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Substance: Ethylenimine

Chemical Substances Control Law Reference No.: 5-2

PRTR Law Cabinet Order No.: 1-55

Molecular Formula: C₂H₅N Structu

Molecular Weight: 43.07

Structural Formula:

1. General information

This substance is freely miscible with water, the partition coefficient (1-octanol/water) (log K_{ow}) is -0.36, and the vapor pressure is 217 mmHg (=2.89×10⁴ Pa) (25°C). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of less than 20%. Its half-life for hydrolysis is 154 d.

This substance is designated as 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 mainly used as a raw material for agricultural chemicals and polyethyleneimine. Polyethyleneimine is used in various fields including paper making and converting, adhesives, textiles, and water purification, where it is used as a flocculant, anti-static agent, and chelating agent. The production and import quantity in fiscal 2011 was not disclosed because the number of reporting businesses was not more than two. The production and import category under the PRTR Law is more than 100 t.

2. Exposure assessment

Total release to the environment in fiscal 2011 under the PRTR Law was 0 t. Quantities of release and transfer to sewage under the PRTR Law could not be obtained. Predictions of proportions distributed to individual media by using a Mackay-type level III fugacity model indicated that if equal quantities were released to the atmosphere, water bodies, and soil, the proportions distributed to water bodies and soil were greater.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around less than 0.0027 μ g/m³. The maximum expected oral exposure was estimated to be generally less than 0.00016 μ g/kg/day on the basis of calculations from data for public freshwater bodies. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on this substance's physicochemical properties.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was generally less than 0.004 μ g/L for both public freshwater bodies and seawater.

3. Initial assessment of health risk

This substance is corrosive and may affect the central nervous system, kidney and liver. Inhalation exposure to the substance may cause coughing, dizziness, headache, labored breathing, nausea and vomiting, and may possibly cause pulmonary edema, while oral ingestion may cause, in addition to these symptoms, abdominal pain, burning sensation, vomiting, shock or collapse. Contact of the substance with skin may cause redness, skin burns and blisters, while contact with eyes may cause redness, pain and severe burns.

As sufficient information was not available to evaluate potential hazards of the substance, its potential health risk could not be assessed, and the hazard index for its oral exposure nor inhalation exposure could not be determined.

In addition, the excess incidence rate for tumor, for the predicted maximum exposure concentration (below about 0.00016 μ g/kg/day), was calculated to be below 1.4×10^{-7} from a slope factor of 8.9×10^{-1} (mg/kg/day)⁻¹ obtained from the oral exposure experiments on B6C3F₁ mice to the substance. As exposure to the substance in the environment

through food intakes would be limited, the excess incidence rate would not change significantly even when this exposure is included. Therefore, collection of information would not be required to assess health risk from oral exposure to the substance.

Additionally, if 100 % absorption were assumed, the predicted maximum exposure level for inhalation exposure to the substance would be converted to $0.00081 \,\mu\text{g/kg/day}$ for oral exposure. The excess incidence rate for tumor would be below 7×10^{-7} from the predicted maximum exposure level and the slope factor. Therefore, collection of further information would not be required at this moment to assess health risk from inhalation exposure to the substance in the ambient air.

		Toxicity		Ех	Exposure assessment					
Exposure Path Criteria for risk assessment Animal Criteria for diagnoses (endpoint) Exposure medium		Exposure medium	Predicted maximum exposure dose and concentration	Result of risk assessment		Judgme nt				
	Oral	'Non-toxic - mg/kg/day	-	-	Drinking water	- μg/kg/day	MOE	-	×	
	Oral	level*'			Freshwater	<0.00016 µg/kg/day	MOE	-	×	()
	Inhalation	'Non-toxic - mg/m ³	-	-	Ambient air	<0.0027 μ g/m ³	MOE	-	×	()
		level*'			Indoor air	- μg/m ³	MOE	-	×	×

Non-toxic level *

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

• 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, the following reliable data were obtained: a 24-h EC₅₀ of 14,000 μ g/L for immobilization in the crustacean *Daphnia magna*. Accordingly, based on this acute toxicity value and an assessment factor of 1,000, a predicted no effect concentration (PNEC) of 14 μ g/L was obtained.

The value of $14 \mu g/L$ obtained from the acute toxicity to the crustacean was used as the PNEC for this substance because reliable chronic toxicity data could not be obtained.

The PEC/PNEC ratio was less than 0.0003 for both freshwater bodies and seawater. Accordingly, further work is considered unnecessary at this time.

	Hazard asses	sment (basi	is for PNEC)	_	Predicted no effect	Exposure assessment			Judgment	
	Species	Acute/ chronic	Endpoint	Assessment factor	concentration PNEC (µg/L)	Water body	Predicted environmental concentration PEC (µg/L)	PEC/PNEC ratio	based on PEC/PNEC ratio	Assessment result
	Crustacean	A outo	EC ₅₀	1.000	14	Freshwater	<0.004	< 0.0003		
I	Daphnia magna	Acute	immobilization	1,000	14	Seawater	< 0.004	< 0.0003		

5. Conclusions

	Conclusions			
Health risk	Oral exposure)
Health HSK	Inhalation exposure	Although risk to human health could not be confirmed, collection of further information would not be required.	()
Ecological risk	No need of further work at present.			

[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			
collecting information.				
() : Further information collection would be required for risk characterization.				