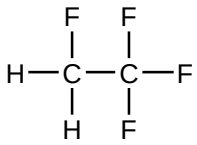
10	CAS No.: 811-97-2	Substance: 1,1,1,2-Tetrafluoroethane

Chemical Substances Control Law Reference No.: 2-3585

PRTR Law Cabinet Order No.:

Molecular Formula: $C_2H_2F_4$ Structural formula:

Molecular Weight: 102.03



1. General information

The aqueous solubility of this substance is 550 mg/1000 g (37°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 1.06, and the vapor pressure is 4.99×10^3 mmHg (=6.65×10^5 Pa) (25°C). Biodegradability (aerobic degradation) was not observed in experiments using activated sludge.

This substance is the most common refrigerant used in reciprocating compressors, and it is widely employed in reciprocating, rotary and turbo-type compressors utilized for refrigeration and air-conditioning in electric refrigerators, window air-conditioners, car air-conditioners, train air-conditioning systems, food refrigeration, and factory cooling equipment. The production (shipments) and import quantity for this substance in fiscal 2007 was 10,000 to <100,000 t/y.

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2. Exposure assessment

Because this substance 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. Predictions of distribution by medium 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 water bodies and the atmosphere would be greater.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was around 1.1 μg/m^3. Data for deriving the predicted maximum oral exposure could not be obtained.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be set because water quality data could not be obtained.

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3. Initial assessment of health risk

When liquid of this substance vaporizes rapidly, it may cause frostbite. It will influence the central nervous system and cardiovascular system, and it may cause cardiac disturbance. When it is inhaled, it will cause dizziness, lethargy or hypesthesia. When its liquid is attached to skin, it will cause frostbite.

Sufficient information could not be obtained on its carcinogenicity, and its initial assessment was conducted on the basis of data on its non-carcinogenic effects.

As for its oral exposure, its 'non-toxic level*' could not be established. For inhalation exposure, NOAEL of 10,000 ppm (for Leydig cell hyperplasia) was obtained from mid-term and long-term toxicity tests for rats, and this was adjusted against exposure conditions to provide 1,790 ppm (7,460 mg/m^3) as its 'non-toxic level*'.

As for oral exposure to this substance, its 'non-toxic level*' was not identified and its exposure was not understood, so its health risk could not be assessed. However, under the mid-term and long-term toxicity tests for rats, its solution in corn oil almost up to its saturation concentration was orally administered compulsory for 52 weeks, but no effect was reported. This substance is mainly used as refrigerant to replace chlorofluorocarbon, and after its release to the atmosphere, nearly all of it will be allocated there. Collection of information on its oral exposure would not be required to assess health risk

associated with oral exposure to this substance.

As for its inhalation exposure, its maximum exposure concentration was estimated to be around 1.1 μg/m^3, when its concentrations in the ambient air were considered. Its MOE would be 680,000, when calculated from its 'non-toxic level*' of 7,460 mg/m^3 and its estimated maximum exposure concentration, and then divided by 10 due to the fact that 'non-toxic level*' was obtained from animal experiments. No further action will be required at the moment to assess health risk from inhalation exposure to this substance in the ambient air.

Information of toxicity				Exposure assessment		Result of risk 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*' — mg/kg/day	—	—	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Groundwater	— μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level*' 7,460 mg/m^3	Rats	Leydig cell hyperplasia	Ambient air	1.1 μg/m^3	MOE	680,000	○	○
				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

A predicted no effect concentration (PNEC) could not be set for this substance because toxicity data applicable to initial assessment could not be obtained.

A judgment concerning ecological risk could not be made because environmental concentrations and toxicity data applicable to initial assessment could not be obtained for this substance. This substance is a CFC substitute and primarily used as a refrigerant. For this reason, it is thought that releases from current uses to water bodies are minimal and that the majority of releases are to the atmosphere. Prediction of distribution by medium in the environment by using a multi-media model assuming releases to the atmosphere indicated that almost all of the substance would be distributed to the atmosphere. While a judgment could not be made on the reliability of data obtained regarding ecotoxicity, toxicity values were close to the substance's water solubility. The boiling point of this substance is –26°C, and ecotoxicity experiments are predicted to be extremely difficult to carry out. No need of further work is considered at present because there is a low probability of distribution into water bodies in the environment.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
—	—	—	—	—	Freshwater	—	—	×
					Seawater	—	—	(○)

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Risk can not be assessed. Collection of information would not to be required.	(○)
	Inhalation exposure	No further action required.	○
Ecological risk	A judgment concerning ecological risk could not be made. This substance is a CFC substitute and primarily used as a refrigerant. For this reason, it is thought that releases from current uses to water bodies are minimal and that the majority of releases are to the atmosphere. The findings of a prediction of distribution by medium in the environment using a multi-media model assuming releases to the atmosphere indicated that almost all of the substance would be distributed to the atmosphere. While a judgment could not be made on the reliability of data obtained regarding ecotoxicity, toxicity values were close to the substance's water solubility. The boiling point of this substance is –26°C and ecotoxicity experiments are predicted to be extremely difficult to carry out. No need of further work is considered at present because there is a low probability of distribution into water bodies in the environment.		(○)

［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.