ACTIONABLE SUMMARY



WHAT ARE THE COSMETIC REGULATIONS IN CHINA?

A cosmetic product is "any article that is meant or intended to be rubbed, poured, sprinkled or sprayed on, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting or increasing attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic" Cosmetic Products are intended to be spread on the outer surface of the human body, the teeth, the nail, and oral mucosa for the purpose of cleaning, protecting, beautifying, deodorizing, and keeping in good condition, by way of smearing, spraying, or other similar means.

Types of Cosmetic Products found in the Chinese Market:

Non-special use cosmetics (non-SUC) - It include skin care products, hair care products, nail care products, make-up and perfumes.

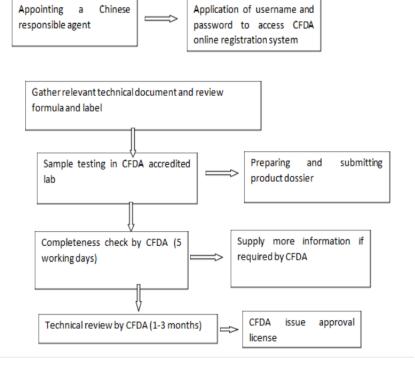
Special use cosmetics (SUC) – **It** include products such as hair growth products, hair dyes, hair perming products, depilating products, breast beauty products, slimming products, deodorants, freckle-removing products, sunscreens and whitening products. Depends upon the product, it may fall into both categories and their classification depends on their composition. Soaps, oral cleansers, and toothpaste are not considered as cosmetics, and they can be imported directly into China after customs clearance.

HOW TO COMPLY?

- 1. Appointing a Chinese responsible agent
- 2. Application of User Name and Password
- 3. Product formula
- 4. Original product package
- 5. Testing requirements
- 6. Registration dossier
- 7. CFDA review

Product Registration

Flowchart of imported cosmetic product approval process



Prohibited ingredients for use in cosmetics

Chinese cosmetics regulation does not allow the use of 1388 substances for cosmetics. This list, along with the list of restricted substances, can be found in Safety and Technical Standards for Cosmetics 2015.

The Chinese version of INCI-

INCI version 2010 is the latest version of the catalogue, and it contains 15,649 ingredients.

Note that the ingredients listed in this catalogue are different from the IECIC list of ingredients. Not all ingredients listed in this catalogue can be found on the IECIC list, which simply means that such ingredients have to be registered before they are used in cosmetics.

For new ingredients

New ingredients, which aren't listed in IECIC, need to go through a stringent and time-consuming pre-market registration procedure. If accredited by NMPA, the applicant will be given a "new cosmetic ingredient trial use certificate", which allows the applicant to use the ingredient in their products for 4 years. If no adverse effects are observedduring that period, the ingredient will be added to IECEC list.



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ACTIONABLE SUMMARY INDIAN CMSR



WHO CAN APPLY AND FOR WHICH CATEGORY OF THE PRODUCT

Table: Discuss key annexes or the regulation – what they require, are these templates, impact on compliance, reporting etc.

Serial No.	Type of Product	Required SFDA License	Who Shall Apply?
1	Ordinary cosmetics- hair care, nail care, skin care, perfumes.		A Chinese responsible agent appointed by a foreign manufacturer
2	Special use cosmetics products for hair growth, hair dye, hair perm, hair removal, breast shaping, fitness,	,	
3	New Cosmetic Ingredient	Hygiene License	

Approval Process

ORIGIN	CATEGORY	OBLIGATIONS	CERTIFICATE	WHO APPLIES?	COMPETENT AUTHORITY
Foreign	Non-SUC	Pre-market online filing	E-filing certificate	Chinese responsible person	NMPA or MPAs in the 11 Free-Trade Zones
	suc	Pre-market registration	Administrative permit certificate	Chinese responsible agent	NMPA
Domestic	Non-SUC	Domestic filing	No certificate	Chinese manufacturer	Provincial MPAs
2 2000	suc	Pre-market registration	Administrative permit certificate	Chinese manufacturer	NMPA

Timeline and Fee Structure

The total costs of application consist of three parts:

- Testing fee
- Risk evaluation fee charged by approved inspection authorities
- Consulting fee

The total application cost of record-keeping certificate for imported ordinary cosmetics is between 10,000 and 30,000 RMB per product. [5]

The total application cost of hygiene license for imported specific use cosmetics is between 20,000 and 60,000 RMB per product.

The total application cost of hygiene license for new cosmetic ingredient is between 80000 and 100000 RMB per ingredient.

It takes 4-6 months to obtain record-keeping certificate for ordinary cosmetics and 8-15 months to acquire hygiene license for imported specific use cosmetics.