

Summary of Initial Risk Assessment Report

Hydrazine CAS No : 302-01-2

PRTR No of Japan: 253

This substance is assessed based on Guideline for Initial Risk Assessment Version1.0

1. General Information

1.1 Physico-chemical properties (Anhydrate)

Appearance	Colorless liquid
Melting point	2.0 degC
Boiling point	113.5 degC
Water solubility	Miscible
Henry's constant	$6.15 \times 10^{-2} \text{Pa} \cdot \text{m}^3/\text{mol}$ ($6.07 \times 10^{-7} \text{atm} \cdot \text{m}^3/\text{mol}$) (25degC, estimated)
Octanol/water partition coefficient (log Kow)	-0.16 (measured), -2.07 (measured), -1.47 (estimated)
Soil adsorption coefficient	Koc = 14 (estimated)

1.2 Environmental fate

Bioaccumulation	Low bioaccumulative Bioconcentration factor (BCF) : 316 (guppy, measured)
Biodegradation	Non-biodegradable
Stability in the environment	(In air) Reaction with OH radical : Reaction rate constant : $6.1 \times 10^{-11} \text{cm}^3/\text{molecule} \cdot \text{sec}$ The half-life is 4-7 hours, given OH radical concentration is $5 \times 10^5 - 1 \times 10^6 \text{molecule}/\text{cm}^3$, Reaction with ozone : Reaction rate constant : $3 \times 10^{-17} \text{cm}^3/\text{molecule} \cdot \text{sec}$ The half-life is 9 hours, given ozone concentration is $7 \times 10^{11} \text{molecule}/\text{cm}^3$, Reaction with nitrate radical: No data of reaction rate constant is available. Hydrazine could react with nitrogen oxides in a short time. Stability in air: Since hydrazine is highly hygroscopic, it can hydrate with moisture in air and yield to hydrazine hydrate. (In water): Hydrazine is hydrated quickly to yield hydrazine hydrate. Hydrazine is not expected to be hydrolyzed in water.
Environmental fate	When released to water, hydrazine is not expected to be removed by volatilization from water surfaces. Hydrolysis is not expected to occur either. Hydrazine is expected to be oxidized easily by dissolved oxygen in the aquatic environments.

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
15,373	--	2,702	--	--

2.2 Uses

Raw material of forming agents for plastics, boiler compounds and water treatment chemicals, raw material for industrial chemicals, pesticides and medical products

2.3 Release from the industries within the scope of PRTR system (in 2001)

Release sources		Air (ton)	Waters(ton)	Soil(ton)	Remarks
Listed industries	Reported release	3	11	0	Release to rivers: 213 tons
	Release outside notification	63	205	0	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		66	216	0	

2.4 Releases from other sources

When derivatives of hydrazine such as hydrazine monohydrochloride are used for water treatment, those derivatives produce hydrazine in water.

2.5 Main release route

Hydrazine is expected to be released mainly during use of hydrazine or the products containing it.

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	--	--	--	--	--	--
River water	--	--	--	--	--	--
Drinking water	--	--	--	--	--	--
Food (microg/g)	--	14/ 45	0.0001-0.0006	0.00044	0.0001	Japan Food Research Laboratories 1999

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)	0.0099	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER)
River water (microg/L)	2.2	Calculated by mathematical model / Integrated River Model to predict the distribution of chemical concentration ver.1 (IRM1)

3.3 Estimated environmental concentration in water (EEC)

EEC(microg/L)	2.2
	Estimated concentration in river water by model was used for the risk assessment, since measured data were not available ¹⁾ .

3.4 Estimated human intake

Intake route		Concentrations used for estimation of intake	Estimated intake (microg/ person/ day)	Estimated intake (microg/ kg-Bodyweight (BW)/ day)
Inhalation	Air	0.0099 (microg/m ³)	0.20	0.004
	Estimated concentration was used, since no measured data was available.			
Oral	Drinking water	2.2 (microg/L)	4.4	0.088
	The estimated concentration in river water was used for risk assessment, since neither drinking water data nor ground water data were available.			
	Food	0.00044 (microg/g)	0.88	0.0176

	A duplicate diet study was performed on 45 households for 3 days by Japan Food Research Laboratories in 1999. The concentrations of hydrazine were measured for each of the 45 household diets. The ninety-fifth percentile (0.00044 microg/g) was used for the risk assessment.		
Subtotal	--	5.28	0.11
Total route	--	5.48	0.114

1) This substance is assessed based on Guideline for Initial Risk Assessment Version 1.0. If adequate measured concentrations are available, they are given priority and used as values for risk assessment. If they are not available, an estimated value calculated using a mathematical model is used.

4. Hazard assessment

4.1 Effects on organisms in the environment

	Acute or Chronic	Species	Endpoint	Concentration
Algae	Chronic	<i>Dunaliella tertiolecta</i>	8 days NOEC Growth inhibition	0.0005(mg/L)
Crustacea	Acute	<i>Hyaella azteca</i>	48 hours LC ₅₀	0.04(mg/L)
Fish	Acute	<i>Poecilia reticulates</i>	96hours LC ₅₀	0.61(mg/L)
Key study		Data of algae 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	Dose term/ dose method	Toxic effects (Key study is underlined)	NOAEL or LOAEL (converted)
Repeated dose toxicity	Inhalation	Rat	12 months	<u>Reduced body weight gain</u> , inflammation and squamous metaplasia of larynx and tracheal mucosa epithelium, alveolar epithelium hyperplasia, hepatocellular hyperplasia, myocardinal degeneration, endometriosis, endometrial hyperplasia, atrophy of ovaries, Leydig cell hyperplasia	LOAEL: 0.066 mg/m ³ (equivalent to 0.0088 mg/kgBW/day)*
	Oral	Rat	Lifetime Drinking water	<u>Reduced body weight gain in females</u> , bile duct hyperplasia, decreased survival rate	LOAEL: 2 mg/L (0.08 mg/kgBW/day)
	Dermal	--	--	--	--
Developmental toxicity	Oral (Develop- mental toxicity)	Mouse	GD 6-9	<u>Reduced fetal body weight</u>	NOAEL: 4 mg/kgBW
Carcinogenicity	Evaluation by IARC: Group 2B (possibly carcinogenic to humans)				

Genotoxicity	Considered to be genotoxic
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*Conversion of LOAEL: $LOAEL * (\text{inhalation amount}) * 6\text{hours} / 24\text{hours} * 5\text{days} / 7\text{days} * (\text{absorption rate}) / (\text{rat body weight})$
 $= 0.066\text{mg}/\text{m}^3 * 0.26\text{ m}^3/\text{day} * 6\text{hours} / 24\text{hours} * 5\text{days} / 7\text{days} * 1.0 / 0.35\text{ kg}$
 $= 0.0088\text{ mg}/\text{kg}/\text{day}$

5. Risk Assessment

5.1 Environmental organisms

Risk character-ization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	2.2	NOEC : 0.0005	0.23	100	Substance of concern
Product of uncertainty factors (UF): Tested in laboratory(10) * One nutritional stage (10) = 100					
Recommendation: The substance is considered to be of concern and it is necessary for further investigation, analysis and assessment.					

* 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	0.0040	LOAEL : 0.0088	2,200	1,000	No immediate concern
Oral	0.11	LOAEL: 0.08	730	1,000	Substance of concern
Total	--	--	--	--	
Product of uncertainty factors (UF) inhalation and oral: Interspecies (10) * Intraspecies (10) * Using of LOAEL (10) = 1,000					

5.2.2 Reproductive and developmental toxicity

Since the NOAEL of developmental toxicity is larger than that of repeated dose toxicity, a risk characterization was not conducted.

5.2.3 Carcinogenicity

Risk characterization of the carcinogenicity of the substance was not conducted in this assessment.

5.2.4 Recommendation

The substance is considered to be of concern, and it is necessary for further investigation, analysis and assessment.

6. Supplement

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