3	CAS No.: 62-73-7	Substance: Dichlorvos

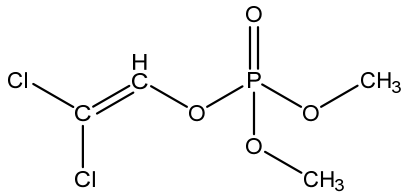
Chemical Substances Control Law Reference No.: 2-3224

PRTR Law Cabinet Order No.: 1-457 (number after law revision*: 1-510)

Molecular Formula: $C_4H_7Cl_2O_4P$

Molecular Weight: 220.98

Structural formula:



1. General information

The aqueous solubility of this substance is $1x10^4$ mg/L, the partition coefficient (1-octanol/water) (log K_{ow}) is 1.43, and the vapor pressure is 1.6 Pa (20°C). A half-life for biodegradability (aerobic degradation) of 3.5 days (20°C) has been reported. In addition, half-lives were 11 days (pH = 5), 5 days (pH = 7), and 21 hours (pH = 9) for hydrolyzability.

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law. The main use of this substance is in quarantine insecticides used to control pests. It is also used as a veterinary drug in the form of insect repellents and insecticides for the control of pests. In fiscal 2020, 8.0 t was shipped in Japan as household insecticide, while 46.5 t was shipped as public health insecticide. The production and import category under the PRTR Law was more than 10 t.

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2. Exposure assessment

Total release to the environment in fiscal 2019 under the PRTR Law was approximately 55 t, of which only 0.023 t were notified, meaning the vast majority of releases went unnotified. The majority of notified releases to the atmosphere and public water bodies were to the atmosphere. In addition, 0.064 t was transferred to sewage and 0.69 t was transferred to waste. All notified releases were from the pharmaceutical manufacturing industry. Including unnotified releases, most releases were to water bodies. 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 atmosphere and public water bodies, the predicted proportion distributed to water bodies was 96.1%.

The maximum expected concentration of exposure to humans via inhalation, based on ambient atmospheric data, was around 0.0019 μg/m^3. Albeit for a limited area, a four-day summer survey of indoor air reported a maximum level of 0.0022 μg/m^3. Further, the mean annual value for atmospheric concentration in fiscal 2020 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law: this model predicts a maximum level of 0.0052 μg/m^3.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was 1 μg/L for public freshwater bodies, and less than 0.00043 μg/L for seawater. No emissions to public freshwater bodies were notified in fiscal 2020 under the PRTR Law, while transfers to sewage were classified under “Other” as the type of sewage treatment facility. As such, river concentration could not be estimated based on notified emissions and transfers to sewage.

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3. Initial assessment of health risk

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

This substance irritates the skin and may cause effects on the nervous system by cholinesterase inhibition. Inhalation will cause pupillary constriction, muscle cramps, excessive salivation, muscle twitching, convulsions, dizziness, sweating, wheezing, labored breathing, and unconsciousness. Ingestion will cause nausea, vomiting, abdominal cramps, and diarrhea, in addition to the same symptoms as inhalation. Contact with the eyes will cause redness, pain, pupillary constriction, and blurred vision. Contact with the skin will cause redness. The substance can be absorbed into the body through the skin and may cause the same symptoms as inhalation. There is a report on this

substance that presented the lowest lethal dose (LDLo) of 1,000 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 0.05 mg/m^3 for inhalation exposure (based on reduced cholinesterase activities in the plasma and the brain), determined from toxicity tests in rats, was adjusted according to exposure conditions. The obtained value of 0.048 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, the predicted maximum exposure concentration in ambient air was approximately 0.0019 μg/m^3. The MOE (Margin of Exposure) would be 510 which is calculated from the predicted maximum exposure concentration and the 'non-toxic level' of 0.048 mg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and by another factor of 5 to take into consideration the carcinogenicity. This would lead to the health risk judgment that no further work would be required at present. In addition, the MOE for reference would be 180 which is calculated from the maximum concentration (annual mean) of 0.0052 μg/m^3 in ambient air near the operators that are releasing a large amount of the substance based on the releases to air reported in FY 2020 under the PRTR Law. Regarding inhalation exposure of the substance in indoor air, the MOE for reference would be 440 which is calculated from the maximum concentration of 0.0022 μg/m^3 observed in the survey in a certain area. Therefore, as a comprehensive judgment, no further work would be required at present.

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			
Oral	'Non-toxic level*' (-) mg/kg/day	(-)	(-)	Drinking water	(-) μg/kg/day	MOE	(-)	(-)
				Groundwater	(-) μg/kg/day	MOE	(-)	
Inhalation	'Non-toxic level*' 0.048 mg/m^3	Rats	Reduced cholinesterase activities in the plasma and the brain	Ambient air	0.0019 μg/m^3	MOE	510	○
				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} exceeding 95,800 μg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 48-h EC_{50} of 0.144 μg/L for swimming inhibition in the crustacean *Daphnia magna*, a 96-h LC_{50} of 6.41 μg/L for the fish *Misgurnus anguillicaudatus* (loach), and a 48-h EC_{50} of 1.17 μg/L for swimming inhibition in the filter-feeding caddisfly *Cheumatopsyche brevilineata*. Accordingly, based on this acute toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.0014 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 11,500 μg/L for growth inhibition in the green alga *R. subcapitata*, a 21-d NOEC of 0.120 μg/L for reproductive inhibition in the crustacean *D. magna*, and a 61-d NOEC of 5.2 μg/L for embryo to post-hatch mortality in the fish *Oncorhynchus mykiss* (rainbow trout). Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.012 μg/L was obtained.

The value of 0.0014 μg/L obtained from the acute toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio is 700 for freshwater bodies and around 0.3 for seawater. This substance is considered a candidate for detailed assessment of ecological risk. A comprehensive review of the above findings draws the same conclusion.

Although registration of this substance as an agricultural chemical has expired, it continues to be employed as an insecticide for disease control. As such, augmenting environmental data measured in the field while taking into account the timing of insecticide spraying and frequency of measurement is considered desirable.

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*	Acute	EC_{50} Swimming inhibition	100	0.0014	Freshwater	1	700	■
					Seawater	<0.00043	<0.3	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	The substance was not subject to evaluation.	(－)
	Inhalation exposure	No need for further work.	○
Ecological risk	Candidates for further work.		■

［Risk judgments］○: No need for further work ▲: Requiring information collection
■: Candidates for further work ×: Impossibility of risk characterization
(－) : The substance was not subject to evaluation

* Number after revision of law implemented on April 1, 2023