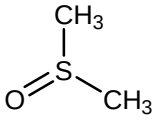
6	CAS No: 67-68-5	Substance: Dimethyl sulfoxide

Chemical Substances Control Law Reference No.: 2-1553

PRTR Law Cabinet Order:

Molecular Formula: C_2H_6OS Structural Formula:

Molecular Weight: 78.13



1. General information

The aqueous solubility of this substance is 2.53×10^5 mg/1000g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is -1.35, and the vapor pressure is 0.63 mmHg (= 84 Pa) (25°C). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 3.1% and bioaccumulation is judged to be non-existent or low. The substance does not have any hydrolyzable groups.

The main uses of this substance are in the synthesis of acrylic fiber, pharmaceuticals, and agricultural chemicals, as well as in the treatment of dyestuff and pigment solvents; paint removers and detergents, and membranes. The production and import quantity in fiscal 2012 was 10,000 t.

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2. Exposure assessment

Because this substance is not classified 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), release and transfer quantities 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 proportion distributed to water bodies and soil would be largest.

The maximum expected concentration of exposure to humans via inhalation, based on ambient air, was around 0.032 μg/m^3. The maximum expected oral exposure could not be obtained. However, albeit past data, the maximum expected oral exposure calculated from groundwater data was around less than 2.4 μg/kg/day. The exposure level to this substance by intake from an environmental medium via food is considered slight, based on its low bioaccumulation.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. However, albeit past data, the concentration in public freshwater bodies was around less than 60 μg/L for freshwater bodies and around 310 μg/L for seawater. Although the measurement results for public water freshwater bodies and seawater are data from more than ten years ago, the likelihood of a significant increase in these concentrations is considered low even when production quantity transfers and existence in nature are considered.

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3. Initial assessment of health risk

This substance may cause irritation to the eyes and skin and for high exposure, decrease of consciousness may occur. When inhaled, headache and nausea may occur, while nausea, vomiting and lethargy may occur when ingested. Contact of the substance with the eyes may cause redness and blurred vision. Contact with the skin may cause dry skin and may possibly cause vomiting if the substance is absorbed.

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

With regard to the oral exposure to the substance, the LOAEL of 1,100 mg/kg/day (based on inhibition of body weight gain), resulted from mid-term and long-term toxicity tests on rats, was adjusted according to the test

conditions to obtain the exposure of 786 mg/kg/day, and divided by a factor of 10 for the use as a LOAEL. The outcome of 79 mg/kg/day was considered to be the reliable lowest dose of the substance and was identified as its 'non-toxic level*'. As for the inhalation exposure, the NOAEL of 954 mg/m^3 (based on the degeneration of the nasal cavity mucous membrane) resulting from mid-term and long-term toxicity tests on rats, was adjusted according to the test conditions to obtain the exposure of 240 mg/m^3, and was divided by a factor of 10 due to the short test periods. The outcome of 24 mg/m^3 was considered to be the reliable lowest dose of the substance and was identified as its 'non-toxic level*'.

Regarding the oral exposure to the substance, the absence of information available on exposure concentrations did not allow the health risk assessment. The MOE of 3,300 was derived from the substance's 'non-toxic level*' of 79 mg/kg/day and the oral exposure level of below 2.4 µg/kg/day, calculated from the maximum concentration in groundwater, as reported in 2000, and after the division by a factor of 10 to convert animal data to human data. As exposure to the substance in the environment through diet is limited, the MOE would not change significantly even when this exposure is included. Therefore, collection of further information would not be required to assess the health risk of this substance for the oral exposure.

Concerning the inhalation exposure to the substance, the predicted maximum exposure concentration in ambient air was approximately 0.032 µg/m^3. The MOE of 75,000 was derived from the substance's 'non-toxic level*' of 24 mg/m^3 and the predicted maximum exposure concentration, after the division by a factor of 10 to convert animal data to human data. Therefore, no further action would be required at present to assess the health risk for the inhalation exposure to this substance in ambient air.

Toxicity				Exposure assessment		Risk characterization			Judgment
Exposure Path	Criteria for risk assessment	Animal	Endpoint	Exposure medium	Predicted maximum exposure quantity and concentration				
Oral	'Non-toxic level*' 79 mg/kg/day Slope factor	Rat	Inhibition of body weight gain	Drinking water	– µg/kg/day	MOE	–	×	(○)
				Groundwater	– µg/kg/day	MOE	–	×	
Inhalation	'Non-toxic level*' 24 mg/m^3 Unit risk	Rat	Degeneration of the nasal cavity mucous membrane	Ambient air	0.032 µg/m^3	MOE	75,000	○	○
				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 72-h EC_{50} of 17,000,000 µg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 24-h LC_{50} of 6,830,000 µg/L in the crustacean *Artemia salina* (brine shrimp), a 96-h LC_{50} exceeding 25,000,000 µg/L in the fish species *Danio rerio* (zebrafish), and a 48-h IC_{50} exceeding 11,000,000 µg/L for growth inhibition in the unicellular ciliated protozoans *Paramecium caudatum* and *Paramecium trichium*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 68,000 µg/L was obtained.

The value of 68,000 µg/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 of this substance could not be obtained. As such, a judgment on ecological risk could not be made. Based on past data of around 310 µg/L for public freshwater bodies and seawater, the PEC/PNEC ratio is 0.005. Although the measurement results for public water bodies are data from more than ten years ago, the likelihood

of a significant increase in concentrations is considered low even when production quantity transfers and existence in nature are considered. Accordingly, the need to collect further data on this substance 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	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)			
Crustacean *Artemia salina*	Acute	LC_{50} mortality	100	68,000	Freshwater	-	-	×	○
					Seawater	-	-		

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5. Conclusions

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

［Risk judgments］ ○: No need for further work ▲: Requiring information collection
■: Candidates for further work ×: Impossibility of risk characterization
（○）: Although risk to human health could not be confirmed, collection of further information would not be required.
（▲）: Further information collection would be required for risk characterization.