1	CAS No: 7440-36-0 (Antimony)	Substance: Antimony and its compounds

Chemical Substances Control Law Reference No.:
PRTR Law Cabinet Order No.: 1-31 (Antimony and its compounds)
Chemical symbol: Sb
Atomic weight: 121.76

1. General information

The major antimony compounds are antimony trioxide and sodium antimonate. The aqueous solubilities of antimony trioxide and sodium antimonite are 19.7 mg/L (20°C, pH=5) and 247±76 mg/L (20°C, pH=6), respectively. The biodegradability of hexahydroxysodium antimonate is judged to be difficult and it is not highly bioaccumulative.

Antimony and its compounds are Class 1 Designated Chemical Substances under the PRTR Law. Antimony is used in alloys with lead in battery electrodes, and in alloys with iridium and gallium in semiconductors. It is also used in the manufacture of lubricants, cable encapsulation materials, ceramics and glass. Antimony trioxide is used as a flame retardant in plastics, PVC insulated wire, curtains, canvas, paper and paints. It is also used as a glass clarifier (an additive to remove bubbles from glass), and as a raw material for coatings and yellow pigments.

Anthropogenic emission sources include coal combustion, incineration of waste materials and sludge, and leachate from landfill sites. Natural sources include soil blown by strong winds into the atmosphere, volcanoes, sea spray, forest fires, and microorganisms for the atmosphere, and soil disturbance and weathering for water bodies.

Production quantities in fiscal 2014 for antimony trioxide and sodium antimonate were 5990 t and approximately 350 t, respectively. The behavior of these substances in water bodies is not fully understood, but the majority that exists dissolved in freshwater and seawater is believed to have a pentavalent. In addition, higher concentrations than expected of trivalent antimony have been detected under aerobic conditions.

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2. Exposure assessment

Total release to the environment in fiscal 2014 under the PRTR Law was approximately 340 t, of which approximately 340 t or 99% of overall releases were reported. The major destination of reported releases was public water bodies. In addition, approximately 0.47 t was transferred to sewage and approximately 550 t was transferred to waste materials. Industries with large reported releases were non-ferrous metals manufacturing, transportation equipment manufacturing, and electrical machinery manufacturing for the atmosphere, and non-ferrous metals manufacturing, the chemical industry, and the steel industry for public water bodies. The largest releases to the environment including unreported releases were to water bodies.

Predicting the proportions distributed to individual media is inappropriate because antimony and its compounds transform into various chemical forms in the environment. Accordingly, the proportions distributed to individual media for antimony and its compounds were not predicted.

The maximum expected concentration of exposure to humans via inhalation, based on ambient atmospheric data, was around less than 0.0057 µg Sb/m^3. In contrast, the mean annual value for the atmospheric concentration in fiscal 2014 was calculated by using a plume-puff model based on releases to the atmosphere reported according to the PRTR Law: this model predicted a maximum level of 0.11 µg Sb/m^3. Furthermore, the predicted maximum oral exposure calculated from drinking water and food data was 0.28 µg Sb/kg/day, while that calculated from public fresh water body and food data was 6.1 µg Sb/kg/day. When releases to public freshwater bodies in fiscal 2014 reported under the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 13 μg Sb/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.52 μg Sb/kg/day.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, is 42 μg Sb/L for public freshwater bodies and around 0.8 μg Sb/L for seawater based on data that is highly likely to be of man-made origin. When releases to public freshwater bodies in fiscal 2014 reported under the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 13 μg Sb/L.

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3. Initial assessment of health risk

Antimony trioxide is mildly irritating to the eyes, skin and respiratory tract. It causes coughs, headache, nausea, sore throat and vomiting, if inhaled or ingested. In addition to these symptoms, abdominal pain, diarrhea and burning sensation in the stomach are caused by ingestion. Contact with the eyes causes redness and pain. Contact with the skin causes redness, pain and blisters.

As sufficient information on the carcinogenicity of antimony and its compounds (except antimony trioxide) was not available, the initial assessment was conducted on the basis of information on its non-carcinogenic effects. In the risk assessment of antimony trioxide, the carcinogenicity was taken into consideration, because there is sufficient evidence in experimental animals for the carcinogenicity of antimony trioxide.

The NOAEL for oral exposure of 6.0 mg Sb/kg/day (based on inhibition of body weight gain), determined from medium-term toxicity tests in rats exposed to antimony potassium tartrate, was divided by a factor of 10 to account for extrapolation from sub-chronic to chronic exposure. The calculated value of 0.60 mg Sb/kg/day was deemed to be the lowest reliable dose and was identified as the 'non-toxic level*' of the substance for oral exposure.

The LOAEL for inhalation exposure of 0.45 mg Sb/m^3 (based on inhibition of body weight gain, increased lung weight, inflammation, etc.), determined from long-term toxicity tests in rats and mice exposed to antimony trioxide, was divided by a factor of 10 to account for uncertainty in using a LOAEL. The calculated value of 0.045 mg Sb/m^3 was deemed to be the lowest reliable concentration and was identified as the 'non-toxic level*' of the substance for inhalation exposure.

With regard to oral exposure, assuming the substance is absorbed via drinking water and food, the predicted maximum exposure level would be 0.28 μg Sb/kg/day. The MOE (Margin of Exposure) would be 210, when calculated from the predicted maximum exposure level and the 'non-toxic level*'of 0.60 mg Sb/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. Assuming the substance is absorbed via public freshwater bodies and food, the predicted maximum exposure level would be 6.1 μg Sb/kg/day. The MOE would be 9.8, when calculated from this exposure level. The predicted maximum exposure level was derived nearly exclusively, i.e. about 98%, from public freshwater bodies. Antimony is already monitored in water including in public freshwater bodies, since it is designated as a water polluting substance subject to monitoring in public freshwater bodies and groundwater, its water quality guideline value being 20 μg Sb/L. According to the monitoring results of public freshwater bodies conducted from FY 2004 to FY 2014 after establishment of the guideline values, the exceedance of the guideline value was stabilized at the low rate of less than 1%, but the substance was detected in a large number of monitoring points. No exceedances of the guideline values have been observed since FY 2007 in groundwater monitoring. For comparison, the maximum exposure level was calculated to be 0.52 μg /kg/day. This value derives from the estimated concentration in the effluents from the high discharging plants, according to the releases reported in FY 2014 under the PRTR Law. The MOE would be 120, when calculated from this level and the 'non-toxic level*'. Despite the fact that the detected concentrations are in compliance with the guideline values for drinking water and groundwater quality, as the MOE calculated from the maximum exposure level via public freshwater bodies and food is less than 10, collection of further information would be required to assess the health risk of this substance via oral exposure, while keeping a close watch on the evolution of the concentration detected in public freshwater bodies.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was 0.0057 µg Sb/m^3, approximately. The MOE would be 160, when calculated from the ‘non-toxic level*’ of 0.045 mg Sb/m^3 and the predicted maximum exposure concentration, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and by another factor of 5 to take into consideration the carcinogenicity of antimony trioxide. For comparison, the maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance was estimated to be 0.11 µg Sb/m^3 based on the releases reported in FY 2014 under the PRTR Law. The MOE would be 8, when calculated from this concentration. Therefore, collection of further information would be required to assess the health risk of this substance via inhalation in 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*’ 470 mgSb/kg/day	Rats	Inhibition of body weight gain	Drinking water	0.28 µgSb/kg/day	MOE	210	○	(▲)
				Public Freshwater bodies	6.1 µgSb/kg/day	MOE	9.8	■	
Inhalation	‘Non-toxic level*’ 0.045 mgSb/m^3	Rats and mice	Inhibition of body weight gain, increased lung weight, inflammation, etc.	Ambient air	0.0057 µgSb/m^3	MOE	160	○	(▲)
				Indoor air	— µgSb/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.

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4. Initial assessment of ecological risk

With regard to acute toxicity of trivalent antimony, the following reliable data were obtained: a 72-h EC_{50} of 7,900 µg Sb/L for growth inhibition in the algae *Isochrysis galbana* (coccolithaceae), a 48-h EC_{50} of 2,510 µg Sb/L for immobilization in the crustacean *Daphnia magna*, a 96-h LC_{50} of 12,400 µg Sb/L for the fish species *Pagrus major* (red sea bream), and a 96-h LC_{50} of 1,770 µg Sb/L for the green hydra *Chlorohydra viridi*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 25 µg Sb/L was obtained.

With regard to chronic toxicity of trivalent antimony, the following reliable data were obtained: a 72-h NOEC of 2,110 µg Sb/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*, and a 21-d NOEC of 1,740 µg Sb/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 17 µg Sb/L was obtained.

With regard to acute toxicity of pentavalent antimony, the following reliable data were obtained: a 72-h EC_{50} of more than 111,000 µg Sb/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of more than 111,000 µg Sb/L for swimming inhibition in the crustacean *D. magna*, a 96-h LC_{50} of 930 µg Sb/L for the fish species *Pagrus major* (red sea bream), and a 7-d EC_{50} of more than 219,000 µg Sb/L for growth inhibition in the common duckweed *Lemna minor*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a PNEC of 9.3 µg Sb/L was obtained.

With regard to chronic toxicity of pentavalent antimony, the following reliable data were obtained: a 72-h EC_{50} of 111,000 µg Sb/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*, and a 21-d NOEC of 29,300 µg Sb/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 290 µg Sb/L was obtained.

The value of 9.3 µg/L obtained from the acute toxicity of pentavalent antimony, whose ecological effects are thought to be greater, to the fish species was used as the PNEC for this assessment.

Assuming that the total concentration of antimony present in the environment is pentavalent, the PEC/PNEC ratio is 5 for freshwater bodies and 0.08 for seawater; accordingly, the substance is considered to be a candidate for detailed assessment. Furthermore, reliable toxicity data for pentavalent antimony for fish species differed greatly for seawater (red sea bream) and freshwater (medaka) species; accordingly, separate assessments for freshwater and seawater should be considered in the future.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg Sb/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 Sb/L)			
Fish *Pagrus major*	Acute	LC_{50} mortality	100	9.3	Freshwater	42	5	■	■
					Seawater	0.8	0.08		

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5. Conclusions

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

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

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

（○）: Although risk to human health could not be confirmed, collection of further information would not be required.

（▲）: Further information collection would be required for risk characterization.