

Studies Specified Separately by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment Pursuant to the Provisions of Article 1, paragraph (2), Article 3, and Article 5, item (iv) of the Ministerial Order to Provide for Tests of New Chemical Substances and Items for Studies Related to Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances

(Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment Public Notice No. 5 of March 31, 2011)

Last amended on March 30, 2018

The Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment Public Notice No. 6

Article 1 Studies specified separately by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment as equivalent to or higher than 28-day repeated dose toxicity test using mammals, and reverse mutation test using bacteria and chromosomal aberration test using cultured mammalian cells pursuant to the provisions of Article 1, paragraph (2) of the Ministerial Order to Provide for Items for Tests of New Chemical Substances and Studies Related to Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances (Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment Order No. 3 of 2010; hereinafter referred to as the “Ministerial Order”) refer to the studies set forth in the right column of the following table opposite to the categories of the studies specified in the same paragraph set forth in the left column of the same table, respectively.

28-day repeated dose toxicity test using mammals	90-day repeated toxicity test using mammals or combined repeated dose toxicity and productive and developmental toxicity tests using mammals
Mutagenicity studies by reverse mutation test using bacteria and chromosomal aberration test using cultured mammalian cells	Mutagenicity studies by reverse mutation test using bacteria and mouse lymphoma TK assay

Article 2 Studies specified separately by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment as equivalent to or higher than the 28-day repeated dose toxicity test using mammals, and mutagenicity studies by reverse mutation test using bacteria and chromosomal aberration test using mammalian cells pursuant to the provisions of Article 3 of the Ministerial Order refer to the studies set forth in the right column of the following table according to the categories of the studies set forth in the left column of the table in the preceding Article, respectively.

Article 3 Studies specified separately by the Minister of Health, Labour and Welfare, the Minister of Economy, Trade and Industry and the Minister of the Environment as equivalent to or higher than the 28-day repeated dose toxicity test using mammals, and the mutagenicity studies by reverse mutation test and chromosomal aberration test using cultured mammalian cells pursuant to the provisions of Article 5, item (iv) of the Ministerial Order refer to the studies set forth in the right column of the following table according to the categories of the studies set forth in the left column of the table in Article 1, respectively.

(Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment Public Notice No. 6 of March 30, 2018) (Extract)

This Public Notice shall apply as of April 1, 2018.