Chinese Cosmetic Registration: Guidance on efficiently entering into Chinese Beauty Market

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Outlines

- Get to know about Chinese Beauty Market
- Status quo of Chinese cosmetic registration
- Finished Cosmetic Registration
- New Cosmetic Ingredient Registration
- Updates on regulations
Get to know about Chinese Beauty Market

◆ Population
  • 1.38 Billion (China mainland, 2016)

◆ Purchasing desire
  • Pursuit of beauty is part of human nature

◆ Purchasing power
  • GDP: 74412.7 Billion
  • Total volume of retail sales: 222.2 Billion (grew 8.3% from a year earlier)
Status quo of Chinese cosmetic registration

- China Food and drug administration, CFDA
- State administration for industry & commerce of the people’s republic of china, SAIC
- General administration of quality supervision, inspection and quarantine of the people’s republic of china, AQSIQ
Status quo of Chinese cosmetic registration

---Regulations

Cosmetic Supervision and Administration Regulation
(2nd Draft, 2015)

Cosmetic label management approach (draft)
Filling Management for Non-special Use Cosmetics through Pudong New Area
Internal cosmetics raw materials standard Chinese INCI name directory (2010)
Inventory of Existing Cosmetic Ingredients in China (IECIC 2015)
Guidance on Application and Review of New Cosmetic Raw Materials
Cosmetics administrative license application dossier requirements

......
Status quo of Chinese cosmetic registration

Mode 1

Local regulation (e.g. REACH)

Manufactured as ingredient

Export to China as ingredient

Used in cosmetics

Customer use

Sale

---Cycle Life

China REACH

China GHS

China new cosmetic ingredient registration

China cosmetic regulations

China business regulation

www.reach24h.com
Status quo of Chinese cosmetic registration

Mode 2

- Manufactured as ingredient
- Export to China as cosmetics
- Used in cosmetics
- Local cosmetics Regulation (e.g. 1223/2009/EC)
- China cosmetic regulations
- China business regulation

Local regulation (e.g. REACH)

--- Cycle Life

Customer use

Sale

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Cosmetics Definition

Article 2 of China’s cosmetic regulation defines cosmetic product as industrially produced chemical product subject to daily use, which are intended to be placed in contact with any external parts of human body (skin, hair system, nails and lips) by spreading, rubbing, spraying, sprinkling etc., with the purpose of cleansing, correcting body odors, protecting, maintain function or changing their appearance.
For finished cosmetic manufacturer

---Finished product registration

Cosmetics

- Domestic
  - Non-special use
  - Special use
- Imported
  - Non-special use
  - Special use

- Notification
- Pre-Market Approval
- Pre-Market Approval

◆ Cosmetic Type

9 Special function: hair growth, hair dye, hair perm, hair removal, beauty breast, body fitness, deodorants, anti-spot (whitening), UV protection
For finished cosmetic manufacturer

<table>
<thead>
<tr>
<th>Party</th>
<th>Roles and responsibilities</th>
</tr>
</thead>
</table>
| **Manufacturer/brand owner/applicant** | • The applicant of registration  
• Provide accurate required documents  
• Responsible for the safety of products  
• Name and address will be listed on product approval license |
| **Real manufacturer/contracted manufacturer (OEM)** | • Not the applicant, but need to provide accurate required documents |
| **Responsible Agent**  
(only for oversea manufacturer) | • Responsible for product registration **ONLY**  
• Must be a legal entity in China  
• Dossier preparation  
• Stamp on the whole dossier and submit to CFDA  
• Name and address will be listed on product approval license |
| **Distributor** | • Collaborations with good sales channels  
• Retailor authorization |
| **Importer** | • Products importation |
For finished cosmetic manufacturer

<table>
<thead>
<tr>
<th>Category</th>
<th>File Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosmetic Registration</td>
<td>---Dossier</td>
</tr>
<tr>
<td>Ingredients/manufacture/safety</td>
<td>Formula</td>
</tr>
<tr>
<td></td>
<td>Manufacture process</td>
</tr>
<tr>
<td></td>
<td>Specifications</td>
</tr>
<tr>
<td></td>
<td>Safety Assessment Report</td>
</tr>
<tr>
<td></td>
<td>Testing Reports</td>
</tr>
<tr>
<td></td>
<td>Product Technical Standard</td>
</tr>
<tr>
<td>Package/claim</td>
<td>Product Naming Statement</td>
</tr>
<tr>
<td></td>
<td>Label/package</td>
</tr>
<tr>
<td>Other files</td>
<td>POA/LOA</td>
</tr>
<tr>
<td></td>
<td>Certificate of Free Sale</td>
</tr>
<tr>
<td></td>
<td>Efficacy Proofs (special products)</td>
</tr>
</tbody>
</table>
For finished cosmetic manufacturer

Cosmetic Registration

◆ CFDA regulate the cosmetic ingredients in the following way,

• Inventory of Existing Cosmetic Ingredients in China (IECIC): the list of ingredients allowable to be used, and the determinant of new ingredients
• Safety and Technical Standard for Cosmetics (STSC): present the list of prohibited & restricted ingredients, preservative, hair dye, colorants, and UV filters.
• BSE (bovine spongiform encephalopathy) Statement
For finished cosmetic manufacturer

Cosmetic Registration

--- Label & Claim

◆ Label

Two options to label the imported cosmetics:

• Original English Label + Chinese Label(sticker)
• Original English Label + Newly designed Chinese label for China market

Mandatory contents: product name, address of producer, country of origin, ingredients (Chinese INCI), date of production and durability, and necessary use instruction or precautions

◆ Claim

• Some claims can’t be used for cosmetics, medical terms, clinical terms, etc.
• Basic principles: Claim on package should not mislead or deceive consumers
For finished cosmetic manufacturer

Cosmetic Registration

---Process

- Testing must be carried out in CFDA-Approved labs in China.
- For non-special use products: 3~4 months*
- For special use products: 6~8 months
For cosmetic ingredient supplier

<table>
<thead>
<tr>
<th>Ingredients</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing ingredient</td>
<td>New cosmetic ingredient</td>
<td></td>
</tr>
</tbody>
</table>

---Cosmetic Ingredient Registration
Regulated in finished product registration Pre-Market Approval for first use in China

◆ Definition

CFDA defines the new ingredients as a natural or artificial ingredient that is firstly used in cosmetic products in China

Self-check:

Inventory of Existing Cosmetic Ingredients in China (IECIC 2015)
For cosmetic ingredient supplier

Cosmetic Ingredient Registration

Statistics of the Applications for new ingredients in China (2008~2015)

- Calculated from the monthly statistics released by CFDA Assessment Center
For cosmetic ingredient supplier

Cosmetic Ingredient Registration

Till Dec. 2015, here are ten ingredients in total being approved by CFDA and the previous competent authority, MoH

<table>
<thead>
<tr>
<th>No.</th>
<th>INCI Name</th>
<th>Trade Name</th>
<th>Applicants</th>
<th>Approved Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alkyl (C12-C22) trimethyl ammonium, bromide and chloride</td>
<td>-</td>
<td>-</td>
<td>Jun 2004 (MoH)</td>
</tr>
<tr>
<td>2</td>
<td>Potassium Methoxysalicylate</td>
<td>4MSK</td>
<td>Shisheido</td>
<td>Apr 2007 (MoH)</td>
</tr>
<tr>
<td>3</td>
<td>Methylisothiazolinone</td>
<td>Kathon</td>
<td>Rohm Haas</td>
<td>May 2007 (MoH)</td>
</tr>
<tr>
<td>4</td>
<td>Carnitine Tartrate</td>
<td>-</td>
<td>-</td>
<td>Jun 2008 (MoH)</td>
</tr>
<tr>
<td>5</td>
<td>Lathyrus odoratus flower extract</td>
<td>-</td>
<td>-</td>
<td>Aug 2008 (MoH)</td>
</tr>
<tr>
<td>6</td>
<td>Fructooligosaccharides</td>
<td>-</td>
<td>-</td>
<td>Aug 2008 (MoH)</td>
</tr>
<tr>
<td>7</td>
<td>Dimethoxytolyl Propylresorcinol</td>
<td>Nivitol</td>
<td>Unigen</td>
<td>Mar 2012 (CFDA)</td>
</tr>
<tr>
<td>8</td>
<td>Polymethacryloyl Lysine</td>
<td>-</td>
<td>-</td>
<td>Mar 2012 (CFDA)</td>
</tr>
<tr>
<td>9</td>
<td>Phenylethyl Resorcinol</td>
<td>Symwhite 377</td>
<td>Symrise</td>
<td>Dem 2012 (CFDA)</td>
</tr>
<tr>
<td>10</td>
<td>Elaeagnus mollis Oil</td>
<td>琪尔康翅果油</td>
<td>琪尔康</td>
<td>Oct 2014 (CFDA)</td>
</tr>
</tbody>
</table>
For cosmetic ingredient supplier

Cosmetic Ingredient Registration

- Analysis of the approved New Ingredients

**Source**

- Plant source: 60%
- Synthetic polymers: 30%
- Synthetic micromolecule chemicals: 10%

**Function**

- Active ingredient (e.g. Brightener): 60%
- Preservative (Restricted ingredient): 30%
- General ingredient (Skin&hair care): 10%

--- Status
<table>
<thead>
<tr>
<th>No.</th>
<th>Items</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The application form</td>
<td>Online submission</td>
</tr>
<tr>
<td>2</td>
<td><strong>R&amp;D Report</strong></td>
<td>Paper form</td>
</tr>
<tr>
<td>3</td>
<td>Description of the manufacturing process</td>
<td>Paper form</td>
</tr>
<tr>
<td>4</td>
<td><strong>Specification and quality control</strong> (Identification methods of the new ingredient and impurities)</td>
<td>Paper form</td>
</tr>
<tr>
<td>5</td>
<td><strong>Toxicological safety assessment report</strong> (including the safety risk substance)</td>
<td>Paper form</td>
</tr>
<tr>
<td>6</td>
<td>Documents of domestic agent</td>
<td>Paper form</td>
</tr>
<tr>
<td>7</td>
<td>Technical Standard</td>
<td>Paper form</td>
</tr>
<tr>
<td>8</td>
<td>Other supportive material (e.g. testing report, etc.)</td>
<td>Paper form</td>
</tr>
<tr>
<td>9</td>
<td>One sample</td>
<td>Commercial product</td>
</tr>
</tbody>
</table>
For cosmetic ingredient supplier

Cosmetic Ingredient Registration

• Generally Required Toxicological Endpoints

1. Acute toxicity (oral and dermal)
2. Irritation/Corrosion (dermal and eye)
3. Skin sensitization
4. Photo-induced toxicity and sensitization
5. Mutagenicity/Genotoxicity
6. Sub-chronic toxicity (oral and dermal)
7. Teratogenicity toxicity
8. Chronic toxicity/Carcinogenicity
9. Toxicokinetics

---Dossier

Good news:

• Testing is not mandatory: Potential Sources---Testing report, scientific literature, published information on the website of government or international organization.
• 5 category of ingredients could enjoy reduced toxicological requirement.
Reduced Requirements

- Toxicological information can be reduced for some special ingredients as below

<table>
<thead>
<tr>
<th>Ingredient Types</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>General ingredients</td>
<td>Refer to the ingredient without intention to be listed as restricted</td>
</tr>
<tr>
<td></td>
<td>substance, preservative, UV Filter, colorant or hair dye.</td>
</tr>
<tr>
<td>Listed general ingredients</td>
<td>Refer to the above general ingredients which have been included</td>
</tr>
<tr>
<td></td>
<td>in related list of regulated ingredients for over 4 years</td>
</tr>
<tr>
<td>Edible ingredients</td>
<td>Refer to the ingredient with edible history or approved by Chinese</td>
</tr>
<tr>
<td></td>
<td>or other national authorities for food</td>
</tr>
<tr>
<td>Polymer ingredients</td>
<td>Refer to the polymer (n&gt;3) with over 1,000 Da</td>
</tr>
<tr>
<td>Reviewed new ingredients</td>
<td>Refer to any new ingredients which has been subject to safety evaluation by oversea recognized institutes, such as SCCS or CIR, or approved by the authorities</td>
</tr>
</tbody>
</table>
Reduced Requirements

• The exempted endpoints (marked as ‘X’) related the special new ingredients present below

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>General Ingredients</th>
<th>Listed general ingredients</th>
<th>Edible ingredients</th>
<th>Polymer ingredients</th>
<th>Reviewed new ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral &amp; dermal)</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Irritation/Corrosion (dermal &amp; eye)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Photo-induced sensitization and Toxicity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>Mutagenicity/Genotoxicity</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sub-chronic toxicity (dermal or oral)</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Teratogenicity toxicity</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Chronic toxicity/Carcinogenicity</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Toxicokinetics</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Updates on regulations

Update Safety Standard

streamline administration and institute decentralization

Classified Management
Update Safety Standard - Ingredient

Safety and Technical Standard for Cosmetic, STSC No.268, 2015-12

- Used 76/768/EEC as reference
- Latest version was implemented on Dec 1st, 2016
- Clarify definition (e.g., leave-on and rinse off), update ingredients’ lists and requirements (prohibited list, 1286 to 1388, restrict list (73 to 47), preservatives (56 to 51), sunscreen agents (28 to 27), colorants (156 to 157), hair dyes (93 to 74), update testing methods for physical and chemical inspection.

- Expected to be updated annually.
- Companies need pay close attention to the transition period and process.
Streamline administration and institute decentralization – Optimize Management Method

- 2013
  - <Decision of the State Council on Matters concerning 50 Administrative Approval Items to Be Cancelled and Delegated to Lower Levels>
  - <Public Consultation on Management Adjustment on Cosmetic Administration Approval and Notification> CFDA

- 2014
  - <Draft for Cosmetic Supervision and Administration Regulation>

- 2015
  - <Adjust 11 administrative approvals in Shanghai Pudong New Area>
  - <Reply on the Proposal for the Pilot Reform of Separation of Business License and Operating Permit in Shanghai>

- 2016
  - <Procedures of Filing Management for First Import Non-special Use Cosmetics through Shanghai Pudong New Area> (Interim)
Streamline administration and institute decentralization – Optimize Management Method

1. Responsible Agent
2. CFDA account application
3. Product Analysis (formula, label)
5. Submit
6. Administrative review
7. Technical review
8. Approve
9. Issue certificate

At least three month, uncontrolled
Streamline administration and institute decentralization – Optimize Management Method

- Responsible Agent
- CFDA account application
  - Product Analysis (formula, label)
  - Product Testing/Documents preparation
  - Submit
  - Notification
  - Technical Review within 3 months
- REACH24H & Manufacturer
- Testing Lab
- CFDA
- Pudong Policy
- Import and Sales
Classified Management – Future trends

Cosmetic Supervision and Administration Regulation

• Ingredients

1. General ingredients ---> Notification
2. High risk ingredients (Preservatives, Sunscreen agents, Colorants, Hair dyes, Whitening) ---> Registration
3. Plant-related ingredients --- Pending

• Product

Classified based on safety risk.

1. Special Use: hair perm, hair dye, whitening, sunscreen
2. General Use or Medical products: hair removal, hair growth, beauty breast, body fitness and deodorant
3. General Use
What is really important?

- Cosmetic Supervision and Administration Regulation
- Filling Management for Non-special Use Cosmetics through Pudong New Area
- Safety and Technical Standard for Cosmetic, STSC
- Post-market Supervision

- Draft of Cosmetic Safety and Risk Evaluation Guidance
- New cosmetic ingredient registration
- Label management
- Production, GMP
Thank you!

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Chemlinked: https://cosmetic.chemlinked.com