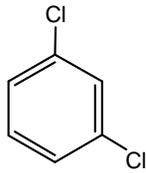


8	CAS No.: 541-73-1	Substance: <i>m</i> -dichlorobenzene
<p>Chemical Substances Control Law Reference No.: 3-41 (dichlorobenzene) PRTR Law Cabinet Order No.:</p> <p style="text-align: center;">Structural Formula:</p> <p>Molecular Formula: C₆H₄Cl₂ Molecular Weight: 147.00</p> <div style="text-align: center;">  </div>		
<p>1. General information</p> <p>The aqueous solubility of this substance is 125 mg/L (25°C) and the partition coefficient (1-octanol/water) (log K_{ow}) is 3.525. The vapor pressure is 2.15 mmHg (= 287 Pa) (25°C). Degradability (aerobic degradation) in terms of BOD-based degradation percentage is estimated to be 0%. This substance is determined to be non or not highly bioaccumulative.</p> <p>This substance is a Type 3 Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances. It is mainly used for organic solvents and intermediates for agricultural chemicals, dyes, pigments, and pharmaceutical products. The totals of production (shipment) and imports in FY 2001 and FY 2004 were both 10,000 to less than 100,000 tons/yr.</p> <hr/> <p>2. Exposure assessment</p> <p>As <i>m</i>-dichlorobenzene is not a Class 1 Designated Chemical Substance under the Law concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law), no information on release and transfer quantities could be obtained. When predictions of distribution ratios by medium were made using the Mackay-Type Level III Fugacity Model, in the event of equal release to the atmosphere, water and soil, the distribution ratio was highest for soil.</p> <p>The predicted maximum exposure concentration for inhalation exposure to human beings was estimated at approximately 0.24 µg/m³ based on data for the ambient air. The highest estimated oral exposure was calculated at approximately 0.0012 to less than 0.04 µg/kg/day based on groundwater and food data.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be 0.04 µg/L for freshwater and 0.03 µg/L for seawater public water bodies.</p> <hr/> <p>3. Initial assessment of health risk</p> <p>The vapor of this substance irritates the eyes, the skin and the respiratory tract. By inhalation, it may cause cough, drowsiness, sore throat and vomiting. By ingestion, it may cause burning sensation, diarrhea, nausea and vomiting. Contact with eyes or skin may cause redness and pain.</p> <p>There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.</p> <p>A lowest-observed-adverse-effect-level (LOAEL) of 9 mg/kg/day (decrease in the colloid density in the thyroid follicles and vacuolation of anterior pituitary cells) was obtained for oral from the medium- and long-term toxicity testing for rats. As this was a LOAEL, it was divided by 10, and because of the short experimental period, the value was further divided by 10, and a value of 0.09 mg/kg/day was derived as the 'Non-toxic level*'. For inhalation exposure, the 'Non-toxic level*' could not be estimated.</p> <p>With regard to oral exposure, in case of intakes of groundwater and food, the predicted maximum exposure ranged</p>		

from 0.0012 µg/kg/day to 0.04 µg/kg/day, approximately. The margin of exposure (MOE) of 230 - 7500 was derived from the 'Non-toxic level' of 0.09 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level*' was established by means of animal testing. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

Concerning inhalation exposure, because its 'Non-toxic level*' is not determined, its health risk can not be identified. For reference, assuming that the absorption rate is 100%, the 'Non-toxic level*' for the oral exposure is converted to the 'Non-toxic level*' for the inhalation exposure. The resulting value is 0.3 mg/m³. The MOE determined from this figure and the predicted maximum exposure concentration of the ambient air is 125.

The half- life of this substance in the atmosphere was estimated to be 7.4 - 74 days, and it is estimated to distribute almost only into the atmosphere, when this substance was released to the atmosphere. Additionally, its production volume was relatively high. Accordingly, it is likely that it is required to examine the need to collect information on inhalation exposure to this substance for its health risk assessment.

Information of toxicity				Exposure assessment		Result of risk assessment			Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration	MOE			
Oral	' Non-toxic level*' 0.09 mg/kg/day	Rats	decrease in the colloid density in the thyroid follicles and vacuolation of anterior pituitary cells	Drinking water, Food	- µg/kg/day	MOE	-	×	
				Groundwater, Food	0.0012 - 0.04 µg/kg/day	MOE	230 - 7,500		
Inhalation	' Non-toxic level*' - mg/m ³	-	-	Ambient air	0.24 µg/m ³	MOE	-	×	
				Indoor air	- µg/m ³	MOE	-	×	

Non-toxic level *

- When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.
- When an adverse effect level for the short-term exposure is available, it is divided by 10 to obtain a level equivalent to an adverse effect level for the long-term exposure.

4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour median effective concentration (EC₅₀) growth inhibition value of exceeding 6,330 µg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC₅₀ immobilization value of 1,200 µg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour median lethal concentration (LC₅₀) value of 5,700 µg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) of 12 µg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 2,160 µg/L was found for the algae *P. subcapitata*, a 21-day NOEC reproduction value of less than 100 µg/L was found for the crustacea *D. magna*, and a 32-day NOEC growth inhibition value of 1,000 µg/L was found for the fish *Pimephales promelas* (fathead minnow). Accordingly, an assessment factor of 10 was used, and a PNEC value of less than 10 µg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of less than 10 µg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio exceeded 0.004 for freshwater bodies and 0.003 for seawater bodies. Accordingly, the ecological risk cannot be determined at this time. The PNEC was calculated based on the lowest chronic toxicity level of less than 100 µg/L for a crustacean, but another chronic toxicity level, 500 µg/L or above, was also obtained for another crustacean. Therefore, it is hardly considered that the NOEC of less than 100 µg/L would be reduced to 10 µg/L or under, and the PEC/PNEC ratio is estimated to be 0.1 or under. Thus no further work might be required at present.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Crustacea (water flea)	Chronic	NOEC reproduction	10	< 10	Freshwater	0.04	>0.004	×
					Seawater	0.03	>0.003	

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	
	Inhalation exposure	Risk cannot be identified, but it needs to be considered whether collection of information is required or not.	()
Ecological risk	Impossibility of risk characterization. No need for further work at this time.		(○)

[Risk judgments] ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization

() : Though a risk characterization cannot be determined, there would be little necessity of collecting information.

() : Further information collection would be required for risk characterization.