

Update of Chinese Cosmetics Regulations for the Management of Cosmetic Ingredients



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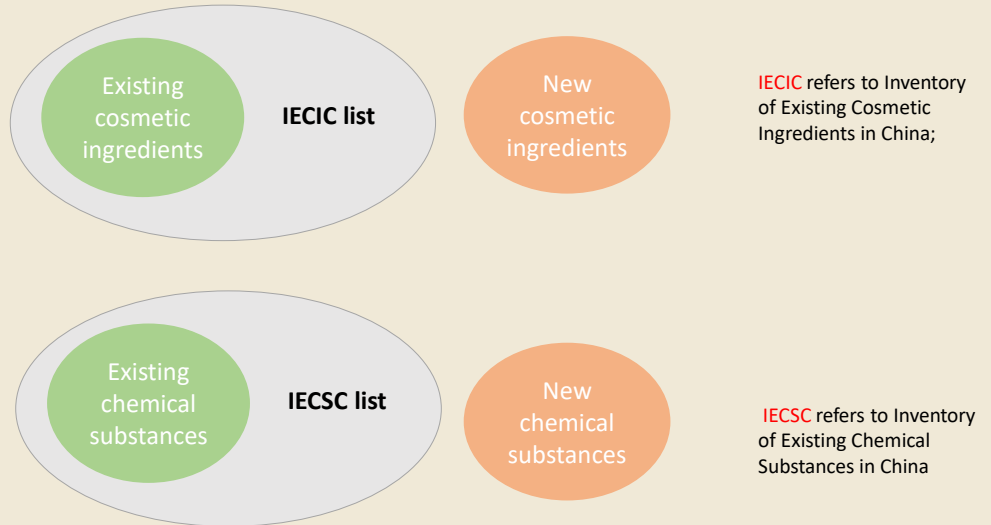
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Type of cosmetic ingredients



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Inventories of cosmetic ingredients

- Inventory of Existing Cosmetic Ingredients in China (2021 Edition)" (IECIC 2021, **NEW**)
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 1 List of banned ingredients in cosmetics (**NEW**)
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 2 List of banned plant (animal) ingredients in cosmetics (**NEW**)
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 3 List of restricted substances in cosmetics
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 4 List of preservatives allowed in cosmetics
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 5 List of sunscreen agents allowed in cosmetics
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 6 List of colorants allowed in cosmetics
- Safety and Technical Standards for Cosmetics (STSC 2015) Table 7 List of hair dyes allowed in cosmetics

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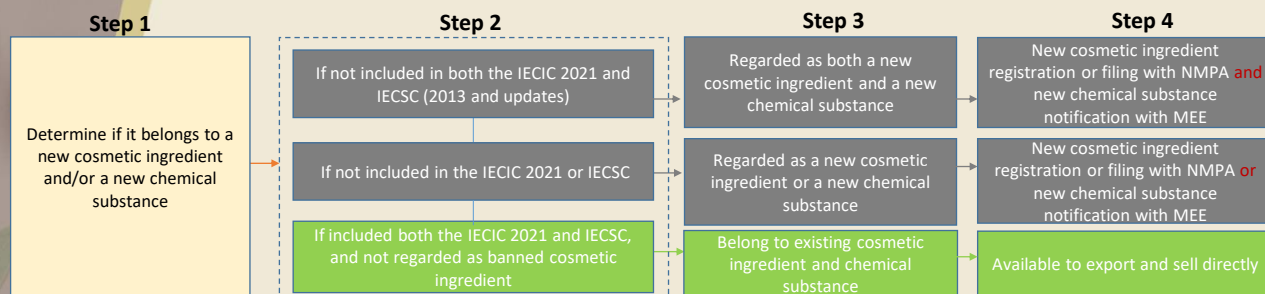
Inventory	Number of cosmetic ingredients
IECIC 2021	8972
List of banned ingredients in cosmetics	1284
List of banned plant (animal) ingredients in cosmetics	109
List of restricted substances in cosmetics	47
List of preservatives allowed in cosmetics	51
List of sunscreen agents allowed in cosmetics	27
List of colorants allowed in cosmetics	157
List of hair dyes allowed in cosmetics	75

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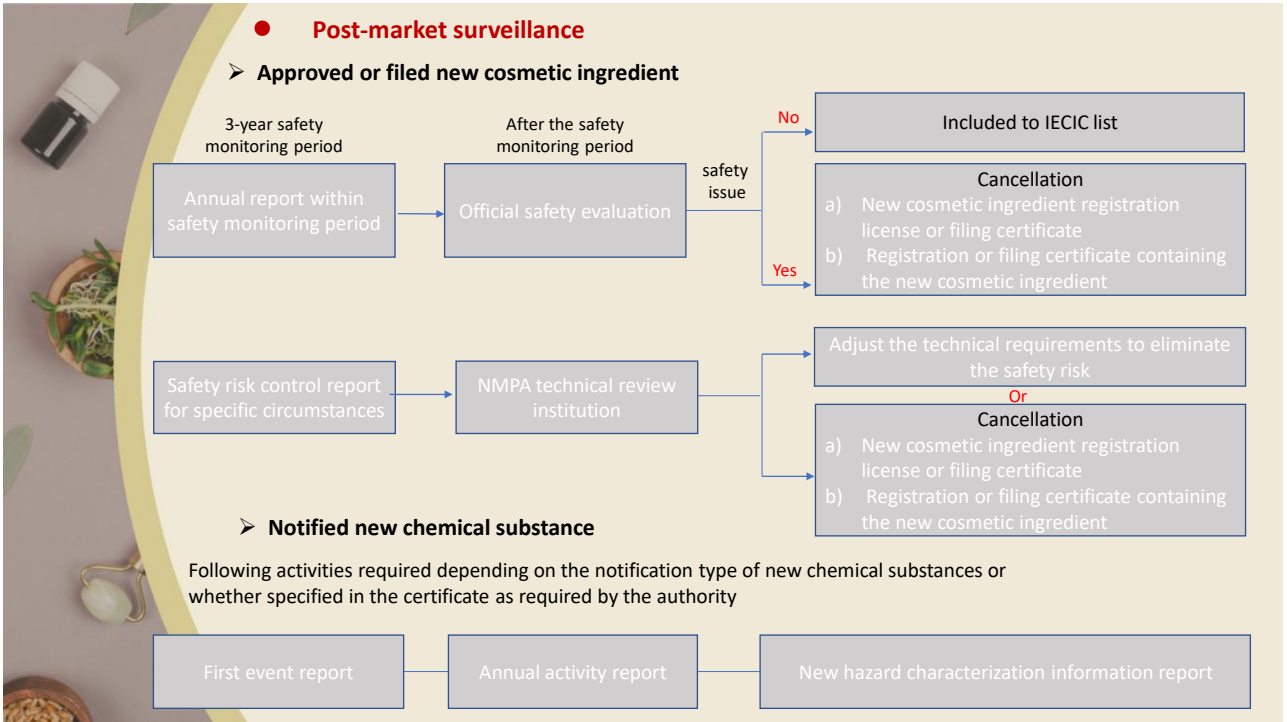
How to export cosmetic ingredients to China?

● Pre-market regulatory requirements

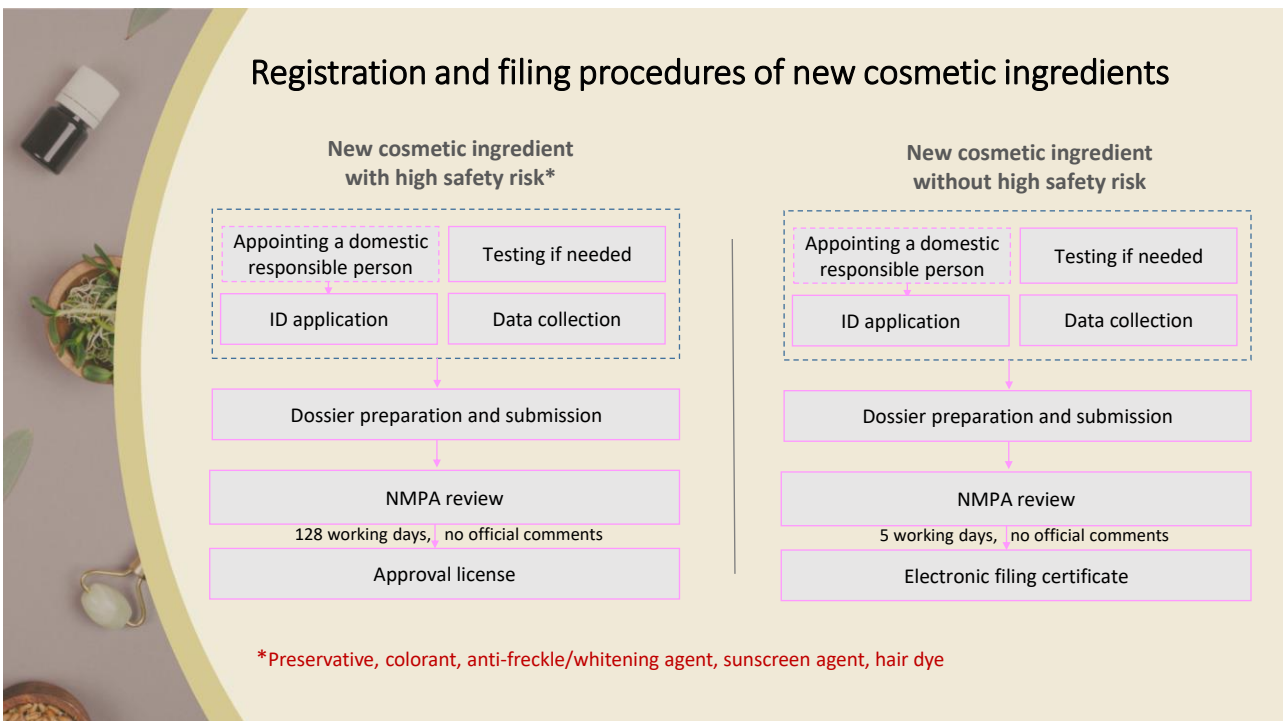
✓ Preliminary evaluation of cosmetic ingredients



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Duty of domestic responsible person

- 1) Register and file the new cosmetic ingredients in the name of the registrant and filer;
- 2) Assist registrants and filers in the safety monitoring and reporting of new cosmetic raw materials;
- 3) Assist registrants and filers in the recall of new cosmetic ingredients
- 4) According to the agreement between the responsible person and registrant/filer, undertaking the corresponding safety and quality responsibilities of new cosmetic ingredients placed in the Chinese market;
- 5) Cooperate with the supervision and inspection work of the supervision departments.

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ID application for the online system of new cosmetic ingredient registration and filing

- Info sheet of registrant/filer
- **Overview of safety risk monitoring and evaluation system of registrant/filer**
- Info sheet of domestic responsible person (required for overseas registrant or filer)
- Original and notarized POA of the domestic responsible person



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化妆品新原料注册人/备案人安全风险监测和评价体系概述

(样例)

项目	内容或措施(概述)
岗位职责	请简述化妆品新原料注册人/备案人的安全风险监测和评价相关岗位设置情况,至少包括: <ol style="list-style-type: none"> 1. 相关机构和岗位设置情况; 2. 相关人员基本要求。
安全风险监测	请简述安全风险监测相关制度,至少包括: <ol style="list-style-type: none"> 1. 安全风险监测体系的整体构成和运行模式; 2. 请简述所有主动或被动的有关化妆品新原料的使用和安全情况信息收集渠道,以及信息收集的频率。
安全风险评价	请简述安全风险评价相关制度,至少包括: <ol style="list-style-type: none"> 1. 安全风险评价的完成方式,如由化妆品新原料注册人、备案人自行完成或委托相关专业机构完成; 2. 安全风险评价标准; 3. 安全风险评价后相应处置措施。
<p>境外化妆品新原料注册人/备案人,还应简述与境内责任人在安全风险监测和评价方面的信息交流、数据共享、风险联动等方面的机制和措施。境内责任人应简述配合化妆品新原料注册人/备案人进行安全风险监测和评价的具体措施,包括岗位职责设置情况、安全风险监测和评价相关制度。</p> <p style="text-align: right;">(化妆品新原料注册人/备案人盖章)</p> <p style="text-align: right;">年 月 日</p>	

Overview of safety risk monitoring and evaluation system

- ① Job responsibility
- ② Adverse reacting monitoring (constitution, running mode, channels and frequency of information collection)
- ③ Adverse reaction evaluation (standard, treatment measure)
- ④ Communication mechanism between the registrants/filers and domestic responsible person

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Full dossier requirements of registration and filing

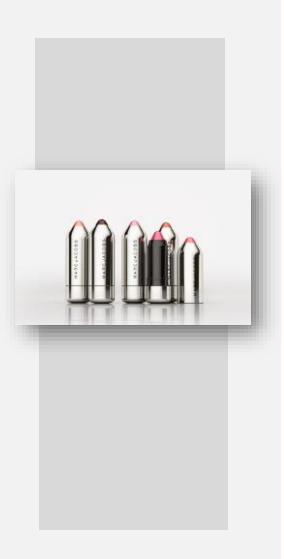
- Application form
- Research and development report
- Production technology, stability and quality control standard
- Safety evaluation
- Technical requirements data (released for public research after registration or filing)



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Full dossier requirements of registration and filing

- **Research and development report**
 - a) R&D background, purpose, process and results, etc.
 - b) Source and properties of the ingredient, etc.
 - c) Safety-based use limit of the new ingredient in cosmetics, the use of raw materials in cosmetics abroad and the approval status, etc.
 - d) Basis of efficacy: scientific literature, regulatory data, test research data, human efficacy evaluation test data, etc.
- **Production technology, stability and quality control standard**
 - a) Main steps, processes and parameters during the production of the new cosmetic ingredient, etc.
 - b) Stability test data
 - c) Quality specification index and testing methods
 - d) Possible risk substances and control standard
- **Safety evaluation**
 - a) Toxicological safety evaluation data: overview of toxicological safety evaluation and necessary toxicological test data (testing report, scientific literature, content issued on the websites of domestic or overseas government or international organizations)
 - b) Safety risk assessment data: evaluation data for the safety use limit of raw material, safety risk substances that may exist in the raw materials and control measures



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Toxicological test items

1. acute oral or acute dermal toxicity;
2. skin and eye irritation/corrosion;
3. skin sensitization;
4. skin phototoxicity (required if the ingredient has the characteristic of ultraviolet absorption);
5. skin photoallergic(required if the ingredient has the characteristic of ultraviolet absorption);
6. mutagenicity (should at least include a gene mutation test and a chromosome aberration test);
7. sub-chronic oral or dermal toxicity;
8. teratogenicity;
9. chronic toxicity/carcinogenicity;
10. inhalation toxicity; (required for the possibility of inhalation exposure)
11. long-term human trial safety test
12. other toxicological tests in terms of the characteristics and use of raw materials



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Toxicological test packages under different conditions

Type of new cosmetic ingredients	Toxicological test
(1)The ingredient is used for the first time at home and abroad for the function of preservative, sunscreen agent, colorant, hair dye, anti-freckle/whitening, hair loss prevention, anti-acne, anti-wrinkle(except for physical anti-wrinkle), anti-dandruff, deodorization and other new cosmetic raw materials with high biological activity used for the first time at home and abroad	1-12
(2) For the new cosmetic ingredient used for the first time at home and abroad, it is not used as preservative, sunscreen agent, colorant, hair dye, anti-freckle/whitening, hair loss prevention, anti-acne, anti-wrinkle(except for physical anti-wrinkle), anti-dandruff, deodorization	1-7
(3) The new cosmetic ingredient is not used as preservative, sunscreen agent, colorant, hair dye, anti-freckle/whitening, hair loss prevention, anti-acne, anti-wrinkle(except for physical anti-wrinkle), anti-dandruff, deodorization and there are sufficient evidentiary materials to prove the ingredient has been used safely in cosmetics marketed abroad for more than 3 years. [Note: if having the safety evaluation report issued by the international and authoritative safety evaluation organization regarding the evaluation conclusion of the ingredient used in cosmetics safely or human safety test report under ethical conditions, acute oral or dermal toxicity test data can be waived]	1-6
(4) The ingredient has the function of preservative, sunscreen agent, colorant, hair dye, anti-freckle/whitening, hair loss prevention, anti-acne, anti-wrinkle(except for physical anti-wrinkle), anti-dandruff, deodorization; and there are sufficient evidentiary materials to prove the ingredient has been used safely in cosmetics marketed abroad for more than 3 years.	1-7

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Type of new cosmetic ingredients	Toxicological test
(5) The new cosmetic ingredient has a safe edible history (the use part of the ingredient should be same as the edible part)	2-5
(6) A chemically synthesized polymer with stable structure and properties, consisting of one or more structural unit linked by covalent bond, has an average molecular weight greater than 1000 Dalton and the content of oligomer with the relative molecular weight less than 1000 Dalton is less than 10%.(except the ingredient with high bioactivity)	2,4
(7) The ingredient is fully new in China and abroad and has the health hazard effects (excluding topical toxicity)	1-12; toxicokinetics
(8)The ingredient is fully new in China and abroad and is subject to oligopeptide, peptide, protein with a high bioactivity	1-12, skin absorption/transdermal test, immunotoxicity test
(9) Nano materials	1-12, skin absorption/transdermal test (if applied on the skin)

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Other testing requirements



Testing reports

<ul style="list-style-type: none"> • Physiochemical test • Microbiological test • Efficacy evaluation test except the function of preservative, sunscreen, whitening/anti-freckle, anti-hair loss 	Tested by its own or third part lab
<ul style="list-style-type: none"> • Toxicological test • Efficacy evaluation test for the function of preservative, sunscreen, whitening/anti-freckle, anti-hair loss 	Tested by the lab with either of the following certifications: <ul style="list-style-type: none"> • CMA • CNAS • GCP • GLP

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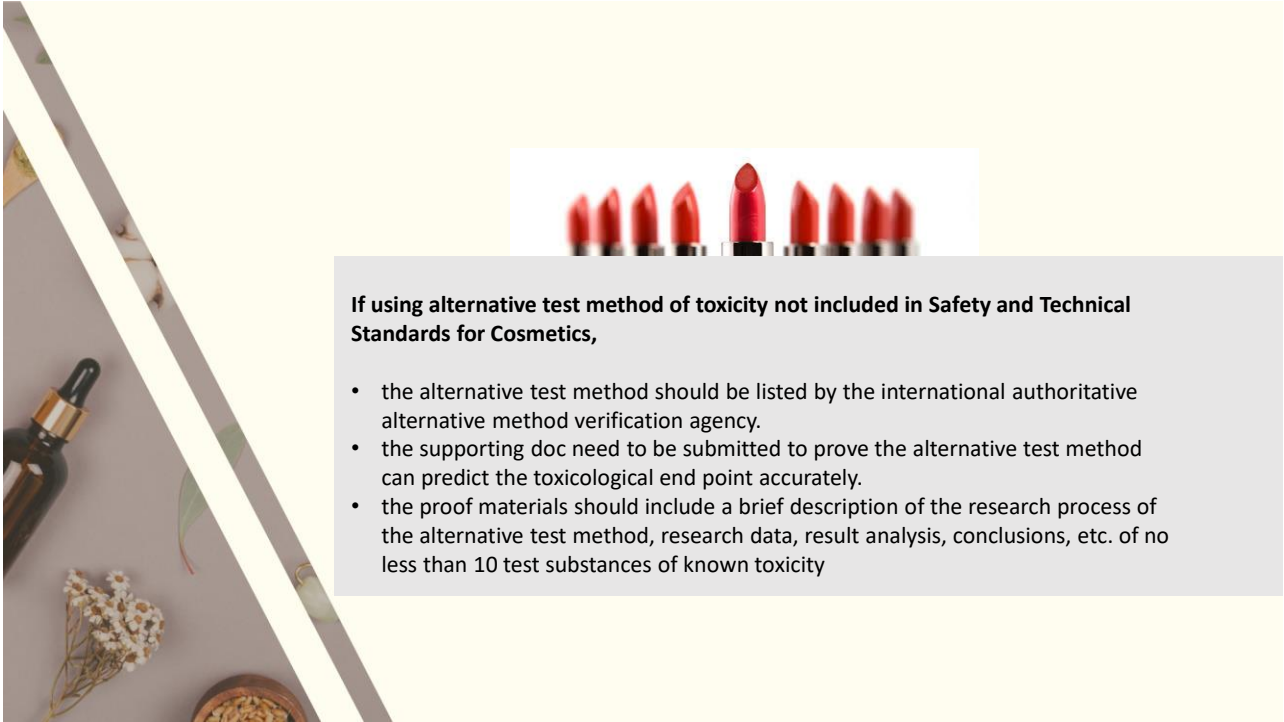
Other testing requirements



Testing methods

<ul style="list-style-type: none"> • Physiochemical test • Microbiological test • Human safety trial • Efficacy evaluation test 	<ul style="list-style-type: none"> • Safety and Technical Standards for Cosmetics (STSC) or Chinese Pharmacopoeia • National standard or internationally accepted method or new developed method if there is no related testing method included in STSC or Chinese Pharmacopoeia <p>When using new developed method, related data for the applicability and reliability required to submit.</p>
<ul style="list-style-type: none"> • Toxicological test 	<ul style="list-style-type: none"> • Safety and Technical Standards for Cosmetics (STSC) • National standard or internationally accepted method if there is no related testing method included in STSC

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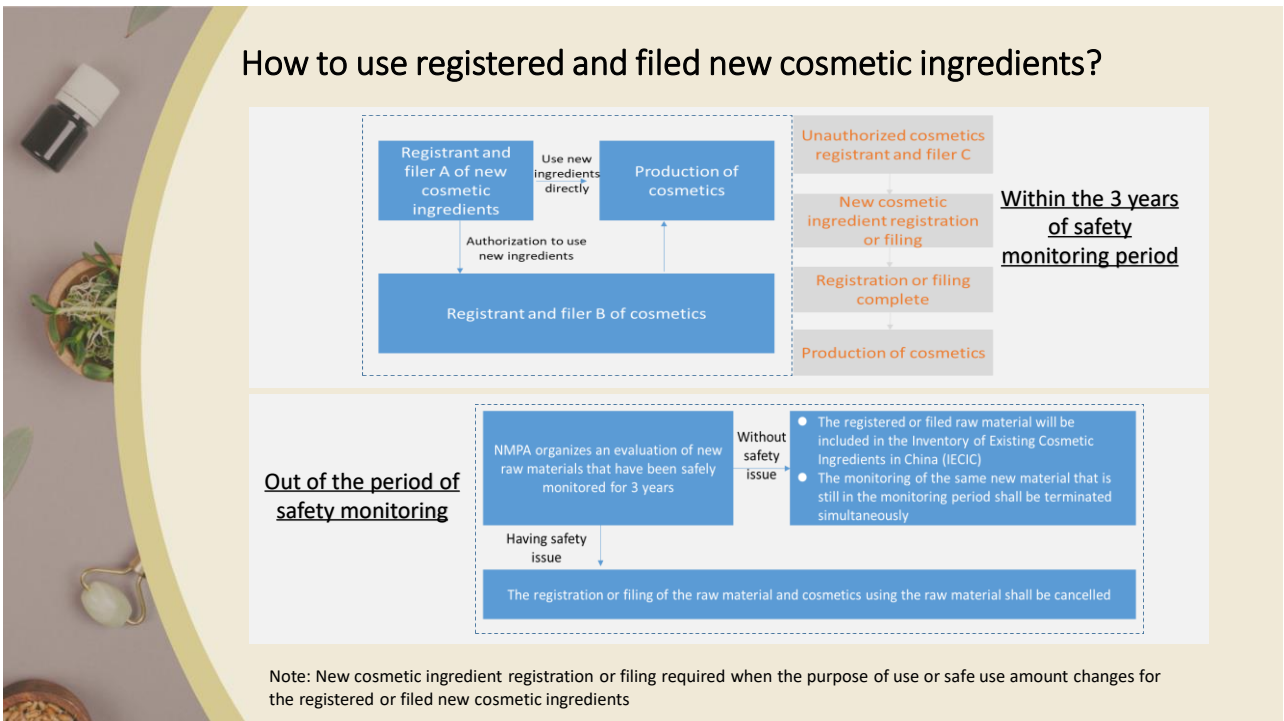


If using alternative test method of toxicity not included in Safety and Technical Standards for Cosmetics,

- the alternative test method should be listed by the international authoritative alternative method verification agency.
- the supporting doc need to be submitted to prove the alternative test method can predict the toxicological end point accurately.
- the proof materials should include a brief description of the research process of the alternative test method, research data, result analysis, conclusions, etc. of no less than 10 test substances of known toxicity

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How to use registered and filed new cosmetic ingredients?



Within the 3 years of safety monitoring period

Unauthorized cosmetics registrant and filer C

New cosmetic ingredient registration or filing

Registration or filing complete

Production of cosmetics

Registrant and filer A of new cosmetic ingredients

Use new ingredients directly

Production of cosmetics

Authorization to use new ingredients

Registrant and filer B of cosmetics

Out of the period of safety monitoring

NMPA organizes an evaluation of new raw materials that have been safely monitored for 3 years

Without safety issue

- The registered or filed raw material will be included in the Inventory of Existing Cosmetic Ingredients in China (IECIC)
- The monitoring of the same new material that is still in the monitoring period shall be terminated simultaneously

Having safety issue

The registration or filing of the raw material and cosmetics using the raw material shall be cancelled

Note: New cosmetic ingredient registration or filing required when the purpose of use or safe use amount changes for the registered or filed new cosmetic ingredients

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Main contents of annual report

- Basic info of new cosmetic ingredient
- Production of new cosmetic ingredient
- Information on cosmetic registrants, filers or entrusted manufacturers who use new raw materials to produce cosmetics
- Information on cosmetics using new raw materials, including product name, product registration or filing number, number of products produced or imported, sold, etc.
- Sampling inspection, investigation and recall of cosmetics produced with new raw materials.
- The adverse reaction monitoring system, statistical analysis of adverse reactions and measures of cosmetics produced with new cosmetic ingredients for cosmetics manufacturers.
- Risk monitoring and evaluation management system and measures of cosmetics produced with new cosmetic ingredients for cosmetics manufacturers

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What kind of circumstances required to submit safety risk control report?

- Other countries (regions) found the use of similar raw materials is suspected of causing serious cosmetic adverse reactions or group adverse reactions
- Other countries (regions)' cosmetics laws, regulations and standards improve the use standard, increase the use limit and prohibit the use of similar raw materials
- Other situations related to the safety of new cosmetic ingredients

Main contents of safety risk control report

- Basic info of new cosmetic ingredient
- Production of new cosmetic ingredient
- Analysis of causes of safety problems or emergencies
- Disposal measures and results

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Quality and safety info of existing cosmetic ingredients

How to submit the quality and safety info?

- ✓ Cosmetic registrant/filer or domestic responsible person uploads the quality and safety info file provided by the ingredient supplier directly

OR

- ✓ The ingredient manufacturer submits the quality and safety related info of cosmetic ingredients to the NMPA specified info system to issue a **code** of the raw material.
- ✓ Cosmetic registrant/filer or domestic responsible person fill in the code to affiliate the quality and safety info file

Online system and official guide not available

How to fill in the quality and safety related info ?

Step 1 : ID application via safety info service platform

- ✓ Record information sheet of cosmetic ingredient manufacturer
- ✓ Documentary evidence as an entity of the enterprise

Step 2 : Filling in quality and safety relate info

- ✓ Trade name
- ✓ Composition of the ingredient
- ✓ Recommended amount of addition in cosmetics
- ✓ Use restrictions of raw material
- ✓ Characters of raw material
- ✓ Description of physical and chemical properties
- ✓ Description of production process
- ✓ Quality control requirements
- ✓ Evaluation conclusion of international authoritative body
- ✓ Use requirements in other industries
- ✓ Limits of risk substances
-

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Transitional solutions of cosmetic ingredients

April 1, 2021-May 1, 2023

New product registration and filing application

Since 1st Apr 2021	<ul style="list-style-type: none"> • ID application available on the new online info service platform of new cosmetics ingredient registration and filing
Since 1st May 2021	<ul style="list-style-type: none"> • New application for the registration and filing of new cosmetics ingredients through the new online info service platform available • Fill in the source and trade name of raw materials of product formula; <p>For the ingredients with the requirements of certificate of analysis in terms of Safety and Technical Standards for Cosmetics, the certificate of analysis or the quality and safety info of the raw material shall be submitted.</p>
Since 1 st Jan 2022	<ul style="list-style-type: none"> • Safety-related info of the raw materials with functions of preservative, sunscreen, colorant, hair dye, anti-freckle and whitening need to be provided
Since 1st Jan 2023	<ul style="list-style-type: none"> • The quality and safety info of all raw materials need to be provided

Products that have been registered and filed

- **All special and ordinary cosmetics registered or filed on both the old and new online system**
- | | |
|---------------------|--|
| Before 1st May 2023 | <ul style="list-style-type: none"> • Supplement to provide the quality and safety info of all ingredients in the formula |
|---------------------|--|

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Thank you for your attention

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