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**Decision Method of Persistent, Bioaccumulative and
Toxic Substances, and Very Persistent and Very
Bioaccumulative Substances**

持久性、生物累积性和毒性物质及高持久性和
高生物累积性物质的判定方法

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Table of Contents

Foreword.....	3
Introduction	4
1 Application Scope	5
2 Terms and Definitions.....	5
3 Identification of PBT Substances.....	6
4 Identification of vPvB Substances	9
5 Identification of PBT or vPvB Substances Using Screening Standard	9

Foreword

This Standard was drafted by referring to REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Regulation Annex XIII *Criteria for the Identification of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances*, the REACH Regulation Guidance *Technical Guidance Document for Preparing the Chemical Safety Assessment*, Chapter R 11 *Evaluation of Persistent, Bioaccumulative and Toxic Substances and Very Persistent and Very Bioaccumulative Substances*, and UN Directive 67/548/EEC *Classification, Packaging and Labelling of Dangerous Substances*. The relevant technical content is fully consistent with the above-mentioned documents. Some editorial modifications are made in the format of the standard.

This Standard was proposed and under the jurisdiction of the National Standardization Technical Committee on Dangerous Chemical Management (SAC/TC 251).

The drafting organization of this Standard: General Administration of Quality Supervision Safety Research Centre of Imported and Exported Cosmetics.

The main drafters of this Standard: Sun Xin, Chen Huipeng, Wang Xiaobing, Mei Jian, Li Xi, Zhang Jing, Li Lei.

This Standard was drafted for the first time.

Decision Method of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances

1 Application Scope

This Standard specifies the criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances.

Chapter 3 and Chapter 4 of this Standard are only applicable to metallo-organic compounds.

2 Terms and Definitions

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

2.1

PBT or vPvB substance

A substance which contains a persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative constituent. And the content of the constituents is 80% or more.

2.2

substance containing maximum $X\%$ (or $X\% \sim Y\%$) PBTs or vPvBs

A substance which contains one or more persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative constituents or impurities; and the content of a single content or impurity is greater than or equal to 0.1% (but less than 80%). The content may be a maximum content ($X\%$) or content range ($X\% \sim Y\%$), as appropriate.

2.3

substance forming PBTs or vPvBs

A substance whose constituents or impurities are degradable or can be transformed into persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative substances; and the content of a single transformation or degradation product formed is greater than 0.1% (of the mass of the original substance). The mass fraction of

There is sufficient evidence of the relationship between the exposure of human body to some substance and cancer.

3.3.2.2 the substance deemed possibly carcinogenic for human body

There is sufficient evidence of the convincing hypothesis that cancer is caused because of exposure of human body to some substance, generally based on:

- a) appropriate long-term research in animals;
- b) other relevant information.

3.3.3 the substance meets the criteria for classification as teratogenic

3.3.3.1 the substance known to be teratogenic

There is sufficient evidence of the relationship between the exposure of human body to some substance and the damage of genetic genes.

3.3.3.2 the substance deemed possibly teratogenic

There is sufficient evidence of the convincing hypothesis that the damage of genetic genes is caused because of exposure of human body to some substance, generally based on:

- a) appropriate long-term research in animals;
- b) other relevant information.

3.3.4 the substance meets the criteria for classification as toxic for reproduction

3.3.4.1 the substance known to damage human reproduction

There is sufficient evidence of the relationship between the exposure of human body to some substance and the damage of reproduction.

3.3.4.2 the substance deemed possibly toxic for the growth of human body

There is sufficient evidence of the relationship between the exposure of human body to some substance and the growth of descendants.

3.3.4.3 the substance deemed possibly damaging for the reproduction of human beings

There is sufficient evidence of the convincing evidence that the damage of reproduction is caused by the exposure of human body to some substance, based on:

- a) there is obvious evidence in the animal research of reproduction damage containing no toxicity or the evidence of reproduction damage of secondary non-

Screening Standard

The existing data of many substances are incapable of identifying the PBT/vPvB properties. Then the screening standard is used as alternative information to identify whether the substance fulfils the criterion of PBT/vPvB properties.

5.1 Indication of P and vP properties

5.1.1 Tests on ready biodegradation

If the substance is capable of ready biodegradation, then it shall not be considered to be a persistent or very persistent substance.

5.1.2 Tests on enhanced ready biodegradation

If the substance is capable of ready biodegradation, then it shall not be considered to be a persistent or very persistent substance.

5.1.3 Tests on inherent biodegradability

a) Zahn-Wellens test

The mineralization rate within 7 d using the DOC subtraction method $\geq 70\%$, the logarithmic phase not more than 3 d, the subtraction before degradation lower than 15% and no cultivated inoculation is needed, so it shall not be considered to be a persistent substance;

b) MITI II test

The mineralization rate within 7 d using the respirometric method $\geq 70\%$, the logarithmic phase not more than 3 d and no cultivated inoculation is needed, so it shall not be considered to be a persistent substance.

5.1.4 Prediction model

a) Biowin 2 (nonlinear model prediction) and Biowin 3 (final biodegradation time)

The biodegradation is not fast (the probability < 0.5)ⁱ and the final biodegradation time range prediction $\geq$ several months (the value < 2.2), and then it is identified to be a persistent substance;

b) Biowin 6 (MITI nonlinear model prediction) and Biowin 3 (final biodegradation time)

The biodegradation is not fast (the probability < 0.5)ⁱ and the final biodegradation time range prediction $\geq$ several months (the value < 2.2), and then it is identified to be a persistent substance;

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