ECSA
Nov 2011

Health Profile
on Perchloroethylene
Executive Summary

The chlorinated solvent, perchloroethylene (also known as PER, PERC, tetrachloroethylene and tetrachloroethene) has been widely used since the 1930s. Major applications are dry-cleaning, metal cleaning and degreasing, and as a chemical intermediate. Sales in the EU 27 countries plus Norway, Switzerland and Turkey totalled 44,000 tonnes in 2010. This figure has fallen substantially since the mid-1980s due to more efficient dry-cleaning processes, greater recycling, use of enclosed systems and other best practices.

Chlorinated solvents have been used extensively for many years. During this time, the only fatalities or serious injuries which have occurred have been due to massive over-exposure through a total disregard for good operating practices, or through deliberate misuse. When used with due care, perchloroethylene poses no threat to human health, safety or the environment.

There is no evidence that exposure to normal levels of chlorinated solvents increases the risk of cancer in humans, based on extensive toxicological and epidemiological research. Of five studies in laboratory animals, three found a significant increase in formation of liver tumours in mice exposed to the solvent. However, the mechanism of tumour formation is specific to rodents and is not relevant to humans. A small increase in incidence of certain kidney cancers and leukaemia has been reported in rats. In humans, there is no evidence of a link with kidney cancer, liver cancer or leukaemia. However, some studies indicate a higher risk of oesophageal cancer among people exposed to perchloroethylene.

Inhalation of solvent vapour is the most frequent route of exposure: solvent vapours are heavier than air and can accumulate in confined or poorly ventilated areas. As a result, good ventilation is essential in areas where the product is made or used. ECSA also strongly encourages use of state-of-the-art, contained systems to avoid the release of perchloroethylene into the environment.

Perchloroethylene does not deplete the ozone layer, and its contribution to global warming, acid rain and smog formation is negligible. Chlorinated solvents are unlikely to accumulate in living organisms or the environment. In sediment and soil, perchloroethylene is fairly mobile and can leach into groundwater.

During production, integrated manufacturing methods ensure that waste from one process is used in another process. This keeps manufacturing waste to a minimum, with any toxic or potentially environmentally damaging wastes recycled and converted to useful products, and final waste disposed of properly. ECSA encourages companies which manufacture and use this solvent to install spillage containment systems in storage and use areas. The Association strongly discourages land filling of waste, even though this may be legal in some areas.

Introduction

Perchloroethylene (also known as PER, PERC, tetrachloroethylene and tetrachloroethene) is a chlorinated hydrocarbon solvent which is a volatile, non-flammable liquid. This efficient and highly recyclable solvent has been extensively used since the 1930s. When used with due care, it poses no threat to human health, safety or the environment.

The use of perchloroethylene can be broken down as follows: as a chemical intermediate, dry cleaning and textile processing, metal cleaning and degreasing, and miscellaneous uses, such as film copying and cleaning.

In Europe, perchloroethylene is manufactured by Dow Europe, Solvay and Spolchemie. Sales in 2010 in the EU 27 countries plus Norway, Switzerland and Turkey totalled 44,000 tonnes. This product remains the solvent of choice for more than 70% of dry-cleaning shops and continues to gain market share as a substitute for trichloroethylene in metal degreasing. However, there has been a decline in production since the mid-1980s due to more efficient dry-cleaning processes, greater recycling, use of enclosed systems and other best practices.

Figure 1: European “non feedstock” market for chlorinated solvents

1 Companies manufacturing perchloroethylene in Europe
Industrial production of perchloroethylene began in 1914 in the UK and Germany and in 1925 in the US. Four grades are made for different applications: an alkaline/dry-cleaning grade, an alkaline/vapour degreasing grade for metal degreasing, a technical grade for formulation purposes, and a high purity grade for extraction. Small quantities of used perchloroethylene from a variety of industries are recycled, usually re-entering commerce for metal degreasing applications.

Stabilizers are normally added to perchloroethylene to prevent its decomposition during storage and use. The total concentration of stabilisers is normally less than 0.05% in dry-cleaning grade, with highly stabilized grades for metal cleaning applications containing up to 0.5%. Due to its relatively high stability, PER requires less stabilizer to be added than other chlorinated solvents. To be effective during use, the stabilisers - which include epoxides (metal degreasing), alkylamines and phenols (inhibiting antioxidation of PER by air), and secondary and tertiary alcohols - must vaporise at the same rate as perchloroethylene, so that both are present in the liquid and vapour phases.

During the production of chlorinated solvents, integrated manufacturing methods are employed so that waste from one process is used in another process. As a result, waste from the manufacturing plant is kept to a minimum, any toxic or potentially environmentally damaging wastes are recycled and converted to useful products, and final waste is disposed of properly.

Health effects

Chlorinated solvents have been used extensively for many years. During this time, the only fatalities or serious injuries which have occurred have been due to massive over-exposure through a total disregard for good operating practices, or through deliberate misuse. When solvents are stored, used and disposed of correctly, there is no risk to human health.

Inhalation of solvent vapour is the most frequent route of exposure: solvent vapours are heavier than air and can accumulate in confined or poorly ventilated areas. As a result, good ventilation is essential in areas where the product is made or used.

Cancer risk

In humans, there is no evidence of a link with kidney cancer, liver cancer or leukaemia. Some studies indicate a higher risk of oesophageal cancer among people exposed to perchloroethylene, which may not be entirely attributable to lifestyle factors such as smoking and drinking alcohol. Two recent studies found no association between dry-cleaning work and cancers (incl.those of the oesophagus and cervix) (Lynge et al., 2006 2, Selden and Ahlborg 2011 3). Overall, there is no evidence that exposure to normal levels of chlorinated solvents increases the risk of cancer in humans, based on extensive toxicological and epidemiological research.4

Five studies of the potential of perchloroethylene to cause cancer in laboratory animals have been conducted. Three of these showed a significant increase in formation of liver tumours in mice exposed to the solvent. A small increase in incidence of certain kidney cancers and leukaemia has been reported in rats. However, the ways these cancers form have been identified and the mechanisms are specific to rodents and not relevant to humans.

CNS and behavioural effects

Individuals exposed in their work to perchloroethylene have been studied over many years. Prolonged exposure to perchloroethylene at concentrations of 200 ppm or more has been linked to dizziness, confusion, headache, nausea, and irritation of the eyes and mucous membranes. These effects become

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4 SCOEL/SUM/133 (2009)
more pronounced at higher exposure (>600 ppm). In addition to central nervous system (CNS) effects, there may also be transient, minor alterations in liver or kidney function. Prolonged exposure to extremely high levels (>1,500 ppm) may lead to unconsciousness or even death from respiratory depression\(^5\). (Indeed, perchloroethylene was used as a human anaesthetic in the past.) Large accidental intakes (estimated at 1.6 - 4.8 g/kg) in children have led to effects such as vomiting, gastrointestinal bleeding, shock and in one case, death\(^6\).

The effects of prolonged or repeated exposure to perchloroethylene on the nervous and sensory systems have been examined in studies with dry cleaners as well as with volunteers. Some have reported minor neurobehavioral effects in people exposed to low levels of the solvent. These studies are difficult to interpret, however, since the changes observed (e.g. visual contrast sensitivity, colour vision, reaction time, visual memory) are small, their toxicological significance is uncertain and the methodologies used are inconsistent. To date, no clear association has been seen between neurobehavioral effects and exposure to perchloroethylene.

**Skin effects**
A few case reports show perchloroethylene to be a skin irritant, but not to be corrosive. In one case, extensive redness (erythema) and blistering were seen on a worker who had lain unconscious in a pool of solvents for about five hours.\(^7\) In a second case, another worker who had been unconscious for half an hour while wearing clothes soaked in perchloroethylene showed similar symptoms Considerable reduction of the symptoms was seen within five days, but some dryness, staining and irritation of the injured areas continued.\(^8\) Slight, transient eye irritation developing within the first hours of exposure and subsiding before the end of a work shift has been reported at exposure levels around 100 ppm. Mild nasal irritation was reported by volunteers exposed at 216 ppm for two hours, but not by those exposed at 106 ppm for one hour.

**Sensitization**
Tetrachloroethylene tested positive in the local lymph node assay in mice. Therefore, classification according to Directive 67/548/EEC and the EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 for skin sensitisation is needed. This experimental result contrasts with the rarity of case reports (n=3) associating skin or respiratory sensitisation with perchloroethylene exposure despite its widespread use\(^9\).

**Liver and kidney effects**
In laboratory animals, acute and repeated inhalation exposure to high levels of perchloroethylene causes kidney and liver effects. Temporary liver and kidney effects are also reported in cases of acute inhalation poisoning of people with high levels of this solvent. High exposures to perchloroethylene cause increasing levels of trichloroacetic acid, a breakdown product of perchloroethylene, which can cause cellular damage. Relative to humans, laboratory animals (especially mice) have higher production rates of trichloroacetic acid.

No effects on markers of liver and kidney toxicity were observed in dry-cleaners with a mean 8-hour exposure of 21 ppm for 6 years\(^10\). Specific hepatotoxicity and nephrotoxicity studies have provided no clear evidence for tetrachloroethylene-induced liver or kidney toxicity at exposure concentrations below 50 ppm.

It is strongly recommended that users stay within legislative or manufacturers’ guidelines to keep human and environmental exposures to a minimum. Compliance with applicable regulations, use of engineering controls, best available work practices and occupational health surveillance, will help ensure that

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\(^{5}\) SCOEL/SUM/133 (2009)


\(^{9}\) NEG-DECOS (2003)

perchloroethylene can continue to be used in a safe and environmentally sound manner.

**Genetic, reproductive and developmental effects**

A large number of studies has been conducted and overall no evidence was found that perchloroethylene-induced effects result from mutations or damage to genetic material.

Epidemiological studies of workers in the dry-cleaning sector have found very limited and inconsistent evidence for effects on fertility (quality of semen) and foetal development (spontaneous abortions). It is unclear whether any such effects may be related to perchloroethylene alone, or to a mixture of solvents. Experimental studies with laboratory animals indicated that developmental effects only occurred at exposure levels at which the parental animals showed clear signs of toxicity.

This confirms the need for all users of perchloroethylene to comply with regulations and to implement best practices at all times.

**Environmental effects**

Perchloroethylene does not deplete the ozone layer, and its contribution to global warming, acid rain and smog formation is negligible. In many applications, it performs as well or better than suggested alternatives, which may themselves have significant impacts on the environment and on human health. Chlorinated solvents account for less than 6% of total solvent emissions to the atmosphere from all sources in Western Europe.

Chlorinated solvents are unlikely to accumulate in living organisms or the environment. Direct photolysis is not expected to be an important removal process for tetrachlorethylene, but it undergoes reactions with hydroxyl radicals in the atmosphere, resulting in a half-life in the atmosphere of around 50 days. Any spills to water or soil are most likely to re-evaporate into the atmosphere within a few days to one month, depending on water movement, depth and wind speed.

In sediment and soil, perchloroethylene is fairly mobile and can leach into groundwater. Under these conditions no physicochemical breakdown (hydrolysis) has been reported. The solvent is not biodegradable under standard test conditions, and may be resistant to breakdown in the presence of oxygen (aerobic conditions). However, in anaerobic conditions, some breakdown has been seen.

ECSA encourages companies which manufacture and use this solvent to install spillage containment systems in storage and use areas. The Association strongly discourages land filling of waste, even though this may be legal in some areas.

**Environmental levels**

Perchloroethylene has been detected at levels of parts per billion (ppb) in all environmental compartments in aquatic organisms and in plants. Background levels in air in remote regions is typically much lower (< 0.1 ppb) than in urban areas (up to 3 ppb). The solvent has been found in indoor air at concentrations of up to one part per million (ppm), mostly due to its use in dry-cleaning; it may also occur in drinking water and foods.

**Ecotoxicity**

In the aquatic environment all trophic levels show similar sensitivity to the acute toxic effects of perchloroethylene, with the Lethal or Effective Concentration for 50% of the test population (LC50 or EC50) in acute screening tests ranging between 1 to 10 mg/l.

In fish and daphnia, chronic exposure to this solvent does not increase its toxicity significantly.

No adverse effects on the aquatic ecosystem have been reported at concentrations below 0.5 mg/l. the No Observed Effect Concentration (NOECs) in soil are of the order of 0.1 mg/kg (dry weight).

Several soil organisms, including micro-organisms, invertebrates and plants have been used to assess the toxicity of perchloroethylene after acute or prolonged exposure. Long term NOECs for earthworm and soil micro-organisms were 20.4 and 0.11 mg/kg solid (dry weight) respectively. The most critical NOEC for
plants was 46 µg/m³ for Phaseolus vulgaris (bean)

Based on its octanol-water partition coefficient, no significant bioaccumulation of perchloroethylene is expected. On the basis of measured bio concentration factors, there is no evidence of biomagnification along the food chain.

**Regulation**

Perchloroethylene use is regulated under the Solvent Emissions Directive (1999/13/EC). The Solvent Emissions Directive was combined recently with six other directives in the Industrial Emissions Directive (2010/75/EU). ECSA welcomes the implementation of this directive, with its goals of reducing workplace exposures and environmental emissions. Modern equipment allows more efficient use of chlorinated solvents, and will continue to contribute to the sustainability of this class of product.

Perchloroethylene has been registered in 2010 in compliance with the REACH regulation (1907/2006/EC on the Registration, Evaluation, Authorisation and Restriction of Chemicals). An excerpt of the registration dossier can be consulted via the ECHA website. Based on the analysis of the most recent review of the available data a number of Derived No Effect Levels (DNEL) and Perceived No Effect Concentrations (PNECs) were proposed in the REACH dossier:

Perchloroethylene REACH dossier (2010) Derived No Effect Levels for workers and general population

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Acute effects</th>
<th>Chronic effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers</td>
<td>275</td>
<td>39.4</td>
</tr>
<tr>
<td>General population</td>
<td>138</td>
<td>23</td>
</tr>
</tbody>
</table>

Perchloroethylene REACH dossier (2010): Perceived No Effect Concentrations (PNECs) of perchloroethylene for Ecotoxicity endpoints

<table>
<thead>
<tr>
<th>Environmental Compartiment</th>
<th>PNEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freshwater</td>
<td>0.051</td>
</tr>
<tr>
<td>Marine water</td>
<td>0.0051</td>
</tr>
<tr>
<td>Freshwater sediment</td>
<td>0.903</td>
</tr>
<tr>
<td>Marine water sediment</td>
<td>0.0903</td>
</tr>
<tr>
<td>Soil</td>
<td>0.01</td>
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<tr>
<td>STP</td>
<td>11.2</td>
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</table>
The European Chlorinated Solvent Association (ECSA) released in 2011 an online toolbox freely accessible via the ECSA website to provide users of chlorinated solvents with information about the safe & sustainable use of these products. The recommendations do take into account REACH as well as other European legislation or voluntary industry commitments. The content of the Toolbox is based on the REACH Chemical Safety Assessment (CSA) of the substances. However, the Toolbox does include recommendations based on experience of ECSA members that go beyond the given legal framework of the CSA under REACH.

**Occupational exposure**

In Europe, the Scientific Committee on Occupational Exposure Limits (SCOEL) published following recommendation for perchloroethylene in 2009:
- 8 hour TWA 20 ppm [138 mg/m³]
- STEL (15 min) 40 ppm [275 mg/m³]
- BLV 0.4 mg tetrachloroethylene per liter blood
  - [sampling time: prior to the last shift of a work-week]
- 3 ppm [0.435 mg/m³] tetrachloroethylene in end-exhaled air
  - [sampling time: prior to the last shift of a work-week]
- SCOEL carcinogen group: D (non-genotoxic carcinogen with threshold)
  - Notation: ‘skin’

**Beyond compliance**

ECSA strongly recommends that perchloroethylene only be used in applications where all relevant workplace, disposal and other environmental regulatory requirements are met. In addition, many prudent operators have chosen to adopt practices and standards that go beyond the strict legal requirements for use, management and disposal of perchloroethylene and perchloroethylene-containing wastes. In addition to taking full responsibility for environmental protection, these operators help to avoid potential liability for any environmental contamination that can be traced to their solvent wastes - whether at their own plant or elsewhere - regardless of whether they have complied with the letter of the law. Such additional measures that go “beyond compliance” make good business sense because they minimise risks of liability.

**Regulatory and other information for perchloroethylene**

Below data is meant as a summary. Information on Classification & Labelling of the substance to be found in a separate document on the ECSA webpage or on the ECHA webpage.

- **Chemical formula:** C₂Cl₄
- **Molecular weight:** 165.85
- **CAS-number:** 127-18-4
- **EINECS-number:** 204-825-9

**Hazard statements:**
- H351: Suspected of causing cancer .
- H411: Toxic to aquatic life with long lasting effects.

**Proposed hazard statements:**
- H351: Suspected of causing cancer .
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H336: May cause drowsiness or dizziness.
- H411: Toxic to aquatic life with long lasting effects.
Revision Date: November 2011

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ECSA – The European Chlorinated Solvent Association

ECSA represents the interests of the producers of chlorinated solvents in the EU that are organized under Euro Chlor.

Euro Chlor is the Brussels based business association representing chlor-alkali producers in the EU and EFTA regions, employing 39,000 people at nearly 70 manufacturing sites. Almost 2,000,000 jobs in Europe are related to chlorine and its co-product caustic soda. These two key chemical building blocks underpin 55% of the European chemical industry turnover. More than 90% of the European drinking water is made safe with chlorine and about 85% of all medicines are synthesized using chlorine chemistry.

Euro Chlor is an affiliate of Cefic – the European Chemical Industry Council.