

This English translation of the “Determination Criteria for Specified New Chemical Substances set forth in Article 4-4 of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances“ has been translated by National Institute of Technology and Evaluation with the assistance of Japan Chemical Industry Association.

This is an unofficial translation. Only the original Japanese texts of laws and regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations.

National Institute of Technology and Evaluation shall not be responsible for the accuracy, reliability or currency of the legislative material provided in this Website, or for any consequence resulting from use of the information in this Website.

For all purposes of interpreting and applying law to any legal issue or dispute, users should consult the original Japanese texts.

この「化学物質の審査及び製造等の規制に関する法律に基づく法第4条第4項の特定新規化学物質の判定基準」の英文翻訳は、（独）製品評価技術基盤機構が、一般社団法人日本化学工業協会の支援を得て作成したものです。

この法令の翻訳は公定訳ではありません。法的効力を有するのは日本語の法令自体であり、翻訳はあくまでその理解を助けるための参考資料です。

この翻訳の利用に伴って発生した問題について、（独）製品評価技術基盤機構は、一切の責任を負いかねますので、法律上の問題に関しては、日本語の法令を参照してください。

Determination Criteria for Specified New Chemical Substances  
set forth in Article 4-4 of the Act on the Regulation of  
Manufacture and Evaluation of Chemical Substances

April 13, 2018

Chemical Safety Office, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau,  
Ministry of Health, Labour and Welfare

Chemical Safety Office, Chemical Management Policy Division, Manufacturing Industries Bureau, Ministry of Economy,  
Trade and Industries

Chemical Evaluation Office, Environmental health Policy Planning and Management Division, Environmental Health  
Department, Ministry of the Environment

The determination criteria for specified new chemical substances set forth in Article 4-4 of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (hereafter referred to as “Act”) shall be as follows.

With the following criteria as basic rule for the present, determination shall be made with consideration of the expert opinions provided by the relevant councils.

Note

Of the new chemical substances determined as falling under any of Items 2-4 of Article 4-1 of the Act, When it falls under any of the followings, the substances shall be determined as specified new chemical substances; provided, however, that this does not apply to substances designated under Article 2-5 of the Act;

-one of the hazard assessment values derived according to II.(3-1) of “the Determination Criteria and Test methods for New Chemical Substances and Monitoring Chemical Substances (April 13, 2018, Chemical Safety Office, MHLW; Chemical Safety Bureau, METI; Chemical Evaluation Office, MOE)” (hereafter referred to as “Determination Criteria”) is equal to or less than 0.0005 mg/kg/day.

-one of (i) the bacterial reverse mutation test and (ii) in vitro mammalian chromosome aberration test or mouse lymphoma TK test is determined to be strongly positive, and the other is determined to be positive or strongly positive.

-the PNEC derived according to II.(4-1) of the Determination Criteria is  $3 \times 10^{-4}$  mg/L or lower in 3 types of chronic toxicity test results,  $3 \times 10^{-5}$  mg/L or lower in 2 types of chronic toxicity test results and 1 type of acute toxicity test results, or  $3 \times 10^{-5}$  mg/L or lower in 1 type of chronic toxicity test results and 2 types of acute toxicity test results.

Notwithstanding the above, determination of specified new substances shall be made comprehensively with the assumption that toxicity could be posed by chronic toxicity tests and with the consideration of test data of general toxicity if the chemical substance has strong mutagenicity.