

Summary of Initial Risk Assessment Report

Hexamethylenediamine CAS No : 124-09-4

PRTR No of Japan: 292

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

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless solid
Melting point	42 degC
Boiling point	205 degC
Water solubility	Miscible
Henry's constant	3.25×10^{-4} Pa·m ³ /mol (3.21×10^{-9} atm·m ³ /mol) (25degC, estimated)
Octanol/water partition coefficient (log Kow)	0.35 (estimated)
Soil adsorption coefficient	Koc = 290 (estimated value under undissociated condition)

1.2 Environmental fate

Bioaccumulation	Low bioaccumulative Bioconcentration factor (BCF): 3.2 (calculated using logKow of 0.32)
Biodegradation	Readily biodegradable
Stability in the environment	(In air) Reaction with OH radical: The reaction rate constant is 6.90×10^{-11} cm³/molecule-sec. (25 degC, estimated) The half-life is 3-6 hours, given OH radical concentration of 5×10^5-1×10^6 molecule/cm³. Reaction with ozone: No data Reaction with nitrate radical: No data Hexamethylenediamine is rarely present in air as vapor. Hexamethylenediamine released as dust particles is expected to react with carbon dioxide in the atmosphere to produce carbonate and settle out. Hexamethylenediamine is not directly degraded by photolysis by sunlight (wavelength of 295 nm or higher). (In water) Hexamethylenediamine is not hydrolyzed in water.
Environmental fate	If released to water, hexamethylenediamine is expected to be removed mainly by biodegradation. Removal by volatilization is not considered an important fate process.

2. Sources of release to the environment

2.1 Annual production, import, export and domestic supply in 2002 (ton/year)

Production	Import	Export	Domestic supply	Remarks
20,000	31,153	45	46,000	

2.2 Uses

Raw material for polyamide resins (65%), raw material for polyamide fibers (7%), raw material for hexamethylene diisocyanate used as raw material for other polyurethanes (28%)

2.3 Release from the industries within the scope of PRTR system (in 2002)

Release sources		Air (ton)	Waters (ton)	Soil (ton)	Remarks
Listed industries	Reported release	4	22	0	Release to rivers: 22 tons
	Release outside notification	--	--	--	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		4	22	0	

2.4 Releases from other sources

No information is available.

2.5 Main release route

Hexamethylenediamine is released into the aquatic environments mainly during synthesis of polyamide.

3. Exposure Assessment

3.1 Measured environmental concentration

No data

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)	0.048	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment ver.1.01 (AIST-ADMER)
River water (microg/L)	110	Calculated by mathematical model / Initial Assessment System for the PRTR chemicals (IAS)

3.3 Estimated environmental concentration in water (EEC)

EEC(microg/L)	110
	Estimated concentration was used, since measured concentrations were not available.

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	0.048 (microg/m ³)	0.96	0.019
		Estimated concentration in air was used for the risk assessment, since measured concentrations in air were not available.		
Oral	Drinking water	110 (microg/L)	220	4.4
		Estimated concentrations in river water were used as substitutes, since measured concentrations in drinking water were not available.		
	Food	0.035 (microg/g)	4.2	0.084
		-Data of intake via food were not available. -The concentration in fish was estimated as a product of the concentration in seawater and a BCF. -Since neither measured concentrations in seawater nor river water were available, the concentration in seawater was assumed to be 1/10 of the estimated concentration in river water.		
	Subtotal	--	224.2	4.5
Total route		--	224	4.5

4. Hazard assessment

4.1 Effects on organisms in the environment

	Acute or Chronic	Species	Endpoint	Concentration
Algae	Chronic	<i>Selenastrum capricornutum</i>	72 hours NOEC Growth inhibition	10 (mg/L)
Crustacea	Chronic	<i>Daphnia magna</i>	21 days NOEC Reproduction	4.16 (mg/L)
Fish	Acute	<i>Leuciscus idus</i>	96 hours LC ₅₀	62 (mg/L)
Key study		Data of crustacea (<i>daphnia magna</i>) was chosen for the key study because effects were observed at the lowest concentration in the hazard assessment.		

4.2 Human health toxicity

Toxicity	Exposure route	Species	Duration / Dose method	Toxic effects (Key study is underlined)	NOAEL or LOAEL
Repeated dose toxicity	Inhalation	Mouse Rat	13 weeks	<u>Degeneration of tracheal epithelium, decreased segmented neutrophil counts,</u> inflammation of laryngeal epithelium, degeneration of olfactory epithelium and respiratory epithelium, decreased WBC and lymphocyte counts	NOAEL: 5 mg HDDC*/m ³ (3.1 mg/m ³) Mouse 0.92 mg/kg/day Rat 0.41 mg/kg/day
	Oral	Rat	Two-generation reproduction test with oral administration (in feed) for 15 weeks	<u>Reduced body weight gains</u>	NOAEL: 150 mg/kg/day
	Dermal	--	--	--	--
	* HDDC: Hexamethylenediamine dihydrochloride				
Reproductive and developmental toxicity	In reproductive toxicity test, reduced body weight gain was observed in dams and offspring in the highest dose level without influence on fertility. In developmental toxicity test, low birth weight and delayed ossification were observed in fetuses at the level at which reduced body weight gain was observed in dams.				
Carcinogenicity	Evaluation by IARC : This substance 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
	110	NOEC: 4.16	38	50	Substance of concern
	Product of uncertainty factors (UF): Extrapolation from laboratory test (10) * Toxicity data on two nutritional stages (5) = 50				
Recommendation : The substance is considered to be of concern, and further investigation, analysis and assessment are necessary. The EEC of this substance was estimated based on the release from a specific business institution. As a result, it is necessary to monitor for large releases in this area in the future. .					

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	0.019	0.41	22,000	500	No immediate concern
Oral	4.5	150	33,000	500	No immediate concern
Total	--	--	--	--	--
Product of uncertainty factors (UF): Inhalation/Oral: Interspecies (10) * Intraspecies (10) * Duration of test (5) = 500					

5.2.2 Reproductive and developmental toxicity

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5.2.3 Carcinogenicity

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5.2.4. Recommendation for Human Health

The substance is considered to be of no immediate concern for the moment, and low priority for further work.
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6. Supplement

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