15	CAS No.: 111-76-2	Substance: 2-butoxyethanol

Chemical Substances Control Law Reference No.: 2-407 (Hydroxyethyl butyl ether) and 2-2424 (Alkylene (C2-8) glycol monoalkyl (C2-8) ether)

PRTR Law Cabinet Order No.:

Molecular Formula: $C_6H_{14}O_2$ Structural Formula:

Molecular Weight: 118.17

1. General information

This substance is freely miscible, and the partition coefficient (1-octanol/water) (log Kow) is 0.81(25°C). The vapor pressure is 0.880 mmHg (= 117 Pa) (25°C). This substance is determinated to be ready biodegradable. But this substance is thought to be one that does not have hydrolyzable groups.

It is mainly used for paints, printing ink, dyes, detergents, brake fluid, solvents for agricultural chemicals, plasticizers, raw materials for agricultural chemicals, penetrants, and softeners. The total of production (shipment) and imports in FY 2001 was 10,000 to less than 100,000 tons/yr, and in FY 2004, 10,000 to less than 100,000 tons/yr as hydroxyethyl butyl ether.

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2. Exposure assessment

As 2-butoxyethanol 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), no information on release and transfer quantities could 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.

Based on data for the ambient air, the predicted maximum exposure concentration for inhalation exposure to human beings was approximately 0.30 μg/m^3. In addition, the highest predicted level for indoor air was calculated at 34 μg/m^3 based on reliable data. The highest oral predicted exposure was calculated to be approximately 0.0032 μg/kg/day based on groundwater data. The risk of exposure to this substance through food in environmental media is considered to be low.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be approximately 0.71 μg/L for freshwater and less than 0.08 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

The substance is irritating to the eyes, the skin and the respiratory tract. The substance may cause effects on the central nervous system, blood, kidneys, and liver. By inhalation or ingestion, it may cause cough, dizziness, drowsiness, headache, nausea and weakness. Additionally, by ingestion, it may cause abdominal pain, diarrhea, nausea and vomiting. The substance absorbed into the body through the skin may cause the similar symptoms. Contact with the eyes may cause redness, pain and blurred vision. The lethal dose lowest (LDL_0) for humans of 143 mg/kg, toxic dose lowest (TDL_0) of 600 mg/kg or 7.8 mL/kg (coma, metabolic acidosis), and toxic concentration lowest (TCL_0) of 940 mg/m^3 or 1,500 mg/m^3 (nausea,vomiting, eye irritation) have been reported.

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 lowest-observed-adverse-effect-level (LOAEL) of 69 mg/kg/day (degeneration of hepatic cells) was obtained for oral exposure from the medium- and long-term toxicity testing for rats. As this was a LOAEL, it was divided by 10, and because of the short experimental period, the value was further divided by 10, and a value of 0.69 mg/kg/day was

derived as the 'Non-toxic level*'.

A lowest-observed-adverse-effect-level (LOAEL) of 62.5 ppm (hyperplasia and ulcer in forestomach) was obtained for inhalation exposure from the medium- and long-term toxicity testing for mice. The LOAEL was adjusted to 11 ppm (53 mg/m^3) taking into account the exposuresituations. As this was a LOAEL, it was divided by 10, and a value of 1.1 ppm (5.3 mg/m^3) was derived as the 'Non-toxic level*'.

With regard to oral exposure, in case of intakes of groundwater, the predicted maximum exposure was approximately less than 0.0032 μg/kg/day. The margin of exposure (MOE) of exceeding 22,000 was derived from the 'Non-toxic level*' of 0.69 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. As the exposure to this substance through food intakes was estimated minor, even when the exposure through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For inhalation exposure to this substance in the ambient air, the predicted maximum exposure concentration was approximately 0.30 μg/m^3. The MOE of 1,800 was derived from the 'Non-toxic level*' of 5.3 mg/m^3 divided by the predicted maximum exposure concentration, and divided by 10 because the 'Non-toxic level*' was established by means of animal testing.

For inhalation exposure to this substance in the indoor air, the predicted maximum exposure concentration was 34 μg/m^3. Accordingly, from the 'Non-toxic level*' of 5.3 mg/m^3 and the predicted maximum exposure concentration, the MOE of 16 was determined.

Therefore, it would not be required at present further action for assessment of its health risk from inhalation exposure to this substance in the ambient air. On the other hand, it would be required to collect information on inhalation exposure to this substance in the indoor air 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*' 0.69 mg/kg/day	rats	degeneration of hepatic cells	Drinking water	— μg/kg/day	MOE	—	×	○
				Groundwater	< 0.0032 μg/kg/day	MOE	> 22,000	○	
Inhalation	'Non-toxic level*' 5.3 mg/m^3	mice	hyperplasia and ulcer in forestomach	Ambient air	0.30 μg/m^3	MOE	1,800	○	○
				Indoor air	34 μg/m^3	MOE	16	▲	▲

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

With regard to acute toxicity, reliable information of a 72-hour median effective concentration (EC_{50}) growth inhibition value exceeding 1,000,000 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value exceeding 1,000,000 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour median lethal concentration (LC_{50}) value exceeding 100,000 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) exceeding 1,000 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 125,000 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of more than 100,000 μg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of more than 1,000 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of more than 1,000

μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.0007 for freshwater bodies and less than 0.00008 for seawater bodies. Accordingly, further work is thought to be unnecessary at this time.

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	≧1,000	Freshwater	0.71	≦0.0007	○
					Seawater	<0.08	<0.00008	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	For the ambient air, further action would not be required at the moment. For the indoor air, it would be required to collect information.	▲
Ecological risk	No need for further work.		○

［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.