5	CAS No.: 75-35-4	Substance: 1,1-Dichloroethylene

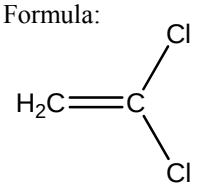
Chemical Substances Control Law Reference No.: 2-103 (Dichloroethylene)

PRTR Law Cabinet Order No.: 1-158

Molecular Formula: $C_2H_2Cl_2$

Molecular Weight: 96.94

Structural Formula:



1. General information

The aqueous solubility of this substance is 2.42×10^3 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 2.13, and the vapor pressure is 600 mmHg (8.0×10^4 Pa) (25°C). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is judged to be non-existent or low. Moreover, hydrolyzation is not considered to be an important degradation pathway.

This substance is designated as 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). The main use of this substance is as a raw material for polyvinylidene chloride resin. It is also used as a raw material for coatings used in plastic films for packaging food and pharmaceuticals. The production and import quantity of dichloroethylene in fiscal 2013 was not disclosed because the number of reporting businesses was not more than two. It was 3,000 t in fiscal 2012. The production and import category under the PRTR Law is more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2013 under the PRTR Law was approximately 83 t, and all releases were reported. The major destination of reported releases was the atmosphere. In addition, 0.006 t was transferred to sewage and approximately 200 t was transferred to waste materials. Industry types with large reported releases were the chemical industry for the atmosphere and sewage treatment for public water bodies. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall or the atmosphere in particular, the predicted proportion distributed to the atmosphere was 99.8%. In regions where the largest quantities were estimated to have been released to public water bodies, the predicted proportion distributed to the atmosphere was 81.8%.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around 1.7 μg/m^3. The mean annual value for the atmospheric concentration in fiscal 2013 was calculated by using a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicted a maximum level of 15 μg/m^3. Note that past data from a survey of a limited area yielded a maximum of less than around 0.05 μg/m^3 for indoor air.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be 10 μg/L for public freshwater bodies and less than 10 μg/L for seawater. When releases to public freshwater bodies in fiscal 2013 reported according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 2.4 μg/L.

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3. Initial assessment of health risk

This substance is irritating to the eyes, skin and respiratory tract. If the substance in its liquid form is

swallowed, aspiration into the lungs may result in chemical pneumonitis. Inhalation exposure causes dizziness, drowsiness and unconsciousness. Oral exposure may cause abdominal pain and sore throat in addition to the symptoms of inhalation exposure.

Contact with the skin or the eyes causes redness and pain.

As sufficient information on the carcinogenicity of the substance was not available, the initial assessment was conducted on the basis of information on its non-carcinogenic effects.

Oral exposure to the substance was outside the scope of the assessment.

The LOAEL of 6.25 ppm for inhalation exposure (based on renal tubule hyperplasia, turbinate atrophy, hyperostosis and olfactory epithelium respiratory metaplasia), determined from medium-term and long-term toxicity tests in mice, was adjusted according to exposure conditions to obtain 1.12 ppm (4.4 mg/m^3), and subsequently divided by a factor of 10 to account for uncertainty in using LOAEL.

The obtained value of 0.44 mg/m^3 was deemed to be the lowest reliable concentration and was identified as the 'non-toxic level*' of the substance for inhalation exposure.

Since this substance can be regarded to be equivalent to IARC "2B" on the basis of the findings in the latest carcinogenicity tests covered in this assessment, it is considered that the carcinogenicity of the substance needs to be taken into account in the risk assessment.

With regard to inhalation exposure, the predicted maximum exposure level in ambient air was 1.7 μg/m^3, approximately. The MOE (Margin of Exposure) would be 5 when calculated from the predicted maximum exposure concentration and the 'non-toxic level*' of 0.44 mg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and another factor of 5 to account for carcinogenicity.

In addition, the maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance to ambient air was estimated to be 15 μg/m^3, on the basis of the data reported in FY 2013 under the PRTR Law. The MOE would be 0.6, when calculated from this value and the 'non-toxic level*'.

On the other hand, the MOE would be over 180, when calculated from the maximum exposure concentration in indoor air in limited area of 0.05 μg/m^3, as reported in 1998. Therefore, while this substance is a candidate for further work to assess the health risk via inhalation in ambient air, it would be necessary for indoor air.

Toxicity				Exposure assessment		Result of risk assessment			Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration				
Oral	'Non-toxic level*' (–) mg/kg/day	(–)	(–)	Drinking water	(–) μg/kg/day	MOE	(–)	(–)	(–)
				Ground water	(–) μg/kg/day	MOE	(–)	(–)	
Inhalation	'Non-toxic level*' 0.44 mg/m^3	Mouse	Renal tubule hyperplasia, turbinate atrophy, hyperostosis and olfactory epithelium respiratory metaplasia.	Ambient air	1.7 μg/m^3	MOE	5	■	■
				Indoor air	— μg/m^3	MOE	—	×	(○)

Non-toxic level *

- When a LOAEL is available, it is divided by 10 to obtain a NOAEL-equivalent level.
- 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.

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4. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 9,120 μg/L for growth inhibition in the green algae *Chlamydomonas reinhardtii*, a 48-h EC_{50} of 15,600 μg/L for swimming inhibition in

the crustacean *Daphnia magna*, and a 96-h LC_{50} of 44,500 μg/L in 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 91 μg/L was obtained.

The value of 91 μg/L obtained from the acute toxicity to the algae was used as the PNEC for this substance because reliable chronic toxicity findings could not be obtained.

The PEC/PNEC ratio is 0.11 for freshwater bodies and less than 0.11 for seawater; accordingly, efforts to collect data on this substance are needed. However, the PEC value of 10 μg/L was only detected at the measurement location once and was not detected in any other fiscal year. Given that public water body quality tests are conducted on an annual basis, the rate of detection is extremely small; on this account, efforts to understand changes in the environmental concentrations of this substance should continue.

Hazard Assessment（Basis for PNEC）			Assessment Coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure Assessment		PEC/PNEC ratio	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)			
Green algae	Acute	EC_{50} Growth Inhibition	100	91	Freshwater	10	0.11	▲	▲
					Seawater	<10	<0.11		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Outside the scope of evaluation	（－）
	Inhalation exposure (atmosphere)	Candidates for further work.	■
	Inhalation exposure (room air)	Although risk to human health could not be confirmed, collection of further information would not be required.	（○）
Ecological risk	Requiring information collection.		▲

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

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

（○）: Although risk to human health could not be confirmed, collection of further information would not be required.

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