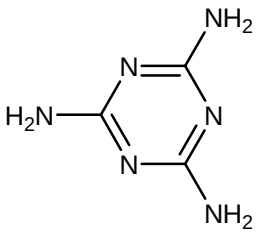
14	CAS No.: 108-78-1	Substance: Melamine

Chemical Substances Control Law Reference No.: 5-1024

PRTR Law Cabinet Order No.:

Molecular Formula: $C_3H_6N_6$ Structural formula:

Molecular Weight: 126.12



1. General information

The aqueous solubility of this substance is 3.23×10^3 mg/1,000 g (20°C), the partition coefficient (1-octanol/water) (log K_{ow}) is –1.37, and the vapor pressure is 3.59×10^{-10} mmHg (=4.79×10^{-8} Pa) (20°C) (extrapolated value). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is thought to be nonexistent or low. Furthermore, the substance does not have any hydrolyzable groups.

The main use of this substance is as a raw material for melamine resin. Melamine resin is used as an adhesive, coating material, molding material, for decorative laminates, for textile and paper processing, and as a raw material for specialized pharmaceuticals. The production, export and import quantities for this substance in 2009 were 62,946 t, 33,871 t and 3,252 t, respectively.

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2. Exposure assessment

Because this substance 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. Predictions of distribution by medium 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 soil and water bodies would be greater.

Data for setting the predicted maximum exposure to humans via inhalation could not be obtained. Further, albeit past data, general environmental atmospheric data indicated a concentration of around 0.044 μg/m^3.

The predicted maximum oral exposure was estimated to be around 0.008 μg/kg/day, based on calculations from data for groundwater and around 0.41 μg/kg/day based on calculations from data for public freshwater. The predicted maximum oral exposure for this substance was estimated to be around 0.41 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight based on estimates of oral exposure using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was about 10.33 μg/L for freshwater bodies and about 0.25 μg/L for seawater, albeit based on past data.

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3. Initial assessment of health risk

There was no information available on acute toxicity of this substance to humans. However, lacrimation, dyspnea, intermittent tremors and coma have been reported as signs of toxicity exhibited by mice following lethal doses administered. Vasodilation in the tail and ears and paralysis of the forequarters have also been reported.

As sufficient information was not available on the carcinogenicity of the substance, an initial assessment was conducted on the basis of information on its non-carcinogenic effects.

With regard to oral exposure to the substance, a $BMDL_{10}$ of 35 mg/kg/day (for formation of stones in urinary

bladders observed) obtained from mid-term and long-term toxicity tests in rats was divided by 2 due to the limited requirement to take into account the short test periods. 18 mg/kg/day derived was deemed as a plausible value for the lowest dose of the substance and was identified as its 'non-toxic level*'. As for inhalation exposure to the substance, its 'non-toxic level*' could not be identified.

As for oral exposure, when intakes of freshwater were assumed, the predicted maximum exposure was approximately 0.41 µg/kg/day. When it was combined with the 'non-toxic level*' of 18 mg/kg/day divided by 10 due to the need to convert the 'non-toxic level*' obtained from the animal experiments to a human equivalent dose, a MOE of 4,400 was derived. Measurements of the concentrations in fish indicated that exposure to the substance through food intakes from the environment would be limited. Even when this exposure was included, considerable changes in the MOE would not be likely. No further action would be required at the moment to assess health risk from inhalation exposure to this substance in the ambient air. Intentional mixing of the substance into diary products and feedstuff became a topic of discussion overseas, and a re-assessment is under way in such countries. In Japan, following inspection orders issued on imported dairy products, contaminant monitoring has been conducted. When the contaminant is detected, they will be disposed of or voluntarily recalled. Food Safety Commission is organising scientific findings on the substance. The contaminant in daily products and feedstuff needs to be kept a vigilant eye on.

With regard to inhalation exposure to the substance, the absence of information available on 'non-toxic levels*' and exposure concentrations did not allow for a health risk assessment. For reference, however, its 'non-toxic level*' for oral exposure, if 100% absorption were assumed, would be equivalent to its 'non-toxic level*' of 60 mg/m^3 for inhalation exposure. When combined with the maximum concentration of approximately 0.044 µg/m^3 in the ambient air reported previously, the MOE derived would be 140,000. Historical production trends in recent years were not indicative of considerable increases in the concentrations in the environment since the last report, and, thus, remarkable changes in the MOE would not be likely. Therefore, information of collection would not be required to assess health risk from inhalation exposure to this substance in the ambient air.

Information of toxicity				Exposure assessment			Result of risk Exposure 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 * ' 18 mg/kg/day	Rats	Formation urinary bladder stones	Drinking water	– µg/kg/day		MOE	–	×	(▲)
				Freshwater	0.41 µg/kg/day		MOE	4,400	○	
Inhalation	'Non-toxic level * ' – mg/m^3	–	–	Ambient air	– 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.

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4. Initial assessment of ecological risk

A PNEC value could not be set for this substance because toxicity data applicable for an initial assessment could not be obtained. Accordingly, a judgment could not be made regarding ecological risk.

If for example the minimum value for chronic toxicity in crustaceans of 18,000 µg/L obtained from OECD SIAR is divided by an assessment coefficient of 10, a provisional PNEC value of 1,800 µg/L is obtained. Based on a comparison of this value with the predicted environmental concentration (PEC), the ecological risk of this substance is thought to be sufficiently low. Accordingly, the need to collect further data for initial assessment of the ecological risk towards aquatic organisms is considered to be minimal.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	End point			Water body	Predicted environmental concentration PEC (μg/L)			
–	–	–	–	–	Freshwater	10.33	–	×	○
					Seawater	0.25	–		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Further information collection would be required for risk characterization.	(▲)
	Inhalation exposure	Though a risk characterization cannot be determined, there would be little necessity of collecting information.	(○)
Ecological risk	Need to collect further data regarding initial assessment of ecological risk towards aquatic organisms considered minimal.		○

［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.