

Summary of Initial Risk Assessment Report

***p*-Chloroaniline** CAS No : 106-47-8

PRTR No of Japan: 72

This substance is assessed based on Guideline for Initial Risk Assessment Version 1.0

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless to yellow solid
Melting point	72.5 degC
Boiling point	232 degC
Water solubility	3.9 g/L (25 degC)
Henry's constant	0.118 Pa*m ³ /mol (1.16*10 ⁻⁶ atm*m ³ /mol) (25degC, estimated)
Octanol/water partition coefficient (log Kow)	1.88 (measured), 1.83 (measured), 1.72 (estimated)
Soil adsorption coefficient	Koc = 73 (estimated under undissociated conditon)

1.2 Environmental fate

Bioaccumulation	Exhibits little to no bioaccumulation Bioconcentration factor (BCF) : Less than 20 (<i>Cyprinidae</i>), 7, 4, 8.1 (<i>Danio rerio</i>), 5.6 (calculated)
Biodegradation	<i>p</i> -Chloroaniline is generally considered non-biodegradable; however, it is expected to be biodegradable in specific conditions involving acclimatized microorganisms.
Stability in the environment	(In air) Reaction with OH radical: Reaction rate constant is 4.3*10 ⁻¹¹ cm ³ /molecule-sec (25 degC, measured). The half-life is 4-9 hours, given OH radical concentration of 5*10 ⁵ -1*10 ⁶ molecule/cm ³ . Reaction with ozone: No data Reaction with nitrate radical: No data <i>p</i> -chloroaniline absorbs light with wavelengths >290 nm and may be degradable by sunlight. (In water) Primary photodegradation half-life was 1 hour and complete degradation half-life was 8 days in the experiment in which a flask containing estuarine surface water (containing 25 microg/L of <i>p</i> -chloroaniline) was placed outdoors in summer (25 degC).
Environmental fate	If released into water, <i>p</i> -chloroaniline is expected to be partially removed by volatilization and biodegradation. It may also be removed by photodegradation in surface water.

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
10-100		--	--	

2.2 Uses

Dyestuff intermediates, raw materials for medical products, raw material for agricultural chemicals, and resin crosslinking agents

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	0	1.9	0	Release to river: 1.7 tons
	Release outside notification	0	0.1	0	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		0	2.0	0	

2.4 Releases from other sources

--

2.5 Main release route

Main release route could not be specified.

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)	--	0/51	--	--	0.25	1990 Ministry of the Environment
River water (microg/L)	1/44	--	nd- 0.02	0.01	0.02	2000 Ministry of the Environment
Drinking water (microg/L)(as ground water)	0/15	--	nd	--	0.02	2000 Ministry of the Environment
Food(fish) (microg/g)	--	0/57	--	--	0.005	1990 Ministry of the Environment

nd: Not detected

For calculation of the 95th percentile, data less than the detection limit are replaced with a value equal to 1/2 of the detection limit.

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)	0	<i>p</i> -chloroaniline in air is likely negligible, since it was not released into air based on 2001 PRTR data.
River water (microg/L)	2.4	Calculated by mathematical model / Initial Assessment System for the PRTR chemicals (IAS)

3.3 Estimated environmental concentration in water (EEC)

EEC(microg/L)	0.01
	The ninety-fifth percentile of measured concentrations in river water was used for the risk assessment 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	-- (microg/m ³)	--	--
	Intake via inhalation was not considered in this risk assessment, since <i>p</i> -chloroaniline is not released into air based on PRTR data as well as <i>p</i> -chloroaniline was not detected in air in the measurement.			
Oral	Drinking water	0.01 (microg/L)	0.02	0.0004
		Measured concentrations in ground water were used, since measured concentrations in tap water were not available. The value (0.01 microg/L) equal to 1/2 of the detection limit was used, since <i>p</i> -chloroaniline was not detected (detection limit: 0.02 microg/L) in ground water.		
	Food	0.0025 (microg/g)	0.30	0.006
		The value (0.0025 microg/g-wet) equal to 1/2 of the detection limit of concentrations in fish surveyed by the Ministry of the Environment was used to calculate intake via food.		
Subtotal		--	0.32	0.0064
Total route		--	0.32	0.0064

1) This substance is assessed based on the 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>Selenastrum capricornutum</i>	72 hours NOEC Growth inhibition (growth rate)	0.32 (mg/L)
Crustacea	Chronic	<i>Daphnia magna</i>	21 days NOEC Reproduction	0.0032 (mg/L)
Fish	Chronic	<i>Danio rerio</i>	32 weeks LOEC Reproduction of F2,F3 generations in a three-generation reproduction test	0.04 (mg/L)
Key study		Data of crustacea (<i>Daphnia magna</i>) is chosen for the key study because effects were observed at the lowest concentration in the hazard assessment.		

4.2 Human health toxicity

Toxicity	Exposure routes	Species	Duration / Dose method	Toxic effects (Key study is underlined)	NOAEL or LOAEL
Repeated dose toxicity	Inhalation	Rat	14 days	Anemia, cyanosis, decreased body weight, methemoglobinemia, decreased RBC, <u>hemosiderin deposits in spleen, increased splenic extramedullary hematopoiesis</u>	LOAEL: 2.2 ppm (11.7 mg/m ³)
	Oral	Rat	103 weeks	<u>Splenic fibrosis in males</u> , fatty metamorphosis in spleen, hyperplasia of adrenal cortex and bone marrow, hemosiderin deposits in liver	LOAEL: 1.6 mg/kg (equivalent to 1.1 mg/kg/day)
	Dermal	--	--	--	--
Reproductive and developmental toxicity	--	--	--	--	--
Carcinogenicity	Evaluation by IARC : Group 2B (possibly carcinogenic to humans)				
Genotoxicity	Considered to be genotoxic.				

5. Risk Assessment

5.1 Environmental organisms

Risk characterization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	0.01	NOEC: 0.0032	320	10	No immediate concern
Product of uncertainty factors (UF): Extrapolation from laboratory test (10) = 10					
Recommendation : The substance is considered to be of no immediate concern for the moment, and 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	No adequate data	Not calculated	Not calculated	--
Oral	0.0064	LOAEL: 1.1	170,000	1,000	No immediate concern
Total	--	--	--	--	--

Product of uncertainty factors (UF): Interspecies (10) * Intraspecies (10) * Using of LOAEL (10) = 1,000

5.2.2 Reproductive and developmental toxicity

--

5.2.3 Carcinogenicity

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

5.2.4. Recommendation for Human Health

In terms of oral exposure, the substance is considered to be of no immediate concern for the moment, and a low priority for further work. As for inhalation exposure, a risk assessment was not conducted because there is no adequate toxicity data.

6. Supplement

--
