3	CAS No.: 111-30-8	Substance: Glutaraldehyde

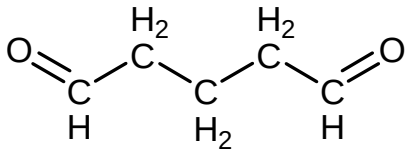
Chemical Substances Control Law Reference No.: 2-509

PRTR Law Cabinet Order No.: 1-85

Structural Formula:

Molecular Formula: $C_5H_8O_2$

Molecular Weight: 100.12



1. General information

This substance is freely miscible with water, the partition coefficient (1-octanol/water) (log K_{ow}) is –0.36 (23°C, pH=7), and the vapor pressure is 17 mmHg (=2.2×10^3 Pa) (20°C). Biodegradability (aerobic degradation) is judged to be good, and its half-lives for hydrolysis are 102 d and 394 d (pH=7, 25°C, measured values).

This substance is designated as a Class 1 Designated Chemical Substance under the PRTR Law.

The main uses of this substance are as a leather tanning agent, as a fixing agent for paper and plastics, as a disinfectant for endoscopic and surgical instruments, as an algicide for cooling towers, as a fungicide and disinfectant for chicken coops and poultry raising equipment, and as a developing solution for X-ray images. The production and import quantity in fiscal 2014 was less than 1,000 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 2014 under the PRTR Law was approximately 4.7 t, of which approximately 0.14 t or 3% of overall releases were reported. The major destination of reported releases was the atmosphere. In addition, approximately 0.18 t was transferred to sewage and approximately 0.87 t was transferred to waste materials. Industries with large reported releases were the plastic product manufacturing industry and tanned leather and leather product/pelt manufacturing industry for the atmosphere, and the pharmaceutical machinery manufacturing industry for public water bodies. The largest releases to the environment including unreported releases were to water bodies.

A multi-media model used to predict the proportions distributed to individual media in the environment indicate that in regions where the largest quantities were estimated to have been released to the environment overall or public water bodies in particular, the predicted proportion distributed to public water bodies was 92.5%. In regions where the largest quantities were estimated to have been released to the atmosphere, the predicted proportion distributed to water bodies was 90.7%.

The maximum expected concentration of exposure to humans via inhalation, based on ambient atmospheric data, was around 0.0086 μg/m^3. Further, the mean annual value for the atmospheric concentration in fiscal 2014 was calculated by using a plume-puff model based on releases to the atmosphere reported according to the PRTR Law: this model predicts a maximum level of 0.0076 μg/m^3.

Information to determine the maximum expected oral exposure could not be obtained. Further, past data for public freshwater bodies yielded a maximum expected oral exposure of around 0.016 μg/kg/day. In contrast, when releases to public freshwater bodies in fiscal 2014 reported under 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 0.8 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.03 μg/kg/day. The exposure level to this substance by intake from an environmental medium via food is considered slight, given the low bioaccumulation of the

substance expected on basis of its physicochemical properties.

Information to determine the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. However, past data yielded a value of around 0.4 μg/L for public freshwater bodies and a value of less than around 0.3 μg/L for seawater. When releases to public freshwater bodies in fiscal 2014 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 0.8 μg/L.

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3. Initial assessment of health risk

This substance is irritating to the eyes, skin and respiratory tract. Inhalation exposure causes coughs, headache, labored breathing, nausea and wheezing. Oral exposure to the substance causes abdominal pain, nausea, diarrhea and vomiting. Contact with the eyes causes redness and pain and contact with the skin causes redness.

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

The LOAEL for oral exposure of 4 mg/kg/day (based on decreased kidney weight), determined from long-term toxicity tests in rats, was divided by a factor of 10 to account for uncertainty in using a LOAEL. The calculated value of 0.40 mg/kg/day was deemed to be the lowest reliable dose and was identified as the 'non-toxic level*' of the substance for oral exposure.

The NOAEL for inhalation exposure of 21 ppb (based on nasal irritation and inhibition of body weight gain), determined from medium-term toxicity tests in rats, was adjusted according to exposure conditions to obtain 3.8 ppb and subsequently divided by a factor of 10 to account for extrapolation from sub-chronic to chronic exposure. The calculated value of 0.38 ppb (0.0016 mg/m^3) was deemed to be the lowest reliable concentration and was identified as the 'non-toxic level*' of the substance for inhalation exposure.

With regard to oral exposure, owing to lack of identified exposure levels, the health risk could not be assessed. Based on the concentration in public freshwater bodies reported in 2000, the maximum exposure level of the substance was 0.016 μg/kg/day. The MOE (Margin of Exposure) would be 2,500, when calculated from this level and the 'non-toxic level*' of 0.40 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. In addition, the maximum exposure level was calculated to be 0.03 μg/kg/day. This value derives from the estimated concentration in the effluents from the high discharging plants, according to the releases reported in FY 2014 under the PRTR Law. The MOE would be 1,300, when calculated from this level. Since exposure to the substance in environmental media via food is presumed to be limited, including this concentration in the calculation would not change the MOE significantly. Therefore, collection of further information would not be required to assess the health risk of the substance via oral exposure.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was 0.0086 $\mu g/m^3$, approximately. The MOE would be 19, when calculated from the predicted maximum exposure concentration and the 'non-toxic level*'of 0.0016 mg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. In addition, the maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance was estimated to be 0.0076 $\mu g/m^3$ based on the releases reported in FY 2014 under the PRTR Law. The MOE would be 21, when calculated from this concentration. Therefore, collection of information would be required to assess the health risk of this substance via inhalation in 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*' 0.40 mg/kg/day	Rats	Decreased kidney weight	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Public Freshwater bodies	— μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level*' 0.0016 mg/m^3	Rats	Nasal irritation and inhibition of body weight gain	Ambient air	0.0086 μg/m^3	MOE	19	▲	▲
				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 96-h IC_{50} of 1,000 μg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*, a 48-h LC_{50} of 3,000 μg/L for in the crustacean *Acartia tonsa*, and a 96-h LC_{50} of 5,500 μg/L for the fish species *Danio rerio* (zebrafish). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 10 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 340 μg/L for growth inhibition in the green algae *P. subcapitata*, a 21-d NOEC of 220 μg/L for reproductive inhibition in the crustacean *Daphnia magna*, and a 62-d NOEC of 1,300 μg/L for hatching inhibition in the fish species *Oncorhynchus mykiss* (rainbow trout). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC of 22 μg/L was obtained.

The value of 10 μg/L, obtained from the acute toxicity to the algae species, was used as the PNEC for this substance.

Information to determine the PEC, which indicates exposure to aquatic organisms, could not be obtained. However, past data yielded a value of around 0.4 μg/L for public freshwater and a value of around less than 0.3 μg/L for seawater, indicating a PEC/PNEC ratio of less than 0.1. Furthermore, when releases to public freshwater bodies in fiscal 2014 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 0.8 μg/L, indicating a PEC/PNEC ratio of less than 0.1. Accordingly, there is little need to collect new data regarding this substance.

Hazard Assessment (Basis for PNEC)			Assessment Coefficient	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	Acute	IC_{50} growth inhibition	100	10	Freshwater	—	—	×	○
					Seawater	—	—		

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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	Requiring information collection.	▲
Ecological risk	No need for further work at present.		○

［Risk judgments］ ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization

（○）: Although risk to human health could not be confirmed, collection of further information would not be required.

（▲）: Further information collection would be required for risk characterization.