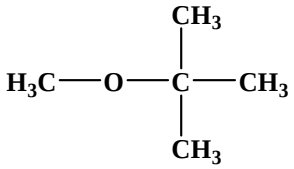
1 7	CAS No.: 1634-04-4	Substance: Methyl-t-butyl ether

Chemical Substances Control Law Reference No.: 2-3220

PRTR Law Cabinet Order No.:

Molecular Formula: $C_5H_{12}O$ Structural Formula:

Molecular Weight: 88.15



1. General information

The aqueous solubility of this substance is 5.1 x 10^4 mg/L (25°C), and the partition coefficient (1-octanol / water) (log Kow) is 0.94. The vapor pressure is 249 mmHg (= 3.32 x 10^4 Pa) (25°C). In terms of biodegradability, the substance is judged to be persistent, and it does not have hydrolyzable groups.

In the past, the substance was used primarily as an octane booster for gasoline, as an anti-knock additive, as a low boiling point solvent, as an agent to improve miscibility of solvents mixed with lacquer, as an extracting agent and refining solvent for vegetable oils, and as a corrosion inhibitor for methanol and other alcohol blended fuels. However, in 2001, primary petroleum distributors in Japan ceased the manufacture of this substance for use as a gasoline additive.

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2. Exposure assessment

As methyl-t-butyl ether is not 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), release and transfer quantities could not be obtained. When predictions of distribution ratios by medium were made using the Mackay-Type Level III Fugacity Model, in the event of equal release to the atmosphere, water and soil, the distribution ratio was highest for water.

The predicted maximum exposure concentration for inhalation exposure to human beings was approximately 0.25 μg/m^3. The predicted maximum oral exposure was 0.06 μg/kg/day. Because the log Kow for this substance is low at 0.94 and bioconcentration is also predicted to be low, exposure from environmental media via the food chain is assumed to be low.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be 0.31 μg/L for freshwater and 0.03 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

Inhalation of this substance even for a brief period may result in drowsiness, dizziness, headache, weakness and unconsciousness. If taken orally, it may also cause abdominal pain and vomiting. Contact with the skin may cause irritation, dryness and redness. Contact with the eyes may cause redness. If swallowed the liquid, it may cause aspiration into the lungs and cause chemical pneumonia.

There is insufficient information regarding the carcinogenicity of the substance, and it is not possible to make a judgment as to whether it causes cancer in human beings. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the 'Non-toxic level' was observed, used to estimate the margin of exposure (MOE), a no observed adverse effect level (NOAEL) of 100 mg/kg/day (increase in relative kidney weight), obtained from rat medium- and long-term toxicity testings, was obtained for oral exposure. As the test period was short, this value was divided by 10 to establish a value of 10 mg/kg/day. For inhalation exposure, a NOAEL value of 1,470 mg/m^3 (increase in liver and kidney weight, swelling of periocular tissues, etc.) was obtained, also from rat medium- and long-term toxicity

testings. This value was corrected to match the exposure circumstances, with the result that a value of 260 mg/m^3 was established.

With regard to oral exposure, when intake of groundwater was postulated, the maximum predicted exposure was 0.06 μg/kg/day. As the 'Non-toxic level' of 10 mg/kg/day, etc. and the maximum predicted exposure were established by means of animal testing, the value was divided by 10 to derive an MOE of 17,000. The food-borne exposure originating in the environment was estimated to be minor, and it is thought that adding this exposure would not greatly affect the MOE. Accordingly, assessment of the health risk from oral exposure to this substance is thought to be unnecessary at this time.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was estimated at 0.25 μg/m^3. Judging from the 'Non-toxic level' of 260 mg/m^3 and the predicted maximum exposure concentration, the MOE derived in the same manner was 100,000. Accordingly, there is thought to be no need at this time for assessment of the health risk with regard to inhalation exposure to the substance in the ambient air.

Knowledge of toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure path	Guidelines for risk assessment	Animal	Impact assessment guideline (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration					
Oral	No observed adverse effect level 10 mg/kg/day	Rat	Increase in relative kidney weight	Drinking water	–	μg/kg/day	MOE	–	×	○
				Groundwater	0.06	μg/kg/day	MOE	17,000	○	
Inhalation	No observed adverse effect level 260 mg/m^3	Rat	Increase in liver and kidney weight, swelling of periocular tissues, etc.	Ambient air	0.25	μg/m^3	MOE	100,000	○	○
				Indoor air	–	μg/m^3	MOE	–	×	×

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4. Initial assessment of ecological risk

Reliable information needed to perform an initial assessment of ecological risk could not be obtained. As manufacture of this substance for use as a gasoline additive ceased in 2001, the trends in production quantities, etc. should be determined and then a study should be conducted regarding the need for a determination of concentrations in the environment and ecotoxicity.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/PNEC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
–	–	–	–	–	Freshwater	0.31	–	×
					Seawater	0.03	–	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Assessment is thought to be unnecessary at this time	○
	Inhalation exposure	Assessment with regard to the ambient air is thought to be unnecessary at this time.	○
Ecological risk	Impossible of risk characterization. Trends in production quantities, etc. should be determined and then a study should be conducted regarding the need for a determination of concentrations in the environment and ecotoxicity.		×

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