

4	CAS No.: 154-21-2	Substance: Lincomycin
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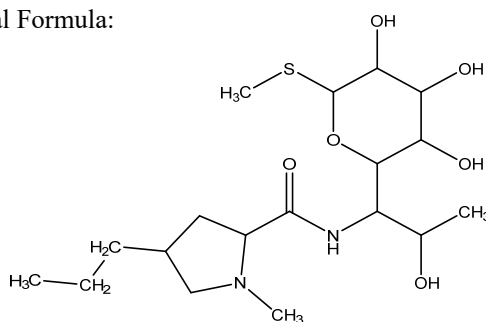
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C₁₈H₃₄N₂O₆S

Structural Formula:

Molecular Weight: 406.54



1. General information

This substance is only slightly soluble in water. The partition coefficient (1-octanol/water) ($\log K_{ow}$) is 0.20 and the vapor pressure is 1.34×10^{-17} mmHg ($=1.79 \times 10^{-15}$ Pa) (25°C) (calculated value). Data regarding biodegradability could not be obtained. In addition, this substance does not possess any hydrolyzable groups and hydrolysis does not occur under ambient environmental conditions.

The main use of this substance is as an antibiotic (pharmaceutical, veterinary drug). Target bacteria include streptococci, pneumococci, and dysentery bacillus, and indications include lymphatic vessels/lymphadenitis, mastitis, osteitis, pharyngitis/ laryngitis/tonsillitis, pneumonia and infectious enteritis. Further, data regarding the production quantity of this substance for human pharmaceuticals could not be obtained. The sales volume (bulk conversion) of this substance as veterinary drugs in fiscal 2018 was 20.8 t.

2. Exposure assessment

Because this substance is not classified as a Class 1 Designated Chemical Substance under the PRTR Law, release and transfer quantities could not be obtained. Predictions of proportions distributed to individual media by use of a Mackay-type level III fugacity model indicate that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to soil would be largest.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 0.017 µg/L for public freshwater bodies and generally less than 0.005 µg/L for seawater. Further, albeit obtained from an environmental survey of a limited area (public water body water quality), a maximum value of around 0.025 µg/L for freshwater was reported.

3. Initial assessment of ecological risk

With regard to acute toxicity of lincomycin, the following reliable data were obtained: a 96-h EC₅₀ of 14 µg/L for growth inhibition in the alga *Raphidocelis subcapitata*, a 48-h EC₅₀ of 12,800 µg/L for swimming inhibition in the crustacean *Ceriodaphnia dubia* (water flea), a 96-h LC₅₀ exceeding 88,200 µg/L for the fish *Oryzias latipes* (medaka), and a 24-h LC₅₀ of 22,900 µg/L for the planktonic rotifer *Brachionus calyciflorus*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.14 µg/L was obtained.

With regard to chronic toxicity of lincomycin, the following reliable data were obtained: a 96-h NOEC of 7.2 µg/L for growth inhibition in the alga *R. subcapitata*, a 7-d NOEC of 70,000 µg/L for reproductive inhibition in the freshwater crustacean *Moina macrocopa*, and a 90-d NOEC of 3,900 µg/L for post-fertilization fatality/growth inhibition in the fish species *O. latipes* (medaka). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC

of 0.72 µg/L was obtained.

The value of 0.14 µg/L obtained from the acute toxicity to the alga was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.12 for freshwater bodies and 0.04 for seawater; accordingly, efforts to collect data are needed for assessment of ecological risk.

Further, albeit for an environmental water quality survey of a limited public water body area, a maximum concentration of around 0.025 µg/L was reported and the ratio of this value to the PNEC was 0.18. Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed.

Environmental concentration data need to be augmented for this substance taking into consideration major emission sources.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Comprehensive judgment
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Green algae	Acute	EC ₅₀ Growth inhibition	100	0.14	Freshwater	0.017	0.12	▲
					Seawater	<0.005	<0.04	

4. Conclusions

	Conclusions	Judgment
Ecological risk	Requiring information collection.	▲

[Risk judgments] ○: No need for further work ▲: Requiring information collection
 ■: Candidates for further work ×: Impossibility of risk characterization