GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 03.120.01

CCS A 00

GB/T 41005-2021

Consumer Products Safety – General Rules on Chemical Hazards Risk Assessment

消费品安全 化学危害风险评估通则

Issued on: December 31, 2021 **Implemented on: December 31, 2021**

Issued by: State Administration for Market Regulation;

Standardization Administration of the People's Republic of China.

Table of Contents

Consumer Products Safety – General Rules on Chemical Hazards Risk Assessment

1 Scope

This Document specifies the principles, procedures and basic methods for assessing possible risks on consumer health from chemical substances in consumer products.

This Document applies to the risk assessment of the health effects of chemical substances in consumer products on consumers.

2 Normative References

The provisions in following documents become the provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 39011-2020 Consumer Product Safety - General Principles for Hazard Identification

3 Terms and Definitions

For the purposes of this Document, the following terms and definitions apply.

3.1 Consumer product

Mainly, but not limited to, products designed and produced for personal use, including product components, parts, accessories, instructions for use and packaging.

[Source: GB/T 35248-2017, 2.2]

3.2 Hazard

Potential source of injury that could result.

[Source: GB/T 28803-2012, 3.2]

3.3 Chemical hazard

The inherent property of a chemical substance that may cause adverse effects upon exposure to humans.

3.4 Risk

Risk arising from a chemical hazard, that is, the likelihood and severity of adverse effects on human exposure to chemical substances in consumer products under a given environment.

3.5 Risk assessment

Risk assessment for chemical hazards, that is, the process of calculating and estimating the risks to consumers' health under the exposure conditions of specific chemical substances in consumer products, thereof, the inherent characteristics of chemical substances and the characteristics of consumers shall be taken into account.

NOTE: The process of risk assessment consists of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

3.6 Hazard identification

The process of discovering, enumerating and describing risk elements.

[Source: GB/T 39011-2020, 3.4]

3.7 Hazard characterization

A qualitative or quantitative description of the inherent characteristics of a chemical hazard that may cause potentially hazardous effects.

NOTE: It includes dose-response assessments and attendant uncertainties.

[Source: GB/T 22760-2020, 2.17]

3.8 Exposure assessment

Assessment of consumer exposure to chemical substances (and their derivatives).

[Source: GB/T 22760-2020, 2.18]

3.9 Risk characterization

Qualitative and quantitative descriptions of the likelihood and associated uncertainty of a chemical substance with known or potential adverse health effects to consumers under a given exposure condition.

[Source: GB/T 22760-2020, 2.19]

3.10 Safety limit value

A limiting quantity value specified for a chemical substance that includes both concentration and time factors.

6.3 Hazard characterization

6.3.1 Overview

The purpose of hazard characterization is to obtain safety limits for chemical substances. Generally, there are two ways: directly adopt the safety limit of the authoritative database on chemical substance toxicity; deduce the safety limit from the chemical substance toxicity data.

6.3.2 Directly adopt the safety limits of authoritative database on chemical substance toxicity

6.3.2.1 See Appendix A for the commonly used chemical substance toxicity database.

6.3.2.2 Although the definitions of safety limits are slightly different in different databases, the characterization objects are almost the same. For example, Acceptable Daily Intake (ADI), Tolerable Intake (TI), Reference Dose (RfD), Maximum Allowable Concentration (MAC), Virtual Safety Dose (VSD) and Carcinogenic Slope Factor (SF) are all different ways of expressing safety limit values.

6.3.2.3 Corresponding to different exposure routes and different toxicity targets, there shall be multiple safety limits for the same chemical substance; and the corresponding safety limit shall be selected according to the nature of the chemical substance itself and the actual exposure scenario during assessment.

6.3.2.4 The safety limit value of the same chemical substance in different databases may be different, it is recommended to select the safety limit with a lower value.

6.3.3 Derivation of safety limits from chemical toxicity data

6.3.3.1 When the safety limit of a chemical substance cannot be obtained from the toxicity database, the safety limit can be derived from the toxicity data of the chemical substance. It shall be noted that for non-threshold chemical substances (including genotoxic carcinogens and mutagenic substances), deriving safety limits from toxicity data requires extremely specialized toxicological knowledge and dedicated data analysis tools; and this Document does not involve related content, if necessary, please consult relevant professionals.

6.3.3.2 When selecting toxicity data, focus on sub-chronic toxicity and chronic toxicity, collect and select as much as possible the no-observed-adverse-effects level (NOAEL) or the lowest-observed-adverse-effects level (LOAEL).

6.3.3.3 See Appendix B for the specific method of deriving safety limits from the toxicity data of chemical substances.

6.4 Exposure assessment

6.4.1 Overview

The purpose of exposure assessment is to obtain the amounts of chemical substances in

consumer products entering the consumer's body during use, that is, exposure. In the exposure assessment, it is necessary to focus on the exposure route, exposure time, consumer characteristics and use behavior characteristics.

6.4.2 Exposure route

Exposure route refers to the way in which chemical substances migrate to and be exposed to the human body, including percutaneous, inhalation, oral, subcutaneous and vascular puncture, and mucosal contact, etc. The percutaneous, inhalation and oral routes are the most common exposure routs to chemicals in consumer products.

6.4.3 Selection of exposure assessment method

6.4.3.1 The specific methods for implementing exposure assessment mainly include direct measurement method, exposure model method and biological monitoring method. See Appendix C for the specific description of each method.

6.4.3.2 This Document recommends the exposure model method, which is the most feasible and cost-effective method for routine risk assessment and ordinary assessors.

6.4.4 Use of exposure models

6.4.4.1 Exposure models are mathematical models used to quantify exposure scenarios and exposure processes. Commonly used exposure models are listed in Appendix D.

6.4.4.2 The reliability of exposure assessment results depends on the rationality of model selection and the data quality of model parameters.

6.4.4.3 The difficulty in using exposure models for exposure assessment is that it is sometimes difficult to obtain sufficiently accurate data for certain parameters in the model. At this time, it can generally be determined according to the "most unfavorable" principle.

6.4.4.4 When conducting exposure assessment, it is necessary to consider all possible exposure routes, and then conduct exposure assessment for different exposure routes and combine them to obtain the total exposure.

6.4.4.5 Exposure assessment can be carried out not only for the chemical hazard of a certain consumer product, but also for the chemical hazard in a certain type of consumer products. When assessing exposure to a certain type of consumer products, the values of the relevant parameters in the exposure model shall be able to represent the overall situation of this type of consumer products. The usual practice is to collect as many similar products as possible to form evaluation samples; and obtain statistical values of relevant parameters (such as: mean, median, percentile, etc.) and substitute them into the exposure model to obtain the corresponding exposure to comprehensively reflect the exposure to chemical substances in such consumer products.

6.5 Risk Characterization

Appendix A

(Informative)

Databases on Chemical Substance Toxicity

Commonly used more authoritative databases on chemical substance toxicity include but are not limited to the following databases:

a) International Program Database on Chemical Safety (IPCS);

b) Global Chemical Information Network Database (GINC);

c) Integrated Risk Information System (IRIS) and Chemical Toxicity Assessment Data (ITER) US Environmental Protection Agency (EPA);

d) US Agency for Toxic Substance and Disease Registry Database (ATSDR);

e) Chemical Database (ChemIDplus) of National Institutes of Health (NIH);

f) Chemical Carcinogenicity Research Information System (CCRIS) of National Cancer Institute (NCI);

g) US National Library of Medicine and Toxicology Data Network (NLM);

h) European Chemicals Agency REACH Registered Chemical Substance Information (ECHA REACH).

Appendix B

(Informative)

General Method for Deriving Safety Limits from Chemical Toxicity Data

Safety Limits (SLs) for chemicals can be derived by using the no-observed adverse effect level (NOAEL) or the lowest observable adverse effect level (LOAEL) based on sub-chronic/chronic toxicity. Relatively speaking, using NOAEL is better than using LOAEL. The derivation formula is shown in Formula (B.1):

$$SL = \frac{NOAEL}{UF_1 \times UF_2 \times \cdots \times UF_n} \qquad \cdots\cdots (B.1)$$

Where: UF is the uncertainty coefficients; the commonly-used UFs include:

a) UF_1 - Interspecies differences, mainly the differences between experimental animals extrapolated to humans, generally set to 10;

b) UF_2 - Intraspecies differences, mainly considering the differences between different individuals in the population. At this time, the data comes directly from human trials, and from the perspective of protecting vulnerable groups, it is generally set to 10;

c) UF_3 - The difference between LOAEL and NOAEL, when LOAEL is used to deduce the safety limit, it is generally set to 10;

d) UF_4 - Data reliability difference, when the data is incomplete or the reliability is very low, it is generally set to 10;

e) UF_5 - Uncertainty due to differences in exposure duration (extrapolated from sub-chronic effects to chronic effects), the range of which is:

1) For 1 month to less than 3 months, the value is 10;

2) For 3 months to less than 6 months, the value is 5;

3) For 6 months to less than 12 months, the value is 2;

4) For 12 months or longer, the value is 1.

Appendix C

(Informative)

Direct Measurement Method, Exposure Model Method, and Biomonitoring Method

C.1 Direct measurement method

The direct measurement method, the contact point method, refers to the use of monitoring data from real situations to directly quantify the level of exposure being assessed. For example, by collecting air or dietary samples, an individual's exposure level at a certain time point can be directly measured.

C.2 Exposure model method

Exposure model method refers to the application of mathematical models to quantify exposure. Use available information on the concentration of the chemical substance in the exposure medium, as well as information on when, where and how the individual is exposed to exposure activities that may result in the transfer of the substance from the exposure medium to the individual. Specific exposure scenarios are generally set, and then data (such as substance concentrations), a range of exposure factors (such as exposure time, exposure frequency, respiratory rate) and exposure models are applied to estimate the exposure in the scenario.

C.3 Biomonitoring method

Biomonitoring method refers to measuring the amounts of stressors in biological matrices. Models can be used in conjunction with biomarker data to estimate the amounts of agents to which an individual is exposed.

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------