1	CAS No.: 818-61-1	Substance: 2-Hydroxyethyl acrylate

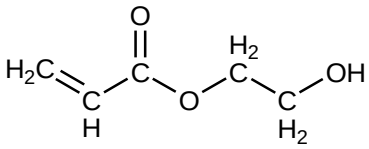
Chemical Substances Control Law Reference No.: 2-995

PRTR Law Cabinet Order No.: － (Cabinet Order No. after revision*: 1-6)

Structural Formula:

Molecular Formula: $C_5H_8O_3$

Molecular Weight: 116.12



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

1. General information

This substance is freely miscible with water (25°C), the partition coefficient (1-octanol/water) (log Kow) is –0.21, and the vapor pressure is 0.0524 mmHg (=6.99 Pa) (25°C). Biodegradability (aerobic degradation) is thought to be good. Its half-life for hydrolysis is more than 270 d (25°C, pH=7).

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. Its main applications are as a thermosetting coating, adhesive, fiber treatment agent, lubricant additive, and copolymer modifier; through copolymerization it is also used as a resin modifier for coatings and adhesives, and as a reactive diluent for UV curing. The production (shipments) and import quantity in fiscal 2004 was 10,000 to <100,000 t. The export quantity in fiscal 2004 was 7,060 t.

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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 soil and water bodies would be higher.

Data for setting the predicted maximum exposure to humans via inhalation could not be obtained. The predicted maximum oral exposure was estimated to be less than around 0.04 μg/kg/day based on calculations from data for groundwater. The risk of exposure to this substance by intake from an environmental medium via food is considered slight.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be less than around 1 μg/L for both public freshwater bodies and seawater.

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3. Initial assessment of health risk

This substance is irritating to eyes, skin and mucous membranes. Its 10 % water solution, when administered to rats, causes reduced activities, dyspnea, roughened fur, muscle weakness and gastrointestinal hemorrhage while its undiluted solution may cause chemical burns to their mouths, throats and gastrointestinal tracts.

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 17 mg/kg/day for the suppressed body weight increases, renal papillary necrosis and chronic nephropathy was obtained for oral exposure from its mid-term and long-term toxicity tests for rats. This LOAEL was divided by 10 to produce 1.7 mg/kg/day as its 'non-toxic level.*'

Its lowest-observed-adverse-effect-level (LOAEL) of 5 ppm for the relative increase of liver weight and ulcerous

keratitis was obtained for inhalation exposure from its repeated toxicity tests for rats. It was then adjusted for exposure conditions to provide 1 ppm or 4.9 mg/m^3. This was divided by 10 due to their short test periods, and divided again by 10 as LOAEL to produce 0.049 mg/m^3 as its 'non-toxic level*'.

As for its oral exposure, its maximum exposure was estimated to be less than around 0.04 μg/kg/day, when intakes of groundwater were assumed. Its margin of exposure (MOE) would be more than 4,300 when calculated from its 'non-toxic level*' of 1.7 mg/kg/day and its estimated maximum exposure, and then divided by 10 due to the fact that 'non-toxic level*' was obtained from animal experiments. Since risk associated with exposure to this substance through food intakes from the environment is presumed to be minimal, this exposure will not increase MOE significantly, and 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, lack of information on its exposure concentration did not allow its risk assessment. Domestic demand for this substance is relatively high and it is exported relatively in large amounts. Its half-life in the atmosphere is 4.2 to 42 hrs. Almost all of this substance is presumed to distribute in media other than ambient air (soils and water bodies) after its release to the atmosphere, but it has not been detected in water bodies (groundwater, and freshwater in public water bodies and seawater). Collection of information on its inhalation exposure to assess health risk associated with exposure to it in the ambient air would not be required.

However, this substance is designated as the Class I Designated Chemical Substance after revision of the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management, and it is desirable to review whether information on its inhalation exposure should be collected or not when the amount of its release to the environment is estimated.

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*', 1.7 mg/kg/day	Rats	suppressed weight increase, renal papillary necrosis, chronic nephropathy	Drinking water	− μg/kg/day	MOE	−	×	○
				Groundwater	< 0.04 μg/kg/day	MOE	>4,300	○	
Inhalation	'Non-toxic level*', 0.049 mg/m^3	Rats	Increase in relative liver weight, ulcerous keratitis	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 5,960 μg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC_{50} of 5,210 μg/L for swimming inhibition in the crustacean *Daphnia magna*; a 96-h median lethal concentration (LC_{50}) of 4,800 μg/L for the fish species *Pimephales promelas* (fathead minnow); and a 40-h median inhibition of growth concentration (IGC_{50}) of 23,700 μg/L for the ciliated freshwater protozoan *Tetrahymena pyriformis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 48 μg/L was obtained.

With regard to chronic toxicity, reliable data of a 72-h no observed effect concentration (NOEC) of 1,000 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 10 µg/L was obtained. The value of 10 µg/L obtained from the chronic toxicity to the algae was used as the PNEC for this substance.
The PEC/PNEC ratio was less than 0.1 for both freshwater bodies and seawater. Accordingly, further work is thought to be unnecessary at this time.

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	10	Freshwater	<1	<0.1	○
					Seawater	<1	<0.1	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Impossibility of risk characterization. Collection of information on inhalation exposure considered unnecessary; review of necessity of collection of information when desirable release amounts into environment are identified.	(○)
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.