

#### 1. General information

The water solubility of this substance is 171 mg/1,000 g (*o*-isomer, 25°C), 161 mg/1,000 g (*m*-isomer, 25°C), and 181 mg/1,000 g (*p*-isomer, 25°C). The partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 3.12 (*o*- isomer), 3.20 (*m*-isomer) and 3.15 (*p*-isomer). The vapor pressure is 6.6 mmHg (=880 Pa) (*o*-isomer, 25°C), 8.5 mmHg (= $1.13 \times 10^3$  Pa) (*m*-isomer, 25°C) and 8.9 mmHg (= $1.19 \times 10^3$  Pa) (*p*-isomer, 25°C). Xylene is readily biodegradable (aerobic degradation), and the substance (*o*-, *m*-, *p*-isomers) does not have any hydrolyzable groups.

Xylene is designated as a Class 1 Designated Chemical Substance under the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law). The main use of *o*-xylene is as a raw material for phthalic anhydride. The main use of *m*-xylene is as a raw material for isophthalic acid, which itself is a raw material for plasticizers and polyester resin. In this use, the *m*-xylene is converted to *o*-xylene and *p*-xylene. The main use of *p*-xylene is as a raw material for terephthalic acid. The main uses of mixed xylenes are as thinners and solvents in oil-based paints, adhesives, printing inks, and agricultural chemicals. The production quantities of this substance in 2010 were 116,314 t (*o*-isomer), 3,716,618 t (*p*-isomer), and 5,935,344 t (as xylene). The import quantities in 2010 were 10,663 t (*m*-isomer) and 9,925 t (*p*-isomer), while the export quantities in 2010 were 47,117 t (*o*-isomer), 5,020 t (*m*-isomer), and 2,332,603 t (*p*-isomer). The production and import category under the PRTR Law is more than 100 t.

#### 2. Exposure assessment

Total release of xylene to the environment in FY 2009 under the PRTR Law was approximately 80,000 t, of which approximately 33,000 t or 41 % of overall releases were reported. Among reported release destinations, the atmosphere was the largest. In addition, approximately 9,800 t was transferred to waste materials. Industry types with large reported releases were the shipbuilding and repair industry, the ship engine manufacturing industry, the transportation equipment and machinery manufacturing industry, the metal products manufacturing industry, the general machinery manufacturing industry, the electrical machinery manufacturing industry, and the plastic products manufacturing industry for the atmosphere, and the fiber industry, the food product manufacturing industry, and the chemical industry for public water bodies. The largest release among releases to the environment including unreported ones was to the atmosphere.

The public water concentration which can be used for assessment by individual isomer for xylene could not be obtained and therefore, predicted environmental concentrations (PEC) could not be set up. From a mixture of isomers of

xylene (combined quantity of *o*-, *m*-, and *p*-isomers), the predicted environmental concentration (PEC) on the safe side was 150  $\mu$ g/L for public freshwater bodies and 40  $\mu$ g/L for seawater. Meanwhile, the maximum river concentration of xylene was 1,600  $\mu$ g/L (as xylene) based on reported releases to public freshwater bodies under the PRTR Law.

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## 3.Initial assessment of ecological risk

### (1) Setting of predicted no effect concentration

# (A) o-xylene

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 799  $\mu$ g/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 24-h IC<sub>50</sub> of 1,000  $\mu$ g/L for immobilization in the crustacean *Daphnia magna*; and a 96-h LC<sub>50</sub> of 7,424  $\mu$ g/L for the fish *Oryzias latipes* (medaka). Also obtained was a 48-h LC<sub>50</sub> of 73,000  $\mu$ g/L for the African clawed frog *Xenopus laevis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 8.0  $\mu$ g/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 732  $\mu$ g/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 630  $\mu$ g/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 6.3  $\mu$ g/L was obtained. This 6.3  $\mu$ g/L obtained from the crustacean chronic toxicity was used as the PNEC for *o*-xylene.

| Hazard Assessment (Basis for PNEC) |                |                      |                          | Predicted no                           | Exposure Assessment |  |                | Judgment based       |                      |
|------------------------------------|----------------|----------------------|--------------------------|--|---------------------|--|----------------|----------------------|----------------------|
| Species                            | Acute/ chronic | Endpoint             | Assessment<br>factor     | effect<br>concentration<br>PNEC (µg/L) | Water body          | Predicted environmental<br>concentration<br>PEC (µg/L) | PEC/PNEC ratio | on PEC/PNEC<br>ratio | Assessment<br>result |
| Crustacean                         | Chronic        | NOEC<br>reproductive | NOEC<br>reproductive 100 | 63                                     | Freshwater          | 150*   | 24             |                      |                      |
| Daphnia magna                      | Chrome         | inhibition           | 100                      | 0.5                                    | Seawater            | <40*   | <6             | _                    | _                    |

\*Note: Concentration as mixture of isomers (o-, m-, p- isomers)

## (B) *m*-xylene

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 4,900  $\mu$ g/L for growth inhibition in the green algae *P. subcapitata*; a 48-h EC<sub>50</sub> of 2,420  $\mu$ g/L for immobilization in the crustacean *D. magna*; and a 96-h LC<sub>50</sub> of 8,400  $\mu$ g/L for the fish *Oncorhynchus mykiss* (rainbow trout). Also obtained was a 48-h EC<sub>50</sub> of 540,000  $\mu$ g/L for developmental inhibition of 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 24  $\mu$ g/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 5,330  $\mu$ g/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 407  $\mu$ g/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 4.1  $\mu$ g/L was obtained. This 4.1  $\mu$ g/L obtained from the crustacean chronic toxicity was used as the PNEC for *m*-xylene.

| Hazard Assessment (Basis for PNEC) |                |                          |                      | Predicted no                           | Exposure Assessment |  |                | Judgment based       |                      |
|------------------------------------|----------------|--------------------------|----------------------|--|---------------------|--|----------------|----------------------|----------------------|
| Species                            | Acute/ chronic | Endpoint                 | Assessment<br>factor | effect<br>concentration<br>PNEC (µg/L) | Water body          | Predicted environmental<br>concentration<br>PEC (µg/L) | PEC/PNEC ratio | on PEC/PNEC<br>ratio | Assessment<br>result |
| Crustacean                         | Chronic        | NOEC<br>reproductive 100 | 41                   | Freshwater                             | 150*                | 37   |                |                      |                      |
| Daphnia magna                      | Childhie       | inhibition               | 100                  |  | Seawater            | <40*   | <10            | ] —                  |                      |

\*Note: Concentration as mixture of isomers (o-, m-, p- isomers)

# (C) *p*-xylene

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 3,200  $\mu$ g/L for growth inhibition in the green algae *P. subcapitata*; a 24-h of IC<sub>50</sub> of 3,600  $\mu$ g/L for immobilization in the crustacean *D. magna*;

and a 96-h  $LC_{50}$  of 2,600 µg/L for the fish *O. mykiss* (rainbow trout). Also obtained was a 48-h IGC<sub>50</sub> of 88,100 µg/L for growth inhibition of the ciliate protozoa *Tetrahymena pyriformis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 26 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 4,360  $\mu$ g/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 1,290  $\mu$ g/L for reproductive inhibition in the in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 13  $\mu$ g/L was obtained. This 13  $\mu$ g/L obtained from the crustacean chronic toxicity to was used as the PNEC for *p*-xylene.

| Hazard Assessment (Basis for PNEC) |                |                          |                      | Predicted no                           | Exposure Assessment |  |                | Judgment based       |                     |
|------------------------------------|----------------|--------------------------|----------------------|--|---------------------|--|----------------|----------------------|---------------------|
| Species                            | Acute/ chronic | Endpoint                 | Assessment<br>factor | effect<br>concentration<br>PNEC (µg/L) | Water body          | Predicted environmental<br>concentration<br>PEC (µg/L) | PEC/PNEC ratio | on PEC/PNEC<br>ratio | Assessmen<br>result |
| Crustacean                         | Chronic        | NOEC<br>reproductive 100 | 13                   | Freshwater                             | 150*                | 12   |                |                      |                     |
| Daphnia magna                      | Childhie       | inhibition               | 100                  |  | Seawater            | <40*   | <3             |                      |                     |

Note: Concentration as mixture of isomers (o-, m-, p- isomers)

### (2) Initial assessment of ecological risk

The average concentration of mixtures of xylene isomers (combined quantity of *o*-, *m*-, and *p*-isomers) in public water bodies were less than 40  $\mu$ g/L for both freshwater bodies and seawater, and the predicted environmental concentrations (PEC) on the safe side were 150  $\mu$ g/L for freshwater bodies and less than 40  $\mu$ g/L for seawater. Assuming that all of the xylene in public water body is either *o*-xylene, *m*-xylene, or *p*-xylene, the ratio of the PEC with the PNEC set for each isomer exceeds 1 for all isomers for freshwater bodies. However, the xylene concentration detected at a certain location of 150  $\mu$ g/L (fiscal 2007) was less than 40  $\mu$ g/L in FY 2008 and FY 2009, and reported releases (PRTR data) of xylenes to rivers in this location are declining. In addition, among survey findings of the most recent three years, excluding the concentration at the above location and using the concentration of xylenes at the location where the second highest concentration was detected among public freshwater bodies (1  $\mu$ g/L) as the PEC gives a PEC/PNEC exceeding 0.1.

Taking this into consideration, efforts to collect data concerning *o*-xylene, *m*-xylene, and *p*-xylene are considered necessary. Understanding of trends in environmental concentrations of xylenes at lower detection limits considered necessary.

### 4.Conclusions

|                 | Conclusions  |            |  |  |  |  |  |
|-----------------|--|------------|--|--|--|--|--|
| Easlagiasl      | Collection of more data considered necessary for <i>o</i> -xylene, <i>m</i> -xylene, and <i>p</i> -xylene. |            |  |  |  |  |  |
| Ecological      | Understanding of trends in environmental concentrations of xylenes at lower                                |            |  |  |  |  |  |
| FISK            | detection limits considered necessary.   |            |  |  |  |  |  |
| [Risk judgments | □ ○: No need for further work ▲: Requiring information collection  |            |  |  |  |  |  |
|                 | ■: Candidates for further work ×: Impossibility of risk characterization                                   |            |  |  |  |  |  |
|                 | $(\bigcirc)$ : Though a risk characterization cannot be determined, there would be little necessity        |            |  |  |  |  |  |
|                 | collecting information.  |            |  |  |  |  |  |
|                 | $(\blacktriangle)$ : Further information collection would be required for risk charact                     | erization. |  |  |  |  |  |