22	CAS No.: 50-32-8	Substance: Benzo[a]pyrene

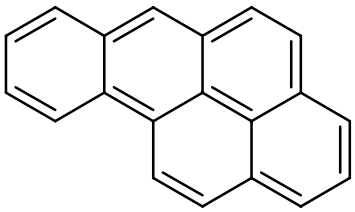
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Structural Formula:

Molecular Formula: $C_{20}H_{12}$

Molecular Weight: 252.32



1. General information

The aqueous solubility of this substance is 1.61×10^{-3} mg/1000g (25°C) and the partition coefficient (1-octanol / water) (log Kow) is 5.97. The vapor pressure is 5.63×10^{-9} mmHg (= 7.51×10^{-7} Pa) (25°C, extrapolated value). The reported half-lives of this substance by the degradability (aerobic degradation) were 875 days (in water area) and 290 days (in soil). There was a report that, in the soil inoculated the isolated bacteria 50-80% of this substance was degraded in 8 days. This substance does not have hydrolyzable groups.

This substance is selected as a substance requiring priority action among Hazardous Air Pollutants. The polycyclic aromatic hydrocarbons (PAHs) containing this substance are produced non-intentionally, and released in the environment. The origins of the release of PAHs in the environment are divided into two, combustion and non-combustion, and more than 90% of the total release is from the combustion. In general, exhaust gas from cars is considered to be the main source in the urban and its suburbs, though approximately 90% of the total release is thought to be from stationary sources. The main sources of release of this substance are the coal and oil plants, productive processing of coke and aluminum, refining of oil, production of carbon black for tires, processing of a raw material containing PAHs such as air blow into asphalt, and production and use of coal tar and its related materials.

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2. Exposure assessment

As this substance 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.

The predicted maximum exposure concentration for inhalation exposure to human beings was 0.0003 μg/m^3. The predicted maximum oral exposure was estimated to be a range of more than 0.00044 μg/kg/day to less than 0.00104 μg/kg/day.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be approximately 0.02 μg/L for freshwater and approximately less than 0.015 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

There was no information about the acute toxic symptoms in human beings. In animal testing, the acute toxicity of this substance is low, and oral administration to MS/Ae and CD-1 mice did not cause death at 1,600 mg/kg. In Fischer 344 rats, however, there are reports that oral administration of this substance caused decrease in the spontaneous activity and motor nerves dysfunction at 25 mg/kg or more, and increase in relative weight of liver and average red cell hemoglobin concentration, and decrease in number of white cells at 100mg/kg or more.

For this substance, the initial assessments were carried out on the basis of the carcinogenic and non-carcinogenic information.

There was no information about the carcinogenic threshold for the oral exposure. As the ‘Non-toxic level’ for the oral exposure, the LOAEL of 3 mg/kg/day (hyperplasia in forestomach) was obtained from the medium- and long-term toxicity testing for rats.

The LOAEL was adjusted to 2.1 mg/kg/day taking into account the exposure situation. This value was divided by 10, because it was LOAEL, and a value of 0.21 mg/kg/day was derived as the ' Non-toxic level'. As the slope factor of carcinogenesis, assuming the non-threshold effects, 7.3 $(mg/kg/day)^{-1}$ was adopted which is the geometric mean of some numerical model results based on the testing for mice and rats.

There was no information about the carcinogenic threshold for the inhalation exposure. As the 'Non-toxic level' for the inhalation exposure, the LOAEL of 0.025 mg/m^3 (decrease in birth ratio) was obtained from the reproductive and developmental toxicity testing for rats. The LOAEL was adjusted to 0.0042 mg/m^3 taking into account the exposure situation. This value was divided by 10, because it was LOAEL, and a value of 0.00042 mg/m^3 was derived as the 'Non-toxic level'. As the unit risk of carcinogenesis, assuming the non-threshold effects, 8.7×10^{-2} $(\mu g/m^3)^{-1}$ was obtained from the epidemiological investigation.

For the oral exposure, in case of intake of the groundwater and food, the predicted maximum exposure was higher than 0.0014 μg/kg/day to less than 0.0020 μg/kg/day. As the non-carcinogenic effects, the MOE of 1,100-1,500 is derived from the 'Non-toxic level' of 0.21 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level' is established by means of animal testing, and considering the carcinogenesis, it is further divided by 10. On the other hand, as the carcinogenic effects, the excess lifetime tumor incidence associated with the predicted maximum exposure, which was calculated based on the slope factors, was determined to 1.0×10^{-5}-1.5×10^{-5}. Accordingly, it is considered that this substance is a candidate of detailed assessment for the health risk with regard to the oral exposure on the view points of the carcinogenesis.

For the inhalation, the predicted maximum exposure concentration was 0.003 $\mu g/m^3$ in the ambient air. As the non-carcinogenic effect, considering the non-toxic level of 0.00042mg/m^3 and the predicted maximum level of exposure concentration, the MOE calculated in the same way as the oral exposure was determined to be 1,4. On the other hand, as for the carcinogenic effects, the excess lifetime tumor incidence associated with the predicted maximum exposure concentration, which was calculated based on the unit risk, was determined to be 2.6×10^{-4}. Accordingly, it is considered that this substance is a candidate of detailed assessment for the health risk with regard to inhalation exposure on the view points of the non-carcinogenic and carcinogenic effects.

Informaiton 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'	0.21 mg/kg/day	Rats	hyperplasia in forestomach	Drinking water, food	– μg/kg/day	MOE	–	×	■
							Excessive developmental rate	–	×	
	'Non toxic level'	7.3 $(mg/kg/day)^{-1}$	Mice/rats	Tumor in forestomach	Groundwater, food	0.0014～0.0020 μg/kg/day	MOE	1,100～1,500	○	
							Excessive developmental rate	1.0×10^{-5}～1.5×10^{-5}	■	
Inhalation	No observed adverse effect level	0.00042 mg/m^3	Rats	Decrease in birth ratio	Ambient air	0.003 $\mu g/m^3$	MOE	1.4	■	■
							Excessive developmental rate	2.6×10^{-4}	■	
	Unit risk	8.7×10^{-2} $(\mu g/m^3)^{-1}$	Humans	Lung cancer	Indoor air	– $\mu g/m^3$	MOE	–	×	×
							Excessive developmental rate	–	×	

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC_{50} growth inhibition value of 5 μg/L was found for the algae *Scenedesmus acutus*, a 96-hour LC_{50} value of 5 μg/L was found for the crustacea *Daphnia pulex* (water flea). Accordingly, an assessment factor of 1,000 was used, a predicted no effect concentration (PNEC) of 0.005 μg/L was obtained based on the acute toxicity values. The PNEC value of this substance was 0.005μg/L because any knowledge of the chronic toxicity could not be obtained.

The PEC/PNEC ratio was 4 for freshwater bodies and less than 3 for seawater bodies. This substance is thought to be a candidate for further work.

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)		
Algae/crustacea (green algae /water flea)	Acute	EC_{50} growth inhibition／ LC_{50} Mortality	1,000	0.005	Freshwater	0.02	4	■
					Seawater	< 0.015	< 3	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	It is considered that this substance is a candidate for further assessment on the view points of the carcinogenesis.	■
	Inhalation exposure	It is considered that this substance is a candidate for further assessment on the view points of the non-carcinogenic and carcinogenic effects.	■
Ecological risk	Candidate for further work.		■

［Risk judgments］ ○: No need of further work ▲: Requiring information collection

■: Candidates for further work ×: Impossible of risk characterization

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.