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

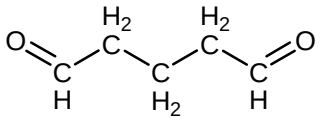
Chemical Substances Control Law Reference No.: 2-509

PRTR Law Cabinet Order No.: 1-66

Molecular Formula: $C_5H_8O_2$

Molecular Weight: 100.12

Structural Formula:



1. General information

The aqueous solubility of this substance is freely miscible, and the partition coefficient (1-octanol / water) (log Kow) is -0.22 (25°C). The vapor pressure is 17 mmHg (= 2.2 x 10^3 Pa) (20°C). Degradability (aerobic degradation) is judged to be good. In terms of hydrolyzability, the half-life at 25°C is 508 days (pH = 5), 102 days (pH = 7) and 46days (pH = 9).

This substance is 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). It is used primarily as a medical disinfectant (germicide), an antiseptic for storage of skin and tissue samples, a tanner, and as a fixer of paper and plastics, etc. Production and import quantities under the PRTR Law came to 1,000 tons.

---

2. Exposure assessment

Total release to the environment in FY2004 under the PRTR Law came to approximately 1.8 tons. Of this quantity, the amount reported came to 0.38 tons (21% of the total). Release to the public water bodies accounted for a large part of the reported release. Tanner, leather and fur industries accounted for high levels of release to the atmosphere. Pulp, paper and paper converting companies, tanner, leather and fur industries reported high levels of release to the public water bodies.

When estimated releases outside notification are included, release to water bodies accounted for the greatest quantity of release to the environment. The distribution into each environment medium predicted by means of a multimedia model was 96.9% for water bodies in the case of the region where the estimated release quantity to the environment and atmosphere was considered to be the maximum. In the case of the region where the estimated release quantity to the public water bodies was considered to be the maximum, the distribution was 99.1% for water bodies.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. The predicted maximum oral exposure was estimated to be approximately less than 0.012 μg/kg/day. Because the 1-octanol/water partition coefficient (log Kow) is low and bioconcentration is also predicted to be low, exposure from environmental media via the food chain is assumed to be low.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be approximately 0.4 μg/L for freshwater and approximately less than 0.3 μg/L for seawater public water bodies.

---

3. Initial assessment of health risk

Exposure to this substance may result in irritation of the eyes, skin and respiratory tract. By inhalation, it may cause coughing, headache, shortness of breath, nausea, and wheezing. By ingestion, it may cause abdominal pains, nausea, diarrhea and vomiting. Contact with eyes and skin may cause redness and pain, and redness, respectively.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the ‘Non-toxic level’, a lowest observed adverse effect level (LOAEL) of 4 mg/kg/day (decrease in the weight of kidney) was obtained for oral from the medium- and long-term toxicity testing for rats. As this was a LOAEL value, it was divided by 10 to establish a value of 0.4 mg/kg/day as the ‘Non-toxic level’. As the ‘Non-toxic level’ for the inhalation, the NOAEL of 21 ppb

(nasal irritation, and depression of body weight gain) was obtained from the medium- and long-term toxicity testing for mice. the NOAEL was adjusted to 3.8 ppb taking account the exposure situations, and because of the short testing period, this value was divided by 10, and a value of 0.38 ppb (0.0016 mg/m^3) was derived as the 'Non-toxic level'.

With regard to oral exposure, in case of groundwater intakes, the predicted maximum exposure was approximately less than 0.012 μg/kg/day. The MOE of exceeding 3,300 was derived from the 'Non-toxic level' of 0.4 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level' was established by means of animal testing. As the exposure to this substance through food intakes was estimated minor, even when the exposure through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For the inhalation, because the exposure concentrations have not been estimated, its health risk can not be identified. Considering the fact that 63 % of the total release of this substance to the environment was released to water bodies, and that most part is estimated to be distributed into water bodies thereafter, there would be low necessity of collecting information on inhalation exposure to this substance in the ambient air for its health risk assessment at present.

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 exposurequantity and concentration				
Oral	'Non toxic level' 0.4 mg/kg/day	Rats	Decrease in the weight of kidney	Drinking water	– μg/kg/day	MOE	–	×	○
				Groundwater	< 0.012 μg/kg/day	MOE	> 3,300	○	
Inhalation	'Non toxic level' 0.0016 mg/m^3	Mice	nasal irritation, and depression of body weight gain	Ambient air	– μg/m^3	MOE	–	×	×
				Indoor air	– μg/m^3	MOE	–	×	×

---

4. Initial assessment of ecological risk

In this substance, at this point, the reliability of the toxicity data and the acceptability could not be confirmed. Accordingly, its ecological risk could not be determined. For this substance, there is thought to be need for the re-assessment through the implementation of the ecotoxicity tests.

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)		
–	–	–	–	–	Freshwater	0.4	–	×
					Seawater	< 0.3	–	

---

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work.	○
	Inhalation exposure	Impossible of risk characterization. However, there is thought to be comparatively little need to collect information, etc.	×
Ecological risk	Impossible of risk characterization. There is thought to be need for the re-assessment through the implementation of the ecotoxicity tests.		×

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

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

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 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.