18	CAS No.: 335-67-1 (Acid) 3825-26-1 (Ammonium salt) 335-95-5 (Sodium salt) 2395-00-8 (Potassium salt) 335-93-3 (Silver salt)	Substance: Perfluorooctanoic acid and its salt forms （Perfluorooctanoic acid: PFOA）

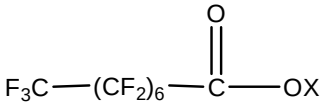
Chemical Substances Control Law Reference No.: 2-2659(Perfluoroalkyl carboxylic acid (C 7 - 13)), 2-1182(Fluoroalkyl (C 2-10) carboxylic acid), 2-1195(Ammonium perfluorooctanoate), 2-1176(Fluoroalkyl (C 5-12) carboxylic acid salt (Na, K, Ca))

PRTR Law Cabinet Order No.: 2-72 (Ammonium pentadecafluorooctanoate)

Molecular Formula: $C_8F_{15}O_2X$ (X indicates H, NH_4, etc.)

Molecular Weight: 414.07 (Acid)

Structural Formula:



X indicates H, NH_4, etc.

1. General information

The aqueous solubility of this substance is 9.5 x 10^3 mg/L (acid, 25°C). The vapor pressure is 0.031 mmHg (= 4.2 Pa) (acid, 25°C, extrapolated value). Perfluorooctanoic acid and ammonium perfluorooctanoate is determinated to be persistent but not highly bioaccumulative.

PFOA and ammonium salts are designated as a Type II Monitoring Chemical Substances under the Low Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances. PFOA is mainly used for export, intermediates, addictives for resins, and catalysts for other products. Perfluorocarboxylic acid is considered to be released intentionally from impurities of products related to perfuloro- octanesulfonyl fluoride and byproducts of fluorotelomer products. It is also reported that perfluorocarboxylic acid, such as PFOA, is generated by degradation of fluorotelomer products in the environment. The totals of production (shipment) and imports of ammonium salt in FY 2001 and FY 2004 were 10 to less than 100 tons/yr, which are categorized as falling within the 10-ton class of production and imports under the PRTR Law.

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2. Exposure assessment

As 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), no information on release and transfer quantities could be obtained. No reliable log Kow value of this substance was obtained and the distribution ratio by medium was not predicted.

Based on data for the ambient air, the predicted maximum exposure concentration for inhalation exposure to human beings was approximately 0.0025 μg/m^3. The highest estimated oral exposure level was calculated at 0.0054 μg/kg/day from data on drinking water and food. The highest estimated oral exposure level was calculated at 2.3 μg/kg/day from data on groundwater and food as a reference. The highest level of 150 μg/L was detected in groundwater from a well located within the factory premises. Using the groundwater and food data, the oral exposure level is 6.0 μg/kg/day, while the oral exposure level is calculated at 1.0 μg/kg/day using the level of 26 μg/L detected in the well 200 meters from the factory.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be approximately 31 μg/L for freshwater and approximately 0.45 μg/L for seawater bodies.

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3. Initial assessment of health risk

The substance irritates the eyes, the skin and the respiratory tract. Contact with the skin and the eyes may cause redness and pain of the skin, and blurred vision in the eyes. By inhalation, it may cause cough and sore throat. By ingestion, it may cause abdominal pain, nausea and vomiting.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

Benchmark dose lower confidence limit ($BMDL_5$) of 0.17 mg/kg/day (increase in the weight of liver of dam) was obtained for oral exposure from the reproductive or developmental toxicity testing that administered the ammonium salt of this substance (APFO) to mice. The $BMDL_5$ was divided by 5, because of the experimental period being short. The value of 0.03 mg/kg/day converted into the dose of this substance from that of APFO was derived as the 'Non-toxic level*'.

A no observed adverse effect level (NOAEL) for the inhalation exposure of 1 mg/m^3 (increase in the weight of liver, increase in ALP, hepatic cells hypertrophy, etc.) was obtained from the medium- and long-term toxicity testing that exposed rats to APFO by inhalation. The NOAEL was adjusted to 0.18 mg/m^3 taking into account the exposure situations. The value was divided by 5, because of the experimental period being short. The value of 0.03 mg/m^3 converted into the concentration of this substance from that of APFO was derived as the 'Non-toxic level*'.

With regard to oral exposure, in case of intakes of drinking water and food, the predicted maximum exposure was approximately 0.0054 μg/kg/day. The margin of exposure (MOE) of 560 was derived from the 'Non-toxic level*' of 0.03 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level*' was established by means of animal testing. For reference, in case of intakes of groundwater and food, the predicted maximum exposure was 2.3 μg/kg/day, and the MOE calculated in the same way as above was determined to be 1.3.

For the inhalation exposure, the predicted maximum exposure concentration was approximately 0.0025 μg/m^3 in the ambient air. The MOE of exceeding 1,200 was derived from the 'Non-toxic level*' of 0.03 mg/m^3 divided by the predicted maximum exposure concentration, and divided by 10, because the 'Non-toxic level*' was established by means of animal testing.

Toxicokinetics and metabolism of this substance largely depend on animal species and sex. Especially, the half-life of this substance in human serum(3.8yrs) is much longer than those in laboratory animals. Accordingly, it would be appropriate to assess the health risk of this substance based on the body burden instead of exposure dose or concentration. Since the MOE based on the body burden was greatly different from the MOE above and little is known about the toxicity mechanisms of this substance, it is difficult to identify its health risk. Accordingly, it would be required to collect information associated with the health risk of this substance.

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*' 0.03 mg/kg/day	mice	increase in the weight of liver of dam	Drinking water, food	0.0054 μg/kg/day	MOE	560	×	(▲)
				Groundwater, food	— μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level*' 0.03 mg/m^3	rats	increase in the weight of liver, increase in ALP, hepatic cells hypertrophy, etc.	Ambient air	0.0025 μg/m^3	MOE	1,200	×	(▲)
				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

The OECD is now developing a hazard assessment report regarding this substance with international cooperation and it is also gathering new data on ecotoxicity. Therefore, after the hazard assessment report is published, an initial assessment of ecological risk to aquatic organisms will be conducted.

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Risk cannot be identified. However, it would be required to collect information.	(▲)
	Inhalation exposure	Risk cannot be identified. However, it would be required to collect information for the ambient air.	(▲)
Ecological risk	The OECD is now developing a hazard assessment report regarding this substance with international cooperation and also gathering new data on ecotoxicity. Therefore, after the hazard assessment report is published, an initial assessment of ecological risk to aquatic organisms will be conducted.		–

［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.