Summary of Initial Risk Assessment Report

2,2'-Azobisisobutyronitrile CAS No: 78-67-1

PRTR No of Japan: 13

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	107 (degC) (Degradation)
Boiling point	None
Water solubility	350 mg/L (at 25 degC)
Henry's constant	0.419 Pa*m^3/mol ($4.14*10^{-6}$ atm*m^3/mol) (25degC, measured)
Octanol/water partition coefficient (log Kow)	1.10 (measured), 2.87 (estimated)
Soil adsorption coefficient	Koc = 51 (estimated)

1.2 Environmental fate

Bioaccumulation	Not or low bioaccumulative Bioconcentration factor (BCF): 1.4 (calculated using logKow of 1.1)
Biodegradation	Non-biodegradable
Stability in the environment	(In air) Reaction with OH radical: Reaction rate constant is $6.69*10^{-13}$ cm^3/molecule-sec. (25 degC, estimated value) The half - life is 0.5 - 1 month, given OH radical concentration of $5*10^5$ - $1*10^6$ molecule/cm^3. Reaction with ozone: The data is not available. Reaction with nitrate radical: The data is not available. 2,2'-Azobisisobutyronitrile is easily degraded in air by heat or light, and generates nitrogen and $(CH_3)_2CCN$ radical. (In water) The hydrolysis half - life is estimated as 263 days (pH = 4), 304 days (pH = 7), 210 days (pH = 9) , and the degradation products are unknown.
Environmental fate	If released into water, 2,2'-Azobisisobutyronitrile is not expected to be removed by biodegradation or volatilization.

2. Sources of release to the environment

2.1 Annual production, import, export and domestic supply in 2003 (ton/year)

Production	Import	Export	Domestic supply	Remarks
2,203		--	--	--

2.2 Uses

Blowing agent for rubber and plastics, radical generator for radical polymerization of vinyl compound and others.

2.3 Release from the industries within the scope of PRTR system (in 2003)

Release sources		Air (ton)	Waters (ton)	Soil (ton)	Remarks
Listed industries	Reported release	0.047	0.011	0	Release to rivers: 0.001 ton
	Release outside notification	--	--	--	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		0.047	0.011	0	

2.4 Releases from other sources

No information about the substance is available.

2.5 Main release route

The amount of release into the environment was 58kg/year in 2003. The release of the substance is expected to be extremely limited.

3. Exposure Assessment

3.1 Measured environmental concentration

No data

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m^3)	3.2 * 10^{-4}	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER) Ver.1.5
River water (microg/L)	0	Release to rivers is considered negligible, since the total amount release was 1 kg based on 2003 PRTR data.

3.3 Estimated environmental concentration in water (EEC)

EEC (microg/L)	0
	0 µg/L was used for the risk assessment, since measured concentrations in river were not available and estimated concentration was 0 µg/L [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	0.00032 (microg/m^3)	0.0064	0.00013
		The estimated value of 3.2*10^{-4} microg/m^3 was used, since measured concentration was not available.		
Oral	Drinking water	0 (microg/L)	0	0
		Concentration in drinking water was not available. It is assumed that exposure via drinking water is negligible, since the estimated concentration in river water was 0 microg/L.		
	Food	0 (microg/g)	0	0
		Measured concentration in food was not available. It is assumed that exposure via food is negligible, since the estimated concentration in fish was 0 microg/kg.* *Concentration in fish = estimated concentration in river water*1/10*BCF		
	Subtotal	--	0	0
Total route		--	0.0064	0.00013

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version2.0. 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	Chronic	*Selenastrum capricornutum*	0 - 72 hours NOEC Growth inhibition (Growth rate)	4.2 (mg/L)
Crustacea	Chronic	*Daphnia magna*	21days NOEC Reproduction	2.2 (mg/L)
Fish	--	--	No adequate data	-- (mg/L)
Key study		Data of crustacea (*Daphnia magna*) 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 (converted)
Repeated dose toxicity	Inhalation	--	--	--	--
	Oral	Rat	6 weeks Gavage	Increased absolute and relative kidney weights, increased eosinophilic bodies/basophilic changes of renal tubular epithelial cells, granular casts in kidneys, increased absolute and relative liver weights, centrilobular hypertrophy of hepatocytes	NOAEL 2 mg/kg/day
	Dermal	--	--	--	--
Reproductive and developmental toxicity	Oral	Rat	--	Abnormal nursing behavior of dams Decreased viability index and body weight of offspring on PND 4	NOAEL 10 mg/kg/day
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 character -ization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	0	NOEC: 2.2	Not calculated	Not calculated	No immediate concern
	Product of uncertainty factors (UF): --				
Recommendation : The substance is considered to be of no immediate concern for the moment, and low priority of further work.					

NOEC* means NOEC, LOEC, EC_{50}, 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	0.00013	No adequate data	Not calculated	Not calculated	--
Oral	0	2	Not calculated	Not calculated	No immediate concern
Total	0.00013	2 (Oral)	15,000,000	1,000	No immediate concern
Product of uncertainty factors (UF): Interspecies (10) * Intraspecies (10) * Duration of test (10) = 1,000					

5.2.2 Reproductive and developmental toxicity

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

5.2.3 Carcinogenicity

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5.2.4. Recommendation for Human Health

Although no adequate toxicity data for the inhalation route was available, MOE of total route of inhalation and oral is larger than the product of uncertainty factor. The substance is considered to be of no immediate concern for the moment, and low priority of further work.

6. Supplement

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