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

GB 38850-2020

List for materials and restricted substances in disinfectant

消毒剂原料清单及禁限用物质

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Table of Contents

Foreword...	3
1 Scope...	4
2 Normative references...	4
3 Terms and definitions...	5
4 Disinfectant raw material list and scope of use...	6
5 Provisions on prohibited substances...	29

1 Scope

GB 38850-2020 is the Chinese national standard on list for materials and restricted substances in disinfectant, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 9 April 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 November 2020. Classification: ICS 11.080, CCS C50. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This Standard specifies the list of ingredients and scope of application of disinfectants for different disinfection objects. At the same time, it also specifies the prohibited and restricted substances in disinfectant formulations. This Standard is applicable to disinfectants for disinfecting drinking water, human body, medical equipment, environment and surface of objects, pollutants, indoor air, centralized air conditioning and ventilation system, swimming pool water, hospital sewage.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 5749, Standards for drinking water quality

GB/T 19104, Peracetic acid solution

GB/T 19106, Sodium hypochlorite

GB/T 20783, Stable chlorine dioxide solution

HG/T 3779, Dichloroisocyanuric acid sodium salt Pharmacopoeia of the People's Republic of China (Edition 2015) Specification for sanitary safety evaluation of sanitary disinfectants and disinfection equipment for drinking water [Ministry of Health (Waijianfa [2005] No. 336)] Technical specifications for cosmetics safety (Edition 2015) (China Food and Drug Administration) In medical and health institutions, disinfectant used to disinfect equipment and supplies that come into contact with human skin, mucous membranes, organs, and tissues.

3.9 disinfectant for environment and object surface Disinfectant used to disinfect surfaces such as walls, floors, articles, instruments and equipment that are not in direct contact with food and feed in homes, public places, factories, medical and health and other institutions.

3.10 disinfectant for contaminants Disinfectant used to disinfect the secretions, excreta, pollutants, medical waste, and microbiological laboratory pollutants and waste of patients and suspected patients in medical institutions and infectious disease epidemic sites.

3.11 disinfectant for indoor air Disinfectant used to disinfect indoor air under unmanned conditions.

3.12 disinfectant for central air-condition Disinfectant used to disinfect central air conditioning ventilation pipes, fan coils, and condensation systems.

3.13 disinfectant for swimming pool water Disinfectant used to disinfect swimming pool water.

3.14 disinfectant for contaminated water of hospital Disinfectant used to disinfect sewage in medical institutions.

4 Disinfectant raw material list and scope of use

4.1 See Table 1 for disinfectant raw material active (effective) ingredient list and range of use.

5 Provisions on prohibited substances

5.1 Medicines and raw materials with the same name that are prohibited to add into the "Pharmacopoeia of the People's Republic of China" (Edition 2015) (except for disinfection and antiseptic drugs) by disinfectants; preparations for generating active or passive immunity such as vaccines, sera or toxins and their products used in human medicine, preparations used to diagnose immune status (except lysozyme and staphylococcus enzyme); prohibited substances listed in the "Technical specifications for cosmetics safety" (Edition 2015) (except iodine) (limited to disinfectants used for human body); other prohibited substances stipulated by the national health administrative department.

5.2 Disinfectant using sodium hypochlorite as raw material, is forbidden to use grade B raw material in GB/T 19106.

5.3 Disinfectant using peroxyacetic acid as raw material, is forbidden to use type III raw material in GB/T 19104.

5.4 For disinfectant using trichlorohydroxydiphenyl ether as raw material, the content of dioxin shall meet the requirements of the "Pharmacopoeia of the People's Republic of China" (Edition 2015).

5.5 When using sodium dichloroisocyanurate as disinfectant for drinking water in emergency, it is prohibited to use type II raw materials in HG/T 3779.

5.6 The raw materials for disinfectants used to disinfect human bodies, medical devices, and drinking water shall meet the "Pharmacopoeia of the People's Republic of China" (Edition 2015), quality requirements of food grade, medical grade, or chemically pure and above grades. Prohibit the use of industrial grade raw materials. If there is no raw material of the above quality grade, industrial grade raw material can be used temporarily, but it shall meet the raw material requirements of the corresponding disinfectant standard.

5.7 The raw materials used for disinfectant for drinking water shall also meet the requirements of GB 5749 and the Ministry of Health's "Specification for sanitary safety evaluation of sanitary disinfectants and disinfection equipment for drinking water" (Edition 2005).