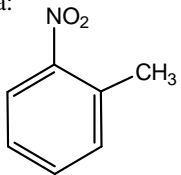


14	CAS No.: 88-72-2	Substance: <i>o</i> -Nitrotoluene
<p>Chemical Substances Control Law Reference No.: 3-437 (Nitrotoluene) PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C₇H₇NO₂ Molecular Weight: 137.14</p> <p style="text-align: center;">Structural Formula:</p> <div style="display: flex; justify-content: center; align-items: center;">  </div>		
<p>1. General information</p> <p>The aqueous solubility of this substance is 537 mg/L (20°C, pH = 7) and the partition coefficient (1-octanol / water) (log Kow) is 2.30. The vapor pressure is 0.188 mmHg (= 25.1 Pa) (25°C, extrapolated value). This substance is determined to be persistent, also to be non or not highly bioaccumulative. In addition, this substance does not have hydrolyzable groups.</p> <p>It is mainly used for intermediates for dyes and in organic synthesis. The total of production (shipment) and imports in FY 2001 was 1,000 to less than 10,000 tons/yr.</p> <hr/> <p>2. Exposure assessment</p> <p>As <i>o</i>-Nitrotoluene is not 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), no information on release and transfer quantities could be obtained. When predictions of distribution ratios by medium were made using the Mackay-Type Level III Fugacity Model, in the event of equal release to the atmosphere, water, and soil, the distribution ratio was highest for soil.</p> <p>Based on data for the ambient air, the previous predicted maximum exposure concentration for inhalation exposure to human beings was 0.12 µg/m³. The highest estimated oral exposure was calculated to be approximately less than 0.008 µg/kg/day based on previous data regarding freshwater bodies. The risk of exposure to this substance through food in environmental media is considered to be low.</p> <p>The previous predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be less than 0.2 µg/L for both freshwater and seawater public water bodies.</p> <hr/> <p>3. Initial assessment of health risk</p> <p>The substance irritates the eyes. The substance may cause effects on the blood, resulting in formation of methemoglobin. Contact with eyes may cause redness and pain. By inhalation and ingestion, it may cause headache, blue lips or finger nails, blue skin, dizziness and laboured breath. Additionally, by ingestion, it may cause abdominal pain. The substance absorbed into the body through the skin may cause the similar symptoms.</p> <p>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.</p> <p>A lowest-observed-adverse-effect-level (LOAEL) of 25 mg/kg/day (depression of body weight gain and degeneration of hepatic cells, etc.) was obtained for oral exposure from the medium- and long-term toxicity testing for rats. As this was a LOAEL, it was divided by 10, and a value of 2.5 mg/kg/day was derived as the 'Non-toxic level*'. For inhalation exposure, the 'Non-toxic level*' could not be estimated.</p> <p>With regard to oral exposure, in case of intakes of freshwater in the public water bodies, the predicted maximum exposure was approximately less than 0.008 µg/kg/day. The margin of exposure (MOE) of exceeding 31,000 was derived from the 'Non-toxic level*' of 2.5 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level*' was established by means of animal testing. As the exposure to this substance through</p>		

food intakes was estimated minor, even when the exposure 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.

Concerning inhalation exposure, because its 'Non-toxic level*' is not determined, its health risk can not be identified. For reference, assuming that the absorption rate is 100%, the 'Non-toxic level*' for the oral exposure is converted to the 'Non-toxic level*' for the inhalation exposure. The resulting value is 8.3 mg/m³. The MOE determined from this figure and the predicted maximum exposure concentration of the ambient air is 6,900. Accordingly, there would be little necessity of collecting information on inhalation exposure to this substance 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	MOE			
Oral	'Non-toxic level*' 2.5 mg/kg/day	Rats	depression of body weight gain and degeneration of hepatic cells, etc.	Drinking water	- μg/kg/day	MOE	-	×	
				freshwater	< 0.008 μg/kg/day	MOE	> 31,000		
Inhalation	'Non-toxic level*' - mg/m ³	-	-	Ambient air	0.12 μg/m ³	MOE	-	×	
				Indoor air	- μg/m ³	MOE	-	×	

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.

4. Initial assessment of ecological risk

With regard to acute toxicity, a 72-hour median effective concentration (EC₅₀) for growth inhibition of green algae *Chlorella pyrenoidosa* was 22,000 μg/L, a 48-hour EC₅₀ for immobilization of crustacea *Daphnia magna* was 5,400 μg/L, a 96-hour median lethal concentration (LC₅₀) for fish (guppy) *Poecilia reticulata* was 29,000 μg/L, and a 96-hour LC₅₀ for mortality and behavior of *Xenopus laevis* was 3,400 μg/L. Based on these reliable acute toxicity data, a predicted no effect concentration (PNEC) based on acute toxicity was determined to be 54 μg/L with an assessment factor 100. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 4,400 μg/L was found for the algae *C. pyrenoidosa*, and a 21-day NOEC reproduction value of 500 μg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of 5 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 5 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.04 for both freshwater bodies and seawater bodies. Accordingly, further work is thought to be unnecessary at this time.

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	5	Freshwater	<0.2	<0.04	○
					Seawater	<0.2	<0.04	

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	
	Inhalation exposure	Risk cannot be determined. However, there would be little necessity of collecting information.	()
Ecological risk	No need for further work.		○

[Risk judgments] : No need for further work : Requiring information collection
 : Candidates for further work × : Impossibility of risk characterization
 () : Though a risk characterization cannot be determined, there would be little necessity of collecting information.
 () : Further information collection would be required for risk characterization.