6	CAS No.: 89-61-2	Substance: 1,4-Dichloro-2-nitrobenzene

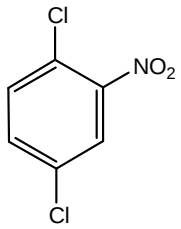
Chemical Substances Control Law Reference No.: 3-455 (Dichloronitrobenzene)

PRTR Law Cabinet Order No.: 1-128

Molecular Formula: $C_6H_3Cl_2NO_2$

Molecular Weight: 192.00

Structural Formula:



1. General information

The aqueous solubility of this substance is 95 mg/L (25°C) and the partition coefficient (1-octanol/water) (log Kow) is 2.93 (25°C). The vapor pressure is 3.8 x 10^{-3} mmHg (= 0.51 Pa) (25°C). Biodegradability (aerobic degradation) is 4 % at the BOD degradation rate. This substance is determinated to be not highly bioaccumulative. The hydrolytic stability was achieved (25°C, pH = 4,7,9).

This substance is a Type 2 Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances and 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 substance is primarily reduced to *p*-dichloroaniline to be used for manufacturing of various dyes and organic pigments. The total of production and imports in FY 2006 was 220 tons, which was categorized as falling within the 100-ton class of production and imports under the PRTR Law.

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2. Exposure assessment

The total releases to the environment in FY 2005 under the PRTR Law were zero tons and the transfers to waste were 1.9 tons. The releases under the PRTR Law and transfers to sewage were both zero tons. The ratio of distribution in soil is estimated to be the highest by the Mackay-Type Level III Fugacity Model, given an equal amount is released to the atmosphere, water, and soil.

Based on previous data for the ambient air, the predicted maximum exposure concentration for inhalation exposure to human beings was less than 0.011 μg/m^3. The highest oral predicted exposure was calculated to be approximately less than 0.0004 μg/kg/day based on groundwater data. The risk of exposure to this substance through food in environmental media is considered to be low.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be less than 0.01 μg/L for both freshwater and seawater public water bodies.

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3. Initial assessment of health risk

There was no report about the acute symptoms of the human from exposure to the substance.

In the oral administration study of laboratory animals, the substance caused disturbance of equilibrium, palmospasms in rats, and methemoglobin formation, disturbance of equilibrium, abdominal position and death in cats, It is reported that no effect other than narrowed palpebral fissures and increased respiratory frequency was observed following 7-hours inhalation exposure of rats to the air saturated with this substance (targeted concentration was 47.6 mg/m^3. measured concentration was 28 mg/m^3 at 2.5hr and 39 mg/m^3 at 4.5hr.)

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.

A no observed adverse effect level (NOAEL) of 10 mg/kg/day (depression of body weight gain and increase in weight of liver, etc.) was obtained for oral exposure from the medium- and long-term toxicity testing for rats. The NOAEL was divided by 10, because of the experimental period being short, and a value of 1 mg/kg/day was derived as the 'Non-toxic level*'. For inhalation exposure, the 'Non-toxic level*' could not be estimated.

With regard to oral exposure, in case of intakes of groundwater, the predicted maximum exposure was approximately less than 0.0004 μg/kg/day. The margin of exposure (MOE) of exceeding 250,000 was derived from the 'Non-toxic level*' of 1 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. As the exposure to this substance through food intakes was estimated minor, even when the exposure through groundwater and food are combined, it would not greatly affect the MOE values. 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. The resulting value is 3.3 mg/m^3. The MOE determined from this figure and the predicted maximum exposure concentration of the ambient air is exceeding 30,000.

The half- life in the atmosphere of this substance is relatively long, being estimated to be 110-1,100 days. However, the substance released into the atmosphere was estimated to distribute mostly into the media other than the atmosphere, and the release of this substance to the atmosphere was zero tons. Considering these situations, there would be little necessity of collecting information on inhalation exposure to this substance in the ambient air 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				
Oral	'Non-toxic level*' 1 mg/kg/day	Rats	depression of body weight gain and increase in weight of liver, etc.	Drinking water	— μg/kg/day	MOE	—	×	○
				Groundwater	< 0.0004 μg/kg/day	MOE	> 250,000	○	
Inhalation	'Non-toxic level*' — mg/m^3	—	—	Ambient air	< 0.011 $\mu g/m^3$	MOE	—	×	(○)
				Indoor air	— $\mu g/m^3$	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.

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour median effective concentration (EC_{50}) growth inhibition value of 8,410 μg/L was found for the algae *Pseudokirchneriella subcapitata*, and a 96-hour median lethal concentration (LC_{50}) value of 5,400 μg/L was found for the fish *Oryzias latipes* (medaka). No applicable data on Crustacea were available and acute toxicity was considered to exceed chronic toxicity based on the chronic data on *Daphnia magna*. Therefore, an assessment factor of 100 was applied to derive a predicted no effect concentration (PNEC) value of above 10μg/L 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 2,000 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 1,000 μg/L was found for the crustacea *D. magna* (water flea). Accordingly, an assessment factor of 100 was used, and a PNEC value of 10 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 10 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0. 001 for freshwater bodies and seawater bodies. 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	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacea (water flea)	Chronic	NOEC reproduction	100	10	Freshwater	<0.01	<0.001	○
					Seawater	<0.01	<0.001	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Risk cannot be determined. However, there would be little necessity of collecting information.	(○)
Ecological risk	No need for further work.		○

[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.