13	CAS No.: 79-41-4	Substance: Methacrylic acid

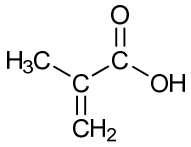
Chemical Substances Control Law Reference No.: 2-1025

PRTR Law Cabinet Order No.: 1-415

Molecular Formula: $C_4H_6O_2$

Molecular Weight: 86.09

Structural Formula:



1. General information

The aqueous solubility of this substance is 8.9×10^4 mg/1,000 g (20°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.93, and the vapor pressure is 0.90 mmHg (=120 Pa) (25°C). Biodegradability (aerobic degradation) is judged to be good. This substance is not hydrolyzed (pH 3, 7, 11).

This substance is designated as a Priority Assessment Chemical Substance 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 main use of this substance is as a raw material for 2-ethylhexyl methacrylate and *n*-butyl methacrylate. 2-ethylhexyl methacrylate is used in paints, encapsulants, lubricant additives, fiber treating agents, adhesives, dental materials, and dispersants. *n*-butyl methacrylate is used in fiber treating agents, paper treating agents, paper coating agents, lubricant additives, and metal surface treatment agents. The production and import quantity in fiscal 2011 was 67,687 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 2011 under the PRTR Law was approximately 66 t, of which approximately 25 t or 38% of overall releases were reported. The major destination of reported releases was the atmosphere. In addition, approximately 370 t was transferred to waste materials, and approximately 55 t was transferred to sewage. Industry types with large reported releases were the chemical industry for the atmosphere and the chemical industry alone for public water bodies. The largest release among releases to the environment including those unreported was to 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 to public water bodies in particular, the predicted proportion distributed to water bodies was 99.1%, In regions where the largest estimated releases were to the atmosphere, the predicted proportions distributed to water bodies and the atmosphere were 72.1% and 16.8%, respectively.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.0028 μg/m^3. The mean annual value for atmospheric concentration in fiscal 2011 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 3.9 μg/m^3. The maximum expected oral exposure was estimated to be less than 0.004 μg/kg/day on the basis of calculations from data for public freshwater bodies. When releases to public freshwater bodies in fiscal 2011 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 0.44 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.018 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, given the low bioaccumulation of the substance expected on the basis of its physicochemical properties.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around

0.1 μg/L for public freshwater bodies and around 0.051 μg/L for seawater. When releases to public freshwater bodies in fiscal 2011 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 0.44 μg/L.

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3. Initial assessment of health risk

This substance may cause corrosion to eyes, skin and respiratory tract. Inhalation exposure to the substance may cause coughing, burning sensation, shortness of breath and labored breathing. Pulmonary edema may occur when its vapors are inhaled. Exposure to the substance through oral ingestion may also cause stomach convulsions, abdominal pain, burning sensation and weakness and even corrosion. Contact of the substance with skin may cause redness, skin burns, pain and blisters, while its contact with eyes may cause redness, pain, loss of vision and severe burns.

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

With regard to oral exposure to the substance, its 'non-toxic level*' could not be identified. As for its inhalation exposure, a LOAEL of 20 ppm (for inflammation and generation in anterior nasal concha) obtained from its mid-term and long-term toxicity tests on rats was adjusted for their durations to provide 3.6 ppm (13 mg/m^3) for its intermittent to continuous exposure, and divided by a factor of 10 for conservative use of the LOAEL. Outcome of 0.13 mg/m^3 was identified to be the reliable lowest dose and its 'non-toxic level*'.

With regard to oral exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' could not be identified. However, if a LOAEL of 5 mg/kg/day were assumed on the basis of its mid-term and long-term toxicity tests on rats, this LOAEL would be divided by a factor of 10 for conservative use of the LOAEL and further divided by a factor of 10 for their short test periods, to provide 0.05 mg/kg/day as its 'non-toxic level*'. The MOE (Margin of Exposure) would be 1,300 when calculated from its 'non-toxic level*' of 0.05 mg/kg/day and its maximum exposure level predicted from its concentrations in freshwater in public water bodies and divided by a factor of 10 to convert animal data to human data. In addition, the MOE would be 280 when calculated for reference from this level and its maximum concentration of 0.018 μg/kg/day in river water with effluents from operators discharging the substance in high concentrations in their discharges reported in FY 2011 under the PRTR Law. Meanwhile, except for the direct effects on respiratory tracts, which are specific to its inhalation exposure in mid-term and long-term toxicity tests on rates, effects on the body weight, liver weight, nodus lymphaticus mandibularis and kidneys were observed in animals of 300 ppm dose group, and its 'non-toxic level*' was obtained from this. If a NOAEL of 100 ppm were assumed for the systemic effects from its inhalation exposure, this NOAEL would be adjusted for their durations to provide 18 ppm (63 mg/m^3) for its intermittent to continuous exposure and divided by a factor of 10 due to their short test periods, and 6.3 mg/m^3 would be identified as its 'non-toxic level*'. If 100 % absorption were assumed, the 'non-toxic level*' for its inhalation exposure would be converted to the 'non-toxic level*' of 1.9 mg/kg/day for its oral exposure. The MOE would be 48,000 when calculated for reference from this level and its maximum exposure concentration in freshwater in public water bodies predicted from animal experiments and divided by a factor of 10 to convert animal data to human data. Moreover, the MOE would be 11,000 when calculated from its maximum exposure concentration in river water with effluents from operators discharging the substance in high concentrations. As its exposure 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 at this moment to assess health risk from oral exposure to the substance.

As for inhalation exposure to the substance, its mean exposure concentration in the ambient air was below

about 0.00077 μg/m^3 while its maximum exposure concentration was predicted to be about 0.0028 μg/m^3. The MOE would be 4,600 when calculated from its predicted maximum exposure concentration and its 'non-toxic level*' of 0.13 mg/m^3 from animal experiments and divided by a factor of 10 to convert animal data to human data. Meanwhile, the MOE would be 3 when calculated for reference from its maximum (annual mean) concentration of 3.9 μg/m^3 in the ambient air near the operators discharging it in high concentrations in their emissions reported in FY 2011 under the PRTR Law. Therefore, collection of further information would be required to assess health risk from inhalation exposure to the substance 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*' — mg/kg/day	—	—	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Freshwater	0.004 μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level*' 0.13 mg/m^3	Rat	Inflammation and generation in anterior nasal concha	Ambient air	0.0028 μg/m^3	MOE	4,600	○	(▲)
				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 45,000 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h LC_{50} of 210,000 μg/L in the crustacean calanoid copepod *Acartia tonsa*, and a 96-h LC_{50} of 85,000 μg/L for the fish species *Oncorhynchus mykiss* (rainbow trout). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 450 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 8,200 μg/L for growth inhibition in the green alga *P. subcapitata*, a 21-d NOEC of 53,000 μg/L for reproductive inhibition in the crustacean *Daphnia magna*, and a 2-d NOEC of 50,000 μg/L for reproductive inhibition in the marine rotifer *Brachionus calyciflorus*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 82 μg/L was obtained.

The value of 82 μg/L obtained from the chronic toxicity to algae was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.001 for freshwater bodies and 0.0006 for seawater. In addition, the river concentration estimated by using releases reported according to the PRTR Law and taking only dilution into consideration gives 0.44 μg/L, resulting in a ratio to PNEC that 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)			
Green algae	Chronic	NOEC Growth inhibition	100	82	Freshwater	0.1	0.001	○	○
					Seawater	0.051	0.0006		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Although risk to human health could not be confirmed, collection of further information would not be required.	(○)
	Inhalation exposure	Collection of further information would 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.