11	CAS No.: 117-84-0	Substance: Di-*n*-octyl phthalate

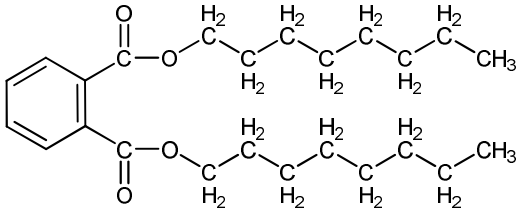
Chemical Substances Control Law Reference No.: 3-1307 (Dialkyl phthalate [C＝6–20])

PRTR Law Cabinet Order No.:

Molecular Formula: $C_{24}H_{38}O_4$

Molecular Weight: 390.56

Structural formula:



1. General information

The aqueous solubility of this substance is 0.02 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 8.06, and the vapor pressure is 2.60×10^{-6} mmHg ($=3.5\times10^{-4}$ Pa) (25°C). The biodegradability (aerobic degradation) is not thought to be limited. Furthermore, its half-life for hydrolysis is 107 years (25°C, pH7).

The main use is as a plasticizer for synthetic resins such as polyvinyl chloride resin used in uses such as synthetic leather. The production quantity in 2001 for dioctyl phthalate was 244,554 t, and the production (shipments) and import quantity for dialkyl phthalates (C=6–20) in fiscal 2007 was 100,000 to <1,000,000 t/y.

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2. Exposure assessment

Total release to the environment in fiscal 2008 under the PRTR Law was approximately 0.25 t, of which 0.25 t, or 99% of overall releases, was reported releases. The sole destination of reported releases was the atmosphere. Besides this, approximately 15 t was transfer to waste. Industry types that reported large releases to the atmosphere were the plastic product manufacturing industry and the transportation machinery manufacturing industry. Including non-reported releases, releases to the atmosphere 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 proportions distributed to sediment and soil would be 56.0% and 42.9%, respectively, while in regions where the largest quantity was estimated to have been released to the atmosphere, the proportion distributed to soil would be 99.6%.

Data for setting the predicted maximum exposure to humans via inhalation could not be obtained. Further, albeit past data, general environmental atmospheric data indicated a value of less than around 0.012 μg/m^3. Data exists based on general environmental measurements made more than 10 years ago, but taking into consideration trends in production and import quantities for this substance, the probability of marked increases in concentration is considered to be low. Meanwhile, the annual mean value of atmospheric concentration estimated from reported releases to the atmosphere under the PRTR Law was a maximum of 0.019 μg/m^3.

The predicted maximum oral exposure was estimated to be around 0.004 μg/kg/day based on calculations from data for public freshwater bodies. Further, the predicted maximum oral exposure calculated using public freshwater body data and past food data was 0.004 μg/kg/day to 0.04 μg/kg/day.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was about 0.10 μg/L for freshwater bodies and less than around 0.01 μg/L for seawater.

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3. Initial assessment of health risk

This substance is irritable to eyes, skin, nose and throat. Symptoms of poisoning of the substance include cough and shortness of breath. Exposure to high concentrations can irritate and may possibly damage the lungs.

As sufficient information was not available on the carcinogenicity of the 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 NOAEL of 0.05% (viz. 36.8 mg/kg/day for males and 40.8 mg/kg/day for females for toxic effects on liver tissue) obtained from mid-term and long-term toxicity tests in rats was divided by 10 due to the short test periods and then was rounded. 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, its 'non-toxic level*' could not be identified.

As to oral exposure to the substance, the predicted maximum exposure to the substance was approximately 0.004 μg/kg/day when intakes of freshwater in public water bodies were assumed. The MOE was 100,000 when calculated from its 'non-toxic level*' of 4 mg/kg/day and the predicted maximum exposure, and then divided by 10 due to the need to convert the 'non-toxic level*' from the animal experiments to a human equivalent dose. Concentrations in food reported previously indicated the maximum exposure to the substance of approximately 0.004 μg/kg/day or above to less than approximately 0.04 μg/kg/day through food intakes, and the MOE would then be 10,000 to 100,000. Therefore, no further action would be required at the moment to assess health risk from oral exposure to the substance.

With regard to inhalation exposure to the substance, the absence of information available on 'non-toxic levels*' and exposure concentrations did not allow for a health risk assessment. The total amount of emissions of the substance released into the environment was 0.25t, and almost all of these were emitted into the atmosphere. When emitted into the atmosphere, few of these would disperse. The 'non-toxic level*' for oral exposure, if 100% absorption were assumed, would be equivalent to the 'non-toxic level*' of 13 mg/m^3 for inhalation exposure. When combined with the maximum concentration of less than 0.012 μg/m^3 in the ambient air reported in 1996, the MOE would be calculated to be greater than 110,000. Historical production and import trends in recent years were not indicative of considerable increases in concentrations in the environment since the last report, and, thus, remarkable changes in the MOE would not be likely. The maximum annual average concentration of the substance in the ambient air around its major sources would be 0.019 μg/m^3 on the basis of its emissions reported under Japanese PRTR for FY2008, and, thus, the MOE would be 68,000. Therefore, collection of information would not 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 * ' 4 mg/kg/day	Rats	Effects on liver	Drinking water	– μg/kg/day		MOE	–	×	○
				Freshwater	0.004 μg/kg/day		MOE	100,000	○	
Inhalation	'Non-toxic level * ' – mg/m^3	–	–	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 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

Usable toxicity values for this substance were obtained from limit tests or tests equivalent to limit tests, and for this reason a PNEC could not be set. However, if for example the value for chronic toxicity in crustaceans of more than 0.607 μg/L is divided by an assessment coefficient of 100, a provisional PNEC value of 0.0061 μg/L is obtained. Based on a comparison of this value with the predicted environmental concentration (PEC), data collection is considered to be required.

Chronic toxicity testing of fish species for this substance is considered desirable.

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)			
–	–	–	–	–	Freshwater	0.10	–	×	▲
					Seawater	<0.01	–		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work	○
	Inhalation exposure	Though a risk characterization cannot be determined, there would be little necessity of collecting information.	(○)
Ecological risk	Data collection considered required.		▲

［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.