21	CAS No.: 75-27-4	Substance: Bromodichloromethane

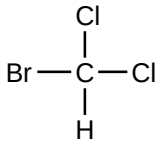
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.: － (Cabinet Order No. after revision*: 1-381)

Structural Formula:

Molecular Formula: $CHBrCl_2$

Molecular Weight: 163.83



*Note: No. according to revised order enacted on October 1, 2009.

1. General information

The aqueous solubility of this substance is 4.7×10^3 mg/L (22°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 2.00, and the vapor pressure is 50 mmHg (=6.7×10^3 Pa) (20°C). The mean biodegradability (aerobic degradation) as determined by BOD, TOC, and GC is 25% (test substance concentration of 5 mg/L) and 10% (test substance concentration of 10 mg/L). Its half-life for hydrolysis is 13.7 to 137 years (pH=8 to 7, calculated value).

A drinking water standard has been set for this substance and, based on a revision of substances regulated by the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law) (enacted on October 1, 2009), this substance was newly designated as a Class 1 Designated Chemical Substance. This substance is a component of trihalomethane, which is formed during the process of water purification by the aqueous reaction of organic substances such as humins with the chlorine in disinfectants. It is unintentionally formed in wastewater and cooling water chlorination processes.

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2. Exposure assessment

Because this substance was not classified as a Class 1 Designated Chemical Substance prior to revision of substances regulated by the 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 higher.

Data for setting the predicted maximum exposure to humans via inhalation could not be obtained. In addition, the predicted maximum exposure for indoor air was around 0.48 μg/m^3 based on past data from a limited area (Sendai City). The predicted maximum oral exposure was estimated to be 1.2 μg/kg/day based on calculations from data for potable water, and around 0.0008 μg/kg/day based on calculations from data for groundwater.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be less than 0.004 μg/L for public freshwater bodies, and generally 0.011 μg/L for seawater.

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3. Initial assessment of health risk

No information was obtained on acute symptoms in humans. Piloerection, sedation, muscular relaxation, ataxia, exhaustion and soiled fur (yellow discoloration) were observed in rats. When administered with 500 mg/kg of this substance, sedation and sensory anesthesia appeared in mice in 30 minutes and they lasted for about 4 hours.

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.

Its lowest-observed-adverse-effect-level (LOAEL) of 6.1 mg/kg/day (for the fatty degeneration of the liver) was obtained for oral exposure from its mid-term and long-term toxicity tests for rats. This LOAEL was divided by 10 to produce 0.61 mg/kg/day as its 'non-toxic level.[*]'

As for its inhalation exposure, its no-observed-adverse-effect-level (NOAEL) of 1 ppm (for the tubule degeneration, etc.) was obtained for inhalation exposure from its repeated toxicity tests for mice. It was then adjusted for exposure conditions to provide 0.25 ppm or 1.7 mg/m^3. This was divided by 10 due to their short test periods to produce 0.17 mg/m^3 as its 'non-toxic level*'.

As for its oral exposure, the predicted maximum exposure was estimated to be 1.2 μg/kg/day, when intakes of drinking water were assumed. Its margin of exposure (MOE) would be 10 when calculated from its 'non-toxic level*' of 0.61 mg/kg/day and the predicted maximum exposure, then divided by 10 due to the fact that 'non-toxic level*' was obtained from animal experiments, and divided again by 5 when its carcinogenicity was considered. When intakes of groundwater are assumed, the predicted maximum exposure will be around 0.0008 μg/kg/day, and this will provide MOE of 15,000.

As for its exposure through food intakes, the predicted maximum exposure is estimated to be 0.046 μg/kg/day from the measurement at some location. When its intakes from food and drinking water are assumed, the predicted maximum exposure is estimated to be 1.2 μg/kg/day, and this will provide MOE of 10. When its intakes from food and groundwater are assumed, the predicted maximum exposure is estimated to be 0.047 μg/kg/day, and this will provide MOE of 260. These suggest that collection of information is required on health risk associated with oral exposure to this substance. There is a quality standard for this substance in drinking water.

As for its inhalation exposure, data at national-level were not available, and its health risk could not be assessed. Report of its concentration in the indoor air for some location suggests that the predicted maximum concentration would be around 0.48 μg/m^3. When combined with its 'non-toxic level*' of 0.17 mg/m^3 and divided by 10, due to the fact that 'non-toxic level*' was obtained from animal experiments, and divided again by 5 when its carcinogenicity was considered, MOE would be 7.1.

This substance is designated as a potential hazardous air pollutant. Its half-life in the atmosphere is as long as 68 to 680 days. Almost all of its emission to the atmosphere is expected to remain there, so collection of information on its inhalation exposure would be required to assess health risk associated with its inhalation from the ambient air. As for its health risk associated with its inhalation exposure in the indoor air, MOE will be 7.1 when calculated from data for some location. Collection of information is required, and more data shall be collected on its exposure.

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*' 0.61 mg/kg/day	Rats	Hepatic steatosis	Drinking water	1.2 μg/kg/day	MOE	10	▲	▲
				Groundwater	0.0008 μg/kg/day	MOE	15,000	○	
Inhalation	'Non-toxic level*' 0.17 mg/m^3	Mice	Tubule degeneration	Ambient air	– 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 is available for the short-term exposure, 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 median effective concentration (EC_{50}) of 11,600 μg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC_{50} of 29,000 μg/L for swimming inhibition in the crustacean *Daphnia magna*; and a 96-h median lethal concentration (LC_{50}) of 28,200 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 120 μg/L was obtained. With regard to

chronic toxicity, reliable data of a 72-h no observed effect concentration (NOEC) of 802 µg/L was obtained for growth inhibition in the green algae *P. subcapitata*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of 8.0 µg/L was obtained. The value of 8.0 µg/L obtained from the chronic toxicity to the algae was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.0005 for freshwater bodies and 0.001 for seawater. Accordingly, further work is thought to be unnecessary at this time. Further, 0.68 µg/L was detected in public freshwater bodies in fiscal 1999, and the ratio between this and PNEC is 0.09.

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)		
Algae (green algae)	Chronic	NOEC Growth inhibition	100	8.0	Freshwater	<0.004	0.0005	○
					Seawater	0.011	0.001	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Collection of information required	▲
	Inhalation exposure	Further information collection would be required for risk characterization.	（▲）
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.