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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 21765-2025

Replacing GB/T 21765-2008

Chemicals - Test method of subchronic inhalation toxicity

化学品 亚慢性吸入毒性试验方法

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. This document supersedes GB/T 21765-2008 "Test Methods for Subchronic Inhalation Toxicity of Chemicals" and is consistent with GB/T 21765-2008. Compared to previous versions, aside from structural adjustments and editorial changes, the main technical changes are as follows:

---The scope of chemicals to be tested in this document has been changed (see Chapter 1, Chapter 1 of the 2008 edition);

---Abbreviations have been added (see Chapter 4);

---Added requirements for feed and water in the laboratory animal housing environment when administering the virus via oral-nasal route and through systemic exposure. (See 6.2.3);

---Added design criteria for exposure concentrations, namely, limit concentrations and dose pre-experiments (see 6.5, 6.6);

---The design for the exposure was modified, a satellite group was added, and it was divided into Test Plan A and Test Plan B based on the properties of the chemicals (see 6.7.2). Appendix A and Appendix B (4.4, 2008 edition);

---The clinical observation method has been changed to laboratory animal observation (see 6.8,

4.7 in the 2008 edition);

---Added bronchoalveolar lavage fluid testing (see 6.9.3);

---Increases lung load (see 6.9.4);

---The pathological examination has been changed to gross pathology examination, organ coefficients, histopathological examination, and pulmonary function (see 6.9.5). 6.9.6, 6.9.7,

and 4.9 (2008 edition).

---The content of the test data and reporting section has been revised (see 7.1, 7.2, Chapter 5 of the 2008 edition). Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Hazardous Chemicals Management (SAC/TC251). This document was drafted by: the Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention; North China University of Technology; and the Affiliated New Campus of Dalian University. Hua Hospital. The main drafters of this document are: Zhang Yanshu, Wang Weixuan, Shi Fan, Li Bin, Chen Xiao, Xiao Jingwei, Zhang Yi, and Li Jihang. The release history of this document and the document it replaces is as follows:

---First published in 2008 as GB/T 21765-2008;

1 Scope

GB/T 21765-2025 is the Chinese national standard covering the ninety-day inhalation study - the exposure chamber and the concentrations, the particle size for an aerosol, the daily and total exposure, the clinical observations and the pathology at the end, and the no-effect level that comes out of it. Issued on 5 October 2025, it has been in force since 1 February 2026, replacing GB/T 21765-2008.

This document specifies the basic principles, test methods, test data, and reporting for the subchronic inhalation toxicity testing of chemicals. This document applies to the detection of subchronic inhalation toxicity of chemicals (including nanomaterials).

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 14925 Laboratory Animal Environment and Facilities

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 The harmful effects that occur when experimental animals repeatedly inhale the test substance continuously (approximately 1/10 of their lifespan).

3.2 Elimination kinetics The ways and rates at which chemicals are eliminated from the

body.

4. Abbreviations The following abbreviations apply to this document. PEO. Post-Exposure Observation

5.1 Experimental animals were exposed to different concentrations of the test substance daily for 6 hours over a 90-day period. It is advisable to have 3 or more concentration groups. Five animals were included in each of the following groups, a negative control group (filtered air) and a solvent control group. Five male and five female animals were included in each group. Animals were observed daily during the exposure period.