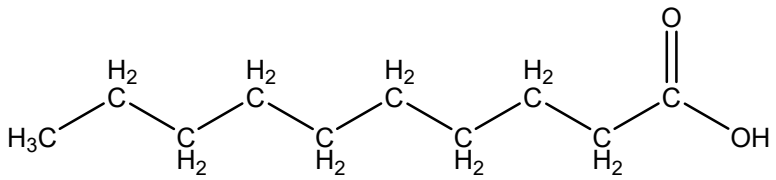
7	CAS No.: 334-48-5	Substance: Decanoic acid

Chemical Substances Control Law Reference No.: 2-608（Alkane number (C = 4–30)）

PRTR Law Cabinet Order No.: 1-256

Molecular Formula: $C_{10}H_{20}O_2$ Structural Formula:

Molecular Weight: 172.26



1. General information

The aqueous solubility of this substance is 150 mg/1000 g (20°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 4.09, and the vapor pressure is $<7.5\times10^{-3}$ mmHg (<1.0 Pa) (20°C). Biodegradability (aerobic degradation) is judged to be good (based on evaluation of a similar substance). Further, the substance does not possess any hydrolyzable groups and as such, it is not thought to hydrolyze under ambient environmental conditions.

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law. The main uses of this substance are as reactive and formulation raw materials for surfactants and metal soaps, quasi-drug additives (medicinal soaps, cosmetics, etc.), food additives (flavorings), synthetic resin lubricants, synthetic resin stabilizers, cosmetic and oleaginous constituents, and synthetic lubricants.

The production and import quantity of alkanoic acids (C=4–30) in fiscal 2017 was 100,000 t. The production and import quantity under the PRTR law is more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2017 under the PRTR Law was approximately 0.66 t, of which approximately 0.39 t or 59% was reported. Most reported releases were to the atmosphere. In addition, approximately 2.2 t was transferred to waste and 0.029 t to sewage. The chemical industry was the main reporter of releases. The largest releases to the environment including unreported releases were to soil. A multimedia model used to predict the proportions distributed to individual media in the environment indicates that in regions where the largest quantities were estimated to have been released to the environment overall or the atmosphere in particular, the predicted proportion distributed to soil was 54.0% and that to water bodies was 33.6%. Where the largest quantities were estimated to have been released to public water bodies, the predicted proportion distributed to water bodies was 76.5% and that to soil was 20.6%. Where the largest quantities were estimated to have been released to soil, the predicted proportion distributed to soil was 94.2%.

The maximum expected concentration of exposure to humans via inhalation could not be determined because ambient atmospheric and indoor air quality data could not be obtained. The mean annual value for the atmospheric concentration in fiscal 2017 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicts a maximum level of 0.031 μg/m^3

Data for potable water, ground water, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. However, when releases to public freshwater bodies in fiscal 2017 reported under the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 3.4 μg/L. Using this estimated concentration for rivers to calculate oral exposure gives 0.14 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, given its nonexistent or low bioaccumulation.

Estimates for exposure to aquatic organisms based on measured data could not be carried out. However, when releases to public freshwater bodies in fiscal 2017 reported under the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 3.4 μg/L.

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3. Initial assessment of health risk

This substance is irritating to the eyes, and corrosive to the skin.

As sufficient information on the carcinogenicity of the substance was not available, the initial assessment was conducted on the basis of information on its non-carcinogenic effects.

The NOAEL of 5,000 mg/kg/day for oral exposure (no observed effect dose), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 500 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.

With regard to oral exposure, owing to the lack of identified exposure levels, the health risk could not be assessed. However, the MOE (Margin of Exposure) for reference would be 360,000, when calculated from the estimated maximum exposure level of 0.14 μg/kg/day and the 'non-toxic level' of 500 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. This maximum exposure level was estimated according to the concentration in effluents from the high discharging plants reported in FY 2017 under the PRTR Law. Since exposure to the substance in environmental media via food is presumed to be limited in spite of data unavailability, including it in the calculation would not change the MOE significantly. Therefore, as a comprehensive judgment, collection of further information would not be required to assess the health risk of this substance via oral exposure.

With regard to inhalation exposure, owing to the lack of identified 'non-toxic level' and exposure concentrations, the health risk could not be assessed. However, the MOE for reference would be 5,400,000, when calculated from the tentative 'non-toxic level' for inhalation exposure of 1,670 mg/m^3 and the concentration in ambient air of 0.031 μg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. The tentative 'non-toxic level' for inhalation exposure above was derived from the conversion of the 'non-toxic level' for oral exposure, assuming that 100% of the inhaled substance is absorbed. The concentration in ambient air was estimated as the maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance based on the releases to air reported in FY 2017 under the PRTR Law. Therefore, as a comprehensive judgment, collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		MOE		Comprehensive judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration	MOE		Comprehensive judgment
Oral	'Non-toxic level' 500 mg/kg/day	Rats	No observed effect dose	Drinking water	- μg/kg/day	MOE	-	○
				Groundwater	- μg/kg/day	MOE	-	
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.

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4. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 12,200 μg/L for growth inhibition in the alga *Raphidocelis subcapitata*, a 48-h EC_{50} exceeding 20,000 μg/L for swimming inhibition in the crustacean *Daphnia magna*, a 96-h LC_{50} exceeding 16,000 μg/L for the fish *Oryzias latipes* (medaka), and a 96-h LC_{50} of 24,000 μg/L for the African clawed frog *Xenopus laevis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 122 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 967 μg/L for growth inhibition in

the alga *R. subcapitata* and a 21-d NOEC of 75 μg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 0.75 μg/L was obtained.

The value of 0.75 μg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

Data for setting the predicted environmental concentration (PEC) could not be obtained for this substance; accordingly, an ecological risk assessment could not be carried out.

However, when releases to public freshwater bodies in fiscal 2017 reported according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gives a maximum value of 3.4 μg/L, and the ratio of this value with PNEC was 4.5. Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed; environmental concentration data needs to be augmented taking into consideration major emission sources.

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)		
Crustacean *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	0.75	Freshwater	—	—	▲
					Seawater	—	—	

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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