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CAS No.: 114-07-8

Substance: Erythromycin

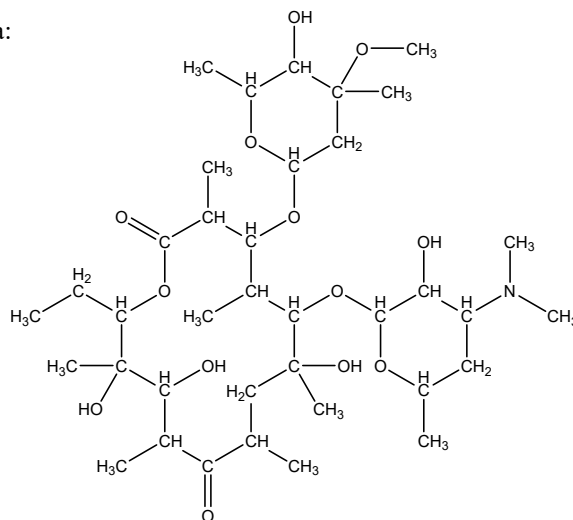
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C₃₇H₆₇NO₁₃

Structural Formula:

Molecular Weight: 733.93



1. General information

The aqueous solubility of this substance is 1.2×10^3 mg/1000 g (30°C), the partition coefficient (1-octanol/water) ($\log K_{ow}$) is 2.54 (pH=8.0), and the vapor pressure is 2.12×10^{-25} mmHg ($=2.83 \times 10^{-23}$ Pa) (25°C, calculated value). This substance does not biodegrade easily (aerobic degradation). Further, no hydrolysis under ambient environmental conditions is predicted.

The main use of this substance is as a 14-ring macrolide-based antibiotic for human and veterinary use. In addition, the export quantity of erythromycin, its derivatives, and their salts in fiscal 2017 was 1.1 t while the import quantity was 188 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 0.03 µg/L for public water bodies and roughly 0.0055 µg/L seawater. Further, albeit based on data that is more than 10 years old, a survey of a limited area of a river gave a maximum of roughly 0.23 µg/L.

3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC₅₀ of 36.6 µg/L for growth inhibition in the alga *Raphidocelis subcapitata*, a 48-h EC₅₀ 10,230 µg/L for swimming inhibition in the crustacean *Ceriodaphnia dubia*, a 96-h LC₅₀ exceeding 100,000 µg/L for the fish *Oryzias latipes* (medaka), and a 24-h LC₅₀ of 27,530 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 0.36 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-d NOEC of 10.3 µg/L for growth inhibition in the green alga *R. subcapitata*, a 21-d NOEC of 11,000 µg/L for reproductive inhibition in the crustacean *D.*

magna, and 40-d and 100-d NOECs of 100,000 µg/L for mortality and growth, respectively, in the fish *O. latipes* (medaka). Accordingly, based on these chronic toxicity valued and an assessment factor of 10, a PNEC of 1.0 µg/L was obtained.

The value of 0.36 µg/L obtained from the acute toxicity to the alga was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.08 for freshwater bodies and 0.02 for seawater; further work to determine the ecological risk is considered unnecessary at this time.

Further, albeit based on data that is more than 10 years old, a survey of a limited area of river gave a maximum of roughly 0.23 µg/L, and the ratio of this concentration to the PNEC is 0.64. Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed, and environmental concentration data needs to be augmented 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	0.36	Freshwater	0.03	0.08	▲
					Seawater	0.0055	0.02	

4. Conclusion

	Conclusion	Judgment
Ecological risk	Requiring information collection.	▲

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