Cosmetics and Cosmetic Ingredient Law

In China, cosmetics and cosmetic ingredients are regulated by the following laws:

- Regulations concerning the hygiene supervision over cosmetics (1990);
- Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics (2005);
- Hygienic Standard for Cosmetics (2007);
- The Measures for the Administration of Hygiene License for Cosmetics (revised in 2010);
- Guideline for Risk Evaluation of Substances with Possibility of Safety Risk in Cosmetics (2010);
- Standard Chinese Names of International Cosmetics Ingredients Inventory (2010);
- Cosmetics Technical Requirement Standard (2011);
- Guidelines for the Registration and Evaluation of New Cosmetic Ingredient (2011);

For finished cosmetics, companies who plan to place cosmetics on Chinese market must apply for and obtain hygiene license or record-keeping certificate from Health Administrative Department of the State Council - the State Food and Drug Administration (SFDA). Foreign companies shall appoint a Chinese responsible agent to deal with registration and obtain such certificate. Manufacturers shall also register a new cosmetic ingredient prior to using it for cosmetics production.

What is New?

26 Oct 2012, CIRS to hold workshop on safety assessment of personal care products and new ingredient in China. Click here for more information.

14 March 2012, China Exit-Entry Inspection and Quarantine Bureau (CIQ) has issued a public notice to stop issuing CIQ labels for imported cosmetics that have passed CIQ's inspections. For more info, please click here.

1 May 2012, Presentations on the latest SFDA regulations on cosmetics and new cosmetics ingredients are available upon request. Click here.

18 August 2012, Guidance on Exporting Cosmetics to China can now be downloaded here for free.

Definition of Cosmetics and Classification

Cosmetics are defined as daily used industrial chemicals which can be spread on the outer surface of human body (e.g. skin, hairs, nails, lips etc) for the purpose of cleaning, deodorizing, providing skin care, beauty and make-up, by way of smearing, spraying or other similar means.

Imported cosmetics are divided into two classes: ordinary cosmetics and special use cosmetics. Each class requires different type of license from SFDA.

<table>
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<tr>
<th>Type of Product</th>
<th>Required SFDA License</th>
<th>Who Shall Apply?</th>
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<tr>
<td>Ordinary cosmetics</td>
<td>Record-keeping Certificate</td>
<td></td>
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<tr>
<td>hair care, nail care, skin care, perfumes and make-up</td>
<td></td>
<td></td>
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<tr>
<td>Special use cosmetics</td>
<td>Hygiene License</td>
<td>A Chinese responsible agent appointed by a foreign manufacturer</td>
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<tr>
<td>products for hair growth, hair dye, hair perm, hair removal, breast shaping, fitness, deodorizing, spots removal and sun block</td>
<td>(More expensive and time-consuming)</td>
<td></td>
</tr>
<tr>
<td>New Cosmetic Ingredient</td>
<td>Hygiene License</td>
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</table>
Important Updates:

On 29 May 2012, the Chinese State Food and Drug Administration (SFDA) has issued a notice No. 263-2012 inviting public comments on the amended categorized management measures for non-special use cosmetics. The draft measures have been amended after the SFDA's notice 57-2012 to propose to move some ordinary cosmetics into type II special use cosmetics has received strong objections from industry associations.

For more info, please click [here](http://www.cirs-reach.com/China_Chemical_ Regulation/China_Cosmetics_Cosmetic_Ingredient_Law.html).

Requirements of Ingredients in Cosmetics

The Hygienic Standard for Cosmetics published by the Ministry of Health in 2007 has banned over 1200 chemicals in cosmetics and restricted the use of 73 chemicals, 56 preservatives, 156 colorants, 28 sun block agents and 93 dyes in cosmetics. Before companies apply for hygiene license or record-keeping certificate, companies shall make sure their formula meets this hygienic standard.

Companies shall also check if there is any new ingredient in their product. A new ingredient that is not currently listed on the Inventory of Existing Cosmetic Ingredients in China (IECIC) also requires registration with SFDA. However, a new ingredient might not require registration if there is proof that the ingredient has been used in approved cosmetics in China before. It can be very difficult and expensive to register a new ingredient. More info about registration of new cosmetic ingredient can be found [here](http://www.cirs-reach.com/China_Chemical_ Regulation/China_Cosmetics_Cosmetic_Ingredient_Law.html).

Please contact April Guo if you would like to know whether all ingredients in your cosmetic product are approved to be used in China.

Application of Hygiene License or Record-keeping Certificate

The following documents are required for application of hygiene license or record keeping certificate:

- Application form for license;
- Product ingredients;
- Effective components, evidence of use and inspection methods;
- Manufacturing technique and diagram;
- Product quality standard;
- Testing report from a cosmetics testing institution approved by the SFDA and related materials;
- Product package (sales package & product label);
- Certified document for production and sales in the manufacturing country (region);
- The statement on related problems of 'Mad Cow Disease'; (new)
- Power of attorney, if responsible person has been appointed;
- Some other documents that may be helpful for inspection;
Testing Requirements

According to the official implementation of the national standard: Procedures and methods of safety evaluation for cosmetics (GB 7919-87), some of the following testing items are required depending on the types of finished cosmetics. Please contact April.guo@cir-s-reach.com if you would like to know what tests are required for your products.

- Physiochemical and microbiological testing;
- Acute oral toxicity and acute dermal toxicity;
- Acute dermal irritation and acute eye irritation;
- Dermal sensitization;
- Dermal photo-toxicity test & dermal photosensitivity;
- Sub-chronic oral toxicity and dermal toxicity;
- Teratogenicity test;
- Authenticity test;
- Chronic toxicity and carcinogenic test;
- Safety evaluation of using tests of cosmetics on human body;

Labeling Requirements

According to the official implementation of the national standard: Instruction for use of consumer products—general labeling for cosmetics (GB5296.3-2008), the following information, in Chinese, needs to appear on a label for cosmetics:

- Product name;
Name and address of the manufacturer;
Net content;
Product ingredients;
Shelf life;
The code of manufacture license and product standard;
The code of hygiene license or record-keeping certificate;
Safety statement and guidance on uses;

In case of imported cosmetics, country of origin and the name and address of the distributor in China shall also be given on the label.

CIQ Inspection of Imported Cosmetics

Even though CIQ labels will no longer be required for imported cosmetics from 1 Feb 2012, CIQ’s inspection is mandatory. For cosmetics imported to China for the first time, Chinese importer needs to provide the following documents when applying for an inspection from CIQ:

- A self-declaration letter stating that the imported cosmetic product complies with relevant Chinese laws and the normal use of the product will not cause any harm to human health;
- Product formula;
- Hygiene license or record-keeping certificate;
- For cosmetics exempted from hygiene license or record-keeping requirement, the following documents are required:
  - Safety evaluation report issued by the qualified institutions for substances of potential safety risks;
  - Documentation that permits the production and distribution of the imported cosmetics in the country of production or a Certificate of Country of Origin;
- Sample labels in Chinese, product labels in the original language and the translated text in Chinese;
- Information on the product name, volume/weight, specifications, country of origin, batch number, expiry date (production date and shelf life), target market, and information about packaging company;
- Other documentation required by AQSIQ.

Please note that the documents required for bringing non-trade cosmetics (for example, product samples, R&D samples) into China are different. More info can be found here.

How Much Does Application Cost Per Product?

The total costs of application consist of three parts: Testing fee, risk evaluation fee charged by approved inspection authorities and consulting fee. The total costs vary among different service providers, quoted prices in various inspection authorities, and test items for the distinct usages of cosmetics.

Generally speaking, the total application cost of record-keeping certificate for imported ordinary cosmetics is between 10,000 and 30,000 RMB per product.

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 80,000 and 100,000 RMB per ingredient.

Please note the above cost estimation does not include risk evaluation fee and human body test.

Our Services

Previously set up by China Inspection and Quarantine Bureau (CIQ), CIRS has strong presence in China and close links with regulatory authorities in China, especially CIQ. CIRS China can act as the Chinese responsible agent, review your ingredients, coordinate testing, prepare application materials and obtain hygiene license or record-keeping certificate and CIQ labels for your cosmetics products.

If you wish to avail of our integrated compliance solutions for the entry of cosmetic products into China, please don't hesitate to consult us.
Related

- Guidance on Exporting Cosmetics to China [pdf]
- SFDA Registration of New Cosmetic Ingredient
- Inventory of Existing Cosmetics Ingredients China (IECIC 2012) - First Batch
- Inventory of Existing Cosmetics Ingredients China (IECIC 2012) - Second Batch
- Presentation: Application of SFDA license and CIQ label for imported cosmetics in China by Ms April Guo
- Download Brochure
- China IECSC