| 6 | CAS No.: 111-30-8 | Substance: Glutaraldehyde |
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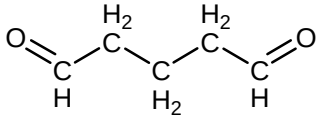
Chemical Substances Control Law Reference No.: 2-509

PRTR Law Cabinet Order No.*: 1-85

Molecular Formula: $C_5H_8O_2$

Molecular Weight: 100.12

Structural formula:



*Note: No. in Revised Cabinet Order enacted on October 1, 2009

**1. General information**

This substance is freely miscible with water, the partition coefficient (1-octanol/water) (log $K_{ow}$) is –0.22 (25°C), and the vapor pressure is 17 mmHg (=$2.2\times10^3$ Pa) (20°C). Biodegradability (aerobic degradation) is thought to be good. Its half-life for hydrolysis is 508 days (25°C, pH5) , 102 days (25°C, pH7), and 46 days (25°C, pH9).

This substance is designated as a Type II Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances, and 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). The main uses are as a leather tanning agent, fixative for paper and plastics, etc., disinfectant and sterilizing agent for endoscopes and surgical instruments, algaecide for cooling towers, etc., disinfectant and sterilizing agent for poultry houses and poultry raising equipment, and X-ray photograph developing solution. The production (shipments) and import quantity for fiscal 2007 was 100 to <1,000 t/y. The production and import category under the PRTR Law was ≥100 t.

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**2. Exposure assessment**

Total release to the environment in fiscal 2008 under the PRTR Law was approximately 5.9 t, of which 0.2 t, or 3% of overall releases, was reported releases. The major destination of reported releases was the atmosphere. Besides this, 4.8 t was transferred to sewage. Industry types that reported large releases to the atmosphere were the plastic product manufacturing industry and the leather and associated product/fur manufacturing industry, while the latter also reported large releases to public freshwater bodies. Including non-reported releases, releases to water bodies are estimated to have been the greatest. A multi-media model used to predict the distribution into each medium in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment and public freshwater bodies, the proportion distributed to water bodies would be 99.1%, while in regions where the largest quantity was estimated to have been released to the atmosphere, the proportion distributed to water bodies would be 93.9%.

Data for setting the predicted maximum exposure to humans via inhalation could not be obtained. Meanwhile, the mean value of atmospheric concentration estimated from reported releases to the atmosphere under the PRTR Law was a maximum of 0.015 μg/$m^3$.

The predicted maximum oral exposure was estimated to be around 0.016 μg/kg/day based on calculations from data for public freshwater bodies. Meanwhile, oral exposure was estimated to be 0.0017 μg/kg/day using the maximum river concentration calculated from reported emissions to public freshwater bodies under the PRTR Law. The risk of exposure to this substance by intake from an environmental medium via food is considered slight based on estimates of oral exposure using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was about 0.4 μg/L for freshwater bodies and less than around 0.3 μg/L for seawater. The river concentration estimated using reported releases based on the PRTR Law was a maximum of 0.043 μg/L.

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**3. Initial assessment of health risk**

This substance is irritable to the eyes, skin and respiratory tract. Symptoms of poisoning via the inhalation route include cough, headache, laboured breathing, nausea and wheezing, while those via the oral route include abdominal pain, nausea, diarrhea and vomiting. Contact with the substance causes redness and pain in the eyes and redness in the skin.

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

With regard to oral exposure to the substance, a LOAEL of 4 mg/kg/day (for reduced kidney weight) obtained from mid-term and long-term toxicity tests in rats was divided by 10 as it is always the case with a LOAEL. 0.4 mg/kg/day derived was deemed as a plausible value for the lowest dose of the substance and was identified as its 'non-toxic level*'. As for inhalation exposure, a NOAEL of 21 ppb (for irritated nose and suppressed body weight increase) obtained from mid-term and long-term toxicity tests in rats was adjusted to 3.8 ppb according to exposure conditions. This value was divided by 10 due to the short test periods and 0.38 ppb (0.0016 mg/m$^3$) derived was deemed as a plausible value for the lowest dose of the substance and was identified as its 'non-toxic level*'.

As for oral exposure to the substance, when intakes of freshwater from public water bodies were assumed, the predicted maximum exposure was approximately 0.016 μg/kg/day. The MOE was 2,500 when calculated from the 'non-toxic level*' of 0.4 mg/kg/day and the predicted maximum exposure divided by 10 due to the need to convert the 'non-toxic level*' from the animal experiments to a human equivalent dose. Concentrations of the substance in rivers as a result of discharges from the major sources were estimated on the basis of releases into freshwater in public bodies reported for FY2008 under Japanese PRTR. The maximum exposure was calculated to be 0.0017μg/kg/day from the concentrations in rivers. A MOE of 24,000 would be derived from the maximum exposure calculated. As the exposure to this substance through food intakes was estimated minor, even when the exposure through groundwater and food were combined, the MOE would not be greatly affected. Therefore, further action for to assess health risk from oral exposure to this substance would not be required at present.

With regard to inhalation exposure to the substance, the absence of information available on exposure concentrations did not allow for a health risk assessment. The maximum annual average concentration of the substance in the ambient air around its major sources was estimated to be 0.015 μg/m$^3$ on the basis of its emissions reported for FY2008 under Japanese PRTR. The MOE derived would be 11 when calculated from this 0.015 μg/m$^3$ and the 'non-toxic level*' of 0.0016 mg/m$^3$ divided by 10 due to the need to convert the 'non-toxic level*' from the animal experiments to a human equivalent dose. Therefore, collection of further information would be required to assess health risk from inhalation exposure to this substance in the ambient air.

| Information of toxicity | | | | Exposure assessment | | | Result of risk Exposure 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 * ' 0.4 mg/kg/day | Rats | Reduced kidney weight | Drinking water<br>Freshwater | －<br>0.016 | μg/kg/day<br>μg/kg/day | MOE<br>MOE | －<br>2,500 | ×<br>○ | ○ |
| Inhalation | 'Non-toxic level * ' 0.0016 mg/m$^3$ | Rats | Irritation of the nose, suppressed body weight increase | Ambient air<br>Indoor air | －<br>－ | μg/m$^3$<br>μg/m$^3$ | MOE<br>MOE | －<br>－ | ×<br>× | (▲)<br>× |

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.

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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 $EC_{50}$ of 8,700 µg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h $LC_{50}$ of 8,800 µg/L for the fish species *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment coefficient 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 *D. 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 coefficient of 10, a predicted no effect concentration (PNEC) of 22 µg/L was obtained. The value of 10 µg/L obtained from the acute toxicity to the algae was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.04 for freshwater bodies and less than 0.03 for seawater. Accordingly, further work is thought to be unnecessary at this time.

| 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 | End point | | | Water body | Predicted environmental concentration PEC (µg/L) | | | |
| Green algae | Acute | $IC_{50}$ growth inhibition | 100 | 10 | Freshwater | 0.4 | 0.04 | ○ | ○ |
| | | | | | Seawater | <0.3 | <0.03 | | |

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**5. Conclusions**

| | Conclusions | | Judgment |
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| Health risk | Oral exposure | No need for further work | ○ |
| | Inhalation exposure | Further information collection would be required for risk characterization. | (▲) |
| Ecological risk | No need of further work at present. | | ○ |

［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.