3	CAS No: 54-21-7	Substance: Sodium salicylate

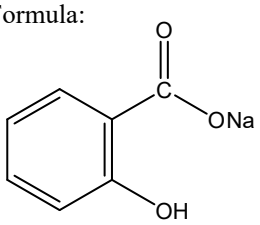
Chemical Substances Control Law Reference No.: 3-1639

PRTR Law Cabinet Order No.:

Molecular Formula: $C_7H_5NaO_3$

Molecular Weight: 160.10

Structural Formula:



1.General information

The aqueous solubility of this substance is 1.25×10^6 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is −1.43 (pH unknown), and the vapor pressure is 4.84×10^{-9} Pa (25°C) (estimated by MPBVPWIN). Its biodegradability (aerobic degradation) is 88.19% based on oxygen consumption. Further, degradability screening tests indicated a residual ratio of 126% after 7 days (initial concentration: 1.24 μg/mL, pH: 7) for hydrolyzability.

The main uses of this substance are in pharmaceuticals and reagents, while it is also formulated in cosmetics, functioning as a denaturing agent and preservative. In pharmaceuticals, it is used in salicylic acid analgesics and is indicated for symptomatic neuralgia. In veterinary medicine, it is used in blends with other drugs for nervous system and metabolic drugs. Further, the production and import quantities in fiscal 2021 were not disclosed because the number of reporting businesses was less than two. The production and import category as pharmaceuticals was 0.03 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 around 1.4 μg/L for public freshwater bodies, and about 1.3 μg/L for seawater.

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3. Initial assessment of ecological risk

With regard to acute toxicity for salicylic acid, the following reliable data were obtained: a 72-h EC_{50} of 65,100 μg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 48-h EC_{50} of 76,800 μg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} exceeding 86,300 μg/L for the fish *Danio rerio* (zebra fish). Accordingly, based on the minimum acute toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of 750 μg/L (for sodium salicylate) was obtained.

With regard to chronic toxicity for salicylic acid, the following reliable data were obtained: a 7-d NOEC of 2,760 μg/L for growth inhibition in the duckweed *Lemna gibba*, a 21-d NOEC of 5,600 μg/L for reproductive inhibition in the crustacean *Daphnia longispina*, and a 34-d of NOEC 20,000 μg/L for mortality and growth of juvenile fish in *Cyprinus carpio* (carp embryos). Accordingly, based on this chronic toxicity value and an assessment factor of 10, a predicted no effect concentration (PNEC) of 310 μg/L (for sodium salicylate) was obtained.

The value of 310 g/L (for sodium salicylate) obtained from the chronic toxicity to the duckweed was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.005 for freshwater bodies and 0.004 for seawater. Accordingly, efforts to collect data for determining ecological risk are considered unnecessary at this time. While PEC and PNEC data are lacking, taking into consideration determination of ecological risk based on the PEC/PNEC ratio, based on a comprehensive review of the

above findings, efforts to collect data are considered unnecessary at this time.

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)		
Lemna gibba	Chronic	NOEC Growth inhibition	10	310	Freshwater	1.4	0.005	○
					Seawater	1.3	0.004	

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4. Conclusions

	Conclusions	Judgment
Ecological risk	No need for further work.	○

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