

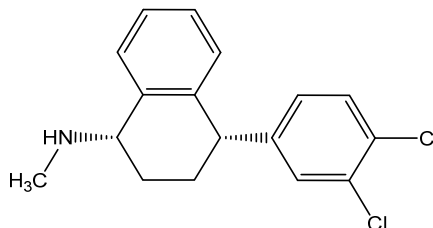
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C<sub>17</sub>H<sub>17</sub>Cl<sub>2</sub>N

Structural Formula:

Molecular Weight: 306.23



### 1. General information

The aqueous solubility of this substance is  $3.8 \times 10^3$  mg/L (25°C) (pH=5.3) (hydrochloride), the partition coefficient (1-octanol/water) ( $\log K_{ow}$ ) is 5.29 (calculated value) or 2.18 (hydrochloride, calculated value), and the vapor pressure is  $1.56 \times 10^{-4}$  Pa (calculated value) or  $1.11 \times 10^{-9}$  Pa (hydrochloride, calculated value). Data could not be obtained regarding biodegradability (aerobic degradation) and hydrolyzability.

The main use of sertraline hydrochloride is as a selective reuptake inhibitor for serotonin. In addition, the production quantity of this substance calculated based on production of sertraline hydrochloride was 6.5 t in 2019.

### 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 0.0036 µg/L for public freshwater bodies and generally 0.00044 µg/L for seawater.

### 3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 96-h IC<sub>50</sub> of 12.1 µg/L for growth inhibition in the green alga species *Raphidocelis subcapitata*, a 48-h LC<sub>50</sub> of 120 µg/L for the crustacean species *Ceriodaphnia dubia*, a 96-h LC<sub>50</sub> of 143 µg/L for the fish species *Pimephales promelas* (fathead minnow), and a 36-h EC<sub>50</sub> of 60 µg/L for abnormal embryonic development in the Pacific oyster *Crassostrea gigas*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.12 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 96-h IC<sub>10</sub> of 4.6 µg/L for growth inhibition in the green alga species *R. subcapitata* and a 14-d NOEC of 4.8 µg/L for F0-generation growth inhibition in the crustacean species *C. dubia*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.046 µg/L was obtained.

The PEC/PNEC ratio is 0.08 for freshwater bodies and 0.01 for seawater; accordingly further work to assess the ecological risk this substance is considered unnecessary at this time. A comprehensive review of the above findings draws the same conclusion.

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	Chronic	IC <sub>10</sub> Growth inhibition	100	0.046	Freshwater	0.0036	0.08	○
					Seawater	0.00044	0.01	

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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