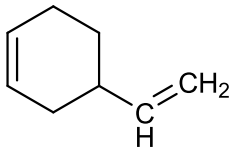
15	CAS No.: 100-40-3	Substance: 4-Vinyl-1-cyclohexene

Chemical Substances Control Law Reference No.: 3-2229

PRTR Law Cabinet Order No.: 1-337

Molecular Formula: C_8H_{12} Structural Formula:

Molecular Weight: 108.18



1. General information

The aqueous solubility of this substance is 50 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log Kow) is 3.93, and the vapor pressure is 14 mmHg (=1.87×10^3Pa) (25°C). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is judged to be non-existent or low. 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). The main uses of this substance are as raw materials for flame retardants and paints. The production and import quantity in fiscal 2009 was 246 t. 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 2010 under the PRTR Law was 7.2 t, and all releases were reported. The major destination of reported releases was the atmosphere. In addition, 180 t was transferred to waste materials. The only source of reported releases was the chemical industry. 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 to the atmosphere in particular, the predicted proportion distributed to the atmosphere was 99.8%. In regions where the largest estimated releases were to public water bodies, the predicted proportions distributed to the atmosphere and water bodies were 60.0% and 39.3%, respectively.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around less than 0.029 μg/m^3. The mean annual value for atmospheric concentration in fiscal 2010 was calculated by using a plume-puff model on the basis of reported releases to the atmosphere according to the PRTR Law; this model predicted a maximum level of 0.93 μg/m^3.

The maximum expected oral exposure could not be obtained. When reported releases to public freshwater bodies in fiscal 2010 according to the PRTR Law were divided by the ordinary water discharge of the national river structure database, estimating the concentration in rivers while taking into consideration only dilution gave a maximum value of 0.12 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.0048 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on estimates of oral exposure obtained using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. The maximum river concentration was estimated to be 0.12 μg/L from reported releases to public freshwater bodies under the PRTR Law.

3.Initial assessment of health risk

This substance may cause irritation to eyes and skin. Contact of this substance with skin and eyes may cause

redness.

As for carcinogenic potential of the substance, an initial assessment was conducted only on the basis of its non-carcinogenic effects since its carcinogenicity to human could not be confirmed although its carcinogenic effects on animals had been reported.

With regard to oral exposure to the substance, a NOAEL of 150 mg/kg/day (for decreased survival rates) obtained from its mid-term and long-term toxicity tests on mice was adjusted for their durations to provide 107 mg/kg/day for its intermittent to continuous exposure, and divided by a factor of 10 due to their short test periods. 11 mg/kg/day was identified to be the reliable lowest dose of the substance as its 'non-toxic level*'. With regard to inhalation exposure to the substance, a NOAEL of 250 ppm (for increased relative liver weight) obtained from its mid-term and long-term toxicity tests on mice and a NOAEL of 250 ppm (for decreased survival rates) obtained from its mid-term and long-term toxicity tests on mice were both adjusted for their durations to provide 45 ppm (200 mg/m^3) for intermittent to continuous exposure, and divided by a factor of 10 due to their short test periods. 20 mg/m^3 identified to be the reliable lowest dose of the substance as its 'non-toxic level*'.

As for its oral exposure to the substance, since its exposure concentrations were not known, its health risk could not be assessed. Its maximum exposure level was then calculated to be 0.0048 μg/kg/day from its concentrations in river water with effluents from operators discharging it in high concentrations, reported in FY 2010 under the PRTR Law. The MOE would be 46,000 when calculated from this maximum exposure level and its 'non-toxic level*' of 11 mg/kg/day from animal experiments and divided by a factor of 10 to convert animal data to human, and further divided by a factor of 5to extrapolate animal data to human carcinogenic hazards. As exposure to the substance in the environment through food intakes would be limited, the MOE would not change significantly even when this exposure was included. Therefore, collection of further information would not be required to assess health risk from its oral exposure.

With regard to inhalation exposure to the substance, , its maximum exposure concentration in the ambient air was predicted to be below 0.029 μg/m^3. The MOE would be above 14,000 when calculated from its 'non-toxic level of 20 mg/m^3 and its maximum exposure concentration predicted from animal experiments, and divided by a factor of 10 to convert animal data to human, and then further divided by a factor of 5 to extrapolate animal data to human carcinogenic hazards. The maximum (annual mean) concentration in the ambient air near operators with its emissions in high concentrations was then calculated to be 0.93 μg/m^3 from its emissions reported in FY 2010 under the PRTR Law. The MOE would be 430 when calculated from this value as its reference. Therefore, no further action would be required at this moment to assess health risk from its inhalation exposure in the ambient 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*' 11 mg/kg/day	Mouse	Decreased survival rates	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Freshwater	— μg/kg/day	MOE	—	×	
Inhalation	Non-toxic level*' 20 mg/m^3	Rat Mouse	Increased relative liver weight, Decreased survival rates	Ambient air	<0.029 μg/m^3	MOE	> 14,000	○	○
				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.

4.Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} exceeding 4,050 µg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 1,870 µg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} of 4,600 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 19 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 2,230 µg/L for growth inhibition in the green alga *P. subcapitata*, and a 21-d NOEC of 227 µg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 2.3 µg/L was obtained.

The value of 2.3 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The risk of this substance could not be judged because the predicted environmental concentration (PEC) could not be obtained. However, the maximum river concentration was estimated to be 0.12 µg/L from reported releases under the PRTR Law. The ratio of this value to the PNEC is less than 0.1.

Accordingly, further work on this substance is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	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)			
Crustacean *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	2.3	Freshwater	－	－	×	○
					Seawater	－	－		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Although risk to human health could not be identified, collection of further information would not be required.	(○)
	Inhalation exposure	No need for further work.	○
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.