6	CAS No.: 7440-45-1 (Cerium)	Substance: Cerium and its compounds

Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Element Symbol: Ce

Atomic Weight: 140.116

1. General information

Cerium compounds include cerium oxide, cerium carbonate, and cerium chloride. Cerium oxide and cerium carbonate are insoluble in water, while cerium chloride is soluble in water.

The main uses of cerium are as a glass abrasive, catalyst, UV-shielding glass, and glass achromatizing agent. The main uses of cerium oxide are sheet glass polishing, lens achromatizing, cathode ray tube polishing, optical glass polishing, and automobile exhaust catalysts. The main uses of cerium chloride are raw materials for misch metals and rare earth compounds, and raw materials for cerium compounds. The production (shipments) and import quantity in FY 2007 for both cerium oxide and cerium carbonate was 1,000 to < 10,000 t. The import quantity of cerium compounds in FY 2010 was 13,892 t, and the export quantity was 5,908 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.

Predicting distribution by individual medium was not considered appropriate because the chemical forms adopted by cerium and its compounds in the environment are not fully understood. Accordingly, a prediction of distribution by individual medium for cerium and its compounds was not carried out.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.0027 μg/m^3. The predicted maximum oral exposure was estimated to be around 0.37 μg/kg/day based on calculations from data for public water bodies and soil.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 0.96 μg/L for public freshwater bodies and around 0.14 μg/L for seawater.

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3. Initial assessment of health risk

Cerium compounds were widely used as anticoagulant agents, and their intravenous injections caused algor, pyrexia, headache, myalgia, abdominal twitch and hemoglobinuria as side-effects. Workers who handled cerium and its compounds, however, have not indicated disorders with such symptoms.

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

As for oral exposure to the substance, a NOAEL of 60 mg/kg/day (for suppressed body weight increase) obtained from mid- and long-term toxicity tests for rats with rare earth elements in nitrate was converted to 21 mg/kg/day for cerium as its ‘non-toxic level*’. It was deemed to be the lowest reliable dose without any effect, and this was identified as its ‘non-toxic level*’. As for inhalation exposure to the substance, a LOAEL of 5 mg/m^3 (for effects such as hyperplasia of lymph tissue in bronchial lymph nodes) was obtained from mid- and long-term toxicity tests on rats that inhaled cerium oxides. It was then adjusted to 0.89 ppm (2.6 mg/m^3) against the exposure condition and divided by 10 as is always the case with LOAELs. It was further divided by 10 due to their short test period, and outcome of 0.0089 mg/m^3 was deemed to be the lowest reliable concentration without any effect. Finally, it was converted to 0.0072 mg/m^3 for cerium as its ‘non-toxic level*’.

As for its oral exposure, its mean exposure would be about 0.12 μg/kg/day and its predicted maximum exposure

would be around 0.37 μg/kg/day, respectively, if its intakes through freshwater from public water bodies and through soil were assumed. The MOE would be 5,700 when calculated from the 'non-toxic level*' of 21 mg/kg/day and the predicted maximum exposure, and divided by 10 for conversion of the 'non-toxic level*' from animal experiments to an equivalent dose for humans. Therefore, further actions would not be required at the moment to assess health risk from oral exposure to this substance through freshwater from public water bodies and through soil. On the other hand, its exposure through food intakes is yet to be studied, and collection of information on its oral exposure through food intakes would be required.

As for its inhalation exposure, its mean exposure concentration would be about 0.0010 μg/m^3 and its predicted maximum exposure concentration would be around 0.0027 μg/m^3, respectively, when its concentrations in the ambient air were considered. The MOE would be 270 when calculated from the 'non-toxic level*' of 0.0072 mg/m^3 and the predicted maximum exposure concentration, and divided by 10 for conversion of the 'non-toxic level*' from animal experiments to an equivalent concentration for humans. Therefore, further actions would not be required to assess health risk from inhalation exposure to the substance in the ambient air at present. However, the latest data are missing at some monitoring stations where its maximum concentrations (0.0027μg/m^3 to 0.0084 μg/m^3) were always recorded from 2003 to 2007, and its concentrations should be measured at the same monitoring stations for confirmation. As for nanomaterials made of cerium oxides, their particles are so small that their metabolism, dynamics and toxicology would be different. Based on the information available on their exposure, separate risk assessment needs to be considered.

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 * ' 21 mg/kg/day	Rats	Suppressed body weight increase	Drinking water/soil	–	μg/kg/day	MOE	–	×	(▲)
				Freshwater/soil	0.37	μg/kg/day	MOE	5,700	○	
Inhalation	Non-toxic level * ' 0.0072 mg/m^3	Rats	Hyperplasia of lymph tissue in bronchial lymph nodes	Ambient air	0.0027	μg/m^3	MOE	270	○	(▲)
				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.

4.Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 2,900 μg Ce/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC_{50} of 430 μg Ce/L for immobilization in the crustacean *Daphnia magna*; and a 96-h LC_{50} of 1,800 μg Ce/L for the fish *Oryzias latipes* (medaka). Also obtained was a 72-h EC_{50} of 327 μg Ce/L for developmental inhibition in the European purple sea urchin *Paracentrotus lividus*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 4.3 μg Ce/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 530 μg Ce/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 5.7 μg Ce/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.057 μg Ce/L was obtained. This 0.057 μg Ce/L obtained from crustacean chronic toxicity was used as the PNEC for this substance.

The PEC/PNEC ratio was 17 for freshwater bodies and 2 for seawater. For this reason, the substances are considered as candidates for further work.

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	0.057	Freshwater	0.96	17	■	■
					Seawater	0.14	2		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Further information collection would be required for risk characterization.	（▲）
	Inhalation exposure	Further information collection would be required for risk characterization.	（▲）
Ecological risk	Candidates 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.