15	CAS No.: 5124-30-1	Substance: Methylenebis (4,1-cyclohexylene) diisocyanate

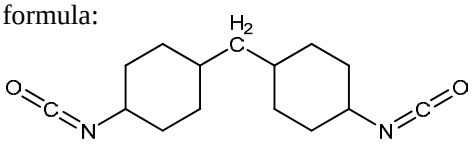
Chemical Substances Control Law Reference No.: 4-119（dicyclohexylmethane diisocyanate）

PRTR Law Cabinet Order No.*: 1-447

Molecular Formula: $C_{15}H_{22}N_2O_2$

Molecular Weight: 262.35

Structural formula:



Note: No. in Revised Cabinet Order enacted on October 1, 2009

1. General information

The vapor pressure of this substance is 1.60×10^{-5} mmHg (=2.13×10^{-3} Pa) (25°C), and the hydrolysis half-life is approximately 2 hours (23°C). This substance is judged not to be readily biodegradable.

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). The main use is as a key raw material for polyurethane. The production (shipments) and import quantity of dicyclohexylmethane diisocyanate in FY 2007 was 1,000 to <10,000 t/y. The production and import category under the PRTR Law is more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2009 under the PRTR Law was 4.9 t, of which 4.9 t or almost all releases were reported. All reported releases were released to the atmosphere. In addition, 11 t was transferred to waste materials. The main sources of reported releases were the general tools and machinery manufacturing industry and the metal products manufacturing industry. The largest release among releases to the environment including unreported ones was to the atmosphere. A prediction of distribution by individual medium was not carried out because the physicochemical properties required for predicting these distribution proportions were lacking.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was around less than 0.00031 μg/m^3. Meanwhile, the mean value of atmospheric concentration estimated from reported releases to the atmosphere under the PRTR Law was a maximum of 1.0 μg/m^3. Data for calculating the predicted maximum oral exposure could not be obtained. The likelihood of exposure to this substance by intake from an environmental medium is considered nonexistent for normal activities when taking into consideration the high hydrolyzability of this substance, PRTR data, etc.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be set because water quality data could not be obtained. Taking into consideration the high hydrolyzability of this substance and PRTR data, etc., the likelihood of exposure to aqueous organisms for this substance from water is considered nonexistent.

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3. Initial assessment of health risk

This substance is irritating to respiratory tracts, skin and eyes.

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

As for oral exposure to the substance, its ‘non-toxic level*’ could not be identified. As for inhalation exposure to the substance, a NOAEL of 1.1 mg/m^3 (for symptoms such as inflammatory changes in respiratory tract) was obtained from mid- and long-term toxicity tests on rats. It was then adjusted to 0.2 mg/m^3 against exposure conditions, and divided by 10 due to their short test periods. Final outcome of 0.02 mg/m^3 was deemed to be the lowest reliable concentration of the substance without any effect and was identified as its ‘non-toxic level*’.

As for oral exposure, lack of available information on its ‘non-toxic levels*’ and exposure concentrations did not

allow its health risk assessment. When its high hydrolyzability and PRTR data are considered, oral exposure to the substance through environmental media is not likely in daily activities of humans. Therefore, collection of information on its oral exposure would not be required to assess health risk from its oral exposure.

As for its inhalation exposure, its mean exposure concentration and the predicted maximum exposure concentration would be less than around 0.00031 μg/m^3 when concentrations in the ambient air were considered. The MOE would be more than 6,500 when calculated from the 'non-toxic level*' of 0.02 mg/m^3 and the predicted maximum exposure concentration, and divided by 10 for conversion of the 'non-toxic level*' from animal experiments to an equivalent concentration for humans. For reference, its releases to the ambient air reported in FY2009 under the PRTR Law suggests that its maximum annual mean concentration in the ambient air around its major sources of emissions would be 1.0 μg/m^3 and associated MOE would be 2. Therefore, collection of information would be required to assess health risk from inhalation exposure to this substance in the ambient air. As a part of such effort, it is desirable to measure its concentrations in the ambient air around its major sources of emissions.

Toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration					
Oral	Non-toxic level * ' — mg/kg/day	—	—	Drinking water	—	μg/kg/day	MOE	—	×	(○)
				Groundwater	—	μg/kg/day	MOE	—	×	
Inhalation	Non-toxic level * ' 0.02 mg/m^3	Rats	Inflammatory changes in respiratory tract, etc.	Ambient air	<0.00031	μg/m^3	MOE	> 6,500	○	(▲)
				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

This substance is used as a key raw material for polyurethane. Total release to the environment of this substance from disclosures through the PRTR Law was 4.9 t, and all 4.9 t was released to the atmosphere. However, the likelihood of detecting this substance released to the atmosphere in public water bodies is considered nonexistent when taking into account its high hydrolyzability (half-life is approximately 2 h) and measured values in the general environmental atmosphere. While releases to the environment from the transfer of this substance contained in waste materials transported from sites handling it (11 t) are unclear, its high hydrolyzability (half-life is approximately 2 h) means that for normal activities, the likelihood of exposure to this substance from water for aqueous organisms is considered nonexistent.

In addition, the toxicity value for this substance obtained from toxicity test findings for aqueous organisms is thought to indicate the toxicity of its hydrolysis products, and not reflect the actual toxicity of the substance.

Accordingly, an initial assessment of ecological risk to aqueous organisms for this substance was not conducted. An another evaluation of the need for an initial assessment of the ecological risk of this substance's hydrolysis products is considered necessary.

5.Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Though a risk characterization cannot be determined, there would be little necessity of collecting information.	(○)
	Inhalation exposure	Further information collection would be required for risk characterization.	(▲)
Ecological risk	Initial assessment of ecological risk to aqueous organisms for this substance was not carried out. Another evaluation of the need for an initial assessment of ecological risk of substance's hydrolysis products considered necessary.		(—)

［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.