1	CAS No.: 124-04-9	Substance: Adipic acid

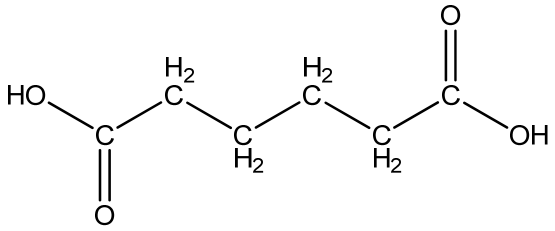
Chemical Substances Control Law Reference No.: 2-858

PRTR Law Cabinet Order No.:

Molecular Formula: $C_6H_{10}O_4$

Molecular Weight: 146.14

Structural Formula:



1. General information

The aqueous solubility of this substance is 1.48×10^4 mg/1,000 g (15°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.08, and the vapor pressure is 7.30×10^{-2} mmHg (9.73 Pa) (18°C). Biodegradability (aerobic degradation) is judged to be good. The substance does not have any hydrolyzable groups and is not believed to hydrolyze in the environment.

The main uses of this substance are as a raw material for polyamide (Nylon 66), urethane, plasticizers, and fragrances, and as a paper strengthening agent. The production and import quantity in fiscal 2013 was 70,000 t.

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2. Exposure assessment

Because this substance is not classified as a Class 1 Designated Chemical Substance under the PRTR Law, release and transfer quantities could not be obtained. Predictions of proportions distributed to individual media by using a Mackay-type level III fugacity model indicated that if equal quantities were released to the atmosphere, water bodies, and soil, the proportions distributed to soil and water bodies would be largest.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was generally less than 0.09 μg/m^3. The maximum expected oral exposure was estimated to be generally less than 0.15 μg/kg/day on the basis of calculations from data for public freshwater bodies. The risk of exposure 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.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, is generally less than 3.8 μg/L for both public freshwater bodies and seawater.

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3. Initial assessment of health risk

This substance is irritating to the eyes and respiratory tract. It causes coughs and sore throat, if inhaled. Inhalation of its aerosol may cause asthmatic reactions. Contact with the eyes causes redness and pain.

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 NOAEL of 470 mg/kg/day for oral exposure (based on suppressed weight gain), determined from medium-term and long-term toxicity tests in rats was deemed to be the lowest reliable dose and was identified as the ‘non-toxic level*’ of the substance for oral exposure. The ‘non-toxic level*’ for inhalation exposure could not be identified.

With regard to oral exposure, assuming the substance is absorbed via public freshwater bodies, the predicted

maximum exposure level was less than 0.15 μg/kg/day approximately. The MOE (Margin of Exposure) would be over 310,000, when calculated from the predicted maximum exposure level and the 'non-toxic level*'of 470 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. Since exposure to the substance in environmental media via food is presumed to be limited, its inclusion in the calculation would not change the MOE significantly. Therefore, no further work would be required at present to assess the health risk of this substance via oral exposure.

With regard to inhalation exposure, owing to lack of identified 'non-toxic level*', the health risk could not be assessed. For comparison, assuming 100% of the ingested substance is absorbed, the 'non-toxic level*' of inhalation exposure, derived by converting that of oral exposure, would be 1570 mg/m^3. The MOE would be over 1,700,000, when calculated from the converted 'non-toxic level*' of inhalation exposure and the predicted maximum exposure concentration of less than 0.09 μg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. Therefore, collection of further information would not 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*' 470 mg/kg/day	Rat	Suppressed weight gain	Drinking water	— μg/kg/day	MOE	—	×	○
				Public Freshwater bodies	<0.15 μg/kg/day	MOE	>310,000	○	
Inhalation	'Non-toxic level*' — mg/m^3	—	—	Ambient air	<0.09 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 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 72-h EC_{50} of 31,300 μg/L for growth inhibition in the green algae *Desmodesmus subspicatus*, a 48-h EC_{50} of 46,300 μg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} exceeding 100,000 μg/L in the fish species *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 313 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 40,600 μg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*, and a 21-d NOEC of 6,250 μg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 62 μg/L was obtained.

The value of 62 μg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio is less than 0.06 for both freshwater bodies and seawater; accordingly, further work is considered 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	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)			
Crustacean *Daphnia magna*	Chronic	NOEC reproductive inhibition	100	62	Freshwater	<3.8	<0.06	○	○
					Seawater	<3.8	<0.06		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work at present.	○
	Inhalation exposure	Although risk to human health could not be confirmed, collection of further information would not be required.	(○)
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.