5	CAS No.: 11070-44-3	Substance: Methyltetrahydrophthalic anhydride

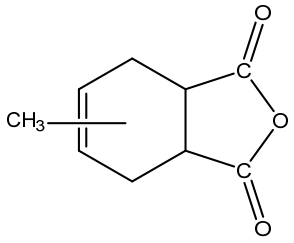
Chemical Substances Control Law Reference No.: 3-2451

PRTR Law Cabinet Order No.: 1-265

Molecular Formula: $C_9H_{10}O_3$

Molecular Weight: 166.17

Structural Formula:



1.General information

The aqueous solubility of this substance is $>1.0\times10^4$ mg/L and the partition coefficient (1-octanol/water) (log K_{ow}) was not estimated by model calculations as the substance hydrolyzes. The vapor pressure is 3.3×10^{-3} mmHg (=0.44 Pa) (25℃) (calculated value). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%. Further, hydrolysis half-lives are 3.2 minutes (pH=7, 20°C) and 2.9 minutes (pH=7, 25°C).

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law.

This substance is used as a raw material for unsaturated polyester resins and alkyd resins, and as a curing agent for epoxy resins. In addition, the production and import quantity in fiscal 2018 was 8,000 t. The production and import category under the PRTR Law is more than 100 t.

2.Exposure assessment

Total release to the environment in fiscal 2018 under the PRTR Law was approximately 0.83 t; all releases were reported. All reported releases were to the atmosphere. In addition, approximately 120 t was transferred to waste materials. The electrical machinery manufacturing industry was the only reporter of releases.

The proportions distributed to individual media were not predicted for this substance because the physico-chemical properties required for such an analysis could not be obtained.

The maximum expected concentration of exposure to humans via inhalation was not established because neither data measured for the ambient atmosphere nor for indoor air could be obtained. However, the mean annual value for atmospheric concentration in fiscal 2018 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law; this model predicts a maximum level of 0.076 μg/m^3. Further, reduction in concentration due to hydrolysis were not considered when estimating atmospheric concentration.

Data for potable water, ground water, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. Taking into consideration the high hydrolyzability of this substance and PRTR data, etc., the likelihood of exposure to aqueous organisms for this substance from environmental media is considered low.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms based on measured water quality data, could not be estimated. Taking into consideration the high hydrolyzability of this substance and PRTR data etc., the likelihood of exposure to aqueous organisms for this substance from an aqueous medium is considered low.

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3. Initial assessment of health risk

Inhalation of this substance will cause a cough and contact to the skin or eyes will cause redness to either of them.

Since sufficient information on the carcinogenicity of the substance was not available, the initial assessment was

conducted based on information on its non-carcinogenic effects.

The NOAEL of 30 mg/kg/day for oral exposure (based on squamous hyperplasia of the forestomach), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 3.0 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 NOAEL of 2.6 μg/m^3 for inhalation exposure (based on rhinitis and shortness of breath etc.), determined from the effects observed in humans, was deemed to be the lowest reliable concentration, and was identified as the 'non-toxic level' of the substance for inhalation exposure.

Regarding the oral exposure, due to the lack of identified exposure levels, the health risk could not be assessed. However, oral exposure to this substance via environmental media seems unlikely in humans, based on the high hydrolyzability of this substance and the data reported under the PRTR Law. Therefore, as a comprehensive judgment, collection of further information would not be required to assess the health risk of this substance via oral exposure.

Regarding the inhalation exposure, due to the lack of identified exposure concentrations, the health risk could not be assessed. However, the MOE for reference would be 34, when calculated from the 'non-toxic level' for inhalation exposure of 2.6 μg/m^3 and the estimated exposure concentration in ambient air of 0.076 μg/m^3. This concentration in ambient air was estimated as the maximum concentration (annual mean) in ambient air, near the operators that are releasing large amount of the substance, based on the releases to air reported in FY 2018 under the PRTR Law. Therefore, as a comprehensive judgment, collection of information would be required to assess the health risk of this substance via inhalation in ambient air, starting from data on concentrations in ambient air, near the operators that are releasing large amount of this substance.

Toxicity						Exposure assessment				MOE		Comprehensive judgment
Exposure Path	Criteria for risk assessment			Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration					
Oral	'Non-toxic level'	3.0	mg/kg/day	Rats	Squamous hyperplasia of the forestomach	Drinking water	-	μg/kg/day	MOE	-	○
						Groundwater	-	μg/kg/day	MOE	-	
Inhalation	'Non-toxic level'	2.6	μg/m^3	Humans	Rhinitis and shortness of breath etc.	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 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.

4.Initial assessment of ecological risk

This substance is presumed to exist as a hydrolysis product under aquatic toxicity test conditions. As such, a predicted no effect concentration (PNEC) was not derived. Data for setting this substance's PEC could not be obtained and therefore, an assessment of its ecological risk was not conducted. Surmising that the risk of exposure to this substance from an aqueous source is exceedingly low considering its high hydrolyzability and PRTR data etc., and the fact that it is unlikely to exist in an unhydrolyzed state in public water bodies, a comprehensive review was not conducted.

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Requiring information collection	▲
Ecological risk	No judgment was made.		(－)

［Risk judgments］ ○: No need for further work ▲: Requiring information collection
■: Candidates for further work ×: Impossibility of risk characterization