4	CAS No. 333-41-5	Substance: Diazinon

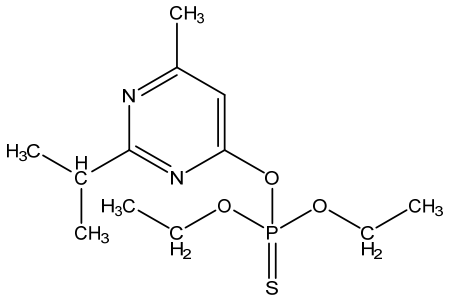
Chemical Substances Control Law Reference No.: 5-923

PRTR Law Cabinet Order No.: 248

Molecular Formula: $C_{12}H_{21}N_2O_3PS$

Molecular Weight: 202.55

Structural formula:



1.General information

The aqueous solubility of this substance is 40 mg/1000 g (20°C), the partition coefficient (1-octanol/water) (log Kow) is 3.806 (pH unknown, 20°C, distilled water), and the vapor pressure is 0.019 Pa (20°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%. Further half-lives for hydrolysis are approximately 7 d (pH = 5, 25°C), approximately 93 d (pH = 7, 25°C), and approximately 65 d (pH = 9, 25°C).

This substance is designated as a Class 1 Chemical Substance under the PRTR Law.

This substance is the active ingredient (raw material) in organophosphate insecticides and is primarily used as an agricultural chemical. It is also utilized as a preventive insecticide in sprays for controlling maggots and mosquito larvae, as residual sprays for cockroaches, and is sometimes included in horticultural insecticides for home use. The production and import quantity in fiscal 2022 was 335.7 kL.

2.Exposure assessment

Total release to the environment in fiscal 2022 under the PRTR Law was approximately 260 t, of which only 0.0003 t were notified. All notified releases were to the atmosphere. In addition, approximately 0.47 t was transferred to waste materials. The agricultural chemicals manufacturing industry was the major emission source. The largest release among releases to the environment including those unnotified was to soil. 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 soil in particular, the predicted proportion distributed to soil would be 95.8%. Where the largest quantities were estimated to have been released to the atmosphere, the predicted proportion distributed to soil would be 70.3%, and the predicted proportion distributed to sediment would be 15.1%. Where the largest quantities were estimated to have been released to public water bodies, the predicted proportion distributed to soil would be 86.3%.

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. In addition, the maximum expected concentration of exposure based on indoor air data was around less than 0.00026 μg/m^3. Further, albeit based on past data, a maximum expected concentration of exposure of around less than 0.012 μg/m^3 was from ambient air measurements. Further, the mean annual value for atmospheric concentration in fiscal 2022 was calculated by use of a plume-puff model on the basis of releases to the atmosphere notified under the PRTR Law for fiscal 2022: this model predicts a maximum level of 0.000062 μg/m^3.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was about 0.20 μg/L for public freshwater bodies, and less than 0.5 μg/L for seawater. An estimate of river concentration was not carried out because neither release to public freshwater bodies nor transfers to sewage were reported.

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3. Initial assessment of health risk

Since this substance has been designated as one of the "monitored substances" for water pollution, the initial assessment of this substance did not cover the health risk via oral exposure.

This substance mildly irritates the eyes and skin and inhibits cholinesterase activity. Inhalation will cause pupillary constriction, muscle cramps, excessive salivation, labored breathing, sweating, nausea, vomiting, dizziness, convulsions and unconsciousness. Ingestion will cause abdominal cramps and diarrhea, in addition to the same symptoms as inhalation. Contact with the skin or the eyes will cause redness and pain.

For the carcinogenicity of this substance, not enough information was available in animals, while there is limited evidence in humans. For this reason, the 'non-toxic level' was identified based on information on the non-carcinogenic effects of the substance. Yet positive evidence provided by a large number of genotoxicity tests both *in vitro* mainly in human cells and *in vivo* in humans etc. would warrant consideration of the carcinogenicity in humans despite the lack of evidence leading to a quantitative assessment of the carcinogenic risk.

The LOAEL of 0.1 mg/m^3 for inhalation exposure (based on the inhibition of erythrocyte ChE activity), determined from toxicity tests in rats, was adjusted according to exposure conditions and subsequently divided by a factor of 10 to account for uncertainty in using a LOAEL, and by another factor of 10 to account for extrapolation to chronic exposure. The calculated value of 0.00025 mg/m^3 was deemed the lowest reliable concentration and was identified as the 'non-toxic level' of the substance for inhalation exposure.

Regarding inhalation exposure of this substance in ambient air, due to the lack of identified exposure concentrations, the health risk could not be assessed. Regarding inhalation exposure of this substance in indoor air, the predicted maximum exposure concentration was approximately less than 0.00026 $\mu g/m^3$. The MOE (Margin of Exposure) would exceed 9.6 which is calculated from the predicted maximum exposure concentration and the 'non-toxic level' of 0.00025 mg/m^3 and subsequently divided by a factor of 10 to account for extrapolation from animals to humans, and by another factor of 10 to take into consideration the carcinogenicity. Since the risk judgment classification could not be fixed based on the MOE above, the health risk could not be assessed. The predicted maximum exposure concentration in ambient air was estimated to be approximately less than 0.012 $\mu g/m^3$ based on the past measurement data in 1993. The MOE would exceed 0.21 which is calculated from the predicted maximum exposure concentration and the 'non-toxic level' of 0.00025 mg/m^3 and subsequently divided by a factor of 10 to account for extrapolation from animals to humans, and by another factor of 10 to take into consideration the carcinogenicity. The maximum concentration (annual mean) in ambient air was estimated to be 0.000062 $\mu g/m^3$ based on the releases into air reported in FY 2022 under the PRTR Law, giving an MOE of 40 for reference. As previously mentioned, the health risk via inhalation of this substance in indoor air could not be assessed with the MOE exceeding 9.6. Therefore, as a comprehensive judgment, the collection of information would be required to assess the health risk of this substance via inhalation in ambient air and in indoor air.

In information collection regarding indoor air, given that failure to fix the health risk judgment classification was attributable to unmeasurability of concentrations due to the detection limit, higher detection sensitivity to enable concentration measurements would be required in order to conduct an initial assessment of the health risk. In addition, potential indoor use of this substance would warrant consideration of exposure conditions. For example, confirmation is required if the concentration of the substance was measured in the room where it was used. Regarding ambient air, given that measurement data have not been obtained in recent years, effective identification of the concentrations in ambient air would be required with surveys on sources of generation and emission and usage of the substance. When a detailed assessment is conducted, full consideration of the inherent properties of this substance will be required. For example, suitable uncertainty factors should be selected for a hazard assessment.

Toxicity					Exposure assessment		Result of risk assessment		Comprehensive judgment
Exposure Path	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	(−)	(−)
					Groundwater	(−) μg/kg/day	MOE	(−)	
Inhalation	'Non-toxic level'	0.00025 mg/m^3	Rats	Inhibition of erythrocyte ChE activity	Ambient air	− $\mu g/m^3$	MOE	−	▲
					Indoor air	< 0.00026 $\mu g/m^3$	MOE	> 9.6	▲

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 96-h EC_{50} of 8540 μg/L for growth inhibition in the green alga *Desmodesmus subspicatus*, a 48-h LC_{50} of 0.21 μg/L of 0.21 μg/L for the crustacean *Ceriodaphnia dubia*, 96-h LC_{50} of 440 μg/L for the fish species *Lepomis macrochirus* (blue gill), and a 96-h LC_{50} of 1.1 μg/L for the caddisfly *Cyrnus trimaculatus*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.0021 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 96-h NOEC of 1000 μg/L for growth inhibition in the green alga *D. subspicatus*, a 7-d NOEC of 0.125 μg/L for reproductive inhibition in the crustacea *C. dubia*, and an approximately 150-d NOEC of 3.46 μg/L for next-generation mortality in the fish *Pimephales promelas* (fathead minnow). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a predicted no effect concentration (PNEC) of 0.012 μg/L was obtained.

The value of 0.0021 μg/L obtained from the acute toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio is 95 for freshwater bodies and less than 238 for seawater. Accordingly, this substance is considered a candidate for detailed assessment of ecological risk. The PEC/PNEC ratio based on chronic toxicity was 17 for freshwater, exceeding 1.

Accordingly, this substance is considered a candidate for detailed assessment of ecological risk. Augmentation of water quality data for this substance using a lower detection limit is desired.

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 *Ceriodaphnia dubia*	Acute	LC_{50} Mortality	100	0.0021	Freshwater	0.20	95	■
					Seawater	<0.5	<238	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Not covered by this assessment	(−)
	Inhalation exposure	Requiring information collection	▲
Ecological risk	Candidates for further work.		■

［Risk judgments］ ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization