

Summary of Initial Risk Assessment Report

Dicyclohexyl phthalate CAS No : 84-61-7

PRTR No of Japan:

This substance is not a Class 1 or a Class 2 Designated Chemical Substance under the PRTR law.

This substance is assessed based on Guideline for Initial Risk Assessment Version 2.0

1. General Information

1.1 Physico-chemical properties

Appearance	White solid
Melting point	66 degC
Boiling point	222-228 degC (500 Pa)
Water solubility	0.2 mg/L (20 degC)
Henry's constant	$1.01 \times 10^{-2} \text{ Pa} \cdot \text{m}^3/\text{mol}$ ($1.00 \times 10^{-7} \text{ atm} \cdot \text{m}^3/\text{mol}$) (25degC, measured)
Octanol/water partition coefficient (log Kow)	6.20 (estimated)
Soil adsorption coefficient	Koc = 1,800 (estimated)

1.2 Environmental fate

Bioaccumulation	Bioconcentration factor (BCF):12,000 (calculated using logKow of 6.2) *Actual bioaccumulation is expected to be lower than indicated by this BCF, since aquatic organisms are known to metabolize phthalates.
Biodegradation	Readily biodegradable
Stability in the environment	(In air) Reaction with OH radical: The reaction rate constant is $2.43 \times 10^{-11} \text{ cm}^3/\text{molecule} \cdot \text{sec}$. (25 degC, estimated) The half-life is 8 hours to 1 day, given OH radical concentration of $5 \times 10^5 - 1 \times 10^6 \text{ molecule}/\text{cm}^3$. Reaction with ozone: No data Reaction with nitrate radical: No data (Stability in water) The hydrolysis reaction rate is slow in the aquatic environment. Mono-cyclohexyl phthalate, phthalic acid, and cyclohexanol are expected to be produced by hydrolysis.
Environmental fate	If released to water, dicyclohexyl phthalate is removed partly by biodegradation under aerobic conditions. Any dicyclohexyl phthalate that is not biodegraded is expected to strongly adsorb to suspended solids in water, transfer to sediments, and remain there.

2. Sources of release to the environment

2.1 Annual production, import, export and domestic supply in 2001 (ton/year)

Production	Import	Export	Domestic supply	Remarks
Approx. 100	--	--	--	

2.2 Uses

Plasticizers for moistureproof cellophane, acrylic lacquers, and heat sensitive adhesives, anti-blocking agents for plastic surfaces

2.3 Release from the industries within the scope of PRTR system

Dicyclohexyl phthalate is not a designated chemical substance under PRTR law. Therefore, there is no PRTR data.

2.4 Releases from other sources

Although dicyclohexyl phthalate might be released from products which contain this substance as a plasticizer, detailed information has not been obtained.

2.5 Main release route

Dicyclohexyl phthalate is expected to be released to the environment during use as plasticizers in plastic products manufacturing industries. Based on known uses of the substance, dicyclohexyl phthalate may also be released into indoor air from products containing dicyclohexyl phthalate as plasticizers.

3. Exposure Assessment

3.1 Measured environmental concentration

Media	No. of points detected / No. of points measured	No. of samples detected / No. of samples measured	Detection range	95th percentile	Detection limit	Year of investigation, Institution
Air (microg/m ³)	--	120/192	nd-0.11	0.053	0.001	2001 Ministry of the Environment
River water (microg/L)	0/124	--	nd	--	0.1	2001 Ministry of the Environment
Drinking water (microg/L)	0/42	--	nd	--	0.05	1999 Japan Water Research Center
Food (microg/g)	0/9	0/81	nd	--	0.01	2001 Japan Food Research Laboratories

nd: Not detected.

For calculation of the 95th percentile, data less than the detection limit are replaced with a value of one half of the detection limit.

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)		Estimation by model was not conducted, since the amounts of release of dicyclohexyl phthalate (PRTR data) were not available.
River water (microg/L)		

3.3 Estimated environmental concentration in water (EEC)

EEC (microg/L)	0.05
	The value equal to 1/2 of the detection limit was used, since dicyclohexyl phthalate was not detected in any samples ¹⁾ .

3.4 Estimated human intake

Intake route		Concentration used for estimation of intake	Estimated intake (microg/ person/ day)	Estimated intake (microg/ kg-Bodyweight (BW)/ day)
Inhalation	Air	0.053 (microg/m ³)	1.1	0.022
	Measured concentration in indoor air was used, since the estimation by model was not conducted.			
Oral	Drinking water	0.025 (microg/L)	0.05	0.001
	The value equal to 1/2 of the detection limit was used, since dicyclohexyl phthalate was not detected in any samples of drinking water.			
	Food	0.005 (microg/g)	10	0.2
	A duplicate diet study was performed on 27 households for 3 days by Japan Food Research Laboratories in 2001. The concentrations of dicyclohexyl phthalate were measured for each of the 81 samples. The value (0.005 microg/g) equal to 1/2 of the detection limit is used, since dicyclohexyl phthalate was not detected in any samples in the survey.			
Subtotal		--	10.05	0.2
Total route		--	11.2	0.22

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version 2.0. Under Version 2.0, a measured concentration and an estimated concentration (calculated by mathematical model) are compared and the larger of two concentrations is used for risk assessment.

4. Hazard assessment

4.1 Effects on organisms in the environment

	Acute or Chronic	Species	Endpoint	Concentration
Algae	--	--	--	--
Crustacea	--	--	--	--
Fish	Chronic	<i>Oryzias latipes</i> Eggs within 24 hours after fertilization	69 days NOEC Hatching rate, mortality, growth	0.0358 or higher (mg/L)
Key study		The data of fish (<i>oryzias latipes</i>) was chosen for the key study.		

4.2 Human health toxicity

Toxicity	Exposure route	Species	Duration / Dose method	Toxic effects (Key study is underlined)	NOAEL
Repeated dose toxicity	Inhalation	--	--	--	--
	Oral	Rat	Two-generation reproductive toxicity test (in feed)	<u>Reduced body weight gains, diffuse hepatocellular hypertrophy, hypertrophy of thyroid follicular epithelial cells</u> , increased absolute and relative weight of liver and thyroid, increased hyaline droplets in renal proximal tubules in males, decreased testicular sperm count, diffuse and/or focal atrophy of testicular seminiferous tubules	240 ppm (15.9 mg/kg/day)
	Dermal	--	--	--	--
Reproductive and developmental toxicity	Oral (reproductive toxicity)	Rat	Two-generation reproductive toxicity test (in feed) (same as repeated dose toxicity through oral route)	Reproductive potential	6,000 ppm (534.2 mg/kg/day)

	Oral (developmental toxicity)	Rat	Two-generation reproductive toxicity test (in feed) (same as repeated dose toxicity through oral route)	Shortened AGD and development of areola in F ₂ offsprings	240 ppm (17.8 mg/kg/day)
Carcinogenicity	Evaluation by IARC : The carcinogenicity of dicyclohexyl phthalate has not been evaluated by IARC.				
Genotoxicity	Unable to determine genotoxicity				

5. Risk Assessment

5.1 Environmental organisms

Risk characterization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	0.05	NOEC: 0.0358 or higher	720 or higher	100	No immediate concern
Product of uncertainty factors (UF): Extrapolation from laboratory test (10) * Toxicity data on one nutritional stage (10) = 100					
Recommendation : The substance is considered to be of no immediate concern for the moment, and a low priority for further work.					

NOEC* means NOEC, LOEC, EC₅₀, etc.

5.2 Human health

5.2.1 Repeated dose toxicity

Exposure route	Intake (microg/kgBW /day)	NOAEL (mg/kgBW/day)	Risk characterization		
			MOE	Product of uncertainty factors	Conclusion
Inhalation	0.022	No adequate data	Not calculated	Not calculated	--
Oral	0.2	15.9	80,000	500	No immediate concern
Total	0.22	15.9 (oral)	72,000	500	No immediate concern
Product of uncertainty factors (UF): Oral/Total: Interspecies (10) * Intraspecies (10) * Duration of test (5) = 500					

5.2.2 Reproductive and developmental toxicity

Since NOAEL of reproductive and developmental toxicity is larger than NOAEL of repeated dose toxicity, risk characterization of reproductive and developmental toxicity was not conducted.

5.2.3 Carcinogenicity

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5.2.4. Recommendation for Human Health

Although there was no adequate toxicity data available to evaluate exposure via the inhalation route, the MOE calculated using total intake from both routes (inhalation and oral) is larger than the product of uncertainty factors. Thus, the substance is considered to be of no immediate concern for the moment and a low priority for further work.

6. Supplement

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