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BSI Standards Publication

Cosmetics — Guidelines on the stability testing of cosmetic products

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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Cosmetics — Guidelines on the stability testing of cosmetic products

Cosmétiques — Lignes directrices relatives aux essais de stabilité des produits cosmétiques

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Foreword

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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Introduction

Stability studies are aimed at assessing the ability of a product to maintain the desired physical, chemical and microbiological properties, as well as functionality and sensorial properties when stored and used under appropriate conditions by the consumer. More simply, the objective of a stability study is to determine the shelf life of a product and to evaluate whether a product in the package is stable when subjected to the market conditions in which it is sold and used. The "market conditions" encompass distribution (transportation), warehouse storage and conditions during use.

Thus, the stability study may be seen as a prerequisite for ensuring product quality. Stability tests on cosmetic products are required for

— obtaining a guidance on the formulation of the product, and the appropriate packaging material,

— optimizing the formulation and manufacturing process,

— determining conditions of transportation, storage, display and manner of use,

— estimating and confirming shelf life, and

— ensuring customer safety.

This document identifies readily available references to assess the stability of cosmetic products on the market. Its purpose is to provide a resource for the selection of the appropriate stability tests. Although these guidelines provide a helpful starting point to evaluate new products and technologies, adapting the testing to reflect differences between product types and formulations may still be necessary.

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TECHNICAL REPORT **ISO/TR 18811:2018**

Cosmetics — Guidelines on the stability testing of cosmetic products

1 Scope

This document gives guidelines for the stability testing of cosmetic products. It reviews readily available bibliographic references that provide a resource for the assessment of the stability of cosmetic products. This review of the available guidelines that assess the stability of cosmetic products can serve as a technical/scientific framework to identify the most suitable methods for the assessment of the stability of cosmetic products.

This document does not aim to specify the conditions, parameters or criteria of stability testing.

Considering the wide variety of cosmetic products, storage and use conditions, it is not possible to define a single way to assess product stability. Therefore, it is up to the manufacturer to specify and justify the stability protocol to cover test methods, specifications and conditions at which products will be tested.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
accelerated stability evaluation
study designed to speed up naturally occurring destabilization processes due to intrinsic or extrinsic factors and which predicts the behaviour over the long term

Note 1 to entry: Typically, physico-chemical, mechanical or thermal procedures are employed.

3.2
real time stability evaluation
study that monitors the state of a product to determine the time course of any alteration to it under reasonably expected conditions of storage and use

Note 1 to entry: Often called “long term test” or “standard stability test”.

3.3
stability
ability of a cosmetic product to resist change or variation of its initial properties over time under stated or reasonably foreseeable conditions of storage and use

Note 1 to entry: See Reference [1].