

6	CAS No.: 116-14-3	Substance: Tetrafluoroethylene
<p>Chemical Substances Control Law Reference No.: 2-112 PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C₂F₄ Structural Formula: Molecular Weight: 100.02</p> <div style="text-align: center;">  </div>		
<p>1. General information</p> <p>The aqueous solubility of this substance is 159 mg/L (25°C, 1 atm), the partition coefficient (1-octanol/water) (log K_{ow}) is 1.2 (calculated using KOWWIN), and the vapor pressure is 2.45×10⁴ mmHg (=3.27×10⁶ Pa) (25°C). The substance does not have any hydrolyzable groups.</p> <p>The main use of this substance is as a raw material for fluororesins. Polytetrafluoroethylene (PTFE) is a common fluororesin whose features include heat resistance, chemical resistance, lubricity, non-stick properties, and water and oil repellency. PTFE is used widely in coatings for equipment components used in the chemical industry, machinery parts and electronic components, as well as in frying pan coatings. The production and import quantity in fiscal 2011 was not disclosed because the number of reporting businesses was not more than two.</p> <hr/> <p>2. Exposure assessment</p> <p>This substance was classified as a Class 1 Designated Chemical Substance prior to revision of substances regulated by the PRTR Law. Total release to the environment in fiscal 2009 under the PRTR Law was approximately 220 t, and all releases were reported. All reported releases were to the atmosphere. The only source of reported releases was the chemical industry. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall or to the atmosphere in particular, the predicted proportion distributed to the atmosphere was 100.0%.</p> <p>The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around 2 µg/m³. The mean annual value for atmospheric concentration in fiscal 2009 was calculated by using a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicted a maximum level of 21 µg/m³. The maximum oral exposure could not be obtained. 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.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained.</p> <hr/> <p>3. Initial assessment of health risk</p> <p>This substance could cause irritation to eyes and respiratory tract, but there are no convincing toxic data. In addition, exposure to pyrolysates of its polymer (polytetrafluoroethylene) may cause a flu-like syndrome called polymer fume fever, and ordinal fever, chills, headache, dizziness, nausea, weakness and rigid tremor in a limb.</p> <p>As sufficient information was not available to evaluate carcinogenicity of the substance, an initial assessment was conducted on the basis of information on its non-carcinogenic effects.</p> <p>With regard to oral exposure to the substance, its 'non-toxic level*' could not be identified. As for its inhalation exposure, a LOAEL of 156 ppm (for symptoms such as renal tubular degeneration, and liver cell</p>		

degeneration) obtained from its mid-term and long-term toxicity tests on rats was adjusted for their durations to provide 28 ppm (115 mg/m³) for its intermittent to continuous exposure, and divided by a factor of 10 for conservative use of the LOAEL. Outcome of 12 mg/m³ was identified to be the reliable lowest dose and its 'non-toxic level*'.

As for oral exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' could not be identified nor its exposure levels were not known. However, although its total emission into the ambient air in FY 2009 was 220 t, it eventually went to every medium of the environment and its vapor pressure was low. Therefore, collection of further information would not be required to assess potential health risk from its oral exposure.

With regard to inhalation exposure to the substance, its mean exposure concentration was estimated to be below about 0.084 µg/m³, while its maximum exposure concentration in the ambient air was predicted to be about 2 µg/m³. The MOE (Margin of Exposure) would be 120 when calculated from its 'non-toxic level*' of 12 mg/m³ and the maximum exposure concentration predicted from animal experiments, and divided by a factor of 10 to convert animal data to human data and further divided by a factor of 5 to extrapolate animal data to carcinogenic hazards for human. Meanwhile, the MOE would be 11 when calculated from the maximum (annual mean) concentration of 21 µg/m³ in the ambient air near the operators with its emissions in high concentrations, reported in FY 2009 under the PRTR Law. Therefore, collection of further information would be required to assess health risk from inhalation exposure to the substance in the ambient air.

Exposure Path	Toxicity			Exposure assessment		Result of risk assessment			Judgment
	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration				
Oral	'Non-toxic level*' - mg/kg/day	-	-	Drinking water	- µg/kg/day	MOE	-	×	(○)
				Ground water	- µg/kg/day	MOE	-	×	
Inhalation	'Non-toxic level*' 12 mg/m ³	Rat	Renal tubular degeneration, liver cell degeneration, etc.	Ambient air	2 µg/m ³	MOE	120		()
				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

Toxicity data required for environmental concentration and initial assessment of this could not be obtained. As such, a judgment on ecological risk could not be made.

All releases of this substance reported under the PRTR Law for the fiscal years 2001 to 2009 were to the atmosphere; reported releases to public water bodies for the same period were 0 t.

A multi-media model used to predict the proportions distributed to individual media in the environment for fiscal 2009 found that all releases were to the atmosphere. The possibility of transfer from the atmosphere to water is thought to be low, based on the high vapor pressure of this substance.

Accordingly, the need to collect further data on this substance for initial assessment of the ecological risk towards aquatic organisms from exposure via water is considered to be minimal.

Hazard assessment (basis for PNEC)			Assessment factor	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)			
-	-	-	-	-	Freshwater	-	-	×	
					Seawater	-	-		

5. Conclusions

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

[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.