



General Technical Requirements for Biotechnology-Derived Ingredients (Draft for Comments)

生物技术来源原料技术要求通则 (征求意见稿)

National Institutes for Food and Drug Control

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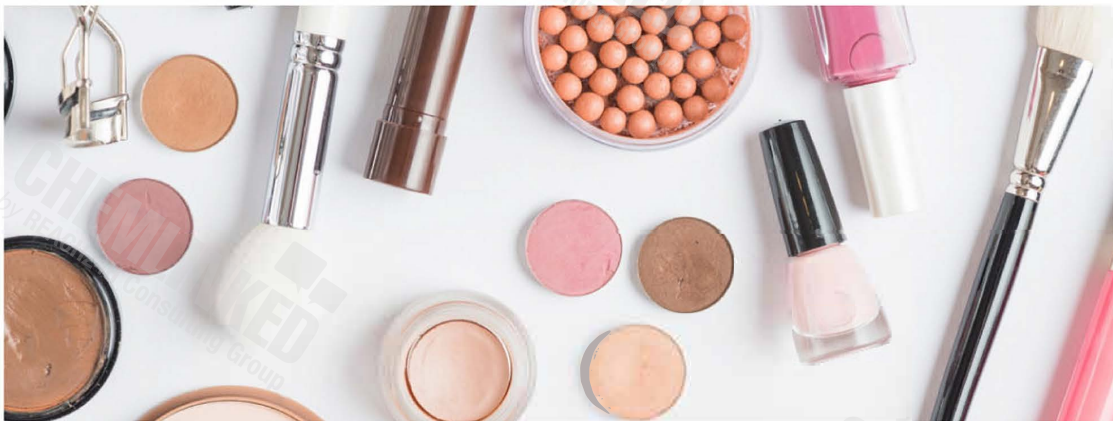
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Attachment 5

General Technical Requirements for Biotechnology-derived Ingredients (Draft for Comments)

1 Scope

This document specifies the terms and definitions, technical requirements, labeling, packaging, transportation, storage, shelf life, etc., of biotechnology-derived ingredients for cosmetics.

This document applies to the biotechnology-derived ingredients for cosmetics.

2 Terms and Definitions

2.1 Biotechnology-derived Ingredients

They refer to the ingredients meeting the quality requirements of cosmetics that are obtained from organisms (including animals, plants and microorganisms) or their components through directional design, processing, metabolic regulation or artificial synthesis using biotechnology (including fermentation engineering, cell engineering, protein engineering, enzyme engineering, gene engineering, etc.), which are intended to be used in the cosmetic field.

2.2 Fermentation Engineering

It refers to the technology of obtaining the required substances by large-scale culture utilizing the growth and metabolic activities of microorganisms under controlled conditions.

2.3 Cell Engineering

It refers to the technology of obtaining the required substances from animal and plant tissues or cells as basic units or production systems through isolated culture and reproduction based on the theories, methods, and technology of cellular biology and molecular biology.

2.4 Protein Engineering

It refers to the technology of modifying existing proteins or designing and synthesizing new proteins through gene modification or de novo design based on the spatial structure and functional mechanism of proteins, as well as bioinformatics analysis.

2.5 Enzyme Engineering

ChemLinked Team, REACH24H Consulting Group

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- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 5

生物技术来源原料技术要求通则 (征求意见稿)

1 范围

本文件规定了化妆品生物技术来源原料的术语和释义、技术要求、标签、包装、运输、贮存和保质期等。

本文件适用于化妆品生物技术来源原料。

2 术语和释义

2.1 生物技术来源原料 (Biotechnology-derived ingredients)

利用生物技术 (包括发酵工程、细胞工程、蛋白质工程、酶工程和基因工程等) 对生物体 (包括动物、植物、微生物) 或其组成部分进行定向设计、加工、代谢调控或人工合成, 从而获得满足化妆品质量要求, 用于化妆品领域的原料。

2.2 发酵工程 (Fermentation engineering)

利用微生物的生长和代谢活动, 在可控条件下进行大规模培养, 从而获得所需要的物质的技术。

2.3 细胞工程 (Cell engineering)

应用细胞生物学和分子生物学的理论、方法和技术, 以动植物组织或细胞为基本单位或作为生产系统进行离体培养、繁殖, 获得所需要的物质的技术。

2.4 蛋白质工程 (Protein engineering)

基于蛋白质的空间结构、功能机制及生物信息学分析, 通过基因修饰或从头设计, 对现有蛋白质进行改造, 或设计合成新的蛋白质的技术。

2.5 酶工程 (Enzyme engineering)

将酶学理论与化学工程相结合大规模生产酶制剂, 或利用酶的特性将原料转化为产物的技术。

2.6 基因工程 (Gene engineering)

在基因水平上对生物体进行基因切割、拼接、修饰和重组等操作, 使细胞具有更强的某种性能或获得全新功能的技术。

3 技术要求

ChemLinked Team, REACH24H Consulting Group

Website: <http://www.chemlinked.com> | Email: contact@chemlinked.com

Tel: +353 1 8899 951 / +86 (0)571 8609 4444



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