10	CAS No.: 106-47-8	Substance: *p*-Chloroaniline

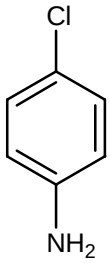
Chemical Substances Control Law Reference No.: 3-194 (as chloroaniline)

PRTR Law Cabinet Order No.: 1-72

Structural Formula:

Molecular Formula: C_6H_6ClN

Molecular Weight: 127.57



1. General information

The aqueous solubility of this substance is 3.9×10^3 mg/L (20-25°C) and the partition coefficient (1-octanol / water) (log Kow) is 1.88. The vapor pressure is 0.027 mmHg (= 3.6 Pa) (26°C, extrapolated value). Degradability (aerobic degradation) in terms of BOD-based degradation percentage is estimated to be 0%, and this substance is determined to be no or little bioaccumulative.

This substance is a Type 2 and Type 3 Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances and a Class 1 Designated Chemical Substance under the Law concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law). It is used primarily as a synthetic raw material. Production (shipment) and import quantities in FY2001 were 10 - below 100 tons.

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2. Exposure assessment

Total release to the environment in FY2004 under the PRTR Law came to approximately 1.5 tons, all of which was reported. Release to the public water bodies accounted for all of the reported release. Chemical Industry reported high levels of release to the public water bodies. The distribution into each environment medium predicted by means of a multimedia model was 83.0% for water bodies and 13.9% for bottom in the case of the region where the release quantity to the environment and public water bodies was considered to be the maximum.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. The predicted maximum oral exposure was estimated to be less than 0.0008 μg/kg/day. Because the bioconcentration of this substance is determined to be low, exposure from environmental media via the food chain is assumed to be low.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be 0.06 μg/L for freshwater and less than 0.02 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

This substance causes irritation of the eyes, and may cause lesion of red cells and formation of methemoglobin. The inhalation or ingestion may result in blue lips, nails and skin, confusion, convulsion, dizziness, headache, nausea and unconsciousness. It may be absorbed to skin and cause the similar symptoms. Contact to the eyes induces redness and pain.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the 'Non-toxic level' for oral exposure, the LOAEL of 2mg/kg/day (decreases in red blood cell counts, fibrosis in spleen) was obtained from the medium- and long-term toxicity testing for rats. This value was adjusted to 1.4 mg/kg/day taking into account the exposure situation. As this adjusted value was LOAEL, it was divided by 10, and a value of 0.14mg/kg/day was

derived as the 'Non-toxic level'. As the 'Non-toxic level' for inhalation, the LOAEL of 11 mg/m^3 (increase in methemoglobin concentration, increase in relative weight of spleen, extramedullary hematopoiesis) was obtained from the medium- and long-term toxicity testing for rats. This value was adjusted to 2 mg/m^3 taking into account the exposure situation. As this adjusted value was LOAEL, it was divided by 10. Furthermore, because of the short experimental period, The value was divided by 10 again, and a value of 0.02 mg/m^3 was derived as the 'Non-toxic level'.

With regard to oral exposure, in case the groundwater intakes, the predicted maximum exposure was approximately less than 0.0008 μg/kg/day. The MOE of exceeding 3,500 was derived from the 'Non-toxic level' of 0.14 mg/kg/day divided by the predicted maximum exposure, and divided by 10, because the 'Non-toxic level' was established by means of animal testing, and considering the carcinogenicity, it was further divided by 5. As the exposure to this substance through food intakes is estimated minor, even when the exposures through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For the inhalation, because the exposure concentrations were not estimated, its health risk cannot be identified. The total amount of release of this substance to the environment was 1.5 tons (reported quantity of release), and all of it was released into the public water bodies. It is estimated that almost all of this substance is distributed into water bodies, and that the half-life of this substance in the atmosphere is 0.77 - 7.7 hrs. Accordingly, there would be low necessity of collecting information on inhalation exposure to this substance in the ambient air for its health risk assessment.

Information of toxicity				Exposure assessment		Result of risk assessment			Judgment
Exposure path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration				
Oral	'Non toxic level' 0.14 mg/kg/day	Rats	decreases in red blood cell counts, increase in fiber in spleen	Drinking water	– μg/kg/day	MOE	–	×	○
				Groundwater	< 0.0008 μg/kg/day	MOE	> 3,500	○	
Inhalation	'Non toxic level' 0.02 mg/m^3	Rat	Increase in methemoglobin concentration, increase in comparative weight of spleen, extramedullary hematopoiesis	Ambient air	– μg/m^3	MOE	–	×	×
				Indoor air	– μg/m^3	MOE	–	×	×

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC_{50} growth inhibition value of 3,830 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 314 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC_{50} value of 5,820 μg/L was found for the fish *Oryzias latipes* (medaka), and a 48-hour EC_{50} immobilization value of 43,000 μg/L was found for the *Chironomus plumosus* (chironomus). Accordingly, an assessment factor of 100 was used, a predicted no effect concentration (PNEC) of 3.1 μg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 320 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 3.2 μg/L was found for the crustacea *D. magna*. So an assessment factor of 100 was used, and a PNEC value of 0.032 μg/L was obtained based on the acute toxicity values. As the PNEC for the substance, a value of 0.032 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was 2 for freshwater bodies and less than 0.6 for seawater bodies. This substance is thought to be a candidate for further work.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacea (water flea)	Chronic	NOEC reproduction	100	0.032	Freshwater	0.06	2	■
					Seawater	< 0.02	< 0.6	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work.	○
	Inhalation exposure	Impossible of risk characterization. However, there is thought to be comparatively little need to collect information, etc.	×
Ecological risk	Candidates for further work.		■

［Risk judgments］ ○: No need of further work ▲: Requiring information collection
■: Candidates for further work ×: Impossible of risk characterization

Non-toxic level *

・When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.

・When an adverse effect level for the short-term exposure is available, it is divided by 10 to obtain a level equivalent to an adverse effect level for the long-term exposure.