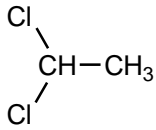


3	CAS No. 75-34-3	Substance: 1,1-Dichloroethane
<p>Chemical Substances Control Law Reference No.: 2-54 (Dichloroethane)</p> <p>PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C₂H₄Cl₂ Structural formula:</p> <p>Molecular Weight: 98.96</p> <div style="text-align: center;">  </div>		
<p>1. General information</p> <p>The aqueous solubility of this substance is 5.0×10³ mg/1000g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 1.79, and the vapor pressure is 228 mmHg (=3.05×10⁴ Pa) (25°C). The biodegradability (aerobic degradation) of halogenated aliphatic hydrocarbons is generally believed to be limited, and the BOD degradation rate of the 1,2-dichloroethane is 0%. Furthermore, its half-life for hydrolysis is 64 years (25°C, pH=7).</p> <p>The main uses are as an intermediate for polyvinyl chloride, 1,1,1-trichloroethane, and rubbers used under high vacuum, while the substance also finds limited use in detergents and degreasing solvents. The production (shipments) and import quantity in fiscal 2007 was 100,000 to <1,000,000 t/y.</p> <hr/> <p>2. Exposure assessment</p> <p>Because this substance 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), release and transfer quantities could not be obtained. Predictions of distribution by medium using a Mackay-type level III fugacity model indicated that if equal quantities were released to the atmosphere, water bodies, and soil, the proportions distributed to water bodies and the atmosphere would be greater.</p> <p>The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was approximately 0.026 µg/m³. The predicted maximum oral exposure was estimated to be around 0.01 µg/kg/day based on calculations from data for groundwater, and 0.011 µg/kg/day based on calculations from the second highest set of data for public freshwater bodies. A predicted maximum oral exposure estimated to be 0.011 µg/kg/day was adopted for this substance. The risk of exposure to this substance by intake from an environmental medium via food is considered slight based on estimates of oral exposure using estimated concentrations in fish species.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was 0.27 µg/L for public freshwater bodies based on the second highest data set and around 0.019 µg/L for seawater.</p> <hr/> <p>3. Initial assessment of health risk</p> <p>This substance may influence the central nervous system, and when taken in high concentrations, it may produce unconsciousness. When inhaled, this substance causes dizziness, lethargy, hypesthesia, nausea and unconsciousness, and when orally taken, it may also cause burning sensation. When attached to skin, its surface will dry and become rough. When taken into eyes, they will be red or it will cause pain.</p> <p>Sufficient information could not be obtained on its carcinogenicity, and its initial assessment was conducted on the basis of data on its non-carcinogenic effects.</p> <p>As for its oral exposure, its no-observed-adverse-effect-level (NOAEL) of 500 mg/kg/day (for suppressed body weight increase, reduced liver weight) was obtained from its mid-term and long-term toxicity tests for rats. It was then adjusted against exposure conditions to provide 360 mg/kg/day. This was divided by 10, due to their short test periods, to provide</p>		

36 mg/kg/day as its ‘non-toxic level’*.

As for its inhalation exposure, its no-observed-adverse-effect-level (NOAEL) of 500 mg/kg/day (for suppressed body-weight increase, effects on kidney) was obtained from its mid-term and long-term toxicity tests for cats. It was then adjusted against exposure conditions to provide 89 ppm (360 mg/m³). This was divided by 10, due to their short test periods, to provide 8.9 ppm (36 mg/m³) as its ‘non-toxic level’*.

As for its oral exposure, its maximum exposure was estimated to be around 0.011 µg/kg/day, when intakes of freshwater from public water supply were assumed. Its margin of exposure (MOE) would be 330,000, when calculated from its ‘non-toxic level’* of 36 mg/kg/day and its estimated maximum exposure, and then divided by 10 due to the fact that the ‘non-toxic level’* was obtained from animal experiments. Since exposure to this substance through food intakes from the environment is presumed to be minimal, this exposure will not change MOE significantly. No further action will be required at the moment to assess health risk from oral exposure to this substance.

As for its inhalation exposure, its maximum exposure concentration was estimated to be around 0.026 µg/m³, when its concentrations in the ambient air were considered. Its MOE would be 140,000, when calculated from its ‘non-toxic level’* of 36 mg/m³ and its estimated maximum exposure concentration, and then divided by 10 due to the fact that ‘non-toxic level’* was obtained from animal experiments. No further action will be required at the moment to assess health risk from inhalation exposure to this substance in the ambient air.

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’ 36 mg/kg/day	Rats	suppressed body weight increase, reduced liver weight	Drinking water	— µg/kg/day	MOE	—	×	○
				Freshwater	0.011 µg/kg/day	MOE	330,000	○	
Inhalation	‘Non-toxic level’ 36 mg/m ³	Cats	suppressed body-weight increase, effects on kidney	Ambient air	0.026 µg/m ³	MOE	140,000	○	○
				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, the following reliable data were obtained: a 72-h median effective concentration (EC₅₀) of more than 94,300 µg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC₅₀ of 34,300 µg/L for swimming inhibition in the crustacean *Daphnia magna*; and a 96-h median lethal concentration (LC₅₀) of more than 112,000 µg/L for the fish species *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 340 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h no observed effect concentration (NOEC) of 94,300 µg/L for growth inhibition in the green algae *P. subcapitata*, and a 21-d NOEC of 525 µg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 5.3 µg/L was obtained. The value of 5.3 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.05 for freshwater bodies and 0.004 for seawater. Accordingly, further work is thought to be unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Crustacean <i>Daphnia magna</i>	Chronic	NOEC Reproductive inhibition	100	5.3	Freshwater	0.27	0.05	○
					Seawater	0.019	0.004	

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No further action required.	○
	Inhalation exposure	No further action required.	○
Ecological risk	No need of further work at present.		○

[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.