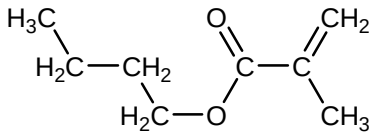
17	CAS No.: 97-88-1	Substance: *n*-Butyl methacrylate

Chemical Substances Control Law Reference No.: 2-1039 (alkyl methacrylates (C=2–20))

PRTR Law Cabinet Order No.: 1-419

Molecular Formula: $C_8H_{14}O_2$ Structural Formula:

Molecular Weight: 142.20



1. General information

The aqueous solubility of this substance is 360 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 2.88, and the vapor pressure is 2.12 mmHg (=283 Pa) (25°C). Biodegradability (aerobic degradation) is judged to be good. Furthermore, the substance is stable towards hydrolysis (pH=4, 7). Its half-life for hydrolysis is 34 d (pH=9, 25°C).

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 uses of this substance are as a raw material for paint-grade resins such as acrylic resins, for resin modifiers, and for photosensitive resins. The production and import quantity in fiscal 2010 as alkyl methacrylates (C=2–20) was 20,000 t. The production and import category under the PRTR Law is more than 100 t.

---

2. Exposure assessment

Total release to the environment in fiscal 2010 under the PRTR Law was approximately 5.9 t, of which approximately 5.8 t or 98% of overall releases were reported. The major destination of reported releases was the atmosphere. In addition, approximately 44 t was transferred to waste materials, and 0.096 t was transferred to sewage. Industry types with large reported releases were the chemical industry and the warehousing industry for the atmosphere, and the chemical industry alone for public water bodies. The largest release among reported releases to the environment including those unreported was to the atmosphere. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall, or to the atmosphere or water bodies in particular, the predicted proportion distributed to water bodies was 87.4%.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.024 μg/m^3. The mean annual value for atmospheric concentration in fiscal 2010 was calculated by using a plume-puff model on the basis of reported releases to the atmosphere according to the PRTR Law; this model predicted a maximum level of 0.32 μg/m^3.

The maximum expected oral exposure was estimated to be around less than 0.00048 μg/kg/day on the basis of calculations from data for public freshwater bodies. However, when reported releases to public freshwater bodies in fiscal 2010 according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers while taking into consideration only dilution gave a maximum value of 0.22 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.0088 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on estimates of oral exposure obtained by using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around less than 0.012 μg/L for both public freshwater bodies and seawater. The maximum river concentration was

estimated to be 0.22 μg/L from reported releases to public freshwater bodies under the PRTR Law.

3.Initial assessment of health risk

This substance may cause irritation to eyes, skin and respiratory tract. Inhalation exposure to the substance may cause coughing, shortness of breath and sore throat, while its oral exposure may cause abdominal pain as well. Contact of the substance with eyes or skin may cause redness and pain.

For carcinogenic potential of the substance, an initial assessment was conducted on the basis of information on its non-carcinogenic effects.

With regard to oral exposure to the substance, a NOAEL of 30 mg/kg/day (for increased spleen weight and atrophy of red pulps of the spleen) obtained from its mid-term and long-term toxicity tests on rats was divided by a factor of 10 due to their short test periods. 3 mg/kg/day was identified to be the reliable lowest dose of the substance as its 'non-toxic level*'. With regard to inhalation exposure to the substance, a NOAEL of 310 ppm (for degenerated olfactory epithelium) obtained from its mid-term and long-term toxicity tests on rats was adjusted for their durations to provide 55 ppm (320 mg/m^3) for its intermittent to continuous exposure. This value was divided by a factor of 10 due to their short test periods, and 32 mg/m^3 was identified to be the reliable lowest dose of the substance as its 'non-toxic level*'.

As for oral exposure to the substance, when intakes of freshwater from public water bodies were assumed, its maximum exposure would be below approximately 0.00048 μg/kg/day. The MOE would be above 630,000 when calculated from its 'non-toxic level*' of 3 mg/kg/day and its maximum exposure concentration predicted from animal experiments, and then divided by a factor of 10 to convert animal data to human. Its maximum exposure level was calculated to be 0.0088 μg/kg/day from its concentrations in river water with effluents from operators discharging it in high concentrations, reported in FY 2010 under the PRTR Law. The MOE would be 34,000 when calculated from this value as its reference. As exposure to the substance in the environment through food intakes would be limited, the MOE would not change significantly even when this exposure was included. Therefore, no further action would be required at this moment to assess health risk from its oral exposure.

With regard to inhalation exposure to the substance, its maximum exposure concentration in the ambient air was predicted to be approximately 0.024 μg/m^3. The MOE would be 130,000 when calculated from its 'non-toxic level*' of 32 mg/m^3 and its maximum exposure concentration predicted from animal tests, and divided by a factor of 10 to convert animal data to human. Its maximum (annual mean) concentration in the ambient air near operators with its emissions in high concentrations was calculated to be 0.32 μg/m^3 from its emissions reported in FY 2010 under the PRTR Law. The MOE, when calculated from this value as its reference, would be 10,000. Therefore, no further action would be required at this moment to assess health risk from its inhalation exposure in the ambient air.

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*' 3 mg/kg/day	Rat	Increased spleen weight, atrophy of red pulps of the spleen	Drinking water	—	μg/kg/day	MOE	—	×	○
				Freshwater	< 0.00048	μg/kg/day	MOE	> 630,000	○	
Inhalation	'Non-toxic level*' 32 mg/m^3	Rat	Degeneration of the olfactory epithelium	Ambient air	0.024	μg/m^3	MOE	130,000	○	○
				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 23,400 µg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 25,400 µg/L for swimming inhibition in the crustacean *Daphnia magna*, a 96-h LC_{50} of 5,570 µg/L for the fish species *Oryzias latipes* (medaka), and a 40-h IGC_{50} of 264,000 µg/L for reproductive inhibition in the ciliate protozoa *Tetrahymena pyriformis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 56 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of less than 5,970 µg/L for growth inhibition in the green alga *P. subcapitata*, a 21-d NOEC of 1,100 µg/L for reproductive inhibition in the crustacean *D. magna*, and a 2-d NOEC of 50,000 µg/L for reproductive inhibition in the marine rotifer *Brachionus calyciflorus*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 11 µg/L was obtained.

The value of 11 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio was less than 0.001 for both freshwater bodies and seawater. The maximum river concentration was estimated to be 0.22 µg/L from reported releases under the PRTR Law, and the ratio of this value to the PNEC is less than 0.1. Accordingly, further work on this substance is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	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 *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	11	Freshwater	<0.012	<0.001	○	○
					Seawater	<0.012	<0.001		

---

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
Ecological risk	No need of further work at present.		○

［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.