5	CAS No.: －	Substance: Dibutyltin Compounds

Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.*: 1-239 (organic tin compounds)

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

1. General information

Dibutyltin compounds is a generic term for compounds in which two butyl groups are covalently bonded to a tin atom. They include dibutyltin dilaurate (DBTL) and dibutyltin oxide (DBTO).

The water solubility of DBTL is 3 mg/L (20°C), its partition coefficient (1-octanol/water) (log K_{ow}) is 3.12, and the vapor pressure of DBTO is 3×10^{-8} mmHg ($=4\times10^{-6}$Pa) (25°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 50% (DBTL) and 0% (DBTO), and bioaccumulation is thought to be nonexistent or low for both DBTL and DBTO.

Organic tin compounds are designated as Class 1 Designated Chemical Substances 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 uses of DBTL are as a polyvinyl chloride resin stabilizer, lubricant, and urethane curing catalyst, while for DBTO the main uses are polyvinyl chloride resin stabilizer raw materials and catalysts. The production (shipments) and import quantity in fiscal 2007 for dibutyltin dialiphatic monocarboxylic acid (C2–31) salts was 10 to <100 t/y.

---

2. Exposure assessment

Total release of organic tin compounds to the environment in fiscal 2007 under the PRTR Law was 10 t, of which 8.4 t or 87% of overall releases was reported. Among reported release destinations, the atmosphere was the largest. In addition 64 t was transferred to waste materials. Industry types with large reported releases were the ceramics and soil and stone product manufacturing industry for the atmosphere, and the transportation equipment manufacturing industry and the chemical industry for public water bodies. 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 could not be set because general environmental atmosphere and indoor air data could not be obtained. The predicted maximum oral exposure was estimated to be 0.035 μg/kg/day based on calculations from data for public freshwater bodies and food. Because these compounds were detected in food groups other than seafood, food data is assumed to include migration of dibutyltin compounds used in plastics (polyvinyl chloride containers, gloves, etc.) and cooking sheets to food.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 0.035 μg/L for public freshwater bodies and around 0.17 μg/L for seawater. Furthermore, both the predicted maximum exposure and the predicted environmental concentration (PEC) are the values for dibutyltin dichloride.

---

3. Initial assessment of health risk

Dibutyltin oxide (DBTO) is irritating to eyes, skin and respiratory tracts. It may influence the central nervous system to cause its dysfunction, which eventually may lead to death. When inhaled or orally taken, it will cause headache, tinnitus, amnesia or disorientation. When taken into eyes, they will be red with pain. When attached to skin, in addition to thermal injury and pain, absorption of this substance may cause symptoms such as headache or tinnitus. Dibutyltin dilaurate (DBTL) is irritating to eyes, and when taken into eyes, they will be red. Dibutyltin diacetate (DBTA), dibutyltin dilaurate (DBTL), dibutyltin malate (DBTM), dibutyltin oxide (DBTO), when their saturated solution was applied only once to back of hands of volunteers, did not cause irritation, but in the case of dibutyltin dichloride (DBTC), it was tested positive

for chemical burns.

Sufficient information could not be obtained on its carcinogenicity, and its initial assessment was conducted on the basis of data on its non-carcinogenic effects.

As for its oral exposure, its LOAEL of 2.5 mg/kg/day (for effects on immunological reactions) obtained from mid-term and long-term toxicity tests for rats with dibutyltin dichloride (DBTC) was divided by 10 due to their short test periods, and divided by 10 again as is always the case with LOAEL, to provide 0.025 mg/kg/day as its 'non-toxic level*'. For inhalation exposure, its 'non-toxic level*' could not be established.

As for its oral exposure, its maximum exposure was estimated to be around 0.035 μg/kg/day, when intakes of freshwater from public water supply were assumed. Its margin of exposure (MOE) would be 71, when calculated from its 'non-toxic level*' of 0.025 mg/kg/day and its estimated maximum exposure, and then divided by 10 due to the fact that the 'non-toxic level*' was obtained from animal experiments. Collection of information would be required on health risk from oral exposure to this substance. Dibutyltin compounds are used as stabilizers in containers and packages made of polyvinyl chloride, and they are used as condensation catalysts for parchment paper made from silicon resin. Total diet studies detected them in various food including processed food products, and this would be attributed to their transfer from containers or packages to food. Further self-regulation would reduce their intakes from processed food products.

As for inhalation exposure to this substance, its 'non-toxic level*' was not identified and its exposure concentration was not understood, so its health risk could not be assessed. In FY2007, total release of organotin compounds, including dibutyltin compounds, to the environment was about 10 t, and nearly all of this would be emitted to the atmosphere. When it is considered that dibutyltin compounds are produced by degradation of tributyltin compounds, collection of information on its inhalation exposure to assess health risk associated with its inhalation exposure in the ambient air would be required.

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*' 0.025 mg/kg/day	Rats	effects on immunological reactions	Drinking water	— μg/kg/da	MOE	—	×	▲
				Freshwater, food	0.035 μg/kg/day	MOE	71	▲	
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.

Note: Estimated maximum exposure (concentration) and 'non-toxic level' are presented as those for dibutyltin dichloride.

---

4. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h median effective concentration (EC_{50}) of 30 μg/L for growth inhibition in the diatom *Skeletonema costatum*; a 48-h EC_{50} of 17 μg/L for swimming inhibition in the crustacean *Daphnia magna*; and a 48-h median lethal concentration (LC_{50}) of 980 μg/L for the fish species *Oryzias latipes* (medaka). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.17 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h no observed effect concentration (NOEC) of 90.3 μg/L for growth inhibition in the green algae *Desmodesmus subspicatus*; a 21-d NOEC of 15 μg/L for reproductive inhibition in the crustacean *D. magna*; a 30-d NOEC of 450 μg/L for F0-generation growth inhibition in the fish species *Cyprinodon variegatus*; and an up to 191-d NOEC of 450 μg/L for F1-generation mortality for the same species. Accordingly, based on these chronic toxicity values and an assessment factor of 10, a predicted no effect

concentration (PNEC) 1.5 μg/L was obtained. The value of 0.17 μg/L obtained from the acute toxicity to the crustacean was used as the PNEC for this substance. All toxicity values were calculated for dibutyltin dichloride (DBTC).

The PEC/PNEC ratio was 0.2 for freshwater bodies and 1 for seawater. For this reason, the substances are considered as candidates for detailed assessment.

Dibutyltin compounds can be hydrolyzed to form dibutyltin oxide (DBTO); however, because the rate at which this occurs varies according to the compound, collecting knowledge regarding behavior in the environment as well as environmental concentrations, and carrying out detailed assessment is considered desirable.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacean *Daphnia magna*	Acute	EC_{50} Swimming inhibition	100	0.17	Freshwater	0.035	0.2	■
					Seawate	0.17	1	

---

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Collection of information required on health risk associated with oral exposure.	▲
	Inhalation exposure	Risk can not be assessed. Collection of information required on health risk associated with inhalation exposure in the ambient air.	(▲)
Ecological risk	Considered as candidates for detailed assessment. These compounds can be hydrolyzed to form dibutyltin oxide (DBTO); however, because the rate at which this occurs varies according to the compound, collecting knowledge regarding behavior in the environment as well as environmental concentrations, and carrying out detailed assessment is considered desirable.		■

[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.