

Ministerial Ordinance on Reporting of Hazardous Properties

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 2 of March 18, 2004)

Final revision: Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 4 of April 1, 2005

The Ministerial Ordinance on Reporting of Hazardous Properties shall be enacted as follows, based on paragraph (1) of Article 31-2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973).

Article 1 (Scope of Knowledge Requiring Reporting)

The knowledge specified by an Ordinance of the Ministry of Health, Labour and Welfare, Ordinance of the Ministry of Economy, Trade and Industry, and Ordinance of the Ministry of the Environment indicating that the substance possesses the properties prescribed in the items of paragraph (1) of Article 31-2 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as the “Act”) shall be the knowledge listed in the following items for each of the properties listed in said items:

(i) The substance subject to reporting is not likely to undergo a chemical transformation through natural processes – the substance is not easily decomposable in a biodegradability test of the chemical substance using microorganisms

(ii) The substance subject to reporting is bioaccumulative – the substance falls under (a) or (b) below:

(a) The substance shows a bioaccumulation factor of 1,000 or over in a bioaccumulation test of the chemical substance in fish or shellfish

(b) The substance shows a partition coefficient of 3.5 or over in the measurement of the partition coefficient between 1-octanol and water

(iii) The chemical substance that poses a risk of impairing human health if ingested continuously – the substance shows effects causing death, cancer, or long-term disability, reproduction/developmental effects, or other toxicologically significant effects equivalent thereto in a chronic toxicity studies, reproduction/developmental toxicity test, prenatal developmental toxicity study, mutagenicity test, carcinogenicity studies, toxicokinetics, pharmacology studies, or repeated-dose toxicity test

(iv) The substance subject to reporting poses a risk of interfering with the inhabitation and/or growth of flora and fauna – the substance falls under any of (a) through (h) below:

(a) The substance shows the death, reproduction/developmental effects, or other toxicologically significant effects equivalent thereto in a test of the effects on the reproductive functions and future generations of mammals

(b) The substance shows effects causing death, a decrease in egg production, or a decrease in hatchability, or other toxicologically significant effects equivalent thereto in avian reproduction test

(c) The substance shows an EC50 of 10mg/l or less, a NOEC of 1mg/l or less, or other toxicologically significant effects in alga, growth inhibition test

(d) The substance shows an EC50 of 10mg/l or less, or other toxicologically significant effects in daphnia acute immobilization test

(e) The substance shows an EC50 of 10mg/l or less or other toxicologically significant effects in fish acute toxicity test

(f) The substance shows a NOEC of 1mg/l or less or other toxicologically significant effects in daphnia reproduction test

(g) The substance shows a NOEC of 1mg/l or less or other toxicologically significant effects in fish, early-life stage toxicity test

(h) The substance shows effects causing death or a decrease in the eclosion rate, or other toxicologically significant effects equivalent thereto in sediment-water chironomid toxicity test

(v) Where the substance subject to reporting is likely to undergo a chemical transformation through natural processes, the chemical substance (including elements) generated in the chemical transformation through natural processes falls under any of the preceding items – knowledge listed in the preceding items

Article 2 (Submission of Reports)

A person who operates the business of manufacturing or importing a substance subject to reporting shall, when having obtained any knowledge prescribed in the preceding Article with regard to a substance subject to reporting which he/she has manufactured or imported, submit a report in the Appended Form to the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry, and the Minister of the Environment within 60 days from the day when he/she obtained said knowledge, based on the provisions of paragraph (1) of Article 31-2 of the Act.

Supplementary Provisions

This Ministerial Ordinance shall come into effect as from April 1, 2004.

Supplementary Provisions

(Ordinance of the Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment No. 4 of April 1, 2005)

This Ministerial Ordinance shall come into effect as from the day of promulgation.