

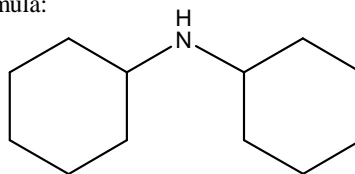
Chemical Substances Control Law Reference No.: 3-2259 and 3-2686

PRTR Law Cabinet Order No.:

Molecular Formula: C₁₂H₂₃N

Molecular Weight: 181.32

Structural Formula:



1. General information

The aqueous solubility of this substance is 800 mg/L (25°C) and the partition coefficient (1-octanol/water) (log Kow) is 4.4 (calculated value). The vapor pressure is 0.0338 mmHg (= 4.5 Pa) (25°C). This substance is determined to be ready biodegradable.

It is mainly used for anticorrosives, rubber chemicals, surfactants, and dyes. The totals of production (shipment) and imports in FY 2001 and FY 2004 both were 1,000 to less than 10,000 tons.

2. Exposure assessment

As dicyclohexylamine 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 and water.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. The highest estimated oral exposure was calculated at approximately 0.008 µg/kg/day to less than 0.2 µg/kg/day based on data regarding freshwater bodies and food.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be 0.2 µg/L for freshwater and generally 0.03 µg/L for seawater public water bodies.

3. Initial assessment of health risk

The substance is corrosive to the eyes, the skin and the respiratory tract. Inhalation of vapor of the substance may cause lung oedema. By inhalation, it may cause sore throat, cough, burning sensation, shortness of breath and laboured breathing. By ingestion, it may cause burning sensation, abdominal pain and shock or collapse. Contact with eyes or skin may cause their pain, redness and burns.

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.

A no observed adverse effect level (NOAEL) of 20 mg/kg/day (salivation and convulsion) was obtained for oral from the medium- and long-term toxicity testing for rats. The NOAEL was divided by 10, because of the experimental period being short, and a value of 2 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 freshwater in the public water bodies and food, the predicted maximum exposure ranged approximately from 0.008µg/kg/day to 0.2 µg/kg/day. The margin of exposure (MOE) of 1,000-25,000 was derived from the 'Non-toxic level*' of 2 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. 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*' was not determined, and the exposure concentrations

were not estimated, its health risk could not be identified.

The half-life of the substance in the atmosphere was estimated to be 0.49 - 4.9 hrs, and in case of releasing the substance into the atmosphere, it was estimated to distribute almost only into the atmosphere. Additionally, the discharge of the substance has not been surveyed. Accordingly, it is likely that it is required to examine the need to collect 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 | | | | |
| Oral | 'Non-toxic level' 2 mg/kg/day | Rats | Salivation, convulsion | Drinking water, Food | - μg/kg/day | MOE | - | × | × |
| | | | | Freshwater, Food | 0.008 ~ 0.2 μg/kg/day | MOE | 1,000 ~ 25,000 | | |
| 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.

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 exceeding 19,400 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC₅₀ immobilization value of 8,000 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour median lethal concentration (LC₅₀) value of 12,000 μg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) of 80 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 2,030 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 49 μg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of 0.49 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 0.49 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was 0.4 for freshwater bodies and 0.06 for seawater bodies. Accordingly, efforts to gather information are thought to be needed. The substance should be required to undergo a more accurate investigation regarding changes of production, imports, and use, and if necessary, collection of further data on ecological effects and environmental concentrations should be considered.

| 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 | 0.49 | Freshwater | 0.2 | 0.4 | ▲ |
| | | | | | Seawater | 0.03 | 0.06 | |

5. Conclusions

| Conclusions | | | Judgment |
|-------------|---------------------|--|----------|
| Health risk | Oral exposure | No need for further work. | |
| | Inhalation exposure | Risk cannot be identified, but it needs to be considered for the ambient air whether collection of information is required or not. | () |

| | | | |
|--|---|---|--|
| Ecological risk | Efforts to gather information are thought to be needed. A more accurate investigation regarding changes of production, imports and use is required, and if necessary, collection of further data on ecological effects and environmental concentrations should be considered. | ▲ | |
| <p>[Risk judgments] ○: No need for further work ▲: Requiring information collection</p> <p> ■: Candidates for further work ×: Impossibility of risk characterization</p> <p> () : Though a risk characterization cannot be determined, there would be little necessity of collecting information.</p> <p> () : Further information collection would be required for risk characterization.</p> | | | |