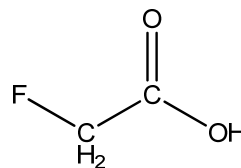


Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C₂H₃FO₂

Molecular Weight: 78.04



1. General information

This substance is freely miscible in water, the partition coefficient (1-octanol/water) (log Kow) is 0.03 (calculated value), and the vapor pressure is 530 Pa (20°C). Biodegradability (aerobic degradation) data could not be obtained. In addition, the hydrolysis half-life was more than 47 years (pH=7, 25°C).

The main use of monofluoroacetate is as an agricultural chemical (rodenticide). The production and import quantity could not be obtained.

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 use of a Mackay-type level III fugacity model indicate that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to water would be largest.

The maximum expected concentration of exposure to humans via inhalation could not be defined because ambient atmospheric and indoor air quality data could not be obtained.

Data for potable water, groundwater, food, and soil to assess oral exposure could not be obtained. Thus, assuming intake solely from public freshwater bodies, a maximum expected exposure of less than around 0.000030 µg/kg/d. The 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, was less than around 0.00076 µg/L for both public freshwater bodies and seawater.

3. Initial assessment of health risk

This substance is corrosive and may cause effects on the cardiovascular system, central nervous system, and kidneys, resulting in impaired functions including cardiac and renal failure. Inhalation will cause coughs, sore throat, shortness of breath, labored breathing, muscle cramps, confusion, and arrhythmia. Ingestion will cause burns in the mouth and throat, abdominal pain, convulsions, and shock or collapse in addition to the same symptoms as inhalation. Contact to the skin will cause redness, serious skin burns, and pain. Contact to the eyes will cause blurred vision and severe deep burns. There is a report that presented the lowest lethal dose of 0.714 mg/kg in humans.

Since not enough information was available on the carcinogenicity of the substance, the initial assessment was conducted based on information on its non-carcinogenic effects.

The NOAEL of 0.039 mg/kg/day for oral exposure (based on the increased weight of the heart, the decreased weight of the testis, and impaired spermatogenesis), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 0.0039 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.

Regarding oral exposure, assuming that the substance is absorbed via public freshwater bodies, the predicted maximum exposure level would be less than 0.000030 µg/kg/day, approximately. The MOE (Margin of Exposure) would exceed 13,000 which is calculated from the predicted maximum exposure level and the 'non-toxic level' of 0.0039 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. This would lead to the health risk judgment that no further work would be required at present. Since exposure to the substance in environmental media via food is presumed to be limited despite the lack of exposure level via food, including it in the calculation would not change the MOE significantly. Therefore, as a comprehensive judgment, no further work would be required at present to assess the health risk of this substance via oral exposure.

Regarding inhalation exposure, due to the lack of identified 'non-toxic level' and exposure concentrations, the health risk could not be assessed. The vapor pressure of this substance is low, and the predictions of the multimedia fugacity model indicated that the proportion distributed to air was very little. Furthermore, the substance was not detected either in public freshwater bodies or in seawater despite the high aqueous solubility. Considering these facts, exposure to this substance stemming from ambient air would be little. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Exposure Path	Toxicity			Exposure assessment		MOE		Judgment
	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	'Non-toxic Level' 0.0039 mg/kg/day	Rats	The increased weight of the heart, the decreased weight of the testis, and impaired spermatogenesis	Drinking water	- µg/kg/day	MOE	-	○
				Public freshwater bodies	<0.000030 µg/kg/day	MOE	>13,000	
Inhalation	'Non-toxic level' - mg/m ³	-	-	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

With regard to acute toxicity for monofluoroacetic acid, the following reliable data were obtained: a 72-h EC₅₀ of 4.2 µg/L for growth inhibition in the green alga species *Raphidocelis subcapitata*, a 48-h EC₅₀ of 17,000 µg/L for swimming inhibition in the crustacean species *Daphnia magna*, and a 96-h LC₅₀ of 83,000 µg/L for the fish species *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.042 µg/L was obtained.

With regard to chronic toxicity for monofluoroacetic acid, the following reliable datum was obtained: a 72-h NOEC of 0.244 µg/L for growth inhibition in the green alga species *R. subcapitata*.

Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 0.0024 µg/L was obtained.

The value of 0.0024 µg/L obtained from the chronic toxicity to the alga species was used as the PNEC for this substance.

Because the PEC/PNEC ratio is less than 0.3 for both freshwater bodies and seawater, an assessment of ecological risk could not be made.

Based on a comprehensive review of the above findings, efforts to collect data are considered necessary. Efforts are considered desirable to elucidate the production and import quantity of this substance as well as substances that transform

into it in the environment, as are augmentation of data related to environmental concentrations and chronic toxicity towards crustacean and fish species.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Comprehensive judgment
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Green algae	Chronic	NOEC Growth inhibition	100	0.0024	Freshwater	<0.00076	<0.3	▲
					Seawater	<0.00076	<0.3	

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work	○
	Inhalation exposure	No need for further work	○
Ecological risk	Requiring information collection		▲

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