| 7 | CAS No.: 120-61-6 | Substance: Dimethyl terephthalate |
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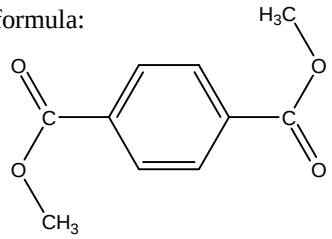
Chemical Substances Control Law Reference No.: 3-1328

PRTR Law Cabinet Order No.: 1-271

Molecular Formula: $C_{10}H_{10}O_4$

Molecular Weight: 194.18

Structural formula:




**1. General information**

The water solubility of this substance is 32.8 mg/1,000g (25°C), the partition coefficient (1-octanol/water) (log Kow) is 2.25, and the vapor pressure is 0.01 mmHg (=1.3Pa) (25°C). This substance is judged to be readily biodegradable (aerobic degradation). The hydrolysis half-life is 320 days (pH=7, 25°C).

This substance is designated as a Priority Chemical Substance for Assessment 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 use is as a raw material for PET (polyethylene terephthalate) resin and PBT (polybutylene terephthalate) resin, but the main process for manufacturing PET is shifting to one that employs terephthalic acid as a raw material. The production (shipments) and import quantity in FY 2007 was 10,000 to <100,000 t. The import quantity in 2009 was 16,731 t, while the export quantity was 10,721 t.

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**2. Exposure assessment**

Total release to the environment in FY 2009 under the PRTR Law was approximately 2.5 t, of which all were reported releases. All reported releases were released to the atmosphere. In addition, approximately 100 t was transferred to waste materials. The main source of reported releases was the industrial waste disposal industry. 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, the proportion distributed to the atmosphere would be 86.8 %.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.00049 μg/$m^3$. Meanwhile, the mean value of atmospheric concentration estimated from reported releases to the atmosphere under the PRTR Law was a maximum of 0.56 μg/$m^3$. Data for calculating the predicted maximum oral exposure could not be obtained. But a predicted maximum oral exposure is less than 0.008 μg/kg/day calculated from past data for public freshwater bodies. While this past data for public water bodies are from more than ten years ago, the likelihood that the concentration in public water bodies is increasing substantially is considered low based on trends for production and PRTR data. In addition, based on estimates of oral exposure using estimated concentrations in fish, the risk of exposure to this substance by intake from an environmental medium via food is considered slight.

Data for setting the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. While the past data, public freshwater water concentration was less than 0.2 μg/L and public seawater concentration was less than 0.5 μg/L. While this past data for public water concentration are from more than ten years ago, the likelihood that the concentration in public water bodies is increasing substantially is considered low based on trends for production and PRTR data.

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**3. Initial assessment of health risk**

This substance may cause mechanical irritation. Contact of eyes with the substance makes them red.

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

As for oral exposure to the substance, a NOAEL of 125 mg/kg/day (for chronic nephritis) obtained from mid- and long-term toxicity tests on rats was deemed to be the lowest reliable dose without any effect, and this was identified as its 'non-toxic level*'. As for its inhalation exposure, a NOAEL of no less than 86.4 mg/m$^3$ was obtained from mid- and long-term toxicity tests on rats (no effect observed even at the highest dose). It was then adjusted to 10 mg/m$^3$ against exposure conditions, divided by 10 due to short test periods, and outcome of 1 mg/m$^3$ was deemed to be the lowest reliable concentration of the substance without any effect and identified as its 'non-toxic level*'.

As for its oral exposure, lack of available information on its exposure did not allow its health risk assessment. For reference, its oral exposure was less than around 0.008 μg/kg/day when calculated from its concentration in river water, reported in 1982 as its maximum concentration in freshwater from public water bodies. When this was combined with a NOAEL of 125 mg/kg/day and divided by 10 for conversion of those obtained from animal experiments to the 'non-toxic level*' for humans, the MOE would be more than 1,600,000. Although its measurement in river water was recorded more than 10 years ago, chronological changes of its production and its PRTR data suggest that significant increases of its concentration in public water bodies is not likely. In addition, exposure to this substance through food intakes from the environment would be limited. Therefore, collection of information would not be required to assess health risk from oral exposure to this substance.

As for its inhalation exposure, its mean exposure concentration would be about 0.000074 μg/m$^3$ and its predicted maximum exposure concentration would be around 0.00049 μg/m$^3$, respectively, when concentrations in the ambient air were considered. The MOE would be 200,000 when calculated from the 'non-toxic level*' of 1 mg/m$^3$ and the predicted maximum exposure concentration, and divided by 10 for conversion of the 'non-toxic level*' from animal experiments to an equivalent concentration for humans. Its releases to the ambient air reported in FY 2009 under the PRTR Law suggest that its maximum annual average concentration in the ambient air around its major sources of emissions would be 0.56 μg/m$^3$ and associated MOE would be 180. Therefore, further actions would not be required at the moment to assess health risk from inhalation exposure to the substance in the ambient air. Nevertheless, the substance was detected in the ambient air more frequently in 2007 than in 2001, and it is necessary to continue to carefully monitor its PRTR data and changes of its concentrations in the 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 * ' | 125 | mg/kg/day | Rats | Chronic nephritis | Drinking water | – | μg/kg/day | MOE | – | × | (○) |
| | | | | | | Groundwater | – | μg/kg/day | MOE | – | × | |
| Inhalation | Non-toxic level * ' | 1 | mg/m$^3$ | Rats | No effect observed even at the highest dose | Ambient air | 0.00049 | μg/m$^3$ | MOE | 200,000 | ○ | ○ |
| | | | | | | 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 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 72-h $EC_{50}$ exceeding 5,270 μg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h $EC_{50}$ exceeding 6,500 μg/L for immobilization in the crustacean *Daphnia magna*; and a 96-h $LC_{50}$ exceeding 5,370 μg/L for the fish *Oryzias latipes* (medaka). This acute toxicity value for algae was obtained from the test in which effects were not observed even for the highest possible concentration level. Further, the acute toxicity values for crustaceans and fish species were obtained from the limit tests at the highest possible concentration. Accordingly, a PNEC based on the acute toxicity value was not set.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 5,270 μg/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 1,720 μg/L for reproductive inhibition in the in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 17 μg/L was obtained. This 17 μg/L obtained from the crustacean chronic toxicity was used as the PNEC for this substance.

A judgment could not be made regarding ecological risk because data for setting a predicted environmental concentration (PEC) for this substance could not be obtained for the past ten years. The past concentration of this substance in public water bodies was reported to be less than 0.2 μg/L for freshwater bodies and generally less than 0.5 μg/L for seawater. Calculating the ratios of these past concentrations with PNEC gives less than 0.01 for freshwater bodies and less than 0.03 for seawater.

The main use of this substance is as a raw material for PET (polyethylene terephthalate) resin and PBT (polybutylene terephthalate) resin but the main process for manufacturing PET is shifting to one that employs terephthalic acid as a raw material. In addition, the likelihood that the concentration in public water bodies is increasing substantially is considered low based on trends for production and PRTR data. Accordingly, the need to gather new data concerning this substance is considered low.

| Hazard Assessment（Basis for PNEC） | | | Assessment factor | 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) | | | |
| Crustacean *Daphnia magna* | Chronic | NOEC reproductive inhibition | 100 | 17 | Freshwater | – | – | × | ○ |
| | | | | | Seawater | – | – | | |

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**5. Conclusions**

| | Conclusions | | Judgment |
|---|---|---|---|
| Health risk | Oral exposure | Though a risk characterization cannot be determined, there would be little necessity of collecting information. | (○) |
| | Inhalation exposure | No need for further work. | ○ |
| Ecological risk | Need to gather new data considered low. | | ○ |

［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.