11	CAS No.: 52829-07-9	Substance: Bis (2,2,6,6-tetramethyl-4-piperidyl) sebacate

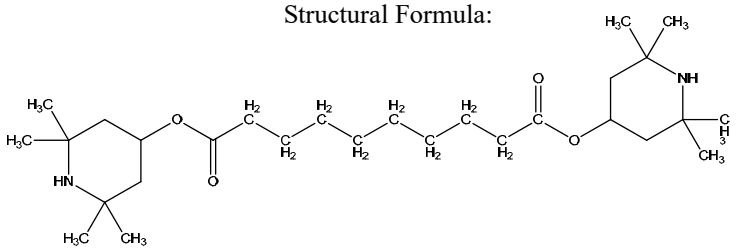
Chemical Substances Control Law Reference No.: 5-3732

PRTR Law Cabinet Order No.:

Molecular Formula: $C_{28}H_{52}N_2O_4$

Molecular Weight: 480.72

Structural Formula:



1. General information

The aqueous solubility of this substance is 18.8 mg/L (pH=7.5) (22°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.35 (pH=7) (25°C), and the vapor pressure is about 9.98×10^{-11} mmHg (= about 1.33×10^{-8} Pa) (20°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 29%, and the bioaccumulation factor is 3.2 (calculated value). Further, the half-lives for hydrolyzation are 206 d (pH=4, 25°C), 57 d (pH=7, 25°C) and 2 d (pH=9, 25°C).

The main use of this substance is as a plastic additive (light stabilizer) and its concentration in final products is 0.1–0.5%. Further, the production and import quantity in fiscal 2015 was 1,000 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 proportion distributed to soil would be largest.

Information to determine the maximum expected inhalation exposure could not be obtained. The maximum expected oral exposure was estimated to be around 0.0036 μg/kg/day based on 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 the basis of its physicochemical properties.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, is around 0.090 μg/L for public freshwater bodies and around 0.69 μg/L for seawater.

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3. Initial assessment of health risk

No information was available on acute symptoms in humans. Dyspnea, salivation, trismus, tremor and sedation were observed in rats exposed to this substance by inhalation. These symptoms became more pronounced as the concentration increased and resolved within 24 hours after cessation of the exposure.

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 LOAEL for oral exposure of 29 mg/kg/day (based on inhibition of body weight gain), determined from medium-term toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure, and by another factor of 10 to account for uncertainty in using a LOAEL. The calculated value of 0.29 mg/kg/day 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 would be 0.0036 μg/kg/day, approximately. The MOE (Margin of Exposure) would be 8,100, when calculated from the predicted maximum exposure level and the 'non-toxic level*'of 0.29 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, including this concentration value in the calculation would not change the MOE significantly. Therefore, no further work would be required at present to assess the health risk of the substance via oral exposure.

With regard to inhalation exposure, owing to the lack of identified 'non-toxic level*' and exposure concentrations, the health risk could not be assessed. Predictions of the multimedia fugacity model indicated that proportion distributed to air was little and the detected levels of the substance in the water bodies were low. Given these facts, the concentration of the substance in ambient air is not likely to become a major concern. 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*' 0.29 mg/kg/day	Rats	Inhibition of body weight gain	Drinking water	— μg/kg/day	MOE	—	×	○
				Public Freshwater bodies	0.0036 μg/kg/day	MOE	8,100	○	
Inhalation	'Non-toxic level*' — mg/m^3	—	—	Ambient air	— $\mu g/m^3$	MOE	—	×	(○)
				Indoor air	— $\mu g/m^3$	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 1,100 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of more than 2,000 μg/L for immobilization in the crustacean *Daphnia magna*, and a 96-h LC_{50} of 4,400 μg/L for the fish species *Lepomis macrochirus* (bluegill). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 11 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 50 μg/L for growth inhibition in the green alga *P. subcapitata*, and a 21-d NOEC of 230 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 0.5 μg/L was obtained.

The value of 21 μg/L obtained from the chronic toxicity to the green algal species was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.18 for freshwater bodies and 1.4 for seawater; accordingly, the substance is considered to be a candidate for detailed assessment. PEC values for freshwater and seawater differ greatly; accordingly, separate assessments for freshwater and seawater should be considered in the future.

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)			
Green algae	Chronic	NOEC Growth inhibition	100	0.5	Freshwater	0.090	0.18	■	■
					Seawater	0.69	1.4		

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5. Conclusions

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

［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.