

Concerning the Confirmation of Biodegradation and Bioaccumulation of Small
Production Volume New Chemical Substances under CSCL

June 30, 2020
Chemical Safety Office
Chemical Management Policy Division
Manufacturing Industries Bureau
Ministry of Economy, Trade and Industry

With regard to Small Production Volume New Chemical Substances, it will be confirmed pursuant to Article 3, paragraph (1), item (v) of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (hereinafter referred to as CSCL), "as determined by already available knowledge, etc., the relevant new chemical substance is not one that poses a risk to human health or cause damage to the inhabitation and/or growth of flora and fauna in the living environment by causing environmental pollution".

Specifically, this confirmation for Small Production Volume New Chemical Substances will be made after hearing opinions from members of the Chemical Substances Council referring to the structural similarities to the Class I Specified Chemical Substances or Monitoring Chemical Substances and the estimation by Quantitative Structure-Activity Relationship (QSAR) *, etc.

Please refer to the attached Assessment Flow Chart for the Biodegradation and Bioaccumulation of Small Production Volume New Chemical Substances under CSCL.

Even if a substance had previously been confirmed, it may not be currently confirmed because the above confirmation is given based on new knowledge, such as test data submitted in the notification of a new chemical substance.

On the other hand, even if a substance had previously been estimated to be not readily biodegradable and high concentration, and the new test data shows it is readily

biodegradable or low concentration, the new data is taken into consideration for confirmation.

If you obtain new test** data, please contact us using the contact information below.

⑦NITE launched a website to support the voluntary evaluation by manufacturing industries/companies using the Assessment Flow Chart for Biodegradation and Bioaccumulation of Small Production Volume New Chemical Substances under CSCL [Japanese only].

[URL] https://www.nite.go.jp/chem/qsar/syouryou_QSAR.html

⑦Structural Analogues of Class I Specified Chemical Substances/ Monitoring Chemical Substances

- NITE released a screening tool for identifying the structural analogues of Class I Specified Chemical Substances/Monitoring Chemical Substances on the above website for you to use as a reference when making a request for Small Production Volume New Chemical Substances.

⑦Estimation by Quantitative Structure-Activity Relationship (QSAR)

- Estimation results by the following QSAR models are considered in the evaluation of biodegradation and bioconcentration:

Biodegradation: BIOWIN5, BIOWIN6, CATALOGIC (OECD 301C)

Bioconcentration: BCFBAF, Arnot-Gobas model, CATALOGIC (Baseline-model)

You can install the BIOWIN5, BIOWIN6, BCFBAF and Arnot-Gobas models from the following sites and use them for free.

[URL]<https://www.epa.gov/tsca-screening-tools/download-epi-suitetm-estimation-program-interface-v411>

- * The estimation by QSAR has been utilized since the seventh term of the New Chemical Substances in Small Volume application in 2019

** GLP or preliminary test, etc.

[Contact Information]

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[Inquiries About the Screening Tool for Identifying the Structural Analogues of Class I Specified Chemical Substances/Monitoring Chemical Substances and QSAR]

Safety Assessment Division, Chemical Management Center,

National Institute of Technology and Evaluation (NITE)

Contact Form: <https://www.nite.go.jp/cgi-bin/contact/?cid=00000130&lang=1>

Please submit inquiries using the contact form.

TEL : +81-03-3481-1812

Assessment Flow Chart for Biodegradation and Bioaccumulation of New Chemical Substances in Small Volume Under CSCL

