4	CAS No.: 80214-83-1	Substance: Roxithromycin

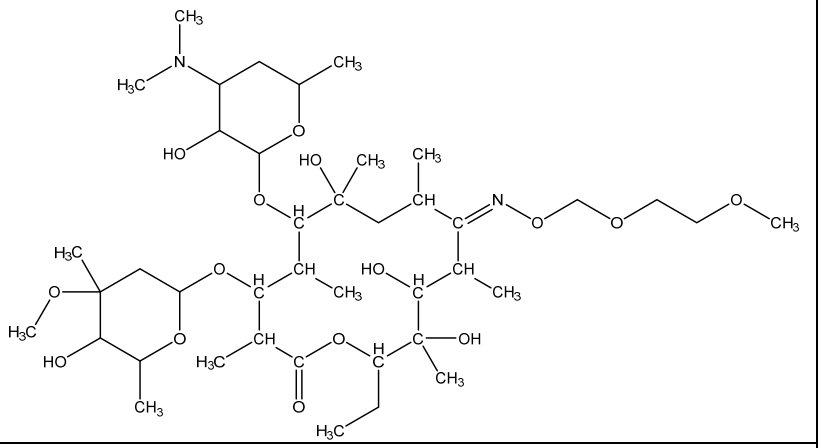
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: $C_{41}H_{76}N_2O_{15}$

Structural Formula:

Molecular Weight: 837.05



1.General information

This substance is essentially insoluble in water, the partition coefficient (1-octanol/water) (log K_{ow}) is 2.75 (calculated value), and the vapor pressure is 1.04×10^{-29} mmHg (= 1.39×10^{-27} Pa) (25°C, calculated value).

This substance is a 14-membered ring macrolide antibiotic that is effective against Staphylococcus, Streptococcus, and Streptococcus pneumoniae bacteria. The production and import quantity in fiscal 2016 was 7 t.

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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, is around 0.047 μg/L for public freshwater bodies and generally 0.0073 μg/L for seawater.

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3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h IC_{50} of 47 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 74,300 μg/L for swimming inhibition in the crustacean *Daphnia magna*, a 96-h LC_{50} of 288,300 μg/L for the fish species *Oryzias latipes* (medaka), and a 7-d EC_{50} of > 1,000 μg/L for growth inhibition in the duckweed *Lemna gibba*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.47 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 10 μg/L for growth inhibition in the green alga *P. subcapitata* and a 7-d NOEC of 1,000 μg/L for growth inhibition in the duckweed *L. gibba*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.1 μg/L was obtained

The value of 0.1 μg/L obtained from the chronic toxicity to the green alga was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.5 for freshwater bodies and 0.07 for seawater; accordingly, efforts to collect data are needed. Further, there is a need to consider developing more comprehensive data concerning environmental concentrations and toxicity taking into account emission sources.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Green algae	Chronic	NOEC Growth inhibition	100	0.1	Freshwater	0.047	0.5	▲
					Seawater	0.0073	0.07	

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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

（▲）: Further efforts to collect data required based on comprehensive review of existing relevant data

（■）: Candidate for further work based on comprehensive review of existing data