

## Summary of Initial Risk Assessment Report

### ***p*-Dichlorobenzene** CAS No : 106-46-7

PRTR No of Japan: 140

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

#### 1. General Information

##### 1.1 Physico-chemical properties

|  |   |
|--|---|
| Appearance                                     | White solid   |
| Melting point                                  | 53.5 degC ( $\alpha$ -type), 54 degC ( $\beta$ -type)   |
| Boiling point                                  | 174.12 degC   |
| Water solubility                               | 81.3 mg/L (25 degC)   |
| Henry's constant                               | 244 Pa*m <sup>3</sup> /mol (2.41*10 <sup>-3</sup> atm*m <sup>3</sup> /mol) (25degC, measured) |
| Octanol/water partition coefficient ( log Kow) | 3.44 (measured), 3.28 (estimated)   |
| Soil adsorption coefficient                    | Koc = 273, 390 (measured), 430 (esimated)   |

##### 1.2 Environmental fate

|                              |  |
|------------------------------|--|
| Bioaccumulation              | Not highly bioaccumulative<br>Bioconcentration factor (BCF) : 33-72 (2 microg/L), 47-190 (0.2 microg/L) (carp), 78 ( <i>Gambusia affinis</i> ), 370-720 ( <i>Oncorhynchus mykiss</i> ), 60 ( <i>Lepomis macrochirus</i> ) (measured)   |
| Biodegradation               | <i>p</i> -Dichlorobenzene is generally considered non-biodegradable; however, it is expected to be biodegradable in specific conditions involving acclimatized microorganisms.   |
| Stability in the environment | (In air)<br>Reaction with OH radical:<br>Reaction rate constant is 3.2*10 <sup>-11</sup> cm <sup>3</sup> /molecule-sec. (25 degC, measured)<br>The half-life is 6 hours to 0.5 days, given OH radical concentration of 5*10 <sup>5</sup> -1*10 <sup>6</sup> molecule/cm <sup>3</sup> .<br>Reaction with ozone: No data<br>Reaction with nitrate radical: No data<br><i>p</i> -Dichlorobenzene is not expected to directly photolyzed.<br>(In water)<br><i>p</i> -Dichlorobenzene is not hydrolyzed in the aquatic environment. |
| Environmental fate           | If released into water, <i>p</i> -dichlorobenzene is expected to be removed from water mainly by volatilization. <i>p</i> -dichlorobenzene may also 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 |
|------------|--------|--------|-----------------|---------|
| 32,500     | 7,500  | 0      | 40,000          |         |

### 2.2 Uses

Insect repellents/air fresheners (50%), raw material for resins (45%), chemical intermediates (5%)

### 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             | 100       | 1            | 0          | Release to river: 0.824 tons |
|   | Release outside notification | 10        | 0            | 0          |                              |
| Release outside notification from non listed industry |                              | --        | --           | --         |                              |
| Households  |                              | 20,000    | 0            | 0          |                              |
| Mobile sources  |                              | --        | --           | --         |                              |
| Total   |                              | 20,110    | 1            | 0          |                              |

### 2.4 Releases from other sources

No information about the substance is available.

### 2.5 Main release route

*p*-Dichlorobenzene is expected to be released mainly to indoor air by volatilization of household products such as insect repellents and air fresheners.

### 3. Exposure Assessment

#### 3.1 Measured environmental concentration

| Media                                    | No. of points detected /<br>No. of points measured | No. of samples detected /<br>No. of samples measured | Detection range | 95th percentile | Detection limit | Year of investigation,<br>Institution            |
|--|--|--|-----------------|-----------------|-----------------|--|
| Air<br>(microg/m <sup>3</sup> ) (indoor) | --   | unspecified /105                                     | 1.1-906         | 466             | 0.7             | 2000-2001<br>Tokyo<br>Metropolitan<br>Government |
| River water<br>(microg/L)                | 5/27   | 104/425  | nd-0.2          | 0.25            | 0.2             | 2000<br>Tokyo<br>Metropolitan<br>Government      |
| Drinking water<br>(microg/L)             | 11/ unspecified                                    | 1/ unspecified                                       | nd-0.1          | --              | --              | 2001<br>Tokyo<br>Metropolitan<br>Government      |
| Food<br>(microg/g)                       | --   | 18/57  | nd-0.23         | 0.06            | 0.01            | 1998<br>Japan Food<br>Research<br>Laboratories   |

nd: Not detected

For calculation of the 95th percentile, data less than the detection limit are replaced with a value equal to 1/2 of the detection limit.

#### 3.2 Estimated environmental concentration

| Media                        | Estimated concentration | Description   |
|------------------------------|-------------------------|---|
| Air (microg/m <sup>3</sup> ) | 4.8                     | Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment ver.1.0 (AIST-ADMER) |
| River water (microg/L)       | 15                      | Calculated by mathematical model / Initial Assessment System for the PRTR chemicals (IAS)                             |

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

|               |  |
|---------------|--|
| EEC(microg/L) | 0.25   |
|               | The ninety-fifth percentile (0.25 microg/L) of measured concentrations in river surveyed by the Tokyo Metropolitan Government in 2000 was used for the risk assessment <sup>1)</sup> . |

### 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            | 466 (microg/m <sup>3</sup> )  | 9,320                                  | 190  |
|   |                | The ninety-fifth percentile (466 microg/m <sup>3</sup> ) of measured concentrations in indoor air of households surveyed by the Tokyo Metropolitan Government <sup>1)</sup> . |  |  |
| Oral  | Drinking water | 0.1 (microg/L)  | 0.2                                    | 0.004  |
|   |                | Measured concentration of 0.1 microg/L surveyed by the Tokyo Metropolitan Government.   |  |  |
|   | Food           | 0.06 (microg/g)   | 120                                    | 2.4  |
| Duplicate diet study was performed on households by Japan Food Research Laboratories in 1999. The ninety-fifth percentile in the survey was used. |                |   |  |  |
|   | Subtotal       | --  | 120                                    | 2.4  |
| Total route   |                | --  | 9,440                                  | 190  |

1) The 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     | Acute            | <i>Selenastrum capricornutum</i>  | 96 hours EC <sub>50</sub>    | 1.6 (mg/L)    |
| Crustacea | Chronic          | <i>Daphnia magna</i>  | 28 days NOEC<br>Reproduction | 0.22 (mg/L)   |
| Fish      | Chronic          | <i>Jordanell floridae</i>   | 14-16 days NOEC<br>Mortality | 0.216 (mg/L)  |
| Key study |                  | The data of fish ( <i>Jordanell floridae</i> ) 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<br>(Key study is underlined)   | NOAEL or LOAEL  |
|---|---|--------------|--|--|---|
| Repeated dose toxicity                  | Inhalation  | Mouse<br>Rat | 104 weeks  | <u>Eosinophilic changes in olfactory epithelium</u> and respiratory epithelium, respiratory metaplasia in the nasal cavity gland, increased weight of liver and kidneys, mineralisation of the papilla collecting tube and urothelial hyperplasia, nephropathy | NOAEL: 75 ppm<br>(458 mg/m <sup>3</sup> )<br>(equivalent to 61 mg/kg/day) |
|   | Oral  | Dog          | 1 year<br>Gavage   | <u>Increased serum ALT, AST and gamma-GTP, increased liver and kidneys weight, hepatocellular hypertrophy and pigment deposition, bile duct hyperplasia, hepatic portal inflammation, kidney duct epithelial vacuolisation</u>                                 | NOAEL:<br>10 mg/kg/day<br>(equivalent to 7.1 mg/kg/day)                   |
|   | Dermal  | --           | --   | --   | --  |
| Reproductive and developmental toxicity | Oral  | Rat          | Two-generation reproduction toxicity study administered by oral gavage | <u>Decreased number of live offspring and reduced body weight at birth, and so on at doses without maternal toxicity</u>   | NOAEL:<br>30 mg/kg/day  |
| Carcinogenicity                         | Evaluation by IARC : Group 2B (possibly carcinogenic to humans) |              |  |  |   |
| Genotoxicity                            | Probably not genotoxic  |              |  |  |   |

### 5. Risk Assessment

#### 5.1 Environmental organisms

| Risk characterization  | EEC<br>(microg/L) | NOEC *<br>(mg/L) | MOE<br>(NOEC * /EEC) | Product of uncertainty factors | Conclusion           |
|--|-------------------|------------------|----------------------|--------------------------------|----------------------|
|  | 0.25              | NOEC: 0.216      | 860                  | 50                             | No immediate concern |
| Product of uncertainty factors (UF):<br>Extrapolation from laboratory test (10) * Toxicity data on two nutritional stages (5) = 50 |                   |                  |                      |                                |                      |
| Recommendation :<br>The substance is considered to be of no immediate concern for the moment, and a low priority for further work. |                   |                  |                      |                                |                      |

\* NOEC means NOEC, LOEC, EC<sub>50</sub>, 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  | 190                      | 61                  | 320                   | 100                            | No immediate concern |
| Oral  | 2.4                      | 7.1                 | 3,000                 | 100                            | No immediate concern |
| Total   | --                       | --                  | --                    | --                             | --                   |
| Product of uncertainty factors (UF): Inhalation/Oral: Interspecies (10) * Intraspecies (10) = 100 |                          |                     |                       |                                |                      |

### 5.2.2 Reproductive and developmental toxicity

Since NOAEL of reproductive and developmental toxicity was larger than NOAEL of repeated toxicity, risk characterization was not carried out.

### 5.2.3 Carcinogenicity

Risk characterization of carcinogenicity of the substance was not carried out in this assessment.

### 5.2.4. Recommendation for Human Health

Though the substance is considered to be of no immediate concern for the moment and a low priority for further work, it should be noted that a carcinogenic risk characterization was not conducted. The possibility remains that this substance may be carcinogenic to humans.

## 6. Supplement

--