7	CAS No.: 688-84-6	Substance: 2-Ethylhexyl methacrylate

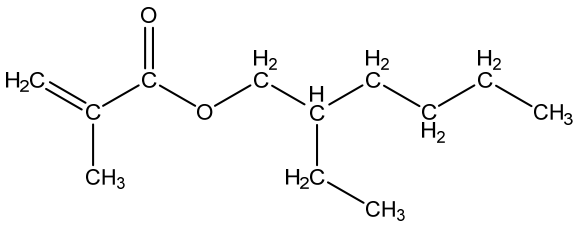
Chemical Substances Control Law Reference No.: 2-1039 (Alkyl (C =2–20) methacrylate)

PRTR Law Cabinet Order No.: 1-416

Molecular Formula: $C_{12}H_{22}O_2$

Molecular Weight: 198.30

Structural formula:



1. General information

The aqueous solubility of this substance is 1.6 mg/L (25℃),the partition coefficient (1-octanol/water) (log K_{ow}) is 4.95 (20℃), and the vapor pressure is 10.1 Pa (25℃) (calculated value). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 88% and biodegradability is judged to be good. In addition, the hydrolysis half-life was 59 days (pH=9, 25°C).

This substance was classified as a Class 1 Designated Chemical Substance under the PRTR Law, but it was removed from the classification by the Cabinet Order partially revising the Enforcement Order for the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement promulgated on October 20, 2021, which came into force on April 1, 2023.

The main uses of this substance are as a raw material for synthetic resins (paints, coatings, adhesives, fiber treatment agents, lubricant additives, and dental materials), as well as plasticizers and dispersants. The production and import quantity in fiscal 2020 was 20,000 t. The production and import category under the PRTR Law was more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2020 under the PRTR Law was approximately 0.18 t, and all releases were notified. The largest notified releases to the atmosphere and public water bodies were to the atmosphere. In addition, 0.0007 t was transferred to sewage and approximately 2.1 t was transferred to waste.

The major source of notified releases to the atmosphere and public water bodies 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 and public water bodies in particular, the predicted proportions distributed to the atmosphere and water bodies would be 56.0% and 43.1%, respectively.

The maximum expected concentration of exposure to humans via inhalation could not be defined because ambient atmospheric and indoor air quality data could not be obtained. Further, the mean annual value for atmospheric concentration in fiscal 2020 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law: this model predicts a maximum level of 0.0091 μg/m^3.

Data for potable water, groundwater, food, and soil to assess oral exposure could not be obtained. Thereupon, assuming ingestion solely from public freshwater bodies, a maximum predicted exposure of around less than 0.00048 μg/kg/day was obtained.

However, while no releases to public freshwater bodies were notified in fiscal 2020 under the PRTR Law, transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from the reported transfer to sewage 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 0.000030 μg/L. Calculating oral exposure based on this gives 0.0000012 μg/kg/day.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was less than 0.012

µg/L for both public freshwater bodies and seawater. Further, while no releases to public freshwater bodies were reported in fiscal 2020 under the PRTR Law, transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from the reported transfer to sewage 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 0.000030 µg/L.

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3. Initial assessment of health risk

This substance irritates the eyes and the skin. Contact with the skin or the eyes will cause redness.

Since not enough information was available on the carcinogenicity of the substance, the initial assessment was conducted based on information on its non-carcinogenic effects.

The NOAEL of 30 mg/kg/day for oral exposure (based on the increased relative weight of the kidneys), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 3 mg/kg/day was deemed the lowest reliable dose and was identified as the 'non-toxic level' of the substance for oral exposure. The 'non-toxic level' for inhalation exposure could not be identified.

Regarding oral exposure, assuming that the substance is absorbed via public freshwater bodies, the predicted maximum exposure level would be approximately less than 0.00048 µg/kg/day. The MOE (Margin of Exposure) would exceed 630,000 which is calculated from the predicted maximum exposure level and the 'non-toxic level' of 3 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. This would lead to the health risk judgment that no further work would be required at present. In addition, the MOE for reference would be 250,000,000 which is calculated from the maximum exposure level of approximately 0.0000012 µg/kg/day, estimated from the concentrations in effluents according to the transfers to the sewage system, reported in FY 2020 under the PRTR Law. Since exposure to the substance in environmental media via food is presumed to be limited despite the lack of exposure level via food, including it in the calculation would not change the MOE significantly. Therefore, as a comprehensive judgment, no further work would be required at present.

Regarding inhalation exposure, due to the lack of identified 'non-toxic level' and exposure concentrations, the health risk could not be assessed. However, the tentative 'non-toxic level' of 10 mg/m^3 for inhalation exposure was derived from the conversion of the 'non-toxic level' for oral exposure, assuming that 100% of the inhaled substance is absorbed. The MOE for reference would be 110,000 which is calculated from the tentative 'non-toxic level' for inhalation exposure and the maximum concentration (annual mean) of 0.0091 µg/m^3 in ambient air near the operators that are releasing a large amount of the substance based on the releases to air reported in FY 2020 under the PRTR Law, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		MOE		Comprehensive judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	'Non-toxic level*' 3 mg/kg/day	Rats	The increased relative weight of the kidneys.	Drinking water	- µg/kg/day	MOE	-	○
				Freshwater	<0.00048 µg/kg/day	MOE	>630,000	
Inhalation	'Non-toxic level*' - mg/m^3	-	-	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 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 4,830 μg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 48-h EC_{50} of 4,560 μg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} of 2,780 μg/L for the for the fish *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 27 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 810 μg/L for growth inhibition in the green alga *R. subcapitata* and a 21-d NOEC of 105 μg/L for the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 1.0 μg/L was obtained.

The value of 1.0 μg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio is less than 0.01 for both freshwater bodies and seawater. Further work to assess the ecological risk of this substance is considered unnecessary at this time.

When releases to public freshwater bodies estimated from the reported transfer to sewage under the PRTR Law in fiscal 2020 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 0.000030 μg/L. The ratio of this value with PNEC is 0.00003. Accordingly, based on a comprehensive review of the above findings, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Comprehensive judgment
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacean *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	1.0	Freshwater	<0.012	<0.01	○
					Seawater	<0.012	<0.01	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
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