6	CAS No.:88-12-0	Substance: *N*-Vinyl-2-pyrrolidone

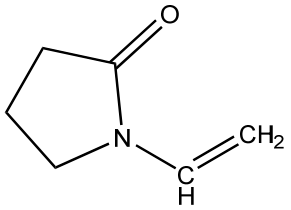
Chemical Substances Control Law Reference No.: 5-114

PRTR Law Cabinet Order No.:

Molecular Formula: C_6H_9NO

Molecular Weight: 111.14

Structural Formula:



1.General information

This substance is miscible with water (20℃), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.37 (pH unknown), and the vapor pressure is 12 Pa (20℃). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 1%, and it is considered to be difficult to decompose. In addition, the half-life for hydrolysis is approximately 1.5 minutes (pH=1.2, 37°C), 20–40 minutes (pH=2.2–2.5, 37°C), more than 6 hours (pH=3.5, 37°C), and more than 24 hours (pH = 7.2, 37°C).

The main uses of this substance are as a raw material monomer for PVP (polyvinyl pyrrolidone) manufacture, a reactive diluent for UV curing resin coatings and paints, and in UV-curing coatings for interior wall finishing and flooring. The production and import quantity in fiscal 2021 was 2,000 t.

2.Exposure assessment

This substance was classified as a Class 1 Designated Chemical Substance prior to revision of substances regulated by the PRTR Law. Total release to the environment in fiscal 2021 under the PRTR Law was 0.0001 t, and all releases were notified. All notified releases were to the atmosphere. In addition, 0.0003 t was transferred to sewage and approximately 1.5 t was transferred to waste materials. The sole source of notified 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 water bodies would be 98.7%.

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 2021 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 0.000019 μg/m^3.

Data for potable water, ground water, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. Further, river concentrations could not be calculated because there were no notified releases to public freshwater bodies under the PRTR Law in fiscal 2021 and the 0.3 kg transferred to sewage was discharged into lakes and marshes. Transfer to sewage was notified in fiscal 2013. Accordingly, when releases to public freshwater bodies estimated from this 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 0.23 μg/L, and the oral exposure calculated thereof was 0.0092 μg/kg/day. The 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.

Data to set the predicted environmental concentration (PEC) at a conservative value for water quality could not be obtained. River concentrations could not be calculated because there were no notified releases to public freshwater bodies under the PRTR Law in fiscal 2021 and the 0.3 kg transferred to sewage was discharged into lakes and marshes. Transfer to sewage was notified in fiscal 2013. Accordingly, when releases to public freshwater bodies estimated from this 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 0.23 μg/L.

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3. Initial assessment of health risk

This substance irritates the respiratory tract. Inhalation of this substance will cause a cough and sore throat. Ingestion will cause abdominal pain, diarrhea, nausea, and vomiting. The substance is corrosive to the eyes, and contact with the eyes will cause redness, pain, and severe deep burns.

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 0.9 mg/kg/day for oral exposure (based on the increased relative weight of the kidney), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 0.09 mg/kg/day was deemed the lowest reliable dose and was identified as the 'non-toxic level' of the substance for oral exposure. The NOAEL of 1 ppm for inhalation exposure (based on inflammation, atrophy of the olfactory epithelium, hyperplasia of the basal cells of the respiratory and olfactory epithelium, etc. in the nasal cavity), determined from toxicity tests in rats, was adjusted according to exposure conditions to obtain 0.18 ppm and subsequently divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 0.018 ppm (0.082 mg/m^3) was deemed the lowest reliable concentration and was identified as the 'non-toxic level' of the substance for inhalation exposure.

Regarding oral exposure, due to the lack of identified exposure levels, the health risk could not be assessed. Concentrations in rivers were not estimated, because the release of this substance to public freshwater bodies was not reported and the transfer of 0.3 kg to the sewage system was discharged to lakes in FY2021 under the PRTR Law. In addition, exposure to the substance in environmental media via food is presumed to be limited, despite the lack of exposure level via food. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via oral exposure.

Regarding inhalation exposure, due to the lack of identified exposure concentrations, the health risk could not be assessed. The maximum concentration (annual mean) in ambient air near the operators that are releasing a large amount of the substance was estimated to be 0.000019 μg/m^3, based on the releases to air reported in FY 2021 under the PRTR Law. The MOE for reference would be 430,000 which is calculated from the estimated maximum concentration (annual mean) in ambient air and the 'non-toxic level' of 0.082 mg/m^3 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 exposure.

Toxicity					Exposure assessment		Result of risk assessment		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*'	0.09 mg/kg/day	Rats	The increased relative weight of the kidney	Drinking water	- μg/kg/day	MOE	-	○
					Groundwater	- μg/kg/day	MOE	-	
Inhalation	'Non-toxic level*'	0.082 mg/m^3	Rats	Inflammation, atrophy of the olfactory epithelium, hyperplasia of the basal cells of the respiratory and olfactory epithelium, etc. in the nasal cavity	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.

4.Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} exceeding 1,000,000 μg/L for growth

inhibition in the green alga *Desmodesmus subspicatus*, a 48-h EC_{50} of 45,000 μg/L for swimming inhibition in the crustacean *Daphnia* sp., and a 96-h LC_{50} of 913,000 μg/L for the fish *Oncorhynchus mykiss* (rainbow trout). Accordingly, based on the minimum possible acute toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) exceeding 450 μg/L was obtained.

With regard to chronic toxicity, the following reliable datum was obtained: a 72-h EC_{10} of 530,000 μg/L for growth inhibition in the green alga *D. subspicatus*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 5,300 μg/L was obtained.

The value of 450 μg/L obtained from the acute toxicity to the crustacean species was used as the PNEC for this substance.

Data for setting the predicted environmental concentration (PEC) could not be obtained for this substance. Accordingly, an assessment of ecological risk could not be made.

River concentrations could not be calculated because there were no notified releases to public freshwater bodies under the PRTR Law in fiscal 2021 and the 0.3 kg transferred to sewage was discharged into lakes and marshes. Transfer to sewage was notified in fiscal 2013. Accordingly, when releases to public freshwater bodies estimated from this 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 0.23 μg/L. The ratio of this value to PNEC was 0.0005. 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* sp.	Acute	EC_{50} Swimming inhibition	100	450	Freshwater	—	—	○
					Seawater	—	—	

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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