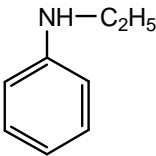


3	CAS No.: 103-69-5	Substance: <i>N</i> -ethylaniline
<p>Chemical Substances Control Law Reference No.: 3-118 (<i>N</i>-alkyl (C2-4) aniline)</p> <p>PRTR Law Cabinet Order No.: 2-10</p> <p style="text-align: center;">Structural Formula:</p> <p>Molecular Formula: C₈H₁₁N</p> <p>Molecular Weight: 121.18</p> <div style="text-align: center;">  </div>		
<p>1. General information</p> <p>The aqueous solubility of this substance is 2.42×10^3 mg/L (25°C) and the partition coefficient (1-octanol/water) (log Kow) is 2.16. The vapor pressure is 0.245 mmHg (= 32.7 Pa) (25°C). 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>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 2 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). The substance is mainly used as a raw material for organic synthesis, azo dyes, major intermediates of triphenylmethane dyes, rubber chemicals, and medicines. The estimated domestic production in FY 2005 was 30 tons, which was categorized as falling within the 10-ton class of total of production and imports under the PRTR Law.</p> <hr/> <p>2. Exposure assessment</p> <p>As <i>N</i>-ethylaniline 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), release and transfer quantities could not 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>The highest predicted inhalation exposure concentration for human beings is determined to be approximately less than $0.13 \mu\text{g}/\text{m}^3$ from the ambient air data of FY 1990, in which production was estimated to be larger than that at present. The highest oral predicted exposure was calculated to be approximately $0.00036 \mu\text{g}/\text{kg}/\text{day}$ based on groundwater data. The risk of exposure to this substance through food in environmental media is considered to be low.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be less than $0.001 \mu\text{g}/\text{L}$ for both freshwater and seawater public water bodies.</p> <hr/> <p>3. Initial assessment of health risk</p> <p>This substance is irritating to the eyes and the skin, and may cause effects on blood, resulting in formation of methemoglobin. Contact with eyes or skin may cause their redness and pain. The inhalation or ingestion of the substance may result in blue lips or finger nails, blue skin, confusion, convulsions, dizziness, headache, nausea and unconsciousness. Additionally, by ingestion, it may cause weakness. Exposure of the skin to this substance 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 no observed adverse effect level (NOAEL) of $1 \text{ mg}/\text{kg}/\text{day}$ (anemia and extramedullary hematopoiesis) was obtained for oral exposure from the medium- and long-term toxicity testing for rats. The NOAEL was divided by 10,</p>		

because of the experimental period being short, and a value of 0.1 mg/kg/day was derived as the ‘Non-toxic level*’. For inhalation exposure, the ‘Non-toxic level*’ could not be estimated.

With regard to oral exposure, in case of intakes of groundwater, the predicted maximum exposure was approximately 0.00036 µg/kg/day. The margin of exposure (MOE) of 28,000 was derived from the ‘Non-toxic level*’ of 0.1 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 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 0.3 mg/m³. The MOE determined from this figure and the predicted maximum exposure concentration of the ambient air is exceeding 230.

The substance is listed as a potential hazardous air pollutant. However, the substance has relatively low production volume, and the half-life of it in the atmosphere was estimated 1.3-13 hrs. The substance released into the atmosphere was estimated to distribute mostly into the media other than the atmosphere. Even in the past when the production volume of the substance was higher, it was not detected in the ambient air. Accordingly, there would be little 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	MOE			
Oral	‘ Non-toxic level*’ 0.1 mg/kg/day	Rats	anemia and extramedullary hematopoiesis	Drinking water	- µg/kg/day	MOE	-	×	
				Groundwater	0.00036 µg/kg/day	MOE	28,000		
Inhalation	‘ Non-toxic level*’ - mg/m ³	-	-	Ambient air	< 0.13 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, reliable information of a 72-hour median effective concentration (EC₅₀) growth inhibition value of 33,200 µg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC₅₀ immobilization value of 4,340 µg/L was found for the crustacea *Daphnia magna* (water flea), a 48-hour median tolerance limit (TLm) value of 33,000 µg/L at death was found for *Oryzias latipes* (medaka), and a 24-hour EC₅₀ growth inhibition value of 160,000 µg/L was found for the other organism *Tetrahymena pyriformis* (tetrahymena). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) of 43 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 3,550 µg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 540 µg/L was found for the crustacea *D. magna*. Thus, an assessment factor of 100 was used, and a PNEC value of 5.4 µg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 5.4 µg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.0002 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	5.4	Freshwater	<0.001	<0.0002	○
					Seawater	<0.001		

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	
	Inhalation exposure	Risk cannot be identified. 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.