# Summary of Initial Risk Assessment Report

## **Tetrachloroethylene** CAS No : 127-18-4

PRTR No of Japan: 200

This substance is assessed based on Guideline for Initial Risk Assessment Version 1.0

## 1. General Information

### 1.1 Physico-chemical properties

| | |
|---|---|
| Appearance | Colorless liquid |
| Melting point | Approx. -22 degC |
| Boiling point | 121 degC |
| Water solubility | 206 mg/L (25 degC) |
| Henry's constant | $1.79*10^3$ Pa*$m^3$/mol ($1.77*10^{-2}$ atm*$m^3$/mol) (24degC, measured) |
| Octanol/water partition coefficient (log Kow) | 3.40 (measured), 2.97 (estimated) |
| Soil adsorption coefficient | Koc = 177-350 (measured) |

### 1.2 Environmental fate

| | |
|---|---|
| Bioaccumulation | Not bioaccumulative or low bioaccumulative<br>Bioconcentration factor (BCF) : 25.8-77.1 (0.1 mg/L), 28.4-75.7 (0.01 mg/L ) (carp, measured), 39 (*Pimephales Promelas*,measured), 49 (*Lepomis macrochirus*,measured) |
| Biodegradation | Non-biodegradable |
| Stability in the environment | (In air)<br>Reaction with OH radical:<br>Reaction rate constant is $1.7*10^{-11}$ $cm^3$/molecule-sec.(25 degC, measured)<br>The half-life is 0.5-1 day, given OH radical concentration of $5*10^5$-$1*10^6$ molecule/$cm^3$.<br>Reaction with ozone:<br>Reaction rate constant is $2.0*10^{-23}$ $cm^3$/molecule-sec or less.(25 degC, measured)<br>The half-life is calculated to be 2,000 years or longer, given ozone concentration of $7*10^{11}$ molecule/$cm^3$. Therefore tetrachloroethylene is not expected to react with ozone.<br>Reaction with nitrate radical:<br>Reaction rate constant is $5.2*10^{-17}$ $cm^3$/molecule-sec or less.(25 degC, measured)<br>The half-life is calculated to be 3 months or longer, given nitrate radical concentration of $2.4*10^9$ molecule/$cm^3$ (100 ppt).<br>(In water)<br>Tetrachloroethylene is not expected to be hydrolyzed in water. |
| Environmental fate | When released to water, tetrachloroethylene is expected to be removed from water mainly by volatilization. Tetrachloroethylene may be removed by biodegradation under specific conditions involving acclimatized microorganisms. |

## 2. Sources of release to the environment

### 2.1 Annual production, import, export and domestic supply in 2001 (ton/year)

| Production | Import | Export | Domestic supply | Remarks |
|---|---|---|---|---|
| 25,049 | 12,750 | 810 | 36,989 | |

### 2.2 Uses

Raw material for chlorofluorocarbon alternatives (69.2%), dry cleaning solvents (17.7%), degreasing cleaners (11.8%), solvents (1.3%)

### 2.3 Release from the industries within the scope of PRTR system (in 2001)

| Release sources | | Air (ton) | Waters (ton) | Soil (ton) | Remarks |
|---|---|---|---|---|---|
| Listed industries | Reported release | 2,332 | 2 | 0 | Release to rivers: 36 tons |
| | Release outside notification | 35,709 | 34 | 0 | |
| Release outside notification from non listed industry | | -- | -- | -- | |
| Households | | -- | -- | -- | |
| Mobile sources | | -- | -- | -- | |
| Total | | 38,041 | 36 | 0 | |

### 2.4 Releases from other sources

Causes of groundwater contamination by tetrachloroethylene are thought to be inappropriate handling of the substance during use and disposal processes and inappropriate landfilling of sludge that contains it.

### 2.5 Main release route

Tetrachloroethylene is expected to be mainly released to air during its use as solvents in dry cleaning and in metal products manufacturing industries.

## 3. Exposure Assessment

### 3.1 Measured environmental concentration

| Media | No. of points detected / No. of points measured | No. of samples detected / No. of samples measured | Detection range | 95th percentile | Detection limit | Year of investigation, Institution |
|---|---|---|---|---|---|---|
| Air (microg/$m^3$) | --/333 | --/3,997 | 0.026-4.4[1)] | -- | -- | 2001 Ministry of the Environment |
| River water (microg/L) | 44/2,248 | 261/7,724 | nd-6.0[1)] | -- | 0.20 - 5.0 | 2001 Environmental Information Center, National Institute for Environmental Studies |
| Drinking water (microg/L) | 5,648 [2)] | -- | nd-5.0[1)] | -- | -- | 2001 Japan Water Works Association |
| Food (microg/g) | 6/24 | 10/72 | nd-0.0010 | 0.0003 | 0.0002 | 1999 Ministry of the Environment |

nd: Not detected.

For calculation of the 95th percentile, data less than the detection limit are replaced with a value of one half of the detection limit.

1) Annual average

2) Number of water purification plants in Japan

### 3.2 Estimated environmental concentration

| Media | Estimated concentration | Description |
|---|---|---|
| Air (microg/$m^3$) | 12 | Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment ver.1.0 (AIST-ADMER) |
| River water (microg/L) | 0.13 | Calculated by mathematical model / Integrated River Model to predict the distribution of chemical concentration ( IRM1 ) |

### 3.3 Estimated environmental concentration in water (EEC)

| | |
|---|---|
| EEC(microg/L) | 6.0 |
| | Maximum of annual average concentration (6.0 microg/L) surveyed by the National Institute for Environmental Studies in 2001[1)]. |

### 3.4 Estimated human intake

| Intake route | | Concentration used for estimation of intake | Estimated intake (microg/ person/ day) | Estimated intake (microg/ kg-Bodyweight (BW)/ day) |
|---|---|---|---|---|
| Inhalation | Air | 4.4 (microg/m$^3$) | 88 | 1.8 |
| | | Measured concentration of 4.4 microg/m$^3$ surveyed by the Ministry of the Environment in 2001 | | |
| Oral | Drinking water | 5 (microg/L) | 10 | 0.2 |
| | | Measured concentration of 5 microg/L surveyed by the Japan Water Works Association in 2001 | | |
| | Food | 0.0003 (microg/g-wet) | 0.60 | 0.012 |
| | | A duplicate diet study was performed on household for 3 days by the Ministry of the Environment in 1999. The concentrations of tetrachloroethylene were measured for each of the household diets. The ninety-fifth percentile (0.0003 microg/g-wet) was used for the risk assessment. | | |
| | Subtotal | -- | 11 | 0.21 |
| Total route | | -- | 99 | 2.0 |

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version1.0. If adequate measured concentrations are available, they are given priority and used as values for risk assessment. If they are not available, an estimated value calculated using a mathematical model is used.

## 4. Hazard assessment

### 4.1 Effects on organisms in the environment

| | Acute or Chronic | Species | Endpoint | Concentration |
|---|---|---|---|---|
| Algae | Chronic | *Chlamydomonas reinbardtii* | 72 hours $EC_{10}$ Growth inhibition (biomass) | 1.77 (mg/L) |
| Crustacea | Chronic | *Daphnia magna* | 21 days NOEC Reproduction | 0.08 (mg/L) |
| Fish | Chronic | *Pimephales promelas* | 32 days NOEC Growth | 0.5 (mg/L) |
| Key study | | The data of crustacea (*daphnia magna*) was chosen for the key study because effects were observed at the lowest concentration in the hazard assessment. | | |

**4.2 Human health toxicity**

| Toxicity | Exposure route | Species | Duration / Dose method | Toxic effects (Key study is underlined) | NOAEL or LOAEL |
|---|---|---|---|---|---|
| Repeated dose toxicity | Inhalation | Mouse ($B6C3F_1$) | 2 years (6 hours/day, 5 days/week) | Karyomegaly of renal tubular epithelial cells, hepatocellular vacuolation, necrosis, inflammatory cell infiltrates, pigmentation and oval cell hyperplasia in liver, nephrosis | LOAEL: 100 ppm (690 mg/$m^3$) (equivalent to 210 mg/kg/day) |
| | Oral | Mouse (Swiss) male | 6 weeks Gavage administration | Increased relative weight of liver, hepatocellular hypertrophy, increased serum TG, hepatic fatty degeneration, nuclear disintegration and necrosis, decreased serum G-6-P, increased serum ALT | NOAEL: 20 mg/kg/day |
| | Dermal | -- | -- | -- | -- |
| Reproductive and developmental toxicity | -- | -- | -- | -- | -- |
| Carcinogenicity | Inhalation | Mouse ($B6C3F_1$) | 103 weeks (6 hours/day, 5 days/week) | Significant increase of hepatocellular cancer | LOAEL: 100 ppm (690 mg/ $m^3$) (equivalent to 210 mg/kg/day) |
| | Oral | Mouse ($B6C3F_1$) | 78 weeks (5 days/week) Gavage administration | Significant increase in the incidence rate of hepatocellular cancer | LOAEL: 386 mg/kg/day (equivalent to 280 mg/kg/day) |
| | Evaluation by IARC : Group 2A (Probably carcinogenic to humans) | | | | |
| Genotoxicity | Not considered to be genotoxic | | | | |

## 5. Risk Assessment

### 5.1 Environmental organisms

| Risk characterization | EEC (microg/L) | NOEC * (mg/L) | MOE (NOEC * /EEC) | Product of uncertainty factors | Conclusion |
|---|---|---|---|---|---|
| | 6.0 | NOEC: 0.08 | 13 | 10 | No immediate concern |
| | Product of uncertainty factors (UF): Extrapolation from laboratory test (10) = 10 | | | | |
| Recommendation : The substance is considered to be of no immediate concern for the moment, and a low priority for further work. Concentrations of tetrachloroethylene in aquatic environments need to be monitored because the MOE is close to the UF and tetrachloroethylene was frequently detected in the environment. | | | | | |

NOEC* means NOEC, LOEC, $EC_{50}$, etc.

### 5.2 Human health

#### 5.2.1 Repeated dose toxicity

| Exposure route | Intake (microg/kgBW/day) | NOAEL (mg/kgBW/day) | Risk characterization | | |
|---|---|---|---|---|---|
| | | | MOE | Product of uncertainty factors | Conclusion |
| Inhalation | 1.8 | LOAEL: 210 | 120,000 | 1,000 | No immediate concern |
| Oral | 0.21 | 20 | 95,000 | 1,000 | No immediate concern |
| Total | 2.0 | 20 (Oral ) | 10,000 | 1,000 | No immediate concern |
| Product of uncertainty factors (UF):<br>Inhalation: Interspecies (10) * Intraspecies (10) * LOAEL is used (10) = 1,000<br>Oral/Total: Interspecies (10) * Intraspecies (10) * Duration of test (10) = 1,000 | | | | | |

#### 5.2.2 Reproductive and developmental toxicity

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#### 5.2.3 Carcinogenicity

| Exposure route | Intake (microg/kgBW/day) | NOAEL (mg/kgBW/day) | Risk characterization | | |
|---|---|---|---|---|---|
| | | | MOE | Product of uncertainty factors | Conclusion |
| Inhalation | 1.8 | LOAEL: 210 | 120,000 | 10,000 | - |
| Oral | 0.21 | LOAEL: 280 | 1,300,000 | 10,000 | - |
| Total | 2.0 | 210 (inhalation ) | 110,000 | 10,000 | - |
| Product of uncertainty factors (UF):<br>Interspecies (10) * Intraspecies (10) * Using of LOAEL (10) * Carcinogenicity (10) = 10,000 | | | | | |

### 5.2.4. Recommendation for Human Health

Further information on the carcinogenicity of tetrachloroethylene should be collected because there were several assumptions in the risk assessment:

- Tetrachloroethylene was not considered to be genotoxic, therefore it was assumed to be a carcinogenic substance with threshold values.

- The MOE was calculated using the lowest dose in the carcinogenicity test instead of the LOAEL. The actual LOAEL for this substance may be lower.

## 6. Supplement

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