{o}C (H_2O = 1)	1.19	1.3	N/A	1.51 (50^{o})
Pour point (^{o}C)	-30	-10	N/A	20
Flash Point (^{o}C) (closed cup)	166	202	N/A	>200
Solubility in water (g/L at 20^{o}C)	negligible	negligible	negligible	negligible

N/A, not available.

Little information is available on chemical and physical properties of individual components of these mixtures. Most is known about the tetrachlorodecanes, $C_{10}H_{18}Cl_4$ (50% chlorine).

Gas chromatography permitted the separation of a commercial mixture (C_{10-13}, 50% chlorine) into nine components, each comprised of mixtures of unstated numbers of congeners. The coefficient of partition between octanol and water, K_{ow}, is usually expressed in logarithmic form so as to avoid the use of exponents. The log K_{ow} value is often taken as a guide to biomagnification (indicated for substances with log K_{ow} > 3.8) and bioaccumulation (when log K_{ow} is > 4.5). The log K_{ow} values for these components were measured (Table 3) and showed that they increase monotonically with the number of heavy atoms, i.e. carbon plus chlorine (Sijm and Sinnige, 1995).

Table 3 - The log K_{ow} values for components of C_{10-13}, 50% chlorine

Congener Group	Heavy Atoms	Molecular Formula	Log K_{ow}
1	13	$C_{10}H_{19}Cl_3$	5.85
2	14 15	$C_{10}H_{18}Cl_4$ $C_{11}H_{20}Cl_4$	5.93
3	15 16	$C_{10}H_{17}Cl_5$ $C_{11}H_{19}Cl_5$	6.04
4	15 16	$C_{10}H_{17}Cl_5$ $C_{11}H_{19}Cl_5$	6.20
5	16 17 18	$C_{11}H_{19}Cl_5$ $C_{11}H_{18}Cl_6$ $C_{12}H_{20}Cl_6$	6.40
6	18 18	$C_{12}H_{20}Cl_6$ $C_{13}H_{23}Cl_5$	6.61
7	18 19	$C_{12}H_{20}Cl_6$ $C_{13}H_{22}Cl_6$	6.77
8	19 19 20	$C_{12}H_{19}Cl_7$ $C_{13}H_{22}Cl_6$ $C_{12}H_{18}Cl_8$	7.00
9	20	$C_{13}H_{21}Cl_7$	7.14

5.2 Thermal degradation

SCCPs are easily degraded thermally, either through prolonged heating at temperatures as low as 70°C or shorter periods at 200°C. The major mode of thermal decomposition is the elimination of hydrochloride (HCl) to form unsaturated materials which are themselves polymerised and/or further degraded. Analogies may be drawn with the thermal degradation of polyvinyl chloride, in which HCl elimination is the first step.

Combustion of chlorinated materials in waste-disposal incinerators gives rise to small but environmentally significant quantities of polychlorodibenzo-dioxins and -furans. No literature makes a direct link between these substances and the chloroparaffins. The Australian inventory '*Sources of Dioxins and Furans in Australia: Air Emissions'* (EA, 1998) did not quantify the production of dioxins and furans from such sources.

6. Manufacture, Importation and Uses

6.1 Manufacture and importation

SCCPs are not manufactured in Australia. Over the two-year period March 1998 to March 2000, approximately 360 tonnes of the materials were imported from Britain and the United States. Importation at this rate is expected to continue in the foreseeable future. In addition, approximately 10 tonnes of SCCPs were imported in the form of mixtures which are adhesives and sealants used in building industry. The concentration of SCCPs in the mixtures is about 15%. Articles such as painted products, rubber articles and finished footwear imported into Australia may contain SCCPs.

6.2 Uses and exports

After entering Australia, SCCPs are passed along a chain of distribution consisting of importers ⇒ formulators ⇒ users. In some cases a further step in the distribution chain may occur, for example, pigment dispersion products containing SCCPs may be incorporated into paints prior to their end use by the worker (see Section 6.2.2).

6.2.1 Use of SCCPs raw material

Importers of SCCPs act as suppliers to a range of local industries which formulate the chloroparaffins into a range of products. SCCPs raw material are not available to the general public. The industry sectors and percentages of SCCPs used in the formulation of products over the period March 1998 to March 2000 are:

- as lubricants in metal working industry (70%);
- building materials (17%);
- pigment dispersions (6%);
- rubbers (4%);
- leather treatment (1%); and
- miscellaneous (2%).

Data pertaining to most users (>0.5 tonne/year, accounting for 95% of SCCPs used) were analysed to correlate the fields of application of the SCCPs with the proportion of chlorine contained in them. The majority (73%) of the SCCPs used contain 50% chlorine, followed by 12%, 10% and 5% of total SCCPs consumption with 70%, 63%, and 56% degree of chlorination, respectively.

The major use of SCCPs is in the formulation of products used as extreme pressure lubricants, where they find application in metal cutting and metal working such as pressing, drawing and forming. SCCPs are blended with mineral oil, water and stabilizers to produce stable solvent-based emulsions containing approximately 50% SCCPs. Water-based emulsions with 2 to 15% SCCPs formed by mixing with water, mineral oil, antioxidants and dispersants are other types of products used in metal cutting and working fluids. These products are marketed for subsequent dilution and use.

SCCPs are used as flame retardants in products used in building materials such as sealers or fillers and adhesives. Sealers or fillers contain up to 30% SCCPs where these are water-based emulsions, or 50% in the case of solvent-based adhesives. Chlorinated waxes and antimony trioxide are also incorporated into adhesives together with SCCPs. Based on the plasticising ability, small amounts of SCCPs are also used as plasticizers in producing chlorinated rubber coating materials and sealants used in the building industry. The concentration of SCCPs in the final products ranges from 1 to 10%.

SCCPs are also used in dispersion of pigments prior to the incorporation of these substances mainly into polyurethane foams and to a lesser extent into other polymer formulations such as industrial paints. Pigments which may be hard to disperse into the final polymer are first blended with SCCPs, together with other additives such as fillers and surfactants, to form pastes or viscous liquids, depending on customer requirements. Formulated products are dilute dispersions of various types of pigment - diazo, azo condensation, phthalocyanine, copper phthalocyanine, or carbon black - in the C_{10-13} chlorinated paraffin. The concentration of SCCPs in the products ranges from 80 to 90%. These dispersions are marketed for addition to the ultimate products by end users.

Flame retardancy is the major reason for their use in rubbers. SCCPs are blended at moderate temperatures with other flame retardants such as hydrated alumina and antimony oxide into rubbers which are used to make drive and conveyor belting and other flexible materials for use in a wide range of industries. These rubber products typically contain 5 to 15 % of SCCPs for use by end users.

A traditional use of SCCPs in formulation of leather treatment products consumes only a small proportion of the chemicals imported and its use in this industry is declining. For this application, SCCPs are blended with animal fats, vegetable and mineral oils and surfactants. The final products contain 15 to 40% SCCPs and sell to footwear manufacturers.

In addition to the use of SCCPs in formulation of products, a very small amount of pure SCCPs is used by footwear manufacturers to flush pipes used to transfer polyurethane resin components.

6.2.2 Use of SCCP products

Both imported and formulated SCCP products are used in a number of applications which are described below. Some of the products containing SCCPs may be sold to the general public.

Extreme pressure lubricants are marketed in the form of either solvent-based or water-based emulsions. They are diluted with water by end users for use in metal cutting and working applications, for example with lathes and milling machines. The final products contain 5 to 10% SCCPs.

Building materials such as insulating foils, in which several layers may be glued together by SCCP-containing adhesives are commonly incorporated into domestic, commercial and industrial buildings. Other applications such as pipe lagging are used in the industrial sphere, where loss of heat or ingress of heat needs to be prevented. The formulated product containing SCCPs are used directly without dilution or further processing.

Pigment dispersions containing 80 to 90% SCCPs are incorporated into products such as paints, plastic or foam materials by users to produce ultimate end products. The concentration of SCCPs in these final products is about 5%. They are used in a number of applications by end users such as painters and plastic product manufacturers.

Rubber belting or items such as scrapers or flaps containing SCCPs find end use in industrial situations where flame retardancy is required by regulation. The most extreme case is that of equipment used in underground mines, which is required to meet anti-friction standards as well.

Leather goods treated with products containing SCCPs are typically shoes or accessories. They are purchased by members of the public and have lifetimes of several years during which they would be used intermittently. The formulated products containing 15 to 40% SCCPs are diluted with water to make final products containing 2 to 5% SCCPs which are applied at the tannery to finished product (shoes) or sheets of leather ‘to impart a waxy feel’.

6.2.3 Exports

Approximately six tonnes of formulated SCCP products were exported overseas over a two-year period from March 1998 to March 2000. This rate is expected to continue in future. Information on types of products exported was unavailable.

7. Potential for Exposure

7.1 Environmental exposure

7.1.1 Environmental release

SCCPs have the greatest potential for environmental release of the chlorinated paraffins, and also exhibit the highest toxicity of polychlorinated n-alkanes (PCAs). Their release into the environment could occur during production, storage, transportation, industrial use of manufactured products, release from plastics, paints and sealants in which they are incorporated, and leaching, runoff or volatilisation from landfills, sewage sludge or other waste disposal sites. However, the major sources are thought to be from production and industrial usage (Tomy et al, 1999).

As discussed in Section 6, around 70% of SCCPs used in Australia are in extreme pressure lubricants where they find application in fluids used in cutting and metal working. The majority of the chemical is expected to be disposed of bound to sludge sent to landfill. For release during reformulation, the OECD SIDS report (1999) provides release to waste water of 0.25% which was derived from information on the discharge consents for oil for blending sites in the UK. Applying this figure to Australian use, in the order of 300 kg per annum may be released to waste water. During end use, between 4 to 6% may be expected to be released to waste water based on UK company data. This means up to 7.74 tonnes per annum may be released to waste water during end use per annum. Therefore, with formulation and end use, over 8 tonnes annually may be released to waste water. While this may be the case in the UK, it is possible that smaller local operators without adequate disposal facilities or on site waste water treatment plants may release much higher quantities to sewer. As a worst case, up to 50% of spent fluids will be assumed to be released in this manner. A much higher release to sewer will result in higher exposure to receiving waters, and further information on this is required.

Where used in building materials, rubber products and leather products, disposal is also expected to be mainly to landfill in a diffuse pattern around the country. There may be some scope for release to sewer where the SCCPs are used as pigment dispersants in industrial paints. However, this is expected to be minimal given that most of these paints are likely to be used in industrial complexes with waste capturing technology such as scrubbers. While it is uncertain if any of this paint is used by members of the public, the amount is expected to be very small.

The following discussion on environmental fate largely centres around the OECD SIDS risk assessment on these compounds. This document is comprehensively written using available test and literature reports, and for the purposes of this preliminary assessment may confidently be used as the primary source document. Some other literature reports have been consulted and these are referenced separately.

The use of SCCPs in Australia has been estimated at around 180 tonnes per annum, and is expected to continue to be used around this level. This is insignificant compared to world use, and the production in the EU alone is estimated to be around 15,000 tonnes per annum (OECD, 1999).

The potential environmental distribution of SCCPs was estimated in the environment using fugacity modelling (OECD, 1999). The model used was a four compartment model which has been circulated for use within the OECD HPV program.

The following chemical specific information was used as input data:

Melting point - -30°C
Molecular weight - 377 g/mole (for $C_{12}H_{20}Cl_6$)
Vapour pressure - 0.0213 Pa (at 40°C)
Water solubility - 0.47 g/m^3
Log K_{ow} - 6.0
Half-life in air - 173 hours (7.2 days)
Half-life in soil - 1×10^{11} hours (not degraded)
Half-life in water - 1×10^{11} hours (not degraded)
Half-life in sediment - 1×10^{11} hours (not degraded)
Amount of chemical - 1,000 kg/hour (nominal value)

SCCPs are complex mixtures and individual components of the mixture may have different physico-chemical properties than used here and so may be expected to distribute slightly differently in the environment. However, the following outcomes may be taken as a guide.

Table 4 - Results of fugacity modelling

Compartment	Release: 100% to air	Release: 100% to water	Release: 100% to soil
Air	0.11%	0.05%	<0.001%
Water	0.02%	1.16%	0.005%
Sediment	0.8%	53.5%	0.23%
Soil	99.0%	45.3%	99.8%

As can be seen from the results of the modelling exercise, once released into the environment, SCCPs are expected to distribute mainly onto the soil and sediment phases. The results also show that if the substance is mainly released to air or water, then transfer to the soil (probably by wet or dry deposition or direct adsorption) and sediment (by direct adsorption from water) is likely to occur.

It should also be noted that despite the high absorbability of the substance onto soil and sediment, a small fraction is predicted to distribute into water and air meaning that SCCPs may be slightly mobile in the environment.

7.1.2 Environmental fate

Atmospheric fate

The vapour pressure for a SCCP with 50% chlorine is given in the OECD SIDS report (1999) as 0.021 Pa at 40 °C. This is significantly lower than that in Section 5 of 0.16 at 20 °C. However, it is likely the vapour pressure reported in Section 5 reflects the vapour pressure of the most volatile components of the commercial product and not necessarily of the SCCP. Based on the scale of Mensink (1995), SCCPs may be considered slightly volatile. As a general rule for SCCPs, vapour pressures tend to decrease with increasing carbon chain length and degree of chlorination (Drouillard et al, 1998).

Second order reaction rate constants have been calculated for C_{10-13}, 49 to 71% wt Cl, chlorinated paraffins as $2.2\text{-}8.2 \times 10^{-12}$ 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 to 7.2 days to be estimated.

Aquatic fate

As mentioned above, during use in extreme pressure lubricants, over 8 tonnes per annum may be released to waste water based on UK release data. Significantly more than this may be released from small operators using inappropriate disposal methods (i.e., release of spent lubricants to sewer). Based on the coupled units test described below, at least 93% may be expected to be removed during residence time in waste water and sewage treatment plants. Therefore, 560 kg per annum could be released to receiving waters, although this figure may be much higher. More information is needed on the likely exposure from release of extreme pressure lubricants.

SCCPs are practically insoluble in water. IUCLID presents data for solubility after exposure to water for 6 months, which was estimated to be 0.15 to 0.47 mg/L (for a chlorine content of 59%). However, SCCPs may be susceptible to partial hydrolysis, and these results may have been affected by this.

The following log K_{ow} values are provided in the OECD SIDS report (1999). The general trend appears to be for increasing partitioning to lipids with increasing degree of chlorination.

% Chlorine	Log K_{ow}
49	4.39 - 6.93
60	4.48 - 7.38 5.85 - 7.14[a]
63	5.47 - 7.30
70	5.68 - 8.69
71	5.37 - 8.01

Values were measured by a high performance thin layer chromatography method except [a] which was measured by a slow stirring method. The values indicate that even for the lower levels of chlorination, when released to water, SCCPs would partition to the organic component of sediments, or be absorbed into the lipids of aquatic organisms.

Volatilisation from water may be predicted by considering the Henry’s Law Constant for these compounds. The OECD SIDS report provides one calculated Henry’s Law Constant of 17.1 Pa.m^3/mole. Henry’s law constants for SCCPs show a tendency of decreasing with increasing degree of chlorination (Drouillard et al, 1998).

According to the scale of Mensink (1995), chemicals considered moderately volatile from water have a Henry’s Law Constant ranging from 0.025 to 74.3 Pa.m^3/mole. Therefore, based on this calculated value, SCCPs may be regarded as moderately volatile from water.

This suggests that where release occurs to water and the compounds do not fully partition to sediments or biota, the SCCPs may volatilise to the atmosphere and thereby be available for atmospheric transport (see Table 4).

Biodegradation is considered further below.

Terrestrial fate

The vast majority of SCCP will be expected to be disposed of to landfill over the lifetime of products containing these compounds, or in sludge after the end of their useful lives in extreme pressure lubricants.

The organic carbon adsorption coefficient (K_{oc}) can be calculated from the formula provided in the European Commission Technical Guidance Document (1996): log K_{oc} = 0.81 X log K_{ow} + 0.1. Using this and a log K_{ow} range of 4.39 to 8.01, the log K_{oc} may be predicted to range from 4.56 to 7.49.

Chemicals with log K_{oc} values greater than 3.6 are considered to be immobile (McCall et al, 1980). Therefore, where released to soils, SCCPs may generally be considered to bind strongly and be immobile. Leaching is unlikely to occur. Based on the log K_{ow} values provided above, sorption tendencies are likely to increase as the level of chlorination increases. This indicates that mobility, albeit very limited, is likely to be greater with lower levels of chlorination.

Degradation

Under aerobic conditions, micro-organisms previously acclimated to specific chlorinated paraffins have demonstrated a greater ability to degrade the compounds than non-acclimated micro-organisms.

The biodegradability of a C_{10-12}, 58% wt Cl, chlorinated paraffin has been tested in the OECD Guideline 301C, Modified MITI I Test. 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. However, it should be noted that the concentrations tested (20 and 100 mg/L) were 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 at concentrations of

50 mg C/L (≡137.4 mg/L) and 25 mg C/L (≡68.7 mg/L). Degradation was followed by monitoring CO_2 evolution over 28 days at 22 °C and comparing this to the theoretical amount of CO_2 that would be evolved, assuming complete biodegradation. The degradation seen during the 28-day period was 7.4% and 16% at the lowest and highest 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 chlorinated paraffin was not toxic to the micro-organisms present.

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 14C-labelled chlorinated n-undecane (59.1% wt Cl) and this was continuously added to the units as an emulsion. 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 shown to be not toxic at the concentration used. The mean concentration 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 and it was thought that the chlorinated paraffin found in the effluent was associated with the suspended matter.

The biodegradation of C_{12}, 63% wt Cl chlorinated paraffin was studied using a variety of microbial cultures. The degradation of the chlorinated paraffin was studied using resting cell cultures of *Pseudomonas aeruginosa*, *Achromobacter delmarvae*, *A. cycloclastes*, *Micrococcus* sp. and *Corynebacterium hydrocarboclastus*. Little or no dechlorination of the C_{12}, 63% wt chlorinated paraffin was seen using these bacteria although they had been shown to dechlorinate 1-chlorohexadecane as well as some other mono- and dichlorinated alkanes. Dechlorination of the chlorinated paraffin was shown to occur using bacterial strains isolated from soil. In these experiments, the isolated bacteria were incubated 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 showing that dechlorination of SCCPs may occur in a co-metabolic process.

It can be concluded from the biodegradation results that SCCPs with low chlorine contents (e.g. <50% wt Cl) may biodegrade slowly in the environment, particularly in the presence of adapted micro-organisms. Certain bacteria have also been shown to dechlorinate SCCPs with high chlorine contents in a co-metabolic process and so under certain conditions, biodegradation of these compounds might also be expected to occur slowly in the environment.

No information on the anaerobic biodegradation of SCCPs is available.

Bioaccumulation

SCCPs have been shown to bioconcentrate to a large extent in fish and molluscs. The following results have all been obtained from the OECD SIDS report (1999) unless specifically referenced.

Rainbow trout (*Oncorhynchus mykiss*) exposed to measured concentrations of 0.033, 0.1, 1.07 and 3.05 mg/L of a C_{10-12}, 58% wt Cl for 60 days returned whole body bioconcentration factors (BCFs) of 1,173 to 7,816 based on radioactivity measurements in the fish and BCFs of 574 to 7,273 were determined based on the parent compound analysis. The BCFs were found to increase with decreasing exposure concentration which may be explained by the fact that two of the exposure concentrations are above the solubility for chlorinated paraffins.

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 using a flow-through system. Lower bioconcentration factors were observed in the flesh (BCF=1,300 to 1,600) as compared to liver (2,800 to 16,000) and viscera (11,700 to 15,500) and the whole fish BCF was estimated to be 3,600 to 5,300. During depuration (168 days), the following half-lives were determined for the chlorinated paraffin: liver 9.9 to 11.6 days; viscera 23.1 to 23.9 days; flesh 16.5 to 17.3 days; and whole body 18.7 to 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 to 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.

The uptake and accumulation of several SCCPs by bleak (*Alburnus alburnus*) was studied. Exposure was 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 under semi-static conditions (renewed every 2nd or 3rd day). Depuration of the SCCPs was studied for an additional 7 days. All three SCCPs were taken up by the fish but uptake was greatest for the lower chlorinated grades (whole body BCFs of around 800 to 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 which is expected given the half lives measured above for depuration.

The uptake and accumulation of SCCPs by bleak (*Alburnus alburnus*) has also been studied via food. The fish were exposed for 91 days to either a C_{10-13}, 49% wt Cl chlorinated paraffin at 590, 2,500 and 5,800 μg/g food or a C_{10-13}, 71% wt Cl chlorinated paraffin at 3,180 μg/g food. Analysis of whole fish bodies was carried out during the exposure period and also during a 316 day depuration period. The 49% wt Cl compound was found to be readily accumulated during the first 56 days of exposure and a direct correlation was found between the amount of chlorinated paraffin in food and the amount in fish tissues. During the next two weeks of exposure, fish in the two lower exposure groups showed a steep increase in the chlorinated paraffin tissue concentration, while tissue levels in the high dose group remained constant (possibly the result of experimental variation). It was estimated that at 91 days, around 45% of the 590 μg/g food dose, 10% of the 2,500 μg/g food dose and 5% of the 5,800 μg/g food dose had been accumulated by the fish, indicating that uptake becomes less efficient and/or metabolism more effective with increasing concentration. Elimination of this compound from fish tissues was found to be rapid. In the case of the 71% wt Cl compound, uptake by the fish was found to be similar to the 2,500 μg/g food dose of the 49% wt Cl compound, with around 6% of the total dose being accumulated. However, the tissue concentration of the 71% wt Cl compound was found to remain fairly constant throughout the 316 day depuration period, indicating very slow elimination.

A similar experiment with fingerling rainbow trout (*Oncorhynchus mykiss*) fed a diet containing 10 mg/kg food of a C_{12}, 60% chlorinated paraffin for 82 days is available. The amount of food given was maintained at 4% of the fish body weight during the study. The concentration of chlorinated paraffin in the fish was found to increase during the study, reaching a level of 1.1 mg/kg tissue (18 mg/kg fat) when the study was terminated. It was thought that equilibrium had not been reached by the end of the experiment.

A recent dietary accumulation study with rainbow trout (*Oncorhynchus mykiss*) is reported where the fish were fed chlorinated paraffin (either C_{12}, 56% Cl or C_{12}, 69% Cl) spiked onto food. A 40 day exposure period was followed by a 160 day depuration period. The daily feeding rate was 1.5% of the mean body weight and two exposure concentrations for each substance were used (26 and 242 ng/g food for the 56% Cl compound and 21 and 222 ng/g food for the 69% Cl compound). At these feeding rates, neither compound was found to have any negative effect on the growth of juvenile rainbow trout. Accumulation was observed for both compounds but steady state was not reached after the 40 day exposure period. Biomagnification factors of 0.60 to 0.93 for the 56% Cl compound and 1.76 to 2.15 for the 69% Cl compound were determined based on the rates of uptake and depuration. The assimilation efficiencies were 20.7 to 25.3% for the 56% Cl compound and 34.1 to 37.6% for the 69% compound.

Very high BCFs have been determined for a C_{10-12}, 58% wt Cl chlorinated paraffin in common mussels (*Mytilus edulis*). 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. Depuration rates were similar for all tissues, with half-lives for the whole mussel being calculated as 9.2 to 9.9 days for the high exposure group and 13.1 to 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. Similarly high BCFs (5,785 to 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 to 0.93 mg/L.

Summary of environmental fate

Where SCCPs are incorporated into extreme pressure lubricants, the main release may be expected to be to landfill bound to sludge with some release to waste water.

Release to the environment will be slow and diffuse over the life of products containing SCCPs such as building materials, paints and rubber and leather products. However, use is widespread and varied and significant quantities of SCCPs are used in Australia giving potential exposure to the wider environment.

Where released to the environment, the compounds are expected to be stable, both microbially and abiotically although partial hydrolysis may be observed. However, SCCPs with low chlorine contents (e.g. <50% wt Cl) may biodegrade slowly in the environment, particularly in the presence of adapted micro-organisms. Certain bacteria have also been shown to dechlorinate SCCPs with high chlorine contents in a co-metabolic process and so under certain conditions, biodegradation of these compounds might also be expected to occur slowly in the environment.

When released to land, they should bind strongly to the organic component of soils and be immobile. In the event of release to water, movement from the water column is likely to be rapid with the compounds partitioning to sediments and biota. Otherwise, they may volatilise to the atmosphere where they are expected to bind strongly to atmospheric particles, and potentially undergo long-range atmospheric transport further increasing environmental exposure.

Reported log K_{ow} values indicate a high potential for bioaccumulation. High bioconcentration factors (ranging from 1,000 to 50,000 for whole body, with high values for individual tissues) have been reported with a variety of freshwater and marine organisms. Chlorinated paraffins were taken up rapidly; uptake may be slower at the higher end of the chlorination range.

Most studies report moderate loss of bioaccumulated chlorinated paraffins on return to ‘clean’ water. Depuration half-lives have been reported at between 9 and 20 days. A single study suggests that 71% chlorinated compounds may be retained longer. It has been suggested that more rapid depuration from the liver, as compared to whole body, is indicative of metabolism and excretion.

No data have been found on levels of SCCPs in the Australian environment including in biota. These compounds are known to occur in marine mammals as determined from measurements conducted in the Arctic and the St. Lawrence River Estuary in Canada. SCCPs were detected in blubber of beluga whales at levels up to 0.23 mg/kg in the Arctic, and at higher levels up to 0.53 mg/kg in the St. Lawrence River Estuary (Tomy et al, 2000).

7.2 Occupational exposure

The intention of this preliminary report is to evaluate the available information on occupational use profiles, obtained from suppliers and users of SCCPs and from site visits, in order to assess potential exposure from use of these chemicals in Australia. No exposure data was requested/sourced by NICNAS or made available for assessment by applicants. It is unlikely any Australian data exists, as there is no occupational exposure standard.

Occupational exposure to SCCPs is discussed for each major activity with likely workplace exposure, namely:

- Importation;
- Formulation; and
- Use of products containing SCCPs.

7.2.1 Routes of exposure

Occupational exposure to SCCPs in Australia may result from direct use of SCCPs either in end-use processes or during formulation of SCCP products. Exposure to SCCPs may also occur during use of products containing SCCPs. Other potential sources of exposure are during transport and storage and during disposal of the contaminated containers.

In the assessment of occupational exposure to chemicals, it is generally necessary to evaluate intake from all potential routes of exposure i.e. ingestion, inhalation and dermal exposure. For SCCPs, ingestion is unlikely during occupational use except at workplaces with poor workplace practice and hygiene. Inhalation and dermal contacts are the more likely routes of exposure to SCCPs in an occupational setting. However, SCCPs have very low vapour pressure and the volatility of the chemicals is low, making inhalation an unlikely route. SCCPs are also absorbed poorly through the skin (see Section 8.1). An evaluation of information on use profiles indicates that for Australian occupational exposure scenarios, dermal contact is likely to be the major route of exposure.

7.2.2 Importation

SCCPs are imported in 200 L sealed steel drums and stored in a cool, well-ventilated, low fire-risk area away from sources of heat or ignition. The drums are not repacked in Australia and are transported by road, unopened, to formulators of products and end users of the raw material. Exposure during importation, transportation and storage of drums is unlikely except in cases of accidental spills or leaks of the chemicals.

7.2.3 Formulation

In Australia, pure SCCPs are used mainly in formulating a range of products including lubricants, building materials, pigment dispersions, rubbers and for leather treatment. No information was available on the number of workers handling SCCPs during formulation.

Although SCCPs are used to formulate a number of different products in various industries the formulation procedure is similar. Formulation is a batch process, in which measured amounts of SCCPs and other components are added to mixing vessels and blended to form products which are transferred to containers and then dispatched to customers. Batch sizes and intervals vary from site to site.

In general, the larger users, accounting for almost half of the imported material, transfer SCCPs using drum lifters so exposure of operators is minimal. The batch operation is conducted under closed conditions for several hours and the product is pumped into large drums for shipping to customers. Smaller users, who account for the other half of the total quantity used, decant SCCPs through taps or use spear pumps to transfer either directly into mixing equipment or into transfer vessels. The subsequent mixing operations are conduced in open systems with vapours and particulate matter sequestered by a vapour collection system. Operators are not in attendance for much of the mixing time but rely on periodic inspection. Batches are processed in this way for up to 8 h, after which the material is transferred in closed systems to containers for shipping.

During formulation of metal cutting and working fluids, each component is pumped into a tared vessel so that quantity is closely controlled. During processing of the batch, it is circulated by the same pump through each of the component vessels, thus effectively removing any residual quantities. The temperature in the mixing tank is kept at 45°C.

In the formulation of building material products the transfer process varies depending on the size of batches. In the production of large batches, SCCPs are pumped from drums directly into mixing equipment, whereas for small batches they are first weighed or measured into 10 L buckets and then manually poured into mixing vessels. The 10 L buckets are used repeatedly and there is a negligible proportion of waste material when these come to the end of their lifetime and are discarded. At the end of the mixing the stirrer is withdrawn and the adhering product is scraped into the mixture. A plunger is then used to pump it into final containers.

Formulation of pigment dispersion products is an open process. The SCCPs and pigment are manually poured into a mixing vessel by an operator wearing gloves and dust mask. The vessel is connected to an exhaust system to mainly extract pigment dust. After initial mixing, the contents of the vessel are circulated through a mill for approximately 8 h to complete the dispersal process. During this time the holding vessel is open to the air.

Components of the rubber product formulation are mixed at approximately 160°C. Operators wear protective clothing and fumes from mixing vessels are removed to vents. The mixed formulation is cooled to approximately 100°C and reworked with addition of accelerants and curing (vulcanising) agents. It is then moulded or extruded to form belts, hose covers, sheets or other products in an open system.

Leather treatment products are formulated by manual addition of the components to mixers where they are blended for several hours.

During formulation and fabrication, small quantities of SCCPs may be emitted to the environment in the form of liquids or solids, but loss as vapour is unlikely given the low volatility of these substances. The disposal of liquid SCCPs, as emulsions or mixtures derived from ‘washing down’ or cleaning of the mixing equipment, may occur as an adjunct to some processes (no more than 1% of total material used would be disposed of in this way), but where the formulation product is an aqueous emulsion or dispersion it is common to incorporate washings into the batch (or a subsequent batch) of the product and so avoid waste altogether.

Approximately 1% of the SCCPs imported are disposed of as residues in ‘empty’ drums. A small proportion of drums to be reconditioned are baked in an oven, with vapours passing to an afterburner. In the majority of cases the drums are washed with caustic solutions and then rinsed clean. Spent liquors pass to a treatment plant where organic liquids are recovered for use as alternative fuels, while aqueous liquids are discharged to sewer as trade waste. Prior to discharge the aqueous fractions are treated with flocculants to remove remaining organic material. Sludges arising from this operation, either stabilised or unstabilised, are transferred to prescribed waste landfills.

In summary, during manufacture of products containing SCCPs, operators are likely to be exposed by skin contact during manual charging of mixing vessels, mixing and inspection, filling of product containers and cleaning. There is also a potential for inhalation exposure when high temperatures are involved such as during production of rubber products. However, since formulation is a batch process, exposure will only occur on the days when SCCP based products are formulated. The potential exposure of workers during formulation is likely to be higher at worksites with an open mixing process.

The formulation process described in the OECD report (OECD, 1999) is similar to that described above.

7.2.4 Use of products containing SCCPs

In Australia, SCCP products are used for metal working, building materials, pigment dispersions, rubbers and leather treatment. Information on the number of workers directly handling SCCP products during use is unavailable. In general, workers handle SCCP products 8 h a day, 5 days a week. Use process and potential exposure during use of products containing SCCPs are discussed below.

Metal working fluids

During metal cutting, cutting tools are lubricated by a continuous supply of cutting fluids containing SCCPs. This working fluid is prepared by end users by adding 5 to 10% of the formulated SCCP product to water in a manual operation. Mixing is achieved by a pumped circulating system in use with cutting machinery. The cutting machine has a sump and a circulating pump which provides a continuous flow of fluid to the cutting edge. Splashes and mists/aerosols can be generated during cutting. In addition, at workplaces where splash guards are not effective or where machine operations are required to wipe down the parts during the machining process there is potential for dermal and inhalational exposure.

The fluid may remain in use for up to three years, after which some operators may choose to break the emulsion and dispose of the oil (containing SCCPs) and water components separately, whereas others simply employ the services of a waste disposal company to remove the unwanted fluids.

In metal forming, drawing and pressing, the liquid is brushed or wiped manually onto the metal, which is usually cold but, in some instances, may be heated.

Information from industry indicates that metal cutting and working fluids are used in various ways, but almost always without the user wearing protective clothing or coming into prolonged contact with the fluids.

Therefore, there is potential for dermal and inhalational exposure to operators during dilution and use of metal working fluid containing SCCPs.

Building materials

There are a number of SCCP products used in building materials. They include sealers or fillers, adhesives and chlorinated rubber coating materials. The concentration of SCCPs in these final products varies and is discussed in Section 6.2.1.

The sealants are usually applied by hand or by means of a package extruder, with clean-up by wiping or trimming with a knife. Protective clothing is not worn during these operations. Scraps (typically 1 to 5%) are disposed of in conventional garbage. The sealant may expect to remain in place for 5 to 10 years.

Some sealants are marketed as two-component products which are mixed manually and used on site. The mixture hardens within one hour to a stiff, rubbery consistency from which egress of SCCPs would be extremely slow. This applies to waste material, which is essentially solid and is disposed of to landfill along with other building waste.

Adhesives and coating products containing SCCPs are usually applied by spray, therefore inhalation as well as skin exposure may occur.

Pigment dispersion

Pigment dispersions containing 80 to 90% SCCPs are further incorporated into different products, such as paints, plastic or foam materials by users to produce ultimate end products. The mixing process is in a closed system, together with resins, solvents and other agents. The concentration of SCCPs in these final products is about 5%. They are used in a number of applications by end users such as painters and plastic product manufacturers. Painters apply SCCP products either manually or by spray. Again inhalation and skin exposure may occur.

Rubber products

Rubber products containing SCCPs include rubber belting or items such as scrapers or flaps. The rubber material will be abraded slowly during its working life, but the SCCPs are likely to remain in the matrix. Exposure to SCCPs during use of the rubber products is minimal.

Leather treatment

Leather treatment products containing 15 to 40% SCCPs are diluted with water before being applied to leather articles. The final products containing 2 to 5% SCCPs are either applied manually to finished leather articles such as shoes or with sprays or rollers to sheets of leather at the tannery. However, leather treatment products consume only a small proportion of the chemicals imported and its use in this industry is declining.

In summary, potential exposure by dermal contact is possible where open mixing process or dilution and manual handling of SCCP products occur, for example, during use of metal working fluids, manual application of sealants, paints and leather treatment products. Inhalation exposure is also likely during use of SCCP products where mists/aerosols may be generated such as the spraying of paints, adhesives, coating and leather treatment products onto the leather sheets and in the use of metal working fluids.

The use pattern described in the OECD report (OECD, 1999) is similar to that described above.

7.3 Public exposure

Although some of the products containing SCCPs may be sold to the general public, a majority appear to be used in industrial applications (Section 6.2.1 and 6.2.2). Amongst those types of products that are likely to be sold to the general public, sealers and fillers used in construction applications may contain up to 50% SCCPs and leather finishing products may contain 2 to 5% SCCPs. The concentration of SCCPs in products in which it is used as a pigment disperser is expected to be low.

Dermal contact with products containing SCCPS such as adhesives, sealers, paint products, plastic articles and leather goods is likely to occur in the proportion of the general public who use these products. Accidental ocular contact with products such as adhesives, sealers and paints may also occur. Exposures via these routes are likely to be infrequent and of short duration. Given the nature of the products and the physico-chemical properties of SCCPs, SCCPs are likely to remain contained within the matrices of these products after curing.

SCCPs have octanol/water partition coefficients ranging from 5.85 to 7.14, indicating that they have the potential to bioaccumulate. Estimated bioconcentration factors for mussels and fish show that SCCPs have a greater potential for bioaccumulation than longer chain chlorinated paraffins. There are no data specifically on the amounts of SCCPs in food. However, short to medium chain chlorinated paraffins (C_{10-20}) have been found in mussels and fish at mean concentrations up to 3250 μg/kg and in vegetable oils and dairy products at concentrations of 150 and 300 μg/kg respectively (IPCS, 1996). Therefore exposure to SCCPs via contaminated food may also occur.

Short to medium chain (C_{10-20}) chlorinated paraffins were found in 24 samples of human adipose tissue at concentrations up to 600 μg/kg, in kidney at concentrations up to 500 μg/kg and in liver at concentrations up to 1500 μg/kg. Short to medium chain (C_{10-20}) chlorinated paraffins were also found on human hands at amounts between 0.8 and 4.0 μg/pair of hands (IPCS, 1996). These results suggest that human exposure to SCCPs is likely to occur.

The Environmental Health Criteria 181 for chlorinated paraffins prepared by IPCS (IPCS, 1996) calculated a Tolerable Daily Intake (TDI) (based on neoplastic effects) of 11 μg/kg bw/day for short to medium chain (C_{10-20}) chlorinated paraffins. This calculation used multistage tumour modelling to estimate 11 mg/kg bw/day as the dose associated with a 5% increase in tumours (combined hepatic carcinoma and adenoma in male mice) and a safety factor of 1000 to account for the non-genotoxic mode of carcinogenesis. A TDI of 100 μg/kg bw/day based on non-neoplastic effects (increased liver and kidney weights and hepatic and thyroid hypertrophy) was also calculated in IPCS report using the lowest reported no observed effect level (NOEL) (10 mg/kg bw/day in a 13-week rat study) and a safety factor of 100.

Although some products containing SCCPs may be sold to the general public, widespread, repeated public exposure as a result of using these products is unlikely. Given the potential for SCCPs to bioaccumulate, exposure of the general public via contaminated food is also a possibility. However, there is no specific data available on the contamination of food by SCCPs and very limited data is available on the contamination of food by short to medium chain chlorinated paraffins. The available data suggests that contamination may occur and humans may be exposed to contaminated food. Based on the available data, the IPCS report (IPCS, 1996) gives worst-case estimates for consumption of short to medium chain chlorinated paraffins (C_{10-20}) in contaminated food. Assuming a daily consumption of 1 kg per day for a 70 kg adult, intake of short to medium chain chlorinated paraffins (C_{10-20}) from dairy products was estimated to be 4.3 μg/kg bw/day. Intake from mussels was estimated to be 6.7 μg/kg bw/day, based on a weekly consumption of 1 kg.

These estimates are likely to be conservative and are based on very limited data that was not collected in Australia. Given the lack of data, an estimate of total dietary exposure to SCCPs in Australia cannot be made. However, given the expected relatively small quantities of SCCPs released to the Australian environment, it is unlikely that there will be high levels of consumption of SCCPs by the general population.

8. Health Effects

This section is a brief summary of the health effects of SCCPs based on international assessments and reviews. It serves as supporting information for the conclusions and recommendations that follow. This summary is based on the OECD SIDS report prepared by the UK HSE and agreed by OECD countries including Australia (OECD, 1999) and Environmental Health Criteria 181 for chlorinated paraffins prepared by IPCS (IPCS, 1996). A literature search undertaken for articles published post 1997 revealed no further published toxicological studies or review articles.

8.1 Toxicokinetics and metabolism

Limited information is available on the toxicokinetics of SCCPs. An in vitro study using human skin showed extremely poor absorption through skin samples. No data on the absorption of SCCPs by inhalation and dermal exposure in animals have been reported. Studies using longer chain chlorinated paraffins (C_{18}) demonstrated very limited dermal absorption. SCCPs are significantly absorbed by oral administration (up to 60%) with absorption decreasing with increasing degree of chlorination.

Distribution of SCCPs in the body occurs mainly in tissues with high cell turnover or high metabolic activity such as intestinal mucosa, bone marrow, brown fat, salivary glands and thymus in mice and in the liver, kidneys, adipose tissue and ovaries in rats following oral administration. Accumulation in tissues increases with increasing degree of chlorine content. SCCPs were also reported in the central nervous system of mice up to 30 days after oral administration.

SCCPs are metabolised by cytochrome P450 oxidation to carbon dioxide (CO_2). No other metabolites have been identified.

SCCPs may be excreted via urine, exhaled air and faeces. The total elimination decreased as the chlorine content increased. Compounds with high degrees of chlorination are mainly excreted as CO_2 (> 50%).

In summary, available data show that the degree of chlorination affects absorption, distribution and excretion of SCCPs.

8.2 Effects on experimental animals

SCCPs are of very low acute toxicity by all routes of administration (oral LD_{50} > 4000 mg/kg, inhalation LC_{50} > 3300 mg/m^3 in rats and dermal LD_{50} approximately 13.5 g/kg in rabbits). Toxic effects such as muscular incoordination and piloerection were evident following oral administration of SCCPs. Microscopic changes noted were blotchy or pale liver and inflamed stomach.

Low level skin irritation was observed with SCCPs, in some studies, following repeated applications in animals. Low level eye irritation was seen in animals after both single and repeated applications.

SCCPs do not induce skin sensitisation. There is no information available on the respiratory sensitising potential of SCCPs.

No repeated dose inhalation studies or well-conducted dermal studies are available in animals. The liver, thyroid and kidneys are the target organs for toxicity of SCCPs in rats and mice following oral administration. Increases in liver weight and activity of hepatic enzymes, proliferation of smooth endoplasmic reticulum and peroxisomes, replicative deoxyribonucleic acid (DNA) synthesis, hypertrophy, hyperplasia and necrosis of the liver have been observed. In thyroid, increases in thyroid weight, hypertrophy and hyperplasia of the thyroid and replicative DNA synthesis in thyroid follicular cells were found in rats and mice. Other toxicological effects after repeated administration of SCCPs include decrease in body weight gain and increase in kidney weight with mild kidney effects including mild nephritis and brown pigmentation in the renal tubules in rats. IPCS report (1996) identified a No observed effect level (NOEL) of 10 mg/kg/day in rats from a 13-week study on the basis that no treatment related microscopic changes were found in any tissue at this dose. A NOEL of 125 mg/kg/day was also identified in a 13-week mice study based on hepatocellular hypertrophy. However, the more recent OECD SIDS report (1999) identified a No Observed Adverse Effect Level (NOAEL) of 100 mg/kg/day in rats from a 90-day study and 1000 mg/kg/day in mice from the same 13-week study as the IPCS report, based on renal effects as the liver and thyroid effects were determined not relevant to humans. The mechanisms underlying these effects are discussed below.

SCCPs do not induce mutations in bacteria both in the absence and presence of S9. A C_{10-13}, 56% chlorinated paraffin tested negative in a gene mutation study in Chinese hamster V79 cells and in a cell transformation assay using BHK21/C13 cells. However, an increase in cell transformation frequency was reported in another assay. SCCPs tested negative in in vivo rat bone marrow cell chromosomal aberration and germ cell studies.

Two-year carcinogenicity studies have been conducted involving administration of SCCPs (C_{12}, 60% chlorinated paraffins) by gavage at doses of 0, 312 and 625 mg/kg/day in rats and 0, 125 and 250 mg/kg/day in mice. In rats, there were significant increases in liver tumours (liver neoplastic nodules and liver carcinomas) in males and females, tumours of the thyroid (follicular cell adenomas and carcinomas) in females and renal tumours (tubular cell adenomas and adenocarcinomas) in males. Significant increases in the incidence of hepatic tumours (hepatocellular carcinomas and adenomas) in both males and females and tumours of the thyroid gland (follicular cell adenomas and carcinomas) in females were observed in mice.

A number of mechanistic studies indicate that SCCPs produce peroxisome proliferation in rats and mice which may be responsible for the liver tumours. Three 14-day mechanistic studies were conducted in guinea pigs after administration of SCCPs by gavage at doses of 0, 500, 1000 mg/kg/day. Peroxisome proliferation was not observed in guinea pigs which are known to be insensitive to these effects. However, no long term studies were conducted in guinea pigs. Peroxisome proliferation is a threshold effect with rodents being most sensitive and humans relatively insensitive.

Mechanistic studies show that the thyroid effects may be caused by stimulation of the thyroid through a negative feed back mechanism. The negative feed back mechanism starts with an increase in activity of uridine diphosphate glucuronosyl (UDPG) -transferase, a liver enzyme. The increased UDPG-transferase activity results in increased excretion of thyroxine (T_4) with decreased plasma T_4 levels. The decrease in plasma T_4 levels stimulates the pituicytes to produce thyroid-stimulating hormone (TSH) which in turn stimulates the thyroid to produce more T_4. The negative feed back mechanism with continuous T_4 excretion, low plasma T_4 levels and stimulation of the thyroid lead to hypertrophy, hyperplasia and thyroid tumours. The mechanism of the increased UDPG-transferase activity is not known. An additional mechanism that has been postulated for the thyroid effects in rodents is the absence of T_4-binding globulin leading to more free T_4 available for metabolism and excretion from the plasma resulting in rodents being highly susceptible to thyroid stimulation. T_4-binding globulin, which has a very high affinity for T_4, is reported in humans with lower levels of free T_4 in plasma. The 2-year study in rodents showed higher incidences of thyroid tumours in mice than in rats and the tumours were found only in females.

Renal tumours (tubular cell adenomas and adenocarcinomas) were reported in male rats. Both tumours were noted in the low dose group with the increase in adenomas reported as statistically significant. Mechanistic studies did not show significant levels of $\alpha 2\mu$ globulin and hyaline droplet nephropathy has not been clearly demonstrated. The available data is insufficient to conclude a male rat specific event. According to the OECD SIDS report, industry is undertaking further research to elucidate the mechanism of renal tumours. However, OECD countries agreed that as SCCPs are not genotoxic, and a NOAEL had been established for overall kidney toxicity (100 mg/kg/day), this would be used as the NOAEL for kidney carcinogenicity on the basis of the data available at the time.

Other neoplastic effects of SCCPs reported were mononuclear cell leukaemia in male and female rats and alveolar/bronchiolar carcinomas in male mice. For mononuclear cell leukaemia, high incidences were noted in all dose groups including controls in females. For alveolar/bronchiolar carcinomas, the historical control incidence for alveolar/bronchiolar carcinomas was high and lung tumours were not observed in female mice.

The International Agency for Research on Cancer reviewed SCCPs (IARC, 1990). IARC classified chlorinated paraffins of average carbon chain length 12 (C_{12}) as possibly carcinogenic to humans, Group 2B (possibly carcinogenic to humans).

The US NTP reviewed a SCCP (CAS No. 108171-26-2). This chemical is listed in the 9th Report on Carcinogens (NTP, 1999) and classified as reasonably anticipated to be a human carcinogen (substances for which there is limited evidence of carcinogenicity in humans and/or sufficient evidence of carcinogenicity in experimental animals).

However, both the IARC and NTP classifications did not consider the mechanistic information which was available in 1990's.

No studies in animals were conducted to specifically investigate the effects of SCCPs on fertility. However, in a repeated dose study, examination of female reproductive organs showed no exposure related effects.

In a rat developmental study, C_{10-13}, 58% chlorinated paraffins caused significant increases in the number of post-implantation losses, adactyly and/or shortened digits in fetuses and a decrease in viable foetuses per dam only at concentrations that caused severe maternal toxicity. No effects on dams or foetuses were observed at 100 mg/kg/day (NOAEL). No developmental effects were noted in a rabbit study.

The information available from acute studies and skin irritation studies indicate that the intensity and nature of effects are independent of chain length and degree of chlorination. However, there are several data gaps with regard to differing chain length and degree of chlorination for other toxicological endpoints.

8.3 Human studies

SCCPs do not cause skin irritation in humans. Available human data indicate that SCCPs are not sensitisers. There is no information available on respiratory sensitising, mutagenic or carcinogenic potential of SCCPs in humans.

8.4 Conclusions

OECD countries agreed on the basis of data available at the time, that overall SCCPs are of low acute toxicity with the principle toxicological issue being for general non-specific toxicity following repeated exposure. NOAELs for general toxicity of 100 and 1000 mg/kg/day were identified in rats and mice respectively.

8.5 Hazard classification

SCCPs are classified as dangerous substances in the EU in accordance with Directive 67/548/EEC. The classification is:

R40	possible risk of irreversible effects (Carcinogen Category 3)
R50/53	very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment

Currently, SCCPs are not listed in the NOHSC *List of Designated Hazardous Substance* (NOHSC, 1999). The EU classification is supported based on data available to NICNAS and should be adopted by NOHSC as soon as possible.

9. Effects on Organisms in the Environment

The OECD SIDS report (1999) includes a comprehensive discussion on the environmental effects of SCCPs. These data have been viewed and validated by the assessing country (UK) and Environment Australia has relied solely on the report for this section.

9.1 Avian toxicity

A good quality avian reproduction study using Mallard ducks has been carried out with a C_{10-12}, 58% Cl chlorinated paraffin (OECD, 1999). The study was carried out to Good Laboratory Practice (GLP) and was based on the Mallard Reproduction Test (August 1982) of the EPA Environmental Effects Test Guidelines (EPA 560/6-82-002) which appears to correspond with the OECD 206 Avian Reproduction Test (April 1984 version), with a few minor variations.

Nominal test concentrations of 28, 166 and 1000 ppm (mg/kg) were administered in the diet. The mean measured concentrations were found to be 29, 168 and 954 ppm. Twenty pairs of adults were used at each concentration and as control. A large number of endpoints are looked at in the study and can be summarised under various headings:

Appearance and mortality

Only one bird in the 166 ppm group died during the test and was not considered dose related. All other adults (controls and exposed) appeared normal in appearance and behaviour.

All surviving hatchlings were normal in appearance and behaviour during the 14-day post hatch period.

A small number of hatchlings did not survive the 14-day observation period. The incidence of mortalities were 0.5%, 1.2%, 1.1% and 2.8% in the control, 28, 166 and 1,000 ppm groups respectively. These are normal for this type of test (the OECD Guideline gives the expected survival rate to be between 94 to 99%).

Adult body weight and food consumption

No significant difference in adult body weight or food consumption was seen between exposed groups and control with one exception. A statistically significant increase in food consumption was seen during week 17 in the 28 ppm group. This was not considered to be of biological importance as a similar increase was not seen at other time periods or in other groups.

Egg, hatching and hatchling parameters

A slight, but statistically significant, decrease in the mean egg shell thickness was noted in the 1,000 ppm group. However, this may not be biologically significant since the mean egg shell thickness in the 1,000 ppm group was still in the range of normal values given in the OECD guidelines and no increase in cracked eggs was seen at this dose.

No significant difference in the number of eggs laid, number of cracked eggs or mean egg weight was seen in any treatment group when compared with controls.

14-day embryo viability over the 10-week egg-laying period saw a decrease of approximately 10% in the 1,000 ppm group compared to controls. While not statistically significant over the 10-week period, decreases at two weekly intervals (weeks 3 and weeks 6) during the 10 weeks were statistically significant compared to controls. The conclusions of the authors of the report was that this reduced viability was treatment related and may represent an effect on reproductive performance.

No effects in the number of live 21-day embryos, hatchlings or 14-day old survivors were seen in any treatment group. Body weights of hatchlings at day 0 and day 14 were not statistically different from controls in any treatment group.

Gross pathology

No changes that were treatment related were noted. Most changes were of a type that are thought to occur normally in Mallard ducks at the end of a controlled reproduction study.

From the above, it can be seen that slight effects on reproduction may have been seen at 1,000 ppm in diet. Therefore the No Observed Effect Concentration (NOEC) is 166 ppm in diet (166 mg/kg food).

9.2 Aquatic compartment

A large number of aquatic toxicity studies have been carried out using SCCPs. It is stated in the OECD SIDS report that the toxicity information is generally of good quality and it is certainly all of sufficient quality for risk assessment, given that the substance is of fairly low water solubility and so is difficult to test. Many of these studies, particularly the long term studies, have been carried out according to GLP.

9.2.1 Fish

Table 5 - Toxicity of SCCPs to fish

Species	Chlorinated paraffin	Test type	Duration	Endpoint (mg/L)
Estuarine: Bleak *Alburnus alburnus*	C_{10-13}, 49% wt Cl	Static^1	96 hour	LC_{50} >5,000
	C_{10-13}, 56% wt Cl	Static^1	96 hour	LC_{50} >10,000
	C_{10-13}, 63% wt Cl	Static^1	96 hour	LC_{50} >5,000
	$C_{11.5}$, 70% wt Cl	Static^1	96 hour	LC_{50} >10,000
	C_{10-13}, 71% wt Cl	Static^1	96 hour	LC_{50} >5,000
Channel catfish *Ictalurus punctatus*	C_{10-12}, 58% wt Cl	Static	96 hour	LC_{50} >300
Bluegill *Lepomis macrochirus*	C_{10-12}, 58% wt Cl	Static	96 hour	LC_{50} >300
Golden orfe *Leuciscus idus*	C_{10-13}, 52% wt Cl	Static	48 hour	LC_{50} >500
	C_{10-13}, 56% wt Cl	Static	48 hour	LC_{50} >500
	C_{10-13}, 58% wt Cl	Static	48 hour	LC_{50} >500
	C_{10-13}, 62% wt Cl	Static	48 hour	LC_{50} >500
	C_{10-13}, 70% wt Cl	Static	48 hour	LC_{50} >500
Fathead minnow *Pimephales promelas*	C_{10-12}, 58% wt Cl	Static	96 hour	LC_{50} >100
Rainbow trout *Oncorhynchus mykiss*	C_{10-12}, 58% wt Cl	Static	96 hour	LC_{50} >300
	C_{10-12}, 58% wt Cl	Flow	15-20 day	NOEC<0.040^3
	C_{10-12}, 58% wt Cl	Flow^1	60 day	LC_{50} = 0.34
Sheepshead minnow *Cyprinodon variegatus*	C_{10-12}, 58% wt Cl	Flow^{1,2}	32 day	NOEC = 0.28

1) Acetone as cosolvent. 2) Salinity=25%. 3) Sublethal effects observed at 0.040 mg/L (progressive loss of motor function leading to immobilisation).

SCCPs appear to be of low acute toxicity to fish with 48 and 96 hour LC_{50}s in excess of 100 mg/L. However, it should be noted that such values are well in excess of the solubility of this group of compounds. Chronic toxicity values include a 60 day LC_{50} at 0.34 mg/L and no observed effect concentrations of <0.040 and 0.28 mg/L for rainbow trout and sheepshead minnow respectively.

Fourteen days exposure of the bleak *Alburnus alburnus* to 125 µg/L of SCCPs (C_{10-13}, 49% Cl; C_{10-13}, 59% Cl; C_{10-13}, 71% Cl) resulted in sub-lethal effects (sluggish movements, lack of shoaling and abnormal posture) which were reversible after two days in clean brackish water.

Mean measured concentrations of a 58% chlorinated short chain length (C_{10-12}) paraffin of 0.033, 0.1, 0.35, 1.07 and 3.05 mg/L resulted in significant mortality to rainbow trout *Oncorhynchus mykiss* 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. Rainbow trout were exposed 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.

Hatchability and survival of larvae of the sheepshead minnow *Cyprinodon variegatus* was shown to be 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. In this study, 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. Results showed 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 NOEC in this study was 279.7 µg/L. No effect on survival or hatchability was observed.

9.2.2 Aquatic invertebrates

Table 6 - Toxicity of SCCPs to *Daphnia magna*

SCCPs	Test conditions	Duration	Endpoint (mg/L)
C_{10-13}, 20% wt Cl	Emulsifier; stabilised	21 day	NOEC = 0.05 EC_{50} = 0.228
C_{10-13}, 56% wt Cl	Cosolvent; stabilised	24 hour	NOEC = 0.1 EC_{50} = 0.44
	Emulsifier; stabilised	24 hour	NOEC = 0.13 EC_{50} = 0.45
	Emulsifier; unstabilised	24 hour	NOEC <0.1 EC_{50} = 0.55
	Cosolvent; unstabilised	24 hour	NOEC = 0.1 EC_{50} = 0.7
	Emulsifier; unstabilised	24 hour	NOEC = 0.13 EC_{50} = 0.82
	Cosolvent; stabilised	24 hour	NOEC = 2 EC_{50} = 11
	Cosolvent; unstabilised	24 hour	NOEC <0.3 EC_{50} = 11.1
	Emulsifier; unstabilised	21 day	NOEC = 0.05 EC_{50} = 0.137
C_{10-12}, 58% wt Cl	Emulsifier	24 hour	NOEC = 0.5 EC_{50} = 1.9
	Cosolvent	24 hour	NOEC = 0.5 EC_{50} = 1.9
		48 hour	EC_{50} = 0.53
	Flow-through test	72 hour	EC_{50} = 0.024
	Flow-through test	96 hour	EC_{50} = 0.018
	Flow-through test	5 day	EC_{50} = 0.014
	With emulsifier	21 day	EC_0 = 0.03 EC_{50} = 0.124
	Flow-through test	21 day	NOEC = 0.005 EC_0 = 0.0089
C_{10-13}, 60% wt Cl	Emulsifier; stabilised	24 hour	NOEC = 0.06 EC_{50} = 0.51
	Cosolvent; stabilised	24 hour	NOEC = 0.1 EC_{50} = 0.7
	Emulsifier; unstabilised	24 hour	NOEC = 1.0 EC_{50} = 4.0
	Cosolvent; unstabilised	24 hour	NOEC = 0.5 EC_{50} = 0.95
	Emulsifier; unstabilised	21 day	NOEC <0.05 EC_{50} = 0.101
C_{10-13}, 61% wt Cl	Emulsifier; stabilised	24 hour	NOEC <0.1 EC_{50} = 0.51
	Cosolvent; stabilised	24 hour	NOEC = 0.1 EC_{50} = 3
	Emulsifier; unstabilised	24 hour	NOEC = 0.1 EC_{50} = 1.02
	Cosolvent; unstabilised	24 hour	NOEC <0.3 EC_{50} = 0.3
	Emulsifier; unstabilised	21 day	NOEC = 0.02 EC_{50} = 0.104

Notes: EC_{50}s are based on immobilization; static tests unless stated otherwise; acetone used as cosolvent

Table 7 - Toxicity of SCCPs to other aquatic invertebrates

Species	SCCPs	Duration	Endpoint (mg/L)
midge *Chironomus tentans*	C_{10-12}, 58% wt Cl	48 hour	NOEC > 0.162
	C_{10-12}, 58% wt Cl	49 day	NOEC = 0.061
mysid shrimp *Mysidopsis bahia*	C_{10-12}, 58% wt Cl	96 hour	LC_{50} = 0.014
	C_{10-12}, 58% wt Cl	28 day	NOEC = 0.007
Mussel *Mytilus edulis*	C_{10-12}, 58% wt Cl	60 day	LC_{50} = 0.074
	C_{10-12}, 58% wt Cl	12 weeks	NOEC < 0.0093

Notes: the mysid shrimp test was a flow-through test (salinity = 20‰); MATC = Maximum Acceptable Toxicant Concentration. All tests were unstabilised and used acetone as a cosolvent.

The toxicity of SCCPs to aquatic invertebrates is summarised in Tables 6 and 7. Twenty four hour EC_{50}s for daphnids range from 0.3 to 11.1 mg/L with acute NOECs ranging from 0.06 to 2 mg/L. There appears to be no clear pattern with regard to the effects of the carrier substance or the degree of chlorination on the acute toxicity of SCCPs to *D. magna*. In 21 day tests EC_{50}s ranged from 0.101 to 0.228 mg/L while NOECs ranged from 0.005 to 0.05 mg/L. The NOEC of 0.005 mg/L for the 58% chlorinated SCCP 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 at levels ranging from 18 to 162 µg/L for 48 hours with no adverse effects noted. The use of this paraffin over the whole 49 day life cycle at concentrations of 61 to 394 µg/L also gave no significant response except in halting adult emergence at 121 and 394 µg/L. 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 was determined. The NOEC was 61 µg/L.

The toxicity of a 58% chlorinated SCCP to the mysid shrimp *Mysidopsis bahia* was studied and found the 96 hour LC_{50} to be between 14.1 and 15.5 µg/L. 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. 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.

The toxicity of the 58% chlorinated SCCP (C_{10-14}) to the mussel *Mytilus edulis* over a period of 60 days was studied. Tests were carried out at measured concentrations of 0.013, 0.044, 0.071, 0.13 and 0.93 mg/L. There was significant mortality at the three highest doses with LT_{50}s of 59.3, 39.7 and 26.7 days for the three exposure concentrations respectively. 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 SCCP was conducted as a follow up to a bioaccumulation study with only two exposure concentrations. 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 other effects were observed.

9.2.3 Algae

Table 8 - Toxicity of SCCPs to algae

Species	SCCPs	Comments	Temp. (°C)	Duration	Result (mg/L)
Selenastrum capricornutum	C_{10-12}, 58% wt Cl	Cell density by particle count	24	96 hour	EC_{50} = 3.7*
	C_{10-12}, 58% wt Cl	Cell density by particle count	24	7 day	EC_{50} = 1.6*
	C_{10-12}, 58% wt Cl	Cell density by particle count	24	10 day	NOEC = 0.39
	C_{10-12}, 58% wt Cl	Cell density by particle count	24	10 day	EC_{50} = 1.3*
Skeletonema costatum	C_{10-12}, 58% wt Cl	Cell density by absorbance; Salinity = 30.5‰	20	96 hour	EC_{50} = 0.056
	C_{10-12}, 58% wt Cl	Cell density by particle count; Salinity = 30.5‰	20	96 hour	EC_{50} = 0.043
	C_{10-12}, 58% wt Cl	Salinity = 30.5‰	20	96 hour	NOEC = 0.012
	C_{10-12}, 58% wt Cl	Growth rate; Salinity = 30.5%	20	48 hour	EC_{50} = 0.032

Note: *These EC_{50} values exceeded the highest mean measured concentrations of the test substance employed in the study (1.2 mg/L). This was considered the maximum that could be tested due to the low solubility of the test substance.

The toxicity of SCCPs to algae is summarised in Table 8. Ninety-six hour EC_{50}s range from 0.043 to 3.7 mg/L with the marine alga *Skeletonema costatum* appearing to be more sensitive to SCCPs than the freshwater alga *Selenastrum capricornutum*. A NOEC of 12.1 µg/L was reported in the study on *S. costatum*. It should be noted that the EC_{50} values given for *Selenastrum* exceeded the highest mean measured concentrations of the test substance; they are, therefore, extrapolated values. Further, the toxic effects seen with the marine alga were transient, with no effects being seen at any concentration after 7 days exposure.

9.2.4 Micro-organisms

Table 9 - Toxicity of SCCPs to micro-organisms

Source of micro-organisms	SCCPs	Effect
Anaerobic activated sludge	C_{10-12}, 58% wt Cl	Toxic* at concentrations of ≥32,000 mg/L over 24 hours
Anaerobic bacteria from a domestic wastewater treatment plant	C_{10-13}, 52% wt Cl	Toxic at 5,000 mg/L over 24 hours
Anaerobic bacteria from a domestic wastewater treatment plant	C_{10-13}, 56% wt Cl	Toxic at 1,700 mg/L over 24 hours
Anaerobic bacteria from a domestic wastewater treatment plant	C_{10-13}, 58% wt Cl	Toxic at 2,500 mg/L over 24 hours
Anaerobic bacteria from a domestic wastewater treatment plant	C_{10-13}, 62% wt Cl	Toxic at 2,000 mg/L over 24 hours
Anaerobic bacteria from a domestic wastewater treatment plant	C_{10-13}, 70% wt Cl	Toxic at 600 mg/L over 24 hours

Note: * inhibition of gas production

The toxicity of SCCPs to micro-organisms is shown in Table 9. SCCPs appear to be of low toxicity to the micro-organisms tested. In anaerobic micro-organisms, measurements of gas production and its inhibition were used to assess the toxicity of a short chain length C_{10-12}, 58% chlorinated paraffin to the anaerobic sludge digestion process. This study showed that significant (>10%) inhibition of gas production occurred when chlorinated paraffin concentrations of 3.2, 5.6 and 10% on digester volatile suspended solids were employed. These effects were observed on the first 3 to 4 days of the experiment, after which, gas production recovered to normal levels until day 10 when the study was terminated. It was concluded that the compound tested caused transient partial inhibition of gas production with rapid recovery and no longer-term effects.

9.3 Sediment dwelling organisms

Sediments may be an area of significant localised exposure. However, no data are available for sediment dwelling organisms. The OECD SIDS report (1999) recommended the need for further information on releases to this compartment (including the need for monitoring data for sediment near to sources of release) and toxicity testing in this area. A proposed test strategy was to include firstly a long-term *Chironomid* test; secondly a long-term *Oligochaete* test; and finally a long-term test with *Gammarus* or *Hyalella* (all using spiked sediment).

9.4 Summary of environmental effects

Available data indicates SCCPs do not demonstrate acute toxicity to fish, however, they do show toxicity to fish in chronic tests. However, they may be considered highly toxic to aquatic invertebrates. The effects of the carrier substance, or the degree of chlorination on the acute toxicity to invertebrates are not well understood. Toxicity was observed within the limits of solubility although there is a possibility the effects could be physical, particularly in the case of Daphnia.

SCCPs may also be considered highly toxic to algae, although in instances, the EC_{50} values exceeded the highest mean measured concentrations of the test substance employed in the study. Some results exceeded the limit of solubility.

No data are available for sediment dwelling organisms. This is an area for further consideration as it is likely to receive significant exposure in localised areas.

10. Discussion and Conclusions

10.1 Importation and uses

In Australia, SCCPs are mainly used in manufacturing of extreme pressure lubricants, which are used in the metal working industry for metal cutting, pressing, drawing and forming. They are also used in the formulation of a range of products such as fillers or sealers, adhesives and coating materials used in the building industry. Other minor uses include manufacture of pigment dispersants, rubber and leather treatment products. The formulated products are either used directly or further diluted or mixed with other components by end users. The final concentration of SCCPs in the products ranges from 1 to 15%. Some of the final products containing SCCPs such as adhesives, paints and sealants may be available to the general public.

SCCPs are not manufactured in Australia. Table 10 provides general information for all SCCPs assessed in this report.

10.2 Environment

SCCPs have the greatest potential for environmental release of the chlorinated paraffins, and also exhibit the highest toxicity of polychlorinated *n*-alkanes (PCAs). Their release into the environment could occur during production, storage, transportation, industrial use of manufactured products, release from plastics, paints and sealants in which they are incorporated, and leaching, runoff or volatilisation from landfills, sewage sludge or other waste disposal sites.

When released to the environment, the compounds are expected to be stable and degrade only slowly. However, they will bind strongly to soils and sediments. There is a high potential for bioaccumulation, supported by the limited available data. Long range transport through the air also appears to occur.

Available data indicates SCCPs do not demonstrate toxicity to fish at levels far in excess of water solubility. However, they may be considered highly toxic to aquatic invertebrates. The effects of the carrier substance, or the degree of chlorination on the acute toxicity to invertebrates are not well understood. Toxicity was observed within the limits of solubility although there is a possibility the effects could be physical, particularly in the case of Daphnia.

SCCPs may also be considered highly toxic to algae, although in instances, the EC_{50} values exceeded the highest mean measured concentrations of the test substance employed in the study. Some results exceeded the limit of solubility.

No data are available for sediment dwelling organisms. This is an area for further consideration as it is likely to receive significant exposure in localised areas.

Table 10 - SCCPs identified in this assessment

SCCPs	CAS No.	AICS Listed	Imported as pure form	Imported as mixtures
Alkanes, C_{6-18}, chloro	68920-70-7	Yes	No	No
Alkanes, C_{10-13}, chloro	85535-84-8	Yes	Yes	No
Alkanes, C_{12-13}, chloro	71011-12-6	No	No	No
Alkanes, C_{12-14}, chloro	85536-22-7	No	No	No
Alkanes, C_{10-14}, chloro	85681-73-8	No	No	No
Alkanes, C_{10-12}, chloro	108171-26-2	No	No	No
Paraffin waxes and hydrocarbon waxes, chlorinated	63449-39-8	Yes	Yes	Yes

Restricted in Australia or overseas:

Australia: no restrictions

USA: no restrictions

Canada: government is consulting with industries on possible risk management measures.

EU government and industries: marketing and use restrictions for leather treatment and metal working fluids. Negotiations underway.

Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR): phase out use of SCCPs as metal working fluids, plasticizers in paint, coating and sealants and flame retardants in rubber, plastics and textiles.

Undergoing further work:

OECD: recommended consideration of national environmental risk assessment; risk reduction activities for the formulation and use of SCCPs in metal working and leather finishing fluids; investigation of the mechanism of kidney tumour formation being performed by industry.

USA: list SCCPs on the Toxic Release Inventory (TRI).

10.3 Health hazards

SCCPs are absorbed significantly by oral administration but show extremely poor absorption through skin samples in an in vitro study using human skin. SCCPs mainly distribute in tissues with high cell turnover or high metabolic activity following oral administration. They are metabolised by cytochrome P450 oxidation to CO_2. Excretion occurs via urine, exhaled air and faeces. Available data show that the degree of chlorination affects the absorption, distribution and excretion of SCCPs.

SCCPs exhibit very low acute toxicity by all three routes in animals. Mild skin and eye irritation were observed in some animal studies, however they do not cause skin irritation in humans. Available human data indicate that SCCPs are not sensitisers.

Principal signs of toxicity in repeated dose animal studies were effects in the liver, thyroid and kidney. However, mechanistic information has indicated that the liver and thyroid effects are probably not relevant to human health.

SCCPs are not mutagenic. Two-year carcinogenicity studies indicate that SCCPs are carcinogenic in animals. The principal tumour sites are the liver, thyroid and kidney. The characteristic patterns in the results and probable underlying mechanisms indicate that in the liver chronic tissue damage was caused by peroxisome proliferation and that in the thyroid there was long-term hormonal stimulation, potentially consequent to the liver effects. OECD consideration of the likely underlying mechanisms for these tumours suggests that they are not relevant to human health. However, the mechanism for kidney tumours is not yet clear and hence SCCPs are classified as Category 3 carcinogens in the EU.

The EU hazard classification for SCCPs needs to be adopted by NOHSC, as these substances are presently not classified in Australia.

10.4 Occupational health and safety

Information on the number of workers handling SCCPs during formulation and use of products in Australia was not collected for this preliminary assessment. The major route of occupational exposure is skin contact as SCCPs are viscous liquids with low volatility. However, an in vitro study using human skin showed extremely poor dermal absorption of SCCPs. There is a potential for inhalation exposure when formulation occurs at high temperatures, in the use of metal working fluids and during spraying of paint, coatings, adhesives and leather treatment products containing SCCPs. Exposure of transport and storage workers is minimal except in accidents.

Exposure by skin contact can be controlled by decontamination of equipment where appropriate and by use of personal protective equipment (PPE). Inhalation exposure during formulation can be minimised by using an enclosed system and local exhaust ventilation. In sectors where SCCPs mists/aerosols may be generated, potential inhalation exposure can be controlled by using splash guards and by using anti-mist additives in the formulations.

The IPCS (1996) report evaluated human health risks and concluded that the risk to the health of workers exposed to chlorinated paraffins including SCCPs is expected to be minimal.

More recently, the OECD SIDS report (OECD, 1999) included a risk characterisation for workers in the EU potentially exposed to SCCPs and concluded that at present there is no need for further risk reduction measures beyond those that are being applied already in the EU, as the use of SCCPs is appropriately controlled and the potential exposure of workers is not considered to be a cause for concern.

The industries using SCCPs and the industrial processes in Australia are similar to those described in the OECD report. Based on the findings discussed above, it can be concluded that the potential for occupational exposure of workers in Australia to SCCPs is low.

10.5 Public health

Although some products containing SCCPs may be sold to the general public, widespread, repeated public exposure as a result of using these products is unlikely.

Based on the available information, the use of SCCPs in lubricants, building materials, surface coatings, rubber products and leather finishing products is not considered to present a significant hazard to public health. However, due to the potential for SCCPs to bioaccumulate, exposure of the general public via contaminated food is possible.

Given the lack of data, an estimate of total dietary exposure to SCCPs in Australia cannot be made. Shellfish collected from areas contaminated with SCCPs may contain high levels of these substances. If high levels are detected in sediments, monitoring in local shellfish would be appropriate.

10.6 Further assessment

Current occupational uses and potential exposures do not indicate a need for further occupational assessment at this time. Use of SCCP products are also considered not to present a significant hazard to public health.

The OECD assessment of the SCCPs recommended a national environmental risk assessment to identify the need for risk reduction and for further work to characterise hazards to the sediment and soil environments.

The OECD also noted that a detailed risk assessment for these substances have been agreed under the European Union Risk Assessment Programme under Regulation EEC/793/93. The assessment concludes that risk reduction measures need to be considered for the formulation and use of SCCPs in metal working and leather finishing fluids. Consequently, risk reduction activity is being discussed at OECD level.

These conclusions may be relevant to Australia, however clarification of the amount which might be disposed of to the sewer from smaller metal working operations is needed to draw final conclusions (see Section 11.4). The main difference seems to be that use in leather finishing consumes only a small proportion of SCCPs in Australia, and as its use in this industry is declining, risk reduction measures for leather use would not seem appropriate.

Based on the above findings it is concluded that a full (risk) assessment is not warranted at this time for occupational and public health, but further work is required for the environment with respect to use in metal working fluids.

10.7 Data gaps

A number of gaps have been identified from the available data for SCCPs. They are:

- effects of different chain lengths and degree of chlorination on toxicological endpoints other than acute effects and skin irritation;
- information on SCCP levels in food;
- information on ecotoxicity to sediment dwelling organisms; and
- information on the amount disposed of to sewer from smaller metal working operations.

11. Recommendations

Recommendation 1 Further assessment

A full (risk) assessment of SCCPs is not recommended at this time for occupational and public health, but is necessary to elucidate the risks for the environment arising from use of metal working fluids (see Recommendation 5). Based on the findings discussed in the previous section, the other recommendations are:

Recommendation 2 Hazard classification

Currently, SCCPs are not listed in the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999). However, SCCPs are classified as dangerous substances in the EU in accordance with Directive 67/548/EEC. The classification is:

R40	possible risk of irreversible effects (Carcinogen Category 3)
R50/53	very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment

The EU classification is supported based on data available to NICNAS and should be adopted by NOHSC as soon as possible.

Recommendation 3 Hazard communication

It is recommended that manufacturers and suppliers update their MSDS, labels and training materials to include the environmental and health effects information and the EU classification and risk phrases.

Recommendation 4 Occupational exposure controls

As SCCPs are possible carcinogens, control measures should be used to minimise exposure during processes where inhalation of and skin contact to SCCPs may occur.

Recommendation 5 Environmental health

The potential for release to the aquatic compartment through inappropriate disposal of extreme pressure lubricants used in metal working fluids may be high, and a worst case assumption in the case of the latter is for 50% to be disposed of to sewer from smaller operators.

There are no data on sediment dwelling organisms, and these may be subject to localised high exposure. Based on the reasonable worst case assessment of 50% disposal to sewer, the potential for environmental risks is of concern. Therefore a full environmental risk assessment for metal working is recommended, unless information on sewer release comes forward which indicates acceptable releases.

Recommendation 6 Public health

SCCPs have a potential to bioaccumulate and are currently considered to be possible carcinogens in humans based on toxicological studies in animals. As such, environmental releases of SCCPs should be kept at a minimum.

12. Secondary Notification

Under Section 65 of the Act, the secondary notification of SCCPs may be required, where a person becomes aware of any circumstances which may warrant a reassessment of the chemicals. Specific circumstances for SCCPs include:

a) the function or uses of SCCPs have changed, or is likely to change, significantly;

b) the amount of SCCPs introduced into Australia has increased, or is likely to increase, significantly;

c) manufacture of SCCPs has begun in Australia; and

d) significant new information about the adverse health and/or environmental effects of SCCPs have become available.

The Director must be notified within 28 days of the introducer becoming aware of any of the above or other circumstances prescribed under Section 65 of the Act.

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