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|--|-------------------|--|
| 1  | CAS No.: 110-80-5 | Substance: Ethylene glycol monoethyl ether |
| <p>Chemical Substances Control Law Reference No.: 2-411 and 2-2424 (as alkylene [C = 2 - 8] glycol monoalkyl [C = 2 - 8] ether)</p> <p>PRTR Law Cabinet Order No.: 1-44</p> <p>Molecular Formula: C<sub>4</sub>H<sub>10</sub>O<sub>2</sub>      Structural Formula:</p> <p>Molecular Weight: 90.12    <b>CH<sub>3</sub>—CH<sub>2</sub>—O—CH<sub>2</sub>—CH<sub>2</sub>—OH</b></p>  |                   |  |
| <p><b>1. General information</b></p> <p>The aqueous solubility of this substance is freely miscible, and the partition coefficient (1-octanol / water) (log K<sub>ow</sub>) is -0.32. The vapor pressure is 5.31 mmHg (= 708 Pa) (25°C). Degradability is thought to be good, but the substance is thought to be one that does not have hydrolyzable groups in the environment.</p> <p>This substance is 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). It is used primarily as a solvent in resins, coatings, and printing inks, as a dye for leather products, as a stain remover in dry-cleaning, and as a solubilizing agent. Production of ethyl glycol in 2003 was estimated at 7,000 tons.</p> <p>-----</p> <p><b>2. Exposure assessment</b></p> <p>Total release to the environment in FY2003 under the PRTR Law came to approximately 980 tons. Of this quantity, the amount reported came to approximately 370 tons. Release to the atmosphere accounted for a large part of the reported release. Transportation equipment, Fabricated metal products, and Electric machinery and equipment accounted for high levels of release to the atmosphere. Chemical Industry reported high levels of release to public water bodies.</p> <p>When estimated releases outside notification are included, release to the atmosphere accounted for the greatest quantity of release to the environment. The distribution into each environmental medium predicted by means of a multimedia model was 76.1% for water bodies and 15.4% for atmosphere.</p> <p>The predicted maximum exposure concentration for inhalation exposure to human beings was approximately 0.36 µg/m<sup>3</sup>. The predicted maximum oral exposure was estimated to be less than 0.036 µg/kg/day. As environmental distribution of this substance is expected to be primarily in water bodies, and because the log K<sub>ow</sub> is low at -0.32 and bioconcentration is also predicted to be low, exposure from environmental media via the food chain is assumed to be low.</p> <p>The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be less than 0.9 µg/L for both freshwater and seawater public water bodies.</p> <p>-----</p> <p><b>3. Initial assessment of health risk</b></p> <p>Even brief exposure to this substance may result in slight irritation of the eyes and respiratory tract. If inhaled, it may cause coughing, drowsiness, headache, shortness of breath, sore throat and weakness. In high concentrations, it may even cause unconsciousness. If taken orally, it may cause abdominal pains, nausea and vomiting. A lethal dose lowest (LDLo) for humans of 143 mg/kg and a toxic dose lowest (TDLo) of 0.8 mL/kg have been reported.</p> <p>There is insufficient information regarding the carcinogenicity of the substance, and it is not possible to make a judgment as to whether it causes cancer in human beings. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.</p> <p>As the ‘Non-toxic level’ was observed, used to estimate the margin of exposure (MOE), a no observed adverse effect level (NOAEL) of 46 mg/kg/day (fetal skeleton anomalies), obtained from rat reproductive and developmental toxicity testings, was established for oral exposure. For inhalation exposure, a value of 9.3 mg/m<sup>3</sup> was established by</p> |                   |  |

correcting the NOAEL of 37 mg/m<sup>3</sup> (fetal skeleton anomalies), also obtained from rat reproductive and developmental toxicity testings, to match the exposure circumstances.

With regard to oral exposure, the maximum predicted exposure was estimated to be less than 0.036 µg/kg/day when intake through groundwater was postulated. As the 'Non-toxic level' and the maximum predicted exposure were established by animal testing, the MOE was derived by dividing by 10, and the result exceeded 130,000. The food-borne exposure originating in the environment was estimated to be minor, and it is thought that adding this exposure would not greatly affect the MOE. Accordingly, assessment of the health risk from oral exposure to this substance is thought to be unnecessary at this time.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was estimated at approximately 0.036 µg/m<sup>3</sup>. The MOE derived in the same manner from the 'Non-toxic level' of 9.3 mg/m<sup>3</sup> and the predicted maximum exposure concentration was 2,600. Accordingly, there is thought to be no need at this time for assessment of the health risk with regard to inhalation exposure to the substance in the ambient air.

| Knowledge of toxicity |   |        |  | Exposure assessment |   | Result of risk assessment |           |   | Judgment |
|-----------------------|---|--------|--|---------------------|---|---------------------------|-----------|---|----------|
| Exposure path         | Guidelines for risk assessment                            | Animal | Impact assessment guideline (endpoint) | Exposure medium     | Predicted maximum exposure quantity and concentration |                           |           |   |          |
| Oral                  | No observed adverse effect level<br>46 mg/kg/day          | Rat    | Fetal skeletal deformity               | Drinking water      | — µ g/kg/day  | MOE                       | —         | × | ○        |
|                       |   |        |  | Groundwater         | < 0.036 µ g/kg/day                                    | MOE                       | > 130,000 | ○ |          |
| Inhalation            | No observed adverse effect level<br>9.3 mg/m <sup>3</sup> | Rat    | Fetal skeletal deformity               | Ambient air         | 0.36 µ g/m <sup>3</sup>                               | MOE                       | 2,600     | ○ | ○        |
|                       |   |        |  | Indoor air          | — µ g/m <sup>3</sup>                                  | MOE                       | —         | × | ×        |

#### 4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC<sub>50</sub> growth inhibition value exceeding 100,000 µg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC<sub>50</sub> immobilization value exceeding 89,500 µg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC<sub>50</sub> value exceeding 94,700 µg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, a predicted no effect concentration (PNEC) exceeding 900 µg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value exceeding 100,000 µg/L was found for the algae *P. subcapitata* and a 21-day NOEC reproduction value exceeding 97,000 µg/L was found for the crustacea *D. magna*, so an assessment factor of 100 was used, and a PNEC value that exceeded 970 µg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value exceeding 900 µg/L obtained from the acute toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.001 for both freshwater bodies and seawater bodies. Accordingly, further work is thought to be unnecessary at this time.

| Hazard assessment (basis for PNEC) |                 |                                 | Assessment factor | Predicted no effect concentration PNEC (µg/L) | Exposure assessment |  | PEC/PNEC ratio | Result of assessment |
|------------------------------------|-----------------|---------------------------------|-------------------|---|---------------------|--|----------------|----------------------|
| Species                            | Acute / chronic | Endpoint                        |                   |   | Water body          | Predicted environmental concentration PEC (µg/L) |                |                      |
| Crustacea                          | Acute           | EC <sub>50</sub> immobilization | 100               | > 900   | Freshwater          | < 0.9  | < 0.001        | ○                    |
|                                    |                 |                                 |                   |   | Seawater            | < 0.9  | < 0.001        |                      |

## 5. Conclusions

|                 | Conclusions              |  | Judgment |
|-----------------|--------------------------|--|----------|
| Health risk     | Oral exposure            | Assessment is thought to be unnecessary at this time.                                | ○        |
|                 | Inhalation exposure      | Assessment with regard to the ambient air is thought to be unnecessary at this time. | ○        |
| Ecological risk | No need of further work. |  | ○        |

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