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Technical Guidelines for Compatibility Evaluation of Cosmetics with Packaging Materials (Draft for Comments) and Drafting Explanation

化妆品与包材相容性评价技术指南（征求意见稿）及起草说明

National Institutes for Food and Drug Control

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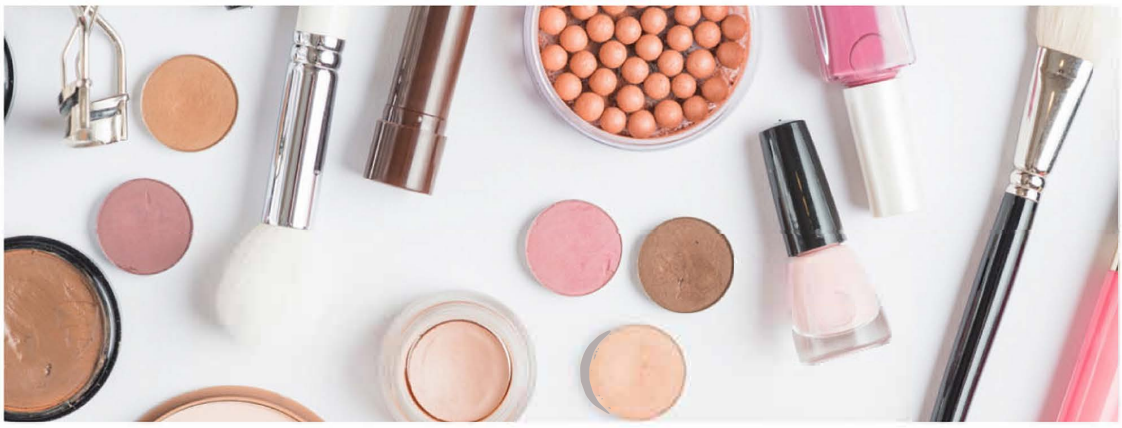

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Attachment 3

Technical Guidelines for Compatibility Evaluation of Cosmetics with Packaging Materials (Draft for Comments)

1 Scope

This "Guidelines" specifies the requirements, test methods, and result evaluation for compatibility evaluation of containers or carriers in direct contact with cosmetic contents with the products.

2 Terms and Definitions

2.1 Extractable substance: a substance that exists in packaging materials of cosmetics and can be extracted using solvents, including additives, residual monomers, degradation products, *etc.*, present in packaging materials of cosmetics.

2.2 Leachate: a substance obtained from migration tests that migrates from packaging materials or is generated in tests and enters cosmetics.

3 Requirements

The packaging materials that come into direct contact with cosmetics shall be safe and not react chemically with cosmetics, and must not migrate or release toxic or hazard substances that pose a threat to human health.

Compatibility studies shall be conducted to investigate whether there is a mutual influence between cosmetics and their packaging materials, which can lead to safety risks in cosmetics.

The compatibility studies between cosmetics and their packaging materials shall be initiated in the early research and development stages of cosmetics or during the selection of packaging materials, and run through the entire research and development process of cosmetics. If it is found that cosmetics interact with their packaging materials, causing an impact on the quality and safety of the cosmetics, the cause shall be identified and corresponding measures shall be taken, including replacing packaging materials, changing storage conditions, *etc.* When conducting the compatibility test between cosmetics and their packaging materials, a sensitive and exclusive testing method shall be established. If necessary, a method research can be conducted. During sampling, attention shall be paid to taking representative samples of blank packaging materials and cosmetics.

4 Test Methods

For conducting the compatibility studies, the first step is to determine the packaging containers and materials that come into direct contact with cosmetics, understand or analyze the composition of the packaging materials, the contact methods and conditions between the packaging materials and the cosmetics, and the production technique and process of the cosmetics; subsequently, an extraction test shall be conducted on the packaging materials used to obtain information on the extractable substances and predict potential leachates; through an interaction study, the degree to which components in the packaging materials migrate into or react with the cosmetics shall be investigated under the accelerated test and long-term stability test conditions, i.e. to obtain information on the leachate levels; a safety assessment shall be conducted for the leachate levels and then a conclusion shall be drawn on whether the packaging materials are suitable for the cosmetics concerned.

4.1 Extraction test

It is a test study on blank packaging materials using suitable solvents for the purpose of obtaining information on extractable substances in the packaging materials to clarify the target leachates for migration tests. Based on the type and level information on the extractable substances obtained in the extraction test study, a sensitive and exclusive analytical method shall be established to provide guidance on subsequent leachate studies (migration tests).

The extraction solvents shall usually have physicochemical properties that are compatible or similar to those of the cosmetics, with a focus on the pH value, polarity, and ion strength, *etc.*, of the solvents. The extraction conditions shall generally refer to the technique conditions of cosmetics, and as much extractable substances shall be extracted as possible by appropriately increasing the heating temperature and prolonging the heating time.

4.2 Interaction study

The interaction study includes a migration test and an adsorption test. The interaction study shall be conducted using actual samples under accelerated test and long-term stability test conditions (referring to the "Technical Guidelines for Stability Evaluation of Cosmetics"). The cosmetics shall be placed in such a way that they are in full contact with the packaging materials.

The migration test is a study conducted based on predicted target leachates, including extractable substances and their degradation products in packaging materials, as well as products produced by reactions between packaging materials and cosmetics, *etc.* The

analytical method used in the migration test shall undergo a method validation to confirm its sensitivity, accuracy, and stability in testing leachates in cosmetics. If the packaging material is composed of different layers of materials, it is not only necessary to assess the possibility of the components of the innermost layer migrating into cosmetics, but also to consider the potential of the components of the middle and outer layers migrating into cosmetics; at the same time, it is also required to investigate whether the ink or adhesive in the outer layer will migrate into cosmetics. If necessary, an adsorption test can be conducted to investigate the effect of packaging material adsorption on cosmetic ingredients.

When conducting the migration test, targeted test plans shall be designed based on the materials of different packaging materials and the types of cosmetics, focusing on the following items.

(1) For plastics, migration of residual monomers, additives, and their degradation products; migration of ink or adhesive in the outer layer of plastics.

(2) For glass, the effect of released basic ions on the pH of cosmetics; migration of harmful elements; migration of additives in light-proof glass containing colorants. For glass containers with internal coated with films, migration of additives in the films, *etc.*, shall also be considered.

(3) For metals, migration of metal ions; corrosion of metals by contents; the integrity of metal coatings before and after test, as well as migration of additives in the coatings, *etc.*

(4) For rubbers, migration of residual monomers, additives, and their degradation products. For film-coated rubber accessories, migration of additives in the films, *etc.*, shall also be considered.

(5) For ceramics, migration of harmful elements in ceramic glazes. For ceramic containers with internal coated with films, migration of additives in the films, *etc.*, shall also be considered.

(6) For mask cloth, migration of additives such as fluorescent whitening agents.

(7) For capsule shells, migration of additives such as colorants.

(8) For others, design a migration test protocol based on the aforementioned contents of packaging materials to be concerned to investigate the compatibility between the packaging materials and the cosmetics.

5 Result Evaluation

Based on the information on the extractable substances obtained from the extraction test and the leachate information obtained from the migration test, the types and contents of the leachates shall be analyzed and summarized, and necessary compound assignment or structural identification shall be conducted. If there are limit requirements in the "Safety and Technical Standards for Cosmetics", such requirements shall be met; otherwise, a safety risk assessment shall be conducted to ensure that there is no harm to the human health under normal, reasonable, and foreseeable application conditions of cosmetics. When necessary, the interaction between cosmetics and their packaging materials can be comprehensively assessed based on the stability test results. It shall be analyzed that whether the compatibility between packaging materials and the cosmetics will affect the quality and safety of the cosmetics. For new or high-risk cosmetic packaging materials, a comprehensive evaluation shall be conducted based on the interaction study to confirm their biocompatibility.

Drafting Explanation of "Technical Guidelines for Compatibility Evaluation of Cosmetics with Packaging Materials (Draft for Comments)"

In order to strengthen the supervision and administration of cosmetics and further improve the safe use of cosmetics, the National Institutes for Food and Drug Control (NIFDC) organized the research and development of the "Technical Guidelines for Compatibility Evaluation of Cosmetics with Packaging Materials" (hereinafter referred to as the "Guidelines"). The relevant work is explained as follows:

1. Drafting Principle

The compatibility test between cosmetics and their packaging materials is a technical study conducted to investigate the interaction between cosmetics and their packaging materials. Due to the numerous materials and shapes of packaging materials, as well as the wide types of packaged cosmetics, this "Guidelines" was hereby formulated to facilitate and effectively conduct the compatibility studies and support the implementation requirements for the complete safety assessment of cosmetics.

2. Drafting Process

The development and revision of the "Guidelines" were initiated in January 2024, led by the Institute for Packaging Materials and Pharmaceutical Excipients Control under the NIFDC, with the participation of the Institute for Food and Cosmetics Control and the Shanxi Institute for Food and Drug Control. Through discussions within the group, conversations with cosmetic enterprises, and other working forms, the development ideas for this "Guidelines" were preliminarily determined based on reference to medical products and foods related standards and combined with the current situation of the cosmetic industry. The overall framework was prepared by the end of January. Comments were solicited from the Department of Cosmetic Regulation under the National Medical Products Administration (NMPA), experts in the Standardization Administration, and some industry representatives, discussion meetings were held on the overall framework, and suggestions on revision were proposed. Subsequently, based on the discussion results, the framework was further revised and supplemented to form this "Guidelines".

3. Relevant Existing Standards

Compared to foods and medical products, there are relatively less studies on the compatibility in the cosmetic industry. In the field of medical products, the "Guidelines for Compatibility Test of Packaging Materials with Medical Products" was introduced in the "National Standard for Packaging Materials of Medical Products" in 2002 in China. Since

2012, NMPA has successively released compatibility guidelines such as the "Technical Guidelines for Compatibility Study of Chemical Medicine Injections with Plastic Packaging Materials (Trial)" based on the current situation of compatibility studies of medical products with packaging materials in China, and has begun to put forward corresponding requirements for the compatibility of medical products with different types of packaging materials. In the field of foods, there are also relevant requirements such as GB 31604.1-2015 "National Food Safety Standard General Rules for Migration Test of Food Contact Materials and Articles" with regard to testing and study of the interaction between food packaging materials and foods. At present, there are relatively few testing standards and related regulations for packaging materials in the cosmetics field both domestically and internationally. The testing of toxic and hazard substances in cosmetic packaging materials mainly refers to relevant regulations in the fields of foods and medical products. On the basis of referring to the relevant existing guidelines in China, this "Guidelines" was drafted basically following scientific and rational principles, taking into account the current testing conditions of cosmetic enterprises and the implementation requirements for complete safety assessments.

4. Main Contents

This "Guidelines" consists of six parts, clearly defining the scope, terms and definitions, requirements, compatibility test methods, result evaluation, and references respectively.

5. Other Issues that Need Explanation

This "Guidelines" specifies that packaging materials that require compatibility studies are packaging containers and materials that come into direct contact with cosmetic ingredients or products, excluding the outer packaging of cosmetics or accessories in cosmetics or packaging that do (does) not come into long-term contact with cosmetics.

Compatibility studies need to be based on the actual situation of cosmetics, including the types of cosmetics, types of cosmetic packaging materials, contact methods, *etc.*, and targeted protocols shall be designed for studies to ensure the quality and safety of cosmetics.

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附件 3

化妆品与包材相容性评价技术指南（征求意见稿）

1. 范围

本指南规定了与化妆品内容物直接接触的容器或载体与产品相容性评价的要求、试验方法和结果评价。

2. 术语和释义

2.1 可提取物：存在于化妆品包材中并可以通过溶剂从中提取出来的物质，包括化妆品包材中的添加剂、残留单体、降解产物等。

2.2 浸出物：通过迁移试验获得的从包材中迁移或因试验产生并进入化妆品中的物质。

3. 要求

直接接触化妆品的包装材料应当安全，不得与化妆品发生化学反应，不得迁移或释放对人体产生危害的有毒有害物质。

相容性研究考察化妆品与其包材之间是否存在相互影响，并导致化妆品产生安全性风险。

化妆品与包材的相容性研究，应在化妆品研发初期或是包材的选择时开始进行，并贯穿于化妆品研发的整个过程。若发现化妆品与包材发生相互作用并对化妆品的质量安全产生影响时，应查找原因并采取相应的措施，包括变更包材、变更贮藏条件等。进行化妆品与其包材相容性试验时，应建立灵敏、专属性的测试方法。必要时，进行方法学的研究。取样时，应注意空白包材与化妆品取样的代表性。

4. 试验方法

开展相容性研究时，首先应确定直接接触化妆品的包装容器及材料，了解或分析包材的组成、包材与化妆品的接触方式与接触条件、化妆品的生产工艺及过程；随后对所用包材进行提取试验，获得可提取物信息，并预测潜在的浸出物；通过相互作用研究，考察加速试验和长期稳定性试验条件下包材中成分迁移进入化妆品或与化妆品发生反应的程度，即获取浸出物水平信息；对浸出物水平进行安全性评估，得出包材是否适用于化妆品的结论。

4.1 提取试验

提取试验是指采用适宜的溶剂，对空白包材进行的试验研究；目的是获得包材中的可提取物信息以明确迁移试验的目标浸出物，依据提取试验研究中获得的可提取物种类和水平信息，建立灵敏的、专属的分析方法，以指导后续的浸出物研究（迁移试验）。

提取溶剂通常应具有与化妆品相容或相似的理化性质，重点考虑溶剂的 pH、极性

和离子强度等。提取条件一般应参考化妆品的工艺条件，通过适当提高加热温度和延长加热时间的方式尽可能多的提取出包材中的可提取物。

4.2 相互作用研究

相互作用研究包括迁移试验和吸附试验。相互作用研究应采用实际样品，在加速试验和长期稳定性试验的条件下（试验条件参考《化妆品稳定性评价技术指南》）进行试验，化妆品的放置方法应保证化妆品与包材充分接触。

迁移试验是根据预测的目标浸出物开展的研究，包括包材中的可提取物及其降解产物、包材与化妆品反应产生的产物等。迁移试验所用的分析方法应进行方法学验证，以证实其方法能灵敏、准确、稳定地检出化妆品中的浸出物。若包材由不同的材料分层组成，不仅需要评估最内层成分迁移至化妆品中的可能性，还应考虑中层、外层成分迁移至化妆品中的可能性；同时还应考察外层的油墨或粘合剂是否会迁移进入化妆品中。必要时，可选择开展吸附试验，以考察包材吸附对化妆品成分的影响。

在进行迁移试验时，应根据不同包材的材质与化妆品的种类，针对性的设计实验方案，关注以下项目。

（1）塑料　残留单体、添加剂及其降解产物等的迁移；塑料外层的油墨或粘合剂的迁移等。

（2）玻璃　碱性离子的释放对化妆品 pH 的影响；有害元素的迁移；含有着色剂的避光玻璃中添加剂的迁移。对于内部镀膜、涂膜等具膜的玻璃容器，膜内的添加剂的迁移等。

（3）金属　金属离子的迁移；内容物对金属的腐蚀；金属涂层在试验前后的完整性，涂层中的添加剂的迁移等。

（4）橡胶　残留单体、添加剂及其降解产物等的迁移。对于覆膜、涂膜等具膜的橡胶配件，膜内的添加剂的迁移等。

（5）陶瓷　陶瓷釉中有害元素的迁移，对于内部镀膜、涂膜等具膜的陶瓷容器，膜内的添加剂的迁移等。

（6）膜布　荧光增白剂等添加剂的迁移。

（7）胶囊壳　着色剂等添加剂的迁移。

（8）其他　参考上述包材关注内容，设计迁移试验方案，考察包材与化妆品的相容性。

5. 结果评价

根据提取试验获得的可提取物信息及迁移试验获得的浸出物信息，分析汇总浸出物的种类及含量，进行必要的化合物归属或结构鉴定，若《化妆品安全技术规范》有限量规定的应符合其规定；未规定限量的，应进行安全性风险评估，确保在正常、合理及可

预见的适用条件下不得对人体健康产生危害。如有必要，可结合稳定性试验结果综合评估化妆品与包材的相互作用。分析包材和化妆品的相容性是否会影响化妆品的质量和安全。对于新型或认为风险较大的化妆品包材，应在相互作用研究的基础上进行综合评价，以确认其生物相容性。

化妆品与包材相容性评价技术指南（征求意见稿）起草说明

为加强化妆品的监督管理，进一步提高化妆品使用安全性，中国食品药品检定研究院组织开展了化妆品与包材相容性评价技术指南（下称“指南”）的研究制定工作，现就工作有关情况说明如下：

一、起草原则

化妆品与其包材相容性试验是为考察化妆品与包材相互作用而开展的技术研究，由于包材的材质众多、形状各异以及被包装化妆品种类繁多，为方便、有效地进行相容性研究，支持化妆品完整版评估实施要求，特制定本指南。

二、起草过程

本指南的制修订工作于 2024 年 1 月启动，由中检院包材所牵头、食化所和山西所参与制定相关指南。通过组内讨论、与化妆品企业座谈等工作形式，在参考药品和食品相关标准的基础上，结合化妆品行业现状初步确定了该指南的制定思路，于 1 月底编写整体框架。在化妆品司、标委会专家和部分行业代表中征求意见，召开讨论会，对整体框架进行讨论并提出修改意见。随后根据讨论结果，对框架进行修订并补充完善，形成本指南。

三、已有相关标准

化妆品领域相对于食品、药品，其相容性研究开展较少。在药品领域，我国于 2002 年就在《国家药包材标准》中出台了《药品包装材料与药物相容性试验指导原则》，自 2012 年开始，我国药品监督管理局根据国内药物和包装材料相容性研究的现状，陆续发布了《化学药品注射剂与塑料包装材料相容性研究技术指导原则（试行）》等相容性指导原则，开始对药品与不同类别包装材料的相容性提出了相应的要求。在食品领域，也有 GB41604.1-2015《食品安全国家标准 食品接触材料及制品迁移试验通则》等相关要求，对食品用包材与食品的相互影响进行检测和研究。目前，国内外在化妆品领域对包材的检测标准及相关规定较少，对于化妆品包材中有毒有害物质的检测主要参考食品及药品领域相关规定。本指南在参考我国现有的相关指导原则的基础上，以科学性和合理性为基本原则，综合考虑目前化妆品企业检测条件和完整版评估实施要求进行起草编写。

四、主要内容

本指南共六部分，分别明确了范围、术语和定义、要求、相容性试验方法、结果评估以及参考文献。

五、其他需说明的问题

本指南明确了需要开展相容性研究的包材为直接接触化妆品原料或产品的包装容器材料，不包括化妆品的外包装以及化妆品中非长期接触化妆品的配件或包装。

相容性研究需要根据化妆品的实际情况，包括化妆品的种类、化妆品包材的种类、接触方式等，针对性的设计研究方案，开展研究，以保障化妆品质量和安全。

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