

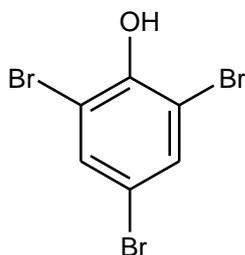
Chemical Substances Control Law Reference No.: 3-959

PRTR Law Cabinet Order No.*: 1-294

Molecular Formula: C₆H₃Br₃O

Structural formula:

Molecular Weight: 330.80



*Note: No. in Revised Cabinet Order enacted on October 1, 2009

1. General information

The aqueous solubility of this substance is 59 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 3.89 (25°C), and the vapor pressure is 3.2×10⁻⁴ mmHg (=0.042 Pa) (25°C). Biodegradability (aerobic degradation) is considered to be good. The substance does not have any hydrolyzable groups.

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). It is primarily used as a flame retardant added to synthetic resins, a preservative, and a raw material for fungicides and flame retardants. The production (shipments) and import quantity in fiscal 2007 was 1,000 to <10,000 t/y.

2. Exposure assessment

Total release to the environment in fiscal 2007 under the PRTR Law was 0.018 t, of which 0.01 t or 56% of overall releases were reported. All reported release destinations were public water bodies. In addition, 0.012 t was transferred to waste materials. The only source of reported releases was the plastic product manufacturing industry. Distribution in the environment by medium predicted by using a multi-media model indicated that the proportion to water bodies was an estimated 96.7% for areas where the greatest releases were to the environment and public water bodies.

There is a report of a predicted maximum exposure to humans via inhalation of 0.00093 µg/m³ for the general environmental atmosphere. The predicted maximum oral exposure was estimated to be less than around 0.0004 µg/kg/day based on calculations from data for public freshwater bodies. 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.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was less than around 0.01 µg/L for public freshwater bodies and around 0.049 µg/L for seawater.

3. Initial assessment of health risk

This substance is irritating to eyes, and when taken into eyes, they will turn red and suffer from pain. Bromophenols other than pentabromophenol will increase the frequency and depth of breath, which is followed by the loss of muscle tone, eventually leading to coma and subsequent death. Histopathologically, congestion and petechiae will be observed in lungs.

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.

As for its oral exposure, NOAEL of 100 mg/kg/day (for salivation) obtained from its mid-term and long-term toxicity tests for rats was divided by 10, due to their short test periods, to provide 10 mg/kg/day as its ‘non-toxic level*’. For its inhalation exposure, its ‘non-toxic level*’ could not be established.

As for its oral exposure, its maximum exposure was estimated to be around less than 0.0004 µg/kg/day, when intakes of freshwater from public water supply were assumed. Its MOE (Margin of Exposure) would be more than 2,500,000, when calculated from its ‘non-toxic level*’ of 10 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 its exposure through intakes of food from the environmental media would be limited, MOE will not change significantly even if this exposure is combined. No further action will be required at the moment to assess health risk from oral exposure to this substance.

As for inhalation exposure to this substance, its ‘non-toxic level’ could not be identified, and its health risk could not be assessed. The ‘non-toxic level’ for its oral exposure, if 100% absorption is assumed for it, turns to be the ‘non-toxic level’ of 33 mg/m³ for its inhalation exposure. When combined with its estimated maximum concentration of around 0.000093 µg/m³ in the ambient air, MOE will be calculated to be 35,000,000. Collection of information on its inhalation exposure to assess health risk associated with exposure to this substance in the ambient air would not be required.

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*’ 10 mg/kg/day	Rats	salivation	Drinking water	— µg/kg/day	MOE	—	×	○
				Freshwater	<0.0004 µg/kg/day	MOE	>2,500,000	○	
Inhalation	‘Non-toxic level*’ — mg/m ³	—	—	Ambient air	0.000093* 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.

Note: * represents two reports.

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 1,870 µg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC₅₀ of 2,200 µg/L for swimming inhibition in the crustacean *Daphnia magna*; a 96-h median lethal concentration (LC₅₀) of 1,500 µg/L for the fish species *Oryzias latipes* (medaka); and a 60-h IGC₅₀ of 2,950 µg/L for inhibition of growth in the ciliate protozoa *Tetrahymena pyriformis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 15 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h no observed effect concentration (NOEC) of 220 µg/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of more than 100 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 ≥1 µg/L was obtained. The value of ≥1 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio was less than 0.01 for freshwater bodies and 0.05 or less for seawater; thus, further work is considered unnecessary at this point in 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	≥1	Freshwater Seawater	<0.01 0.049	<0.01 ≤0.05	○

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No further action required.	○
	Inhalation exposure	Risk can not be assessed. Collection of information would not be 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.