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HEALTH RISK ASSESSMENT:
CONSUMER EXPOSURE TO PERCHLOROETHYLENE

MAY 2024

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CLIENT REPORT No:	FW24008
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CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
bw	Body weight
CAS RN	Chemical Abstracts Service Registry Number
CNS	Central nervous system
CSF	Cancer slope factor
DIA	Drycleaning Institute of Australia
DLANZ	Drycleaners & Launderers Association of New Zealand
ECHA	European Chemicals Agency
EU	European Union
GSH	Glutathione
HCIS	Hazardous Chemical Information System
HQ	Hazard quotient
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
LCR	Lifetime cancer risk
LC_{50}	Median lethal concentration (causes death in 50% of animals)
LD_{50}	Median lethal dose (causes death in 50% of animals)
LOAEL	Lowest observed adverse effect level
NEDT	New England Disposal Technologies, Inc.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No observed adverse effect level
NTP	National Toxicology Program
NZ EPA	New Zealand Environmental Protection Authority

PCE	Perchloroethylene
PHE	Public Health England
POD	Point of departure
Pow	Octanol-water partition coefficient
REACH	Registration, Evaluation, Authorisation and Restriction
RfD	Reference dose
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and Environment, Netherlands)
UF	Uncertainty factors
US EPA	United States Environmental Protection Agency
VOC	Volatile organic compound
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this report is to develop a generic health risk assessment for consumer exposure to perchloroethylene through the use of carpet cleaners and through residual perchloroethylene in dry-cleaned clothes. This report will only consider domestic, non-occupational, routine and incidental exposure to perchloroethylene.

Perchloroethylene is an excellent solvent for organic materials. It is volatile, highly stable, and non-flammable. It is used in all-purpose spray cleaners (spot removers, mould cleaners), non-spray lubricants, glues and adhesives, and all-purpose waxes and polishes. It is also widely used in dry cleaning. According to the New Zealand Drycleaners & Launderers Association most dry cleaners in New Zealand use perchloroethylene because of its cleansing properties.

The United States Environmental Protection Agency has recently proposed a ban on the use of perchloroethylene, under the Toxic Substances Control Act due to health concerns such as neurotoxicity and carcinogenicity. The proposal bans the use of perchloroethylene in all products for consumer use and restricts many industrial/commercial applications, with strict workplace controls.

There were few reports in the literature that have determined or reported the levels of perchloroethylene in consumer products and the residual perchloroethylene in dry-cleaned clothes. According to the National Industrial Chemicals Notification and Assessment Scheme, perchloroethylene was found at a maximum concentration of 12% in carpet spot removers. Perchloroethylene levels up to the concentration of 4.8 mg/m^3 were detected in the newly dry-cleaned clothes.

Consumer exposure to perchloroethylene from the use of carpet spot remover and due to residues in dry-cleaned clothes is considered incidental. In this assessment, dermal and inhalation exposure to PCE as a result of using carpet spot remover was estimated using ConsExpo Web. For residual perchloroethylene in dry-cleaned clothes, only the inhalation route of exposure was considered relevant. The consumer exposure to residual perchloroethylene from dry-cleaned clothes was calculated by using the US Environmental Protection Agency conventional approaches.

In this assessment, the human health risks of perchloroethylene through dermal and inhalation pathways were characterised by determining the hazard quotient. The hazard quotient was less than 1 for both carpet spot remover (12% PCE) and dry-cleaned clothes (0.08 mg/m^3), indicating that the presence of PCE is unlikely to be a cause for concern with respect to non-cancer effects.

Lifetime cancer risks were also estimated for adults based on the dermal and inhalation pathways of exposure. The results indicated that lifetime exposure to perchloroethylene from carpet spot remover and dry-cleaned clothes equates to an excess cancer risk of $<10^{-5}$, or less than 1 excess cancer case in 100,000 individuals, which is the risk level that has been used in New Zealand for standard setting.

In the author's opinion, a concentration of 12% perchloroethylene for carpet spot removers is likely to be an overestimate, as this was reported over 20 years ago in 2001. Based on the limited information available on the composition of carpet cleaners in the current market, it seems likely that perchloroethylene has since been replaced by alternative chemicals. Similarly, it has been reported that the use of perchloroethylene in dry cleaning has declined sharply over the past 40 years because of improved solvent recycling systems and worker health concerns.

Despite the decrease in use of perchloroethylene in carpet spot removers and dry cleaning, its overall worldwide production is slowly increasing.

Perchloroethylene exposure from other sources such as food, water (1 µg/day or 1.4 x 10^{-5} mg/kg bw/day), and air (120 µg/day or 0.0007 mg/kg bw/day) is also possible but available information suggests that exposure from these sources is negligible compared with the sources of exposure considered in the current report. The World Health Organization has not provided any data on perchloroethylene exposure from food.

1. INTRODUCTION

The purpose of this report is to develop a generic health risk assessment for consumer exposure to perchloroethylene (PCE) through the use of carpet spot remover and due to residual PCE in dry-cleaned clothes. This report will only consider domestic, non-occupational, incidental exposure to PCE. Exposure scenarios will be developed for the most common or likely exposure events.

1.1 CONSUMER PRODUCT DESCRIPTION – PERCHLOROETHYLENE (PCE)

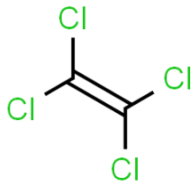
PCE is an excellent solvent for organic materials. It is volatile, highly stable and non-flammable. For these chemical properties, it is widely used in dry cleaning. It is used to degrease metal parts in the automotive and other metal work industries. PCE is also used in all-purpose spray cleaners (spot removers, mould cleaners), non-spray lubricants, glues and adhesives, and all-purpose waxes and polishes). PCE can be found in household products such as spot removers, lubricants, and water repellents (IARC, 1995).

PCE is also widely used in dry cleaning as its high grease solvency allows shorter processing times than other dry-cleaning solvents, giving improved productivity. According to the Drycleaners & Launderers Association of New Zealand (DLANZ), most dry cleaners in New Zealand currently use PCE as a solvent for dry-cleaning purposes (DLANZ, 2024). It is also the most commonly used solvent in Australia for commercial dry cleaning (DIA, 2022; NICNAS, 2001).

1.2 PHYSICO-CHEMICAL PROPERTIES OF PCE

Some of the physical and chemical properties of PCE are presented in Table 1.

Table 1. Chemical identification and physico-chemical properties of PCE (IARC, 1995; USEPA, 2023a)

Property	Value
Chemical name	Tetrachloroethylene
Synonyms	Ethylene tetrachloride, per, PERC, perchloro, perchloroethylene, tetrachloroethene
Chemical structure	
CAS RN	127-18-4
Chemical formula	C_2Cl_4
Molecular weight	165.83
Boiling point	121.3°C
Density	1.6230 g/mL
Vapour pressure	18.5 mmHg at 20°C
Partition coefficient (log Pow)	3.40

Property	Value
Solubility	206 mg/L in water at 20°C Miscible with alcohol, ether, chloroform, benzene, solvent hexane, and most of the fixed and volatile oils

CAS RN: Chemical Abstract Service Registry Number, Pow: octanol-water partition coefficient

1.3 QUANTIFICATION OF PCE

1.3.1 PCE in consumer products

There were only two studies identified that have quantified or reported the presence of PCE in consumer products. However, it is well known that PCE was once widely used in household cleaning products such as carpet cleaners, spot removers and 'dry' carpet cleaning products (NEDT, 2022; Networx, 2018). The studies that reported or quantified PCE in household cleaning products are summarised below.

1. A survey of household products (n = 1159) was conducted in the USA to detect the presence of 31 volatile organic compounds (VOCs) (Sack *et al*., 1992). The products were distributed among 65 product categories within eight category classes: automotive products (14.4% of the products); household cleaners/polishes (9.6%); paint-related products (39.9%); fabric and leather treatments (7.9%); cleaners for electronic equipment (6.0%); oils, greases and lubricants (9.6%); adhesive-related products (6.6%); and miscellaneous products (6.1%). The VOCs in the products were determined by purge-and-trap gas chromatography/mass spectrometry using United States Environmental Protection Agency (US EPA) Method 624. PCE was not detected in any of the 63 product categories.

2. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) conducted an assessment of the use and exposure to PCE in Australia (NICNAS, 2001). Data were analysed and compiled on the manufacture, import volume (pure chemical), and industrial and consumer product applications. The import of PCE was found to be declining, which was consistent with its declining use worldwide. About 80% of the PCE that was imported was used in the dry-cleaning industry. Only small quantities of formulated industrial and consumer products containing PCE were imported. PCE was reported at a concentration of 12% in a carpet stain removal product intended for public use.

1.3.2 Residual PCE in dry-cleaned clothes

Non-aqueous solvents are used to clean fabrics in dry-cleaning. PCE is one of the most commonly used non-aqueous solvent in dry-cleaning operations to help dissolve greases, oils and waxes without damaging the fabric. Hence, the general public may be exposed to residual PCE in dry-cleaned clothes. People who live above or next to a dry cleaner may also be exposed to PCE. There are some studies that have determined the amount of residual PCE in dry-cleaned clothes, as outlined below.

1. Kawauchi and Nishiyama (1989) examined PCE residues in different fabric types (wool, nylon, acrylics/nylon, polyester/cotton and polyester/nylon) that had been dry cleaned at several different establishments using a hexane extraction protocol with gas chromatographic-electron capture detection. The concentrations varied greatly among the establishments as well as among types of clothes, ranging from 0.009 to 68 mg/kg. The highest concentration was found in a wool winter jacket.

2. Emissions of PCE from dry-cleaned fabrics was evaluated and found that bringing newly dry-cleaned clothes into a residence increased the levels of PCE (NICNAS, 2001). PCE levels in the closet where the clothes were stored were highest (up to 3 mg/m^3, 0.4 ppm), while levels in the bedroom containing the closet reached 0.2 mg/m^3 (0.03 ppm) and levels at the other end of the house (average three-bedroom house) were 0.08 mg/m^3 (0.01 ppm). These levels peaked on the second day after dry cleaning.

3. Volunteers were asked to measure breathing zone PCE concentrations emitted by newly dry-cleaned clothes that included six charmeuse blouses, six men's cotton sweaters, six silk blouses, and six women's blazers (NICNAS, 2001). Measured concentrations of PCE in the breathing zone ranged from below detection limits to 4.8 mg/m^3 (0.69 ppm). The median concentrations were 0.032 mg/m^3 (4.6 ppb) for charmeuse blouses, 0.043 mg/m^3 (6.2 ppb) for men's cotton sweaters, 0.094 mg/m^3 (13.6 ppb) for silk blouses, and 0.22 mg/m^3 (31.9 ppb) for women's blazers. Although average concentration follows this order: charmeuse blouse < men's sweater < silk blouse < blazer, the scatter is so wide for each garment type that the differences are not statistically significant except that between the charmeuse blouses and the blazers. The same garment type cleaned at the same cleaner in the same run often yielded vastly different concentrations.

4. Thomas *et al.* (1991) investigated the effect of dry-cleaned clothes on indoor levels of PCE in several homes in New Jersey. PCE concentrations in the indoor air, personal air and breath were measured over multiple 12-hour periods before and after newly dry-cleaned clothes were introduced into nine of the homes. Elevated indoor air levels and human exposures to PCE were recorded at seven of the nine homes with dry-cleaned clothes. Indoor air concentrations of PCE reached 0.3 mg/m^3 in one home and elevated indoor levels persisted for at least 48 hours in all seven homes.

1.4 HUMAN HEALTH HAZARD CLASSIFICATIONS OF PCE

1.4.1 New Zealand

The New Zealand Environmental Protection Authority (NZ EPA) has classified PCE as (NZEPA, 2024): Skin Irrit. 2 (may cause skin irritation), Eye Irrit. 2 (may cause eye irritation), Carc. 1 (may cause cancer), STOT Single Exp. 3 (may cause drowsiness or dizziness) and STOT Rep Exp. 3 (may cause damage to organs through prolonged or repeated exposure).

1.4.2 European Union (EU)

According to the harmonised classification and labelling approved by the EU, PCE is classified as Carc. 2 (suspected of causing cancer) (ECHA, 2024).

Additionally, the classification provided by companies to the European Chemicals Agency (ECHA) in Registration, Evaluation, Authorisation and Restriction (REACH) registrations identifies that this substance causes serious eye irritation, causes skin irritation, may cause an allergic skin reaction and may cause drowsiness or dizziness (ECHA, 2024).

1.4.3 Australia

Safe Work Australia has classified PCE as Carc. 2 (may cause cancer) (HCIS, 2024).

1.4.4 USA

The US EPA has classified PCE as 'likely to be carcinogenic' in humans by all routes of exposure.

The US EPA has recently proposed a ban on the use of PCE in all products for consumer uses and restricting the use for many industrial/commercial uses with strict workplace controls (USEPA, 2023b).

2. HAZARD IDENTIFICATION

2.1 PREVIOUS ASSESSMENTS

No previous health impact assessments for PCE were found for New Zealand.

2.2 HEALTH EFFECTS – INCIDENT SURVEILLANCE AND CASE REPORTS

The 40th report of America's Poison Centers National Poison Data System reported 1129 exposure cases due to the use of spot removers / dry-cleaning agents (household) (Gummin *et al.*, 2023). However, only four of these (0.35%) were specifically due to PCE. All the cases were classified to have minor health effects, i.e. they were minimally bothersome, often limited to the skin or mucous membranes and generally resolved rapidly with no residual disability or disfigurement. It is not clear if the PCE exposures were due to using carpet spot removers or from its residues in dry-cleaned clothes.

2.3 TOXICITY

The toxicity of PCE has been extensively reviewed by a number of authorities, such as the International Agency for Research on Cancer (IARC), Agency for Toxic Substances and Disease Registry (ATSDR), NICNAS, US EPA, and ECHA. Hence, only brief summaries of each toxicity endpoint are provided below.

2.3.1 Absorption, distribution, metabolism and excretion

2.3.1.1 Absorption

PCE is readily absorbed following inhalation, oral and dermal exposure in animals. In humans, approximately 70% of PCE is absorbed in 1 hour after inhaling air containing 100 ppm PCE and 50% is absorbed after 8 hours (PHE, 2016). There are no quantitative data available on the oral absorption of PCE in humans. Animal studies have reported the rapid and near-complete absorption of PCE following oral administration (USEPA, 2012). The absorption of PCE vapours through the skin is approximately equal to that from inhalation at low exposures (410 mg/m^3) but may be as low as 1% of the amount absorbed via inhalation at higher exposures (4100 mg/m^3) (USEPA, 2012).

2.3.1.2 Distribution

PCE is lipophilic (log octanol-water partition coefficient [Pow] = 3.4) and is distributed to the fatty tissues. The half-life of PCE in human adipose tissue is estimated to be 55 hours. PCE may be found in human and animal milk and has been shown to cross the placenta and distribute to the foetus in mice (NICNAS, 2001).

2.3.1.3 Metabolism

There are major differences in the metabolic pathway between mice, rats and humans (NICNAS, 2001). The rate of metabolism is highest in mice and lowest in humans among these three species.

The metabolism of PCE has been extensively studied in both human volunteers and animals, using both *in vitro* and *in vivo* methods (INCHEM, 2006). In humans, less than 2% of absorbed PCE is metabolised in the liver to trichloroacetic acid and trichloroethanol, which are then excreted in the urine.

PCE is metabolised by two major pathways:

a) **Oxidative pathway:** The cytochrome P450 dependent oxidative pathway is predominant, particularly at environmental exposure levels, but is readily saturable and limited.

b) **Glutathione (GSH) conjugation pathway:** The formation of GSH conjugation metabolites primarily occurs in the kidney and is linked to renal toxicity. This pathway results in reactive metabolites, some of which are considered mutagenic.

Schematic diagrams of these two pathways are provided in Figure 1.

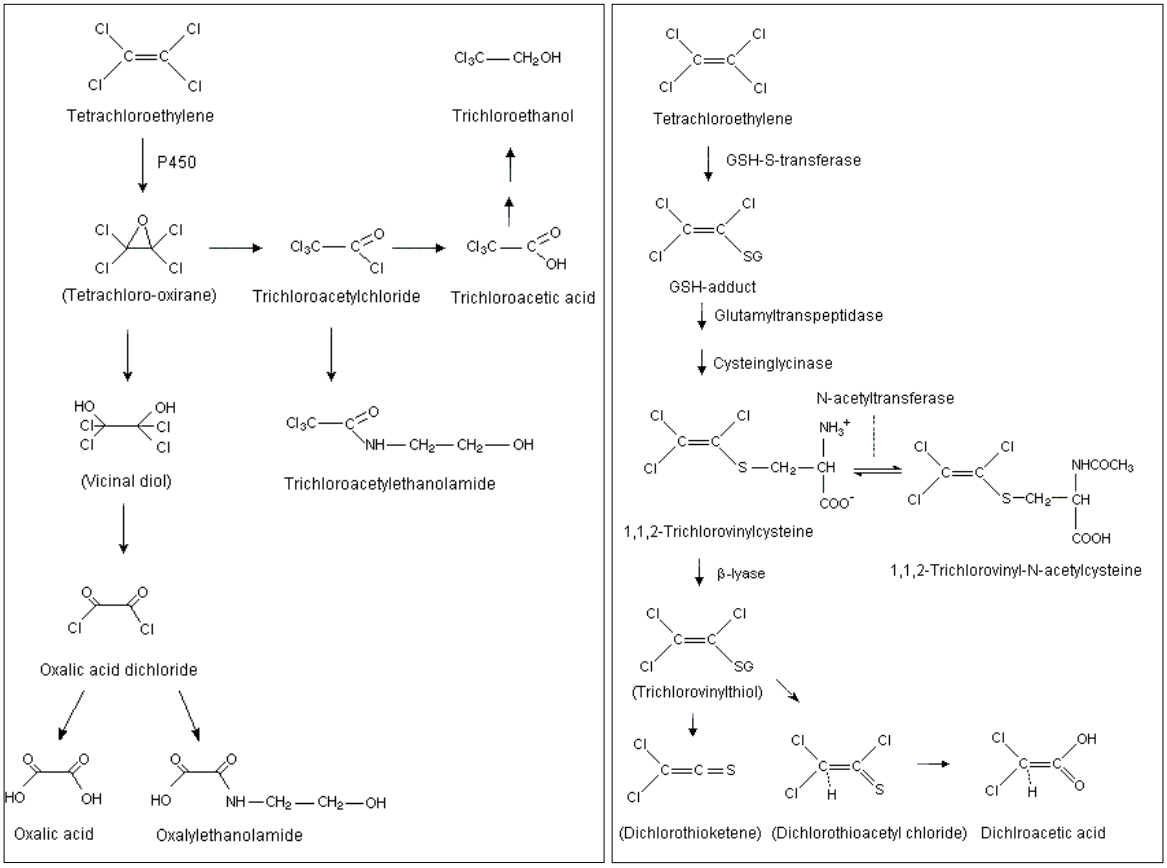


Figure 1. Metabolism of PCE (source: INCHEM, 2006)

It has been reported that at higher exposure dose of PCE, the oxidative pathway is saturated and the metabolism shifts to the GSH conjugation pathway (NICNAS, 2001). In humans, metabolism to trichloroacetic acid appears to plateau at concentrations above 100 ppm PCE. By contrast, in a study where mice were administered PCE by gavage, the amount of total metabolites in the urine plateaued at doses above 1000 mg/kg body weight (bw)/day.

2.3.1.4 Excretion

In humans, the metabolism of PCE is relatively limited and the unmetabolised PCE is excreted. Exhalation is the primary pathway of PCE excretion in humans for all routes of administration (USEPA, 2012), with 80–90% of unmetabolised PCE being excreted unchanged in the breath. A smaller fraction of PCE is excreted in the urine as metabolites (predominantly trichloroacetic acid) (NICNAS, 2001; PHE, 2016).

2.3.2 Acute toxicity

PCE is of low acute toxicity in humans and experimental animals (HealthCanada, 1993; INCHEM, 2006). Acute inhalation exposure to PCE in humans results in central nervous system (CNS) depression. High doses have also been documented to cause liver and kidney toxicity. Other effects observed include irritation of the upper respiratory tract and eyes, neurological effects, such as reversible mood and behavioural changes, impairment of coordination, dizziness, headaches, sleepiness, and unconsciousness.

In a controlled inhalation study in humans (*n* = 6), exposure to 730 mg/m^3 (106 ppm) PCE vapour for 1 hour did not cause any adverse health effects. However, eye irritation and slight dizziness were observed when the concentration was increased to 1500 mg/m^3 (216 ppm) (HCIS, 1990).

The oral median lethal dose (LD_{50}) in mice and rats range from 6000-8571 and 2400-13,000 mg/kg bw, respectively (HCIS, 2024; INCHEM, 2006). The 4-hour median lethal concentration (LC_{50}) in rats is reported to be in the range of 16,577 to 35,005 mg/m^3 (HealthCanada, 1993; IARC, 1995; INCHEM, 2006). Acute exposure in animals is associated with hypoactivity, ataxia, anaesthesia, tremors and CNS depression. Liver and kidney dysfunction have also been observed at near-lethal doses.

2.3.3 Repeated-dose toxicity

Chronic inhalation exposure to PCE in humans is associated with neurological effects, including sensory symptoms such as headaches, impairments in cognitive and motor neurobehavioural functioning, and declines in colour vision (HealthCanada, 1993; IARC, 1995). Other effects noted in humans, generally at higher exposures, include liver damage, kidney effects, immune and haematological effects, and effects on development and reproduction.

Limited repeated-dose studies have been carried out in laboratory animals (HealthCanada, 1993). Dose-dependent adverse effects have been observed in the liver, kidney, haematopoietic, reproductive and central nervous systems of animals following repeated exposure to PCE. Mice are more sensitive to PCE than rats in terms of effects on the liver. Liver damage in mice following either inhalation exposure or oral administration has been shown to involve peroxisomal proliferation. However, these effects are not relevant to humans.

The ingestion of PCE up to 316 mg/kg bw/day had no effects on body weight gain or mortality in mice, whereas doses of 100 (females) or 178 (males) mg/kg bw/day and above resulted in decreased body weight gain in rats in subchronic toxicity studies.

Inhalation exposure to 50 mg/m^3 for approximately 5 weeks resulted in neurological effects and alterations in biochemical parameters and organ weights in rats, although no morphological changes were noted upon examination (HealthCanada, 1993). No signs of neurotoxicity were reported in rats at any concentration and mice up to the concentration of 1400 mg/m^3 after inhalation exposure to PCE at concentrations of 0, 690, 1400, 2800, 5500 or 11,000 mg/m^3 for 6 hours/day, 5 days/week for 13 weeks (INCHEM, 2006). Although at higher concentrations ≥ 2800 mg/m^3, mice became hunched, lacked movement and appeared irritated. Lack of coordination and loss of consciousness was also seen in some animals. Mice also showed minimal renal tubular karyomegaly at all concentrations except the lowest concentration. Kidney lesions were not observed in rats. No hepatic effects were seen at 690 mg/m^3 in mice, while minimal mitotic changes were observed at 1400 mg/m^3 and there were minimal to mild hepatic leukocytic infiltration, centrilobular necrosis and bile stasis at concentrations of 2800 mg/m^3 and above. By contrast, rats showed only minimal to mild hepatic congestion when exposed to concentrations of 1400 mg/m^3 and above.

2.3.4 Genotoxicity

The overall evidence from extensive series of bacterial tests both *in vitro* and *in vivo* suggest that PCE is not mutagenic (HealthCanada, 1993; IARC, 1995; IRIS, 2012; USEPA, 2023a).

Positive results for frameshift mutation were observed in a host-mediated assay by implanting *Salmonella typhimurium* into mice exposed to PCE, but without a clear dose-response effect. A number of mutagenicity studies in *S. typhimurium* have indicated that PCE is not a mutagen in the absence or presence of metabolic activation. However, when PCE was activated with rat liver glutathione-S-transferase, GSH and a rat kidney fraction, PCE exhibited a clear dose response. These findings support a role of metabolic activation of PCE in its *in vitro* genotoxicity.

Positive results were also obtained *in vitro* with metabolites of PCE associated with both the cytochrome P450 oxidative pathway and the glutathione-S-transferase conjugation pathway. However, positive results were not observed in *in vivo* tests.

The PCE glutathione conjugation metabolite (1,2,2-trichlorovinyl)glutathione gave a positive result for genotoxicity when assessed by induction of unscheduled DNA synthesis and mutagenicity in the Ames assay when the culture medium was supplemented with GSH and kidney, but not liver, subcellular fractions (Cichocki *et al.*, 2016). This suggests that renal metabolism of PCE has the potential to generate genotoxic metabolites. Trichlorovinyl cysteine also tested positive for genotoxicity in the Ames assay.

2.3.5 Carcinogenicity

Several agencies have investigated PCE's association with cancer. IARC classified PCE as 'probably carcinogenic to humans (Group 2A)' based on sufficient evidence in laboratory animals and limited evidence in humans (IARC, 1995).

The National Toxicology Program (NTP) classified PCE as 'reasonably anticipated to be a human carcinogen' based on sufficient evidence of carcinogenicity from studies in experimental animals (NTP, 1989). NTP considered that the human epidemiological studies were inadequate to evaluate the relationship between human cancer and exposure specifically to PCE.

In carcinogenicity studies, benign and malignant liver tumours (hepatocellular adenomas and carcinomas) were observed in all male and female mice after inhalation of PCE (doses up to 1360 mg/m^3) and oral exposure to PCE (doses up to 1072 mg/kg bw/day) (HealthCanada, 1993; IARC, 1995; NTP, 1986). The incidence of tumours was dose dependent and statistically significantly higher than the control animals. No carcinogenic effects were observed in rats after oral administration of PCE (IARC, 1995; USEPA, 2012).

In an inhalation bioassay, mice were exposed to PCE at concentrations of 0, 100 or 200 ppm for 6 hours/day, 5 days/week for 103 weeks (IARC, 1995; USEPA, 2012). PCE caused significant dose-related increases in the incidences of hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas in both sexes. The incidences of hepatocellular neoplasms (adenomas and carcinomas combined) in males and females were 17/49, 31/49, 41/50 and 4/45, 17/42, 38/48, respectively.

In another study mice were exposed to 0, 10, 50 or 250 ppm PCE for 6 hours/day, 5 days/week for 104 weeks (IARC, 1995; USEPA, 2012). Dose-related increased incidences of liver carcinomas and combined liver adenomas and carcinomas were observed in both sexes. The incidences of hepatocellular adenomas were 7/50, 13/50, 8/50 and 26/50, respectively, for males and 3/50, 3/47, 7/49 and 26/49, respectively, for females. The occurrence of

hepatocellular carcinomas also increased, with reported incidences of 7/50, 8/50, 12/50 and 25/50, respectively, for males and 0/50, 0/47, 0/49 and 14/49, respectively, for females.

In an oral cancer bioassay, mice were administered PCE in corn oil by gavage (5 days/week for 78 weeks) (USEPA, 2012). The time-weighted average doses of PCE were 0, 536 or 1072 mg/kg bw/day for males and 0, 386 or 772 mg/kg bw/day for females. Mortality was significantly higher in the treatment groups as compared to control group, and the incidence of hepatocellular carcinomas was also significantly higher in all treated animals. The incidences in males and females were 2/20, 32/48, 27/45 and 0/20, 19/48, 19/48, respectively.

In rats, inhalation exposure (6 hours/day, 5 days/week for 103 weeks) to PCE at concentrations of 0, 1356 or 2720 mg/m^3 caused dose-related increases in the incidence of mononuclear cell leukaemia in all animals (IARC, 1995). The incidence of mononuclear cell leukemia in male and female rats was 28/50, 37/50, 37/50, and 18/50, 30/50, 29/50, respectively. The historical incidence of mononuclear-cell leukaemia in rats at the same laboratory was 47% in males and 29% in females. Kidney tumours (adenomas or adenocarcinomas) were also noted in males, which are very uncommon in rats. It is not clear if the tumours that developed in these animals are relevant to humans.

2.3.6 Reproductive and developmental toxicity

Studies have reached inconsistent conclusions on the status of PCE as a reproductive and developmental toxicity in either humans or animals (HealthCanada, 1993; INCHEM, 2006). Fetotoxic effects were observed in the offspring of rats, mice and rabbits exposed to PCE during pregnancy in several developmental toxicity studies (INCHEM, 2006). However, the effects were only seen at doses that caused maternal toxicity (neurotoxicity and nephrotoxicity) (HealthCanada, 1993; INCHEM, 2006).

In a developmental toxicity study, rats were exposed (whole-body) to PCE at nominal concentrations of 0, 75, 250 or 600 ppm (actual chamber concentrations = 0, 65, 249 or 600 ppm) for 6 hours/day, 7 days/week on gestation days 6−19 (USEPA, 2012). Maternal toxicity was observed at the highest dose, which comprised of slight, but statistically significant, decreases in body weight gain during the first 3 days. Thus, the no observed adverse effect level (NOAEL) for dams was 249 ppm. Developmental effects observed at 600 ppm consisted of reduced gravid uterus, placental and foetal body weights, and decreased ossification of the thoracic vertebral centra. From ≥ 249 ppm, mean foetal and placental weights were significantly decreased by 4.3 and 12.3% from control, respectively. Other effects were of minor toxicological significance. No effects were observed at 65 ppm, so this concentration was established as the NOAEL for developmental toxicity. The incidence of malformations was low and showed no relationship to treatment with PCE, and nor were there any treatment-related effects on the incidence of visceral or cartilage variations. There was, however, an increase in the incidence of incomplete ossification of thoracic vertebral centra in animals exposed to 600 ppm, which was outside the historical control range and appeared to be correlated with reduced foetal body weights and was therefore considered to be a treatment-related effect.

Reproductive effects of PCE exposure in mammalian animal models are based on a two-generation reproduction study in rats (USEPA, 2012). In this study, animals were exposed to 100, 300 or 1000 ppm PCE by the inhalation route for 6 hours/day, 5 days/week for 11 weeks prior to being housed for mating (within their treatment groups) and then for 6 hours/day during mating and through GD 20 for up to 21 days. One litter (F1A) was produced in the first generation when the dams together with their litters were exposed daily from day 6 to day 29 postpartum. The second generation (F1) parents were selected from the F1A litters on day 29 postpartum and were exposed to PCE 5 days/week for at least 11 further weeks prior to mating. Three litters (F2A, F2B and F2C) were produced in the second generation. For the

F2A litters, the dams and litters were exposed from days 6 to 29 postpartum (control and 100 ppm groups) or days 7 to 29 post-partum (300 ppm group). The dams and litters in the 1000 ppm group were not exposed during lactation for this F2A litter. The F2B litter was generated by mating the males and females in the control, 300 and 1000 ppm groups. There was no exposure of the dams and F2B litters during lactation. The F2C litter was produced by mating the male controls and the males exposed to 1000 ppm with unexposed stock females.

There was evidence of toxicity at an exposure level of 1000 ppm, with signs of CNS depression (decreased activity and reduced response to sound) during the first 2 weeks in both adult generations and again when the exposure was resumed on Day 6 postpartum in the F1 generation (adults and pups). The signs disappeared approximately 30 minutes after the end of each exposure. Other signs of toxicity observed at 1000 and 300 ppm included irregular breathing and piloerection. However, the animals recovered by the end of exposure at 300 ppm or 30 minutes after the end of exposure at 1000 ppm. The NOAEL for parental toxicity was 100 ppm. Reductions in parental body weight gain during the pre-pairing and lactation periods in both generations and during pregnancy in the second generation were also observed at 300 and 1000 ppm. But the effects were not statistically significant as compared to the control group.

The mean pup body weights showed a statistically significant decrease throughout the lactation period at 300 and 1000 ppm for the F1A litters and in early lactation for the F2A and F2B litters. Additionally, the mean F1A male pup body weight was significantly decreased (5% less than the control) at 100 ppm on postnatal day 29. Since a decrease in pup weight was observed at the lowest dose, a NOAEL could not be established. Hence, the lowest observed adverse effect level (LOAEL) for offspring was 100 ppm. Exposure to PCE was also associated with poor growth of the offspring at 300 and 1000 ppm, but reduced pup survival was confined to 1000 ppm. This represented a toxic effect which, in part, may have been maternally mediated. A reduction in the proportion of pups born live at 1000 ppm provided evidence for a reproductive effect at this exposure level.

3. DOSE-RESPONSE INFORMATION

In this section, concerns associated with exposure to PCE are related to chronic exposure events due to the low acute toxicity of this chemical.

3.1 NON-CANCER EFFECTS

A reference dose (RfD) is generally used in non-cancer health assessments. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral or inhalation exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (USEPA, 1993). It can be derived from a NOAEL, LOAEL or benchmark dose and is generally corrected with uncertainty factors (UF) to reflect limitations of the data used using the following equation:

$$\mathrm{RfD} = \frac{\mathrm{NOAEL\ or\ LOAEL}}{\mathrm{UF}}$$

The US EPA has established oral and inhalation reference doses for PCE based on neurotoxic effects observed in workers, which are provided in Table 2.

Table 2. Reference doses for PCE

Study / key effect	POD	UF	RfD*		Reference
Oral reference dose					
Occupational exposure/ neurotoxicity (reaction time, cognitive effects) in adults	LOAEL: 9.7 mg/kg bw/day	1000	0.0097 mg/kg bw/day	0.006 mg/kg bw/day	(IRIS, 2012)
Occupational exposure/ neurotoxicity (colour vision) in adults	LOAEL: 2.6 mg/kg bw/day	1000	0.0026 mg/kg bw/day		
Inhalation reference dose					
Occupational exposure/ neurotoxicity (reaction time, cognitive effects) in adults	LOAEL: 56 mg/m^3	1000	0.056 mg/m^3	0.04 mg/m^3	(IRIS, 2012)
Occupational exposure/ neurotoxicity (colour vision) in adults	LOAEL: 15 mg/m^3	1000	0.015 mg/m^3		

PCE: perchloroethylene, POD: point of departure, UF: uncertainty factor, RfD: Reference dose, LOAEL: lowest observed adverse effect level, bw: body weight

* The individual RfD is supported by the two principal studies, as a midpoint of the range of available values (then rounded to one significant figure).

3.2 CANCER EFFECTS

The US EPA has estimated an oral cancer slope factor (CSF) for PCE, which has been published in its Integrated Risk Information System (USEPA, 2012). The CSF is a parameter derived from the low-dose region of the dose-response relationship for a chemical or agent being evaluated as a carcinogen. It represents a measure of the cancer risk from a lifetime exposure to that chemical/agent and is typically expressed as the proportion of a population affected per milligram of substance per kilogram of body weight per day.

The oral CSF for PCE provided by the US EPA is 2×10^{-3} per mg/kg bw/day. This value was derived from inhalation data because the only available oral bioassay had several limitations for extrapolating to lifetime risk in humans (USEPA, 2012). The study from which this value was derived investigated male mouse hepatocellular tumours and is summarised in section 2.3.5 of this report.

4. EXPOSURE ASSESSMENT

For exposure estimation, the concentration of chemical in interest is essential for risk assessment. The studies summarised in section 1.3 are limited that quantify the levels of PCE in consumer products as well as residual PCE in dry-cleaned clothes.

The maximum concentration of PCE reported in consumer products is 12% in a carpet spot remover (NICNAS, 2001), so this value was used in the exposure assessment as a conservative approach.

PCE was found up to a maximum concentration of 3 mg/m^3 in a closet where newly dry-cleaned clothes were stored (NICNAS, 2001). However, the levels of PCE in dry-cleaned clothes are reported to decrease to between half the initial value and not detected in various fabrics after 24 hours (Brodmann, 1975; Tichenor *et al.*, 1990), suggesting that an exposure assessment at the maximum concentration would be overly conservative. Therefore, PCE concentration of 0.08 mg/m^3 reported in a three bedroom house after bringing the dry-cleaned clothes was used for exposure assessment (NICNAS, 2001).

4.1 RELEVANT EXPOSURE SCENARIOS

Consumer exposure to PCE is considered incidental. Therefore, the scenarios considered in this exposure assessment were related to the intended uses of the products.

For consumer use, carpet spot removers are generally ready-to-use products. Hence, exposure from mixing and loading is not expected. According to the ConsExpo factsheet (RIVM, 2018), the user sprays the spot remover on an area of 0.1 m^2. The foam is left on the stain to soak for 5 minutes. The dirt is then absorbed with (paper) towels and the surface is patted dry. Inhalation exposure is anticipated during the leave-on stage, as volatile substances may evaporate from the stain, while dermal exposure is expected from rubbing the carpet/upholstery with towels.

For residual PCE in dry-cleaned clothes, only the inhalation route of exposure was considered relevant. Dermal exposure to residual PCE was considered negligible as dry-cleaned clothes generally do not come in direct contact with the skin.

The exposure routes considered in this assessment are summarised in Table 3.

Table 3. Exposure routes considered for PCE

Population	Product type	Exposure pathway		
		Inhalation	Dermal	Oral
Adults	Carpet cleaner	X	X	
Adults	Residual PCE in dry-cleaned clothes	X		

PCE: perchloroethylene

4.2 EXPOSURE MODELS AND TIERED APPROACH

Risk assessment may follow a tiered approach. Under this approach, initial exposure estimates are derived using highly conservative assumptions. If such estimates indicate no cause for concern, then more refined approaches may be applied.

Tier 1 assessment is generally used to screen consumer exposure based on the summation of high percentile product use levels and maximum concentrations of the substance of interest in products, which gives a worst-case exposure scenario.

As the current study considered exposure to PCE by both the inhalation and dermal exposure routes, combination of these exposures requires conversion of external exposure doses to internal (systemic) doses, through application of an absorbed proportion.

4.2.1 PCE in carpet spot remover

For the current exposure assessment, ConsExpo Web was used to estimate exposure to carpet spot remover (RIVM, 2024). ConsExpo is a modelling tool that can be used to estimate consumer exposure to a wide variety of products in a wide range of circumstances. ConsExpo Web provides a number of generally applicable exposure models and a database of exposure factors for a broad set of consumer products. Therefore, together, the models and the database provide the tools needed to assess exposure to a wide variety of consumer products. Only basic additional information on product composition and the physicochemical properties of the substance under assessment being needed (RIVM, 2024).

ConsExpo Web contains models that can be used to estimate exposure via inhalation, dermal contact and oral ingestion (RIVM, 2024). The exposure models vary in complexity, from simple screening models to more advanced, physics-based models. The factsheets within ConsExpo Web provide general background information on exposure models, as well as important information to ensure consistent and harmonised estimation and assessment of the exposure to substances from consumer products when using ConsExpo Web. They also describe various exposure scenarios for the specific products and set default values for relevant exposure parameters. The default values are presented as deterministic values, but, if available, the statistical information is also provided if possible (RIVM, 2024).

Various models are available in the ConsExpo. For estimating inhalation and dermal exposure to carpet spot remover, the exposure to vapour model mode of release: evaporation model and direct product contact–instant application loading model were used, respectively (RIVM, 2018).

The default parameters for estimating consumer exposure are detailed in the cleaning products factsheet (RIVM, 2018) and include the following:

5. **Product amount – inhalation:** This is the amount of product needed to treat a stain. In general, carpet cleaner product information recommends an amount of 40 - 77 g/m^2. Hence, a default value of 8 g of product to treat a 0.1 m^2 stain is provided based on the expert judgement of the authors of the factsheet.
6. **Exposure duration:** This is interpreted as the leave-on time plus the time the consumer needs to remove the spot with a cloth or towel. It is assumed that the duration for spot treatment for laundry products also applies to carpet products. The laundry pre-treatment takes 10 minutes/task. Hence, a conservative default value of 15 minutes is assumed since there is no supporting product data are available.
7. **Molecular weight matrix:** This parameter needs to be defined if the substance in question is not in its pure form, but part of a product. It is the average molecular weight of the rest of the total product (the product minus the substance in question). If the

product consists largely of a single component (e.g. water), the molecular weight matrix is roughly equal to the molecular weight of that component (e.g. 18 g/mol for water). The fraction of water in carpet cleaning liquid is estimated to be 0.6 (60%). Therefore, following the conservative approach, the default molecular weight matrix is calculated as the molecular weight of water (18 g/mol) divided by the fraction of water in the product (0.6), which yields 30 g/mol.

8. **Exposed area:** The top phalanges of all five fingers of one hand are considered as the exposed area because the rest of the hand is protected by the cloth or towel. The default surface area of an adult hand is 450 cm^2. Thus, based on the assumptions that the fingers have half the surface area of the hand (225 cm^2) and the phalanges have one-third the surface area of the fingers (75 cm^2), the default is set to 75 cm^2.
9. **Product amount – dermal:** It is conservatively assumed that the amount per m^2 applied to the stain is equal to the amount per m^2 on the exposed skin area of the consumer. For carpet spot remover, the default product amount subject to dermal exposure is thus calculated as 77 g/m^2 x 75 cm^2 = 0.6 g.

A summary of the exposure parameters used in the exposure assessment for PCE in carpet spot remover are given in Table 4.

Table 4. Parameters used in the exposure assessment of PCE in carpet spot remover (RIVM, 2018)

Parameter	Value	Comment
Frequency of product use	10/year	75th percentile value
Inhalation – exposure to vapour–evaporation–constant release area		
Exposure duration	15 minutes	Duration of spot treatment
Product amount	8 g	Product information (Vanish)
Concentration	12%	From NICNAS (1991) report
Room volume	58 m^3	Living room
Ventilation rate	0.5/hour	Living room
Release area	0.1 m^2	Area of carpet treated; assumption
Application temperature	20°C	Room temperature
Inhalation rate	1.52 m^3/hour	Light exercise
Inhalation absorption	100%	Conservative assumption
Dermal – direct product contact, instant application loading		
Exposed area	75 cm^2	Area of phalanges of all five fingers of one hand
Product amount	0.6 g	Calculated, see above
Concentration	12%	From NICNAS (1991) report
Retention factor	1	
Absorption	10%	Conservative assumption
Body weight	70 kg	25th percentile body weight for a New Zealand adult (66.8 kg, rounded value)

Exposure estimates

The ConsExpo Web model provides estimates of various measures for each route of exposure. Integrated doses (i.e. doses summed over various routes) are also evaluated if absorption models are used in the assessment.

The following measures are estimated:

- **Internal event dose:** This is the total absorbed dose per kg body weight during one exposure event.
- **Internal dose on day of exposure:** This is the absorbed dose per kg body weight during 1 day. Note that this value can be higher than the 'event dose' for exposure frequencies above 1 per day.
- **Internal year average dose:** This is the daily absorbed dose per kg body weight averaged over 1 year.

Based on the exposure parameters provided in Table 4, exposure estimates from dermal and inhalation absorption of PCE from carpet spot remover were calculated. These are summarised in Table 5.

Table 5. Exposure estimates for inhalation and dermal exposure to PCE

Exposure measure	Estimate
Inhalation exposure model: Exposure to vapour, instantaneous release	
Absorption model: Fixed fraction	
External event dose	2.1×10^{-2} mg/kg bw
External dose on day of exposure	2.1×10^{-2} mg/kg bw
Internal event dose	2.1×10^{-2} mg/kg bw
Internal dose on day of exposure	2.1×10^{-2} mg/kg bw
Internal year average dose	5.7×10^{-4} mg/kg bw/day
Dermal exposure model: Exposure to vapour, instantaneous release	
Absorption model: Fixed fraction	
External event dose	1 mg/kg bw
External dose on day of exposure	1 mg/kg bw
Internal event dose	1.0×10^{-1} mg/kg bw
Internal dose on day of exposure	1.0×10^{-1} mg/kg bw
Internal year average dose	2.8×10^{-3} mg/kg bw/day
Integrated exposure*	
Internal event dose	1.2×10^{-1} mg/kg bw
Internal dose on day of exposure	1.2×10^{-1} mg/kg bw
Internal year average dose	**3.4×10^{-3} mg/kg bw/day**

PCE: perchloroethylene, bw: body weight

* The integrated doses were calculated by adding the respective inhalation and dermal exposure estimates together.

4.2.2 Residual PCE in dry-cleaned clothes

The inhalation exposure to PCE from dry-cleaned clothes was calculated by using the US EPA's conventional approaches (USEPA, 2024) with the following equation:

$$\text{Exposure dose} = \frac{C \times \text{IR} \times \text{ET} \times \text{EF}}{\text{BW} \times \text{AT}}$$

where *C* is the concentration of product (mg/m^3), IR is the inhalation rate at rest (m^3/hour), ET is the exposure time (hours/day), EF is the exposure frequency (days/year), BW is the body weight (kg) and AT is the averaging time (days), i.e. the amount of time over which exposure is averaged.

The parameters and result of this assessment to estimate exposure from residual PCE in dry-cleaned clothes are provided in Table 6.

Table 6. Parameters used in the exposure assessment of residual PCE in dry-cleaned clothes and the exposure estimate for inhalation exposure to PCE

Parameter	Value	Comment
Concentration	0.08 mg/m^3	Level of PCE in average three-bedroom house after bringing dry-cleaned clothes
Inhalation rate	0.63 m^3/hour	At rest
Exposure time	12 hours/day	Assumption: time spent in the house
Exposure frequency	100 days/year	Assumption: a person brings dry-cleaned clothes into their home once per week and PCE is dissipated after 2 days
Averaging time	365 days	Averaged over 1 year
Body weight	70 kg	25th percentile body weight for a New Zealand adult (66.8 kg, rounded value)
Exposure dose	**0.0023 mg/kg bw/day**	Using the US EPA (2024) equation

It should be noted that exposure to background levels of PCE in residential properties will be lower than the calculated exposure (0.0023 mg/kg bw/day). This is due to the fact that background levels in residential properties are usually lower than the residual PCE levels in dry-cleaned clothes (Liu *et al.*, 2022).

5. RISK CHARACTERISATION

5.1 NON-CANCER RISK

The hazard quotient (HQ) is calculated to evaluate the potential for non-cancer health hazards to occur from exposure to a chemical or contaminant. HQ is the ratio of the potential exposure to a substance and the level at which no adverse effects are expected and is calculated using the formula:

$$\mathrm{HQ} = \frac{\mathrm{Exposure}}{\mathrm{RfD}}$$

For a chemical substance with health thresholds (i.e. that is not genotoxic or carcinogenic), HQ < 1 is generally considered to be protective.

The HQ values calculated for PCE in carpet spot remover and dry-cleaned clothes are presented in Table 7.

Table 7. HQ values for PCE in carpet spot remover and dry-cleaned clothes

Product	PCE concentration	Exposure dose (mg/kg bw/day)	RfD (mg/kg bw/day)	HQ
Carpet spot remover	12%	0.0034	0.006	0.56
Dry-cleaned clothes	0.08 mg/m^3	0.0023		0.38

HQ: hazard quotient, PCE: perchloroethylene, bw: body weight, RfD: reference dose

The HQ was less than 1, which indicates that the presence of PCE in carpet spot remover and residual PCE from dry-cleaned clothes is unlikely to be a cause for concern with respect to non-cancer effects.

5.2 CARCINOGENIC RISK

The lifetime cancer risk (LCR) is usually investigated for carcinogenic chemicals. In this assessment, LCR was determined by using the following equation:

$$LCR = ED \times CSF$$

where ED is the estimated daily exposure to PCE and CSF represents the cancer slope factor (mg/kg/day), which approximates the cancer risk per unit intake dose of PCE that would cause cancer over an average lifetime. Since CSF is related to oral exposure, ED should also be expressed in terms of oral exposure. Animal studies have reported the rapid and near-complete absorption of PCE following oral administration, so ED in the above equation will be equal to ED determined in section 4.2 for PCE in carpet spot remover and residual PCE from drycleaned clothes.

A life-stage weighted average was calculated for PCE exposure in adults to estimate the overall lifetime exposure. It was assumed that childhood refers to the first 15 years of life and adulthood is the balance (55 years) of a 70-year lifetime. Hence, the life-stage weighted average for an adult.

- **PCE in carpet spot remover:** 0.0034 x 55/70 = 0.0026 mg/kg bw/day
- **Residual PCE in dry-cleaned clothes:** 0.0023 x 55/70= 0.0018 mg/kg bw/day

The WHO (2017) recommends that the LCR for exposure to a carcinogenic contaminant in drinking water and air should be 10^{-5} or less. This value has been used in New Zealand for standard setting, particularly for drinking water (TaumataArowai, 2021). Table 8 summarises the estimates of LCR due to exposure to PCE in carpet spot remover and dry-cleaned clothes.

Table 8. Life-stage weighted average exposure and lifetime cancer risk due to exposure to PCE in carpet spot remover and dry-cleaned clothes

Product	PCE concentration	Exposure dose (mg/kg bw/day)	CSF (mg/kg bw/day)	LCR
Carpet spot remover	12%	0.0026	2×10^{-3}	5.34×10^{-6}
Dry-cleaned clothes	0.08 mg/m^3	0.0018		3.6×10^{-6}

PCE: perchloroethylene, bw: body weight, CSF: cancer slope factor, LCR: lifetime cancer risk

The LCR values due to exposure to PCE in carpet spot remover and dry-cleaned clothes were both lower than an excess cancer risk of 10^{-5}.

5.3 ACCURACY OF THE RISK ESTIMATES

The concentration of 12% PCE that was used for carpet spot removers is likely to be an overestimate in the author's opinion, as this was reported more than 20 years ago in 2001. Based on the limited information available on the composition of carpet cleaners in the current market, it is likely that PCE has since been replaced by alternative chemicals. It has also been reported that the use of PCE in dry cleaning has declined sharply in the past 40 years due to improved solvent recycling systems and concerns about worker health.

Despite this decrease in use of PCE in carpet spot removers and dry cleaning, the overall worldwide production of PCE is slowly increasing (ACS, 2017). However, while PCE exposure

from other sources such as food, water (1 µg/day or 1.4 x 10^{-5} mg/kg bw/day) and air (120 µg/day or 0.0007 mg/kg bw/day) is also possible, the available information suggests that exposure from these sources is negligible compared with the sources of exposure considered in the current report (WHO, 2020). The WHO has not provided any data on PCE exposure from food.

6. CONCLUSIONS

PCE is an excellent solvent for organic materials. It is volatile, highly stable, and non-flammable. It is used in all-purpose spray cleaners (spot removers, mould cleaners), non-spray lubricants, glues and adhesives, and all-purpose waxes and polishes. It is also widely used in dry cleaning. According to DLANZ, most dry cleaners in New Zealand use PCE because of its cleansing properties.

There are few studies that have determined and reported the levels of PCE in consumer products and residual PCE levels in dry-cleaned clothes. According to NICNAS, PCE was found at a maximum concentration of 12% in carpet spot removers. Newly dry-cleaned clothes were found to have PCE up to the levels of 4.8 mg/m^3.

In this assessment, the ConsExpo Web model was used to estimate inhalation and dermal exposure to PCE in carpet spot remover. The consumer exposure to PCE from dry-cleaned clothes was calculated by using the US Environmental Protection Agency conventional approaches.

The human health risks of PCE through the dermal and inhalation pathways were characterised by determining HQ values. HQ was less than 1 for both carpet spot remover (12% PCE) and dry-cleaned clothes (0.08 mg PCE/m^3), indicating that the presence of PCE in these items is unlikely to be a cause for concern with respect to non-cancer effects.

LCR values were also estimated for adults based on the dermal and inhalation pathways of exposure. The results indicated that lifetime exposure to PCE from carpet spot remover and dry-cleaned clothes equated to an excess cancer risk of $<10^{-5}$, or less than 1 excess cancer in 100,000 individuals, which is the risk level that has been used in New Zealand for standard setting.

PCE exposure from other sources such as food, water (1 µg/day or 1.4×10^{-5} mg/kg bw/day) and air (120 µg/day or 0.0007 mg/kg bw/day) is also possible, but the available information suggests that exposure from these sources is negligible compared with the sources of exposure considered in the current report. WHO has not provided any data on PCE exposure from food.

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