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The guidelines for the generic name of new chemical substances(Publicity version)

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Foreword

This standard is established in order to implement the Provisions on the Environmental Administration of New Chemical Substances, regulate declaration and registration of new chemical substances while keeping trade and technical secrets of new chemical substances involved in declaration and registration.

This standard specifies the method of preparing generic names of new chemical substances during their declaration and registration.

Technical contents of this standard have adopted relevant technical methods regarding internationally accepted new chemical substance declaration, borrowing experience on preparing and supplementing the directory of China's existing chemical substances and new chemical substance evaluation.

Annex A, Annex B and Annex C in this standard are informative annexes.

This standard is the first release.

This standard is a directive standard.

The standard is proposed by the Department of Science & Technology Standards of the State Environmental Protection Administration.

This standard mainly drafted by: the Chemical Registration Center of the State Environmental Protection Administration

This standard is approved by the State Environmental Protection Administration on January 15, 2008.

This standard is implemented on April 1, 2008.

This standard shall be interpreted by the State Environmental Protection Administration.

The guidelines for the generic name of new chemical substances

1. Scope

This standard specifies the method of preparing generic names of new chemical substances during their declaration and registration.

This standard applies to the preparation of generic names of new chemical substances when declaring and registering new chemical substances. Evaluation of generic names of new chemical substances when declaring and registering new chemical substances may also refer to this standard.

2 Normative References

For articles of the following documents cited in this standard, the latest edition of any cited document not annotated with the date will be applicable to this standard.

Provisions on the Environmental Administration of New Chemical Substances (SEPA Order No. 17) 3 Terms and definitions

The following terminology and definitions apply to this standard.

3.1

New chemical substances

The new chemical substances described in the Provisions on the Environmental Administration of New Chemical Substances are those which were not yet imported into the territory of the People's Republic of China or produced within the territory of the People's Republic of China.

3.2

Generic names of new chemical substances

Generic names refer to names which replace chemical names of new chemical substances in unclassified literatures when declaring and registering new chemical substances and reflect basic chemical types of new chemical substances while keeping trade secrets or technical secrets of the chemical names of new chemical substances. Generic names include Chinese generic names and English generic names.

3.3

Chemical names of new chemical substances

English chemical names of new chemical substances generally refer to names according to the nomenclature recommended by the International Union of Pure and Applied Chemistry(IUPAC) or the International Union of Biochemistry and Molecular Biology (IUBMB) or corresponding index names in Chemical Abstracts (CA) of U.S.A.; Chinese chemical names refer to names meeting the systematic nomenclature recommended by the China National Committee for Terms in Sciences and Technologies or Chinese Chemical Society.

Index numbers of new chemical substances of dye and pigment are regarded as parts of the chemical names of the substances.

For new chemical substances without definite chemical structures, definitional descriptions on sources or precursors, production processes or technological conditions of the chemical substances declared shall be regarded as parts of the chemical names of the substances.

3.4

New chemical substances with definite chemical structures

Definite structural formulas can be used to represent new chemical substances with the structures. The chemical names usually reveal the following structural information:

A) Structural types of basic structures (such as carbon chains, ring systems or coordinated metals, etc.)

B) Types, quantities and positions of basic structures and substituent groups on other chemical groups

C) Types and quantities of ions;

D) Stereochemical information.

3.5

New chemical substances without definite chemical structures

The new chemical substances which cannot be represented with definite structural formulas are complicated reaction products or biological materials with unknown or uncertain chemical compositions. Their chemical names often reveal the following information:

E) sources or precursors of chemical substances ;

F) Production processes or technological conditions of chemical substances

4 General provisions on generic names of new chemical substances

4.1 Generic names of chemical substance should be based on the new chemical substances not violating the chemical types reflected by the chemical names of new chemical substances and try not to conceal chemical characteristics and basic structures reflected by chemical names of the new chemical substances. 4.2 specific descriptors which represent characteristics of various chemical structures, material sources and production processes etc.in the chemical names can be hidden or replaced with general descriptors.

4.3 Usually only one to two specific descriptors in the chemical names can be hidden or replaced.

4.4 The purpose of fully protecting secrets of specific information of the new chemical substances cannot be realized only hiding one to two specific descriptors. If reasons are proposed, dual or multiple confidential generic names can be provided.

4.5 generic names of new chemical substances cannot be expressed with trade names, common names or abbreviated names of chemical products of new chemical substances or chemical products containing new chemical substances (if the names do not comply with the provision of Article 4.1), nor can they be simply expressed with letters or digits. 4.6 Avoid using the same generic names of new chemical substances published as far as possible.

5 provisions on generic names of new chemical substances with determined chemical structures

5.1 Types of Basic Structures

General descriptors can be used to replace specific descriptors that represent basic structures in the chemical names, such as alkyl or alkane, alkenyl or alkene, alkynyl or alkyne, carbomonocyclic or carbomonocycle, carbopolycyclic or carbopolycycle, heteromonocyclic or heteromonocycle, heteropolycyclic or heteropolycyle, alkali metal, alkaline earth metal, transition metal and halogen etc.

5.2 Types of Chemical Groups

General descriptors can be used to replace specific descriptors representing chemical group types in the chemical names, such as halosubstituted and substituted etc.

5.3 Amount and Positions of Chemical Groups

For single chemical groups, descriptors indicating their positions in the chemical names can be omitted.

For multiple chemical groups, general descriptors can be used to replace specific descriptors indicating their amount and positions in the chemical names, such as multi, poly etc.

5.4 Types and Amount of Ions

General descriptors can be used to replace specific descriptors representing ion types and amount in the chemical names, such as anion, cation, amphoteric ion, multi etc.

5.5 Stereochemical Information

Descriptors representing stereochemical information can be omitted.

5.6 Examples of Generic Names

See Annex A for examples of generic names of new chemical substances with definite chemical structures.

6 Provisions on Generic Names of New Chemical Substances without Definite Chemical Structures

6.1 Sources or Precursors of New Chemical Substances

For new chemical substances with biogenetic derivation can be expressed with the most critical specific descriptors representing biogenetic derivation in the hidden chemical names (such as biological tissues and organs, strains, or subspecies, species, genus, etc.)

For new chemical substances in raw materials with definite chemical structures, the generic names of the raw materials can be used to prepare generic names of new chemical substances. Refer to Chapter 5 for detail.

6.2 Production Processes or Technological Conditions of New Chemical Substances

6.2.1 If there are technological conditions contained in the chemical names, the technological conditions can be hidden.

6.2.2 If there are no technological conditions contained in the chemical names, specific descriptors for various synthesizing or extracting processes can be replaced with general descriptors, such as polymer, compound, chemical reaction product, enzyme catalyzed reaction product, chemical derivative, physical derivative etc.

6.3 Examples of Generic Names

See Annex B for examples of generic name of new chemical substances without definite chemical structures.

7 Special provisions on generic names of new chemical substances of enzymes

7.1 generic names of enzyme can be realized by hiding the 4th level digit and its specific descriptor in the numeric code designated by the Enzymology Committee.

7.2 There is only 1 digit at the 4th level numeric code of the Enzymology Committee, then the 3rd level and the 4th level digits can be hidden, and the name reflecting the front 2 level numeric codes is the generic name.

 $7.3\,\text{See}$ annex C for examples of generic names of new

chemical substances of enzymes.

8 Implementation Requirements

County level or higher level competent administrative department of environmental protection of the people's government is responsible for supervision and implementation of this standard.

Annex A (Informative annex) example of generic names of new chemical substances with definite chemical structures

Example 1 CF₃CF₂CF₂CF₂CF₂CH₂N(CH₂CH₂OH₎₂ Chemical name 2,2,3,3,4,4,5,5,6,6,6 - 11 fluoro - N , N - bis (2 - hydroxyethyl) hexylamine Generic name • Confidential fluorine atom

2,2,3,3,4,4,5,5,6,6,6-11 halogenated - N,N-bis (2- hydroxyethyl) hexylamine , or 2,2,3,3,4,4,5,5,6,6,6-11 substituted-N,N-bis (2 - hydroxyethyl) hexylamine

• Number of confidential fluorine atoms

Multi fluoro - N, N - bis (2- hydroxyethyl) hexylamine

• Confidential hydroxy

2,2,3,3,4,4,5,5,6,6,6 - 11 fluoro - N , N - bis (2 - substituted ethyl) hexylamine

Basic structure and locator of the confidential hexane 11 fluoro-N, N-bis (2- hydroxyethyl) alkylamine

Example 2



Chemical name

1 - vinyl-5, 8 - dihydro-5, 8 - dioxo -6,7 - dichloro - 4 - isoquinoline sulfonic acid

Generic name

• Confidential vinyl

1 -alkenyl-5, 8 - dihydro-5, 8 - dioxo -6, 7 - dichloro - 4 - isoquinoline sulfonic acid

- Confidential oxo
- 1 vinyl-5, 8 dihydro-5, 8 bis substituent -6,7 dichloro 4 isoquinoline sulfonic acid
- Confidential Chlorine atom
- 1-vinyl-5, 8 dihydro--5, 8 dioxo -6,7 bis-halogenated 4 isoquinoline sulfonic acid
- Confidential sulfonic group
- 1 vinyl-5, 8 dihydro-5, 8 dioxo -6, 7 dichloro 4 substituted isoquinoline
- Confidential isoquinoline ring and locator

Dichloro- ethyl- dihydro- dioxo heteropolycyclic sulfonic acid, or dichloro- ethyl- dihydrodioxygen sulfonic group heteropolycyle

Example 3



Chemical name

4-[(5-chloro-4- methyl-2- sulfophenyl) azo]-3- hydroxy-2- naphthoic acid calcium salt (1:1) (C.I.Pigment Red 48:2)

Generic name Monoazo calcium salt red pigment Annex B (informative annex) example of generic names of new chemical substances without definite chemical structures

Example 1
Chemical name

Generic names of polymers of linseed-oil fatty acid, ethylene glycol fumaric acid

and maleic anhydride

Confidential flaxseed oil
Polymers of fatty acid, ethylene glycol fumaric acid and maleic anhydride
Confidential fumaric acid

Polymers of linseed-oil fatty acid, ethylene glycol dicarboxylic acid and maleic anhydride

Example 2

Chemical name Narrow-leaved straw flower extract Generic name • Confidential narrow-leaved straw flower species

Straw flower extract

Example 3 Chemical name Mulberry bark extract Generic name

• Confidential dermal tissue

Mulberry extract

Annex C

(informative annex)

Examples of generic names of new chemical substances of enzymes

Example 1

The 4th level code name of the Enzymology Committee Cholesterol keto 5P - reducing enzyme with Enzymology Committee number of 1.3.1.22 Generic name NADP+ oxidation-reduction enzyme with Enzymology Committee number of 1.3.1

Example 2

The 4th level code name of the Enzymology Committee

6- Hydroxy nicotinic acid reducing enzyme with Enzymology Committee number of 1.3.7.1 Generic name Receptor oxidation-reduction enzyme with Committee number of 1.3