CHEMLINKED
by REACH24H Consulting Group

Technical Guidelines for Application of Threshold of Toxicological Concern (TTC) Method (Draft for Comments)

毒理学关注阈值(TTC)方法应用技术指南(征求意见稿)

National Institutes for Food and Drug Control

Release Date: Mar 19, 2024
Implementation Date: /

Translated by ChemLinked

Disclaimer

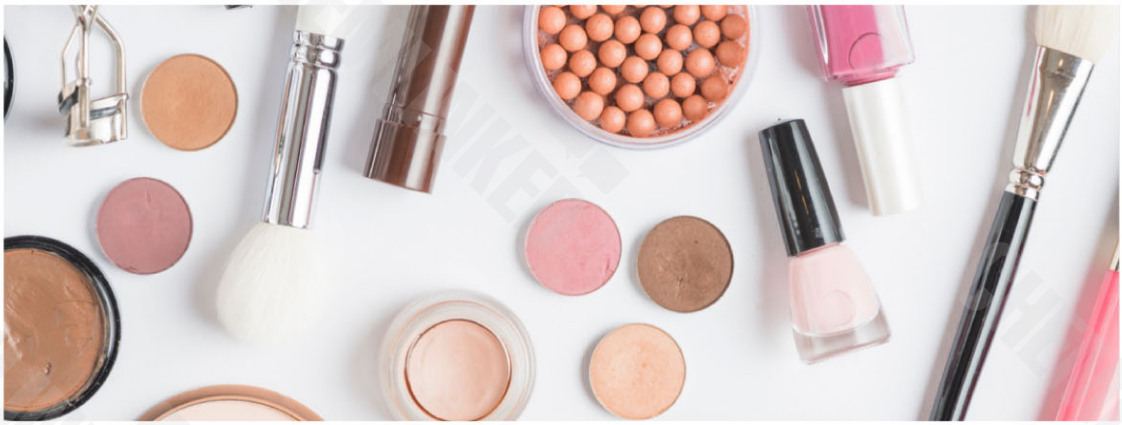
This is an unofficial document provided by **ChemLinked (**chemlinked.com**)**, a platform of REACH24H Consulting Group, as an informational service to assist non-Chinese companies to better understand Asia Pacific especially China Chemical, Cosmetic, Food and Agrochemical regulatory issues.

This document should only be used as a reference and in case of any discrepancy between the English and original versions the original version shall prevail.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our Privacy Policies or contact us at cosmetic@chemlinked.com



You can now catch up with the latest updates of China CSAR on ChemLinked:

Stay tuned for more translations:
We will provide English, Japanese and Korean translations of CSAR and supporting rules soon.

Watch our webinars:
Interpretation of China's Cosmetic Supervision and Administration Regulation

Check out the breaking news:
China Finalises the Long-Awaited Cosmetic Supervision and Administration Regulation

Visit the featured page for more information:
Featured — China Cosmetic Regulatory Reform Tracking

— CSAR —

Technical Guidelines for Application of Threshold of Toxicological Concern (TTC) Method

(Draft for Comments)

ChemLinked Team, REACH24H Consulting Group | http://cosmetic.chemlinked.com
14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121
Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566 | Email: cosmetic@chemlinked.com

Contents

1. Overview

The threshold of toxicological concern (TTC) method is based on the fundamental assumption that the toxic effects of a chemical is mainly related to its structure. The key to this is to determine whether the chemical is suitable for the TTC method and to conduct structural classification, and not to underestimate the exposure level.

This "Guidelines (Draft for Comments)" introduces TTC application in cosmetic safety assessments, clarifying the scope of application, terms and definitions, substance classification, assessment procedures, and use requirements for mixtures with regard to the TTC method.

2. Scope of Application

This "Guidelines (Draft for Comments)" is applicable to cosmetic ingredients or risk substances that have a clear chemical structure, have no structural alert for serious mutagenicity, have a low concentration, and lack of systemic toxicologic research data.

It is not applicable to these ingredients or risk substances, including metals or metal compounds, potent carcinogens (e.g., aflatoxins, nitroso compounds, and benzidines), proteins, steroids, high-molecular weight substances, very bioaccumulative substances, radioactive chemicals, *etc.*; ingredients with preservative, sunscreen, coloring, hair dyeing, freckle-removing and whitening, anti-hair loss, anti-acne, anti-wrinkle (excluding physical anti-wrinkle), anti-dandruff, deodorant functions, and with high bioactivity; ingredients, nanomaterials, and inorganics, *etc.* with risk of inhalation.

3. Terms and Definitions

3.1 Threshold of toxicological concern (TTC)

The level of exposure at or below which it is expected to have no risk to human health.

3.2 Systemic exposure dosage (SED)

The estimated level of a substance to be assessed entering the systemic circulation through various exposure pathways, usually expressed in μg/kg bw/day.

3.3 Potential DNA-reactive mutagens/carcinogens

Substances that directly act on DNA and may cause DNA damage, leading to replication errors or potentially inducing cellular canceration.

3.4 Cramer class

In TTC assessment, chemicals are classified into Cramer I, Cramer II, and Cramer III

CHEMLINKED

SUBSCRIBE TO CHEMLINKED NOW

REMOVE COSMETIC REGULATORY BARRIERS
EXPEDITE ASIA MARKET ACCESS

· In-time regulatory information and market access requirements
· Supported by local and experienced technically adept technical team
· Strategic partnerships with competent authorities and industrial associations worldwide
· Customized consulting service for complete compliance solutions.

OUR SERVICES

Information
News, Alerts

Knowledge
Pedia-articles,
Regulatory Analysis, Market Insights, Reports

Databases
Regulatory Database,
English Translations, Lists/Inventories, Q&A

Training
Webinars, Online courses, Offline events

Solutions
Translation, Consultancy, Advertising,
Tailored Regulatory Report,
Business-matching services,
Tailored online and offline training

CHEMLINKED.COM

14th Floor, Building 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China (311121)
Tel: +86 (0)571 8609 4444 / Fax: +86 571 8700 7566 / E-mail: cosmetic@chemlinked.com
Visit our website for more information about AP cosmetic News & Regulation updates