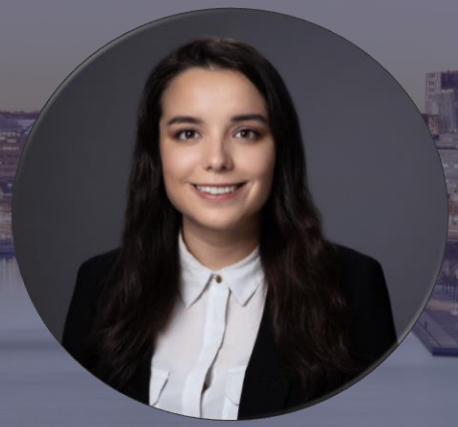
GPC
Global Product Compliance

Cosmetic Finished Product Regulations in China



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Management of Finished Cosmetic Products in China

国家药品监督管理局
National Medical Products Administration

- **Regulatory Body:** National Medical Products Administration (NMPA)
- **Regulation:** Cosmetic Administration & Supervision Regulation (CSAR)

According to the regulation, cosmetics are defined as

- *daily chemical industrial products*
- *applied to skin, hair, nails, lips, and other human surfaces*
- *by scrubbing, spraying or other similar methods*
- *for the purpose of cleansing, protecting, beautifying & modifying*

Classification of Finished Cosmetic Products in China

- Finished cosmetic products may have ordinary or special cosmetic classification
- Classification determines the management type; be it filing or registration
- They will be classified as ordinary if no special claims such as SPF function or use on children are used. These claims give rise to special classification resulting in a different management type

	Ordinary	Other
Hair Dye	Cosmetics which are not special cosmetics	Toothpaste
Hair Perm		
Freckle-Removing		
Sunscreens		Soap (without a special claim)
Anti-Hair Loss		
***Products with New Efficacy**		

*Products with new efficacy refers to cosmetics with efficacies & application methods not listed in the *Classification Rules & Catalog*, as well as cosmetics targeted at children, pregnant women & breast-feeding women.

Responsible Person for Finished Cosmetic Products in China

- A domestic responsible person (DRP) is required to file/register on behalf of the overseas company

- The DRP should meet the following criteria:

  1. Legal entity established on **mainland** China

     (Taiwan, Hong Kong not acceptable)

  2. Business license of a cosmetic nature & import/export related

- The DRP is authorized by the filer/registrant by signing a power of attorney (POA) which should be notarized in China.

Filing vs Registration Management

Filing

Examples: perfume, makeup, hand cream etc.

- Appointment of DRP
- Filing account set-up
- Testing
- Dossier preparation
- Submission
- Format review **(5 days)**
- E-certificate
- Import to China

Technical review spot-check will be carried out at a later time for ordinary cosmetics

Registration

Examples: Sunscreen, moisturizer for children etc.

- Appointment of DRP
- Registration account set-up
- Testing
- Dossier preparation
- Submission
- Format review **(5 days)**
- Technical review **(90 days)**
- Registration certificate

Key Steps for Compliance

- Create an inventory list of products
  - Do they meet definition of cosmetic in China?
  - What are their classifications?
  - What is their management type based on classification?
- Appoint a DRP
- **Consider the testing data required such as animal testing**

Animal Testing for Finished Cosmetic Products

- Animal testing may be waived for certain finished cosmetic products under the following conditions:
  - ✓ Ordinary cosmetics e.g. perfume, makeup, skincare etc. with no special claim
  - ✓ GMP certificate issued by the government of country of origin e.g. ANSM for France
  - ✓ Claims for use on children/infants, pregnant women, breastfeeding women not acceptable
  - ✓ Filer should not be a key supervision target by the NMPA
  - ✓ Product formula should not contain ingredients in 3-year monitoring period
  - ✓ Safety assessment report should prove safety of the product based on hygiene tests alone

- If animal testing is waived, only hygiene tests apply. Testing must always be carried out in **NMPA accredited labs**

- Testing data from EU labs is not acceptable for China for ordinary or special cosmetic products

- If certain claims are made such as sun protection, anti-acne etc., efficacy tests may also be required to support the claim. The type of claim determines if test data from an NMPA or foreign lab can be accepted

Efficacy Evaluation Report for Finished Cosmetic Products

Efficacy Claim	Evaluation Method	Evaluation Institution
Whitening/ freckle removing, sunscreen	Human trial only	NMPA accredited lab in China
Anti-acne, repairing, nourishing, strong specific claim	Human trial only	NMPA accredited lab in China
Sensitive skin	Human trial, consumer use test, or lab test & lit data	Foreign institution accepted
Anti-wrinkle, firming, oil-control, exfoliator (non-physical effect), mild (no irritation), quantitative indicators (e.g. efficacy retention time)	Human trial, consumer use test or lab test & lit data	Foreign institution accepted
Moisturizing, claims on ingredients	Human trial, consumer use test, lab test or lit data	Foreign institution accepted
Any other efficacy claims	Evaluation method should be chosen based on the claim	NMPA accredited lab in China
Claims directly recognized by senses or physical covering, adhesion, friction	Exempt	Exempt

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- Appoint a DRP
- Consider the testing data required such as animal testing
- **Do you have a safety info code or safety info of cosmetic ingredients in the product formulas?**

Reporting the Safety Information of Cosmetic Ingredients to the NMPA

- CSAR implementation date

- Original Deadline for reporting safety info of all cosmetic ingredients to the NMPA

Jan 1st, 2021 → Jan 1st, 2022 → May 1st, 2023 → Jan 1st, 2023

- NMPA Platform Launch

- Extended Deadline for reporting safety info of all cosmetic ingredients to the NMPA

- The safety information of cosmetic ingredients used in the product formula of finished cosmetic products should be reported to the NMPA before **Jan 1st 2024**

Reporting the Safety Info of Cosmetic Ingredients

There are two ways to report the information:

- Filer/registrant can complete Annex 14 for each cosmetic ingredient and submit with filing/registration dossier

Pros	Cons
Less dependence on supplier	Safety info not always readily available (confidentiality issues)

or

- The supplier of the cosmetic ingredients **responsible for the safety** can generate a code on the NMPA safety information platform and share it with downstream filer/registrants

Pros	Cons
Less workload for filer/registrant	Platform only available in Chinese
More reliable safety data	

Key Steps for Compliance

- Create an inventory list of products
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  - What are their classifications?
  - What is their management type based on classification?
- Appoint a DRP
- Consider the testing data required such as animal testing
- Do you have a safety info code or safety info of cosmetic ingredients in the product formulas?
- **Consider labelling requirements**

Labelling Requirements

1. Product Name, certificate number
2. Name, address of registrant/notifier & DRP
3. Name & address of manufacturer
4. Executive Standard Number
5. Complete Ingredient List
6. 6. Net Weight
7. Other contents that shall be marked in administrative laws, national standards
8. Instructions of use
9. Warning
10. Expiry Information

- The primary and secondary packaging requires translation to CN
- A CN label should be on the secondary packaging with the product info and another CN label should be on the primary packaging with the product name, expiry date and batch number.

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- Do you have a safety info code or safety info of cosmetic ingredients in the product formulas?
- Consider labelling requirements
- **Safety Assessment**

Safety Assessment Report

- This is a new requirement since 2022 and must be prepared according to *''Technical Guidelines for Cosmetic Safety Assessment''*
- Safety Assessment Report used for EU cosmetic compliance cannot be used directly for China but may be used as a reference
- The Safety Assessment should be based on existing scientific data with reference to full-text publicly available technical reports, announcements, professional books, academic papers or risk assessment materials released by recognised institutions.
- Safety Assessor must meet the following criteria:
    - Professional knowledge of cosmetics quality and safety
    - 5 years professional experience
    - Relevant scientific data analysis skills

Comparison of Cosmetic Regulations

	EU	China
Authority	EU Commission	NMPA
Regulation	Regulation (EC) N° 1223/2009	CSAR Regulation
Classification	Cosmetic	Ordinary Cosmetic/Special Cosmetic
Registrant	Legal Entity established in the EU (Responsible Person)	Legal Entity in mainland China (Domestic Responsible Person)
Dossier Type	Product Information File (PIF)	Filing/Registration Dossier
Safety Information	Cosmetic Product Safety Report (CPSR) prepared by qualified Safety Assessor	Safety Assessment Report prepared by qualified Safety Assessor; NMPA platform code or Annex 14 for raw materials
Dossier Submission	Cosmetic Product Notification Portal (CPNP)	NMPA Filing/Registration Account
Animal Testing Requirement	Banned	Ordinary Cosmetic exemption only (must meet certain conditions; see above). Mandatory for special cosmetics
Pre-market Authority Review Process	No official pre-market approval required before import. The RP should have a PIF always readily available for authority review check	Pre-market approval needed. Extent of pre-market approval depends on classification

Thank You!

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